DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Freedom of Information Office
Building 31, Room 5B-35
31 Center Drive, MSC 2107
Bethesda, Maryland 20892-2107
phone: (301) 496-5633
fax: (301) 402-4541

June 28, 2019

William Marshall
Judicial Watch, Inc.
425 third Street, S.W.
Suite 800
Washington, D.C. 20024

RE: NIH FOIA No. 48505

Dear Mr. Marshall,

This is the final response to your Freedom of Information Act (FOIA) request addressed to the National Institutes of Health (NIH) FOIA Office, dated September 28, 2018 and received October 4, 2018. Department of Health and Human Services (HHS) policy calls for the fullest possible disclosure provided by the FOIA, 5 U.S.C. §552, consistent with the protections contained therein. The implementing HHS Regulations establish the criteria pursuant to which the FOIA is administered, see 45 C.F.R. Part 5. Copies of the FOIA and the HHS Regulations are located at: http://www.nih.gov/icd/od/foia/efoia.htm and http://www.nih.gov/icd/od/foia/cfr45.htm.

You requested a copy of:

1. All contracts and related documentation between NIH and Advanced Bioscience Resources ("ABR") for provision of human fetal tissue to be used in humanized mice research.
2. All records reflecting the disbursement of funds to ABR for the provision of human fetal tissue to be used in humanized mice research.
3. All guidelines and procedural documents provided to ABR by NIH relating to the acquisition and extraction of human fetal tissue for its provision to the NIH for humanized mice research.
4. All communications between NIH officials and employees and representatives of ABR related to the provision by ABR to the NIH of human fetal tissue for the purpose of humanized mice research.

The time frame for the requested records is 2013 through the present.

NIAID searched their files and found the enclosed 676 pages. The information redacted from those records is protected from release pursuant to Exemptions 4 and 6 of the FOIA, 5 U.S.C. 552(b)(4) and 5 U.S.C. 552 (b)(6) of the HHS FOIA Regulations, 45 C.F.R. Part 5. Exemption 4 protects from disclosure trade secrets and commercial or financial information that is privileged

and confidential. Exemption 6 exempts from disclosure records the release of which would cause a clearly unwarranted invasion of personal privacy.

You have the right to appeal the determination to deny you access to information in the Agency's possession. Should you wish to do so, your appeal must be sent within ninety (90) days of the date of this letter, following the procedures outlined in Subpart F of the HHS FOIA Regulations (https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations) to:

Assistant Secretary for Public Affairs/Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201
FOIARequest@hhs.gov
FAX: 202-690-8320

Clearly mark both the envelope and your letter "Freedom of Information Act Appeal."

If you are not satisfied with the processing and handling of this request you may contact the NIH FOIA Public Liaison and/or the Office of Government Information Services (OGIS):

NIH FOIA Public Liaison
Stephanie Clipper
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20814
301-496-2411 (phone)
301-402-0818 (fax)
nhlbieo@mail.nih.gov (email)

OGIS
National Archives and Records Admin.
8601 Adelphi Rd – OGIS
College Park, MD 20740-6001
202-741-5770 (phone)
1-877-684-6448 (toll-free)
202-741-5769 (fax)
ogis@nara.gov (email)

In certain circumstances provisions of the FOIA and HHS FOIA Regulations allow us to recover part of the cost of responding to your request. In this case, there is no charge associated with our response.

If you have any questions about this response, please call 301-496-5633.

Sincerely,

Gorka Garcia-Malene
Freedom of Information Officer, NIH

ADVANCED BIOSCIENCE RESOURCES, INC.

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
12/21/2016	(b)(6)	1033052
	TERMS	CUSTOMER #
	Due Upon Receipt	0522

BILL TO

Rocky Mountain Labs
NIH/NIAID
Kim J. Hasenkrug
903 S. 4th Street
Hamilton, MT 59840

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
12/21/2016	672104	6376	21	Thymus, 2nd Trimester	KIM	(b)(4)
12/21/2016	672104	6377	21	Liver, 2nd Trimester	KIM	
				01/10/17 PAID (b)(6) Request by Kim Hasenkrug.		

Sale
Entry Method: Manual
Total: $ 680.00
01/10/17 15:47:04
Inv #: 000002 Appr Code: 021690
Approval: Online Batch#: 010001
AVS Code: ZIP MATCH Z
CVV2 Code: MATCH M

Total $680.00

SEQ: 1823136	PO#: (b)(6)	Requester: Messer, Ronald

CAN: 8335424 FY: 17 Owner: (b)(6)
Order Total: 680.00 Project: 107833
Date Needed: 11/14/2016 Emergency: Yes Order Type: Purchase Card
Requestor Phone: +1 406 363 9276 Order Status: Archive

Vendor Advanced Bioscience Resources,1516 Oak Street, Suite 303, Alameda, CA 94501
Phone: 510-865-5872 SmlBs: No FSS:
EIN: BPA: GSA:
Site: Clerk:
E-mail:

#	Description	CAN	Catalog	OC Code	Category	Qty at Price	Total
1	Tissue, 2nd Trimester (1 each of liver and thymus)	8335424	none	2613	6509	(b)(4)	680.00
2	shipping	8335424		2613	6509	1 each at $0	.00
Order Total: 680.00							

Ship To: Ronald Messer,3220 ,RML CNTRL REC,RMTLAB

QUOTES

Vendor	Price	Good Until	Available
There are no quotes in the order			

JUSTIFICATION

These tissues, liver and thymus, are required Ron Messer for ongoing studies of HIV in the Hasenkrug Lab. Our mice will be ready for reconstitution soon. Please let me know when I can contact Perrin Larton at ABR to place our request on their schedule. Please contact the vendor at 510-865-5872 ext (b)(6) -give her the PO number Thanks, Ron. *** I certify that I have checked the sources of supply and services listed in FAR 8.002. ( ) I have purchased from the highest priority source available. (X) I did not purchase from a priority source because none could satisfy the requirement of the government either in product/service specifications, quality or required delivery time. **********NOTE to Purchasing Agent: Call vendor at 510-865-5872 ext (b)(6) (b)(6) -give her the PO number and credit card information.

Alternate Sources:

NIH Surplus: No UNICOR: No GSA Stock Catalog: No GSA Self Service: No Federal Supply: No Open Market: Yes

AGENT

Purchase Order #: (b)(6)
Custodial Code: 30102
Order Reference: (b)(6)
FSS:
NBS Ref Order #: 4396875

Estimated Ship Date:
Date Entered into NBS: 11/14/2016
Expected Delivery Date: 11/14/2016
Select Agents: No
Clearance Requested: No

SF-37 Code:

Notes

(b)(6) +1 406 375 9840 11/14/2016 em'd the po # to ABR (Perrin) and end user.

IT Clearance

Never seen by IT officer

ROUTE HISTORY

Role Summary

User Role	Name
Requester	Messer, Ronald
Releaser	Messer, Ronald
Admin Officer	(b)(6)
Lead Admin Officer	
Purchase Agent	(b)(6)
Lead Agent	
IT Clearance Officer	
Releaser1	
Releaser2	
NBS	
Receiving Official	

Dates

Description	Date
Needed By	11/14/2016
Submitted to NBS	11/14/2016
NBS Confirmation	11/15/2016
Award Created	11/14/2016
Award Received	11/14/2016
Estimated Ship Date	
Received	12/07/2016
Canceled	

Routing History

Name	Role	Date In	STATUS IN	ACTION
Messer, Ronald	Requester	11/14/2016	New order	Approved
(b)(6)	Administrative Officer	11/14/2016	Released	Take
	Administrative Officer	11/14/2016	Released	Approved
	Purchasing Agent	11/14/2016	Approved	Take
	Purchasing Agent	11/14/2016	Approved	Approved
NBS, NBS	NBS	11/14/2016	Sent to NBS	Approved
Messer, Ronald (b)(6)	Requester for receiving	11/14/2016	Pending receiving	Take
(b)(6)	Requester for receiving	12/07/2016	Pending receiving	Approved
	Archive	12/07/2016	Archive	(N/A)

Receiving Report

#	Description	Total Qty Ordered	Total Qty Received	Date Received
1	Tissue, 2nd Trimester (1 each of liver and thymus)	2	2	12/07/2016

OHSR RESPONSE TO REQUEST FOR REVIEW OF RESEARCH ACTIVITY
INVOLVING HUMAN SUBJECTS

FAX:

Exempt: #: 4980

To: Hasenkrug, Kim
NIAID
RML - Rocky Mountain Laboratories, 3/218

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
Recent reports have demonstrated that immunodeficient mice reconstituted with 17-19 week old human fetal tissue develop a human immune system and are susceptible to HIV infection and disease. The goal of this project proposal is to create such humanized mice to study the role of immune cell subsets and virus-neutralizing antibodies in vaccine protection. The experiments will entail the development of a cohort of mice all reconstituted with the same human cells so as to be histocompatible. This will require transplantation of

Original Request Received in OHSR on: 11/19/2009

Responsible NIH Research Investigator(s): Kim Hasenkrug, NIAID

OHSR review of your request dated Thu, Nov 19, 2009 has determined that:

☒ Federal regulations for the protection of human subjects do not apply to above named activity. The OHSR determination of Not Human Subjects Research is based on the interpretation of 45 CFR 46 under "Research Involving Coded Private Information or Biological Specimens" (OHRP, Revised October 16, 2008) and Guidance on Engagement of Institutions in Human Subjects Research (October 16, 2008). NOTIFY OHSR VIA AN E-MAIL AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESEARCH ACTIVITY.

☐ The activity is designated **EXEMPT**, and has been entered in the OHSR database. PLEASE NOTIFY OHSR OF ANY **SIGNIFICANT** CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.

☐ **NOT EXEMPT**. OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additional information in order to determine whether expedited or full review is appropriate.

☐ Confidentiality Agreement

☐ Reliance

☐ Amendment

☐ Other

Office Person LB Admin Assist. CB

Note: (b)(6)

CIP

for Charlotte Holden, JD — Acting Director, OHSR — 12/14/2009

Signature — Title — Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: Yes

OHSR Use Only
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

#4980

REQUEST FOR REVIEW OF RESEARCH ACTIVITY INVOLVING HUMAN SUBJECTS

INSTRUCTIONS: Please type directly on this form. You can expand the document if you need more space. If your research involves a survey or questionnaire, please attach it to this completed form.

Completed forms (with all required signatures) may be sent to OHSR by FAX (301-402-3443), email to ohsr_nih_ddir@od.nih.gov, or by mail (2C146). If you have any questions, call OHSR at (301) 402-3444.

Date: 11/19/2009

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146

From: Kim J Hasenkrug
(Signature)

Through: (b)(6) (acting)
(Signature of appropriate Official for IC, e.g., Lab/Branch Chief)

Protocol Title: Study of HIV infection and vaccine protection in mice reconstituted with a human immune system

Name of NIH Principal Investigator(s): Kim J Hasenkrug, Senior Investigator

IC NIAID Laboratory/Branch LPVD Building & Room No. RML 3218
Tel. No. 406-363-9310 FAX No. 406-363-9286
Is the Principal investigator an NIH employee? x **Yes** ____ **No**

If no, please explain: ____

1. What is the proposed research activity that you intend to perform at NIH (please use lay terms):

Recent reports have demonstrated that immunodeficient mice reconstituted with 17-19 week old human fetal tissue develop a human immune system and are susceptible to HIV infection and disease. The goal of this project proposal is to create such humanized mice to study the role of immune cell subsets and virus-neutralizing antibodies in vaccine protection. The experiments will entail the development of a cohort of mice all reconstituted with the same human cells so as to be histocompatible. This will require transplantation of the mice with 1 mm^3 pieces of fetal thymus as well as reconstitution with stem cells isolated from cord blood and liver. Once the humanized mice have been established some will be vaccinated to prime distinct subsets of immune cells. Immune cell subsets from vaccinated mice will be adoptively transferred into naïve mice, which will then be infected with HIV to

test the antiviral activity of the immune cells. The goal of these experiments is to establish correlates of immunity against HIV.

2. If applicable, list your non-NIH Collaborating Investigator(s).

Name Institution Address Tel. # FAX #

3. Proposed start date of your research __April, 2010_____
Proposed completion date _April, 2013_____

4. Will you be _____these samples or data?

Collecting Yes/(No)
Receiving (Yes)/No
Sending Yes/(No)

5. Do the samples or data:
(a) Already exist?___Yes _x__No

(b) Or are they being collected for the express purpose of this study? _X__Yes __No
If "yes," please describe:_

17-19 week fetal cells and tissue will be obtained from Advanced Bioscience Resources, Inc., a non-profit foundation established under California law to provide biomedical researchers access to human tissues in compliance with state, federal, and NIH guidelines. Consent to donate is obtained in accordance with UAGA and NOTA guidelines. Related documents including the consent form are attached._____

(c) Or a combination of (a) and (b)? ____Yes _____No

6. What role will you have in this research project? (Check all that apply)

___ Analyze samples/data only.

___ Consultant/advisor to collaborator(s) listed above.

___ Author of the protocol that is being implemented by your collaborating investigator (identified in question #2).

___ Co-authorship on publication(s)/manuscript(s) pertaining to this research.

___ You or NIH hold an IND for this research.

__X_ Decisional authority over the design or implementation of the research at the IRB approved site? If so, please explain.

I am the PI and lead investigator on this project which will take place in my laboratory and the animal care facilities at Rocky Mountain Labs, NIAID, NIH.

___Other (If necessary, use this space to describe your role in this research).

7. Where are the subjects of this research activity located?
The material for this research is obtained from natural or induced abortions from females in California. Thus the tissues and cells involved will not be from living humans.

8. If human subjects are located elsewhere (not at NIH), will you have direct contact or intervention with them? (Examples: as subject's physician; in obtaining samples directly from the subject; by interviewing the subject?) ____ Yes __x__No

9. What kind of human samples (e.g., tissue, blood) or data (e.g., private information, responses to questionnaires) will be involved in your research?
_Samples will include cord blood, fetal blood, thymus, liver, and bone marrow. No private information will be involved._____

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10. If the samples, data do not come from an IRB approved protocol, do they come from:

(a) Repository ____Yes ___ No

(b) Pathological waste ___ Yes _____No

(c) Autopsy material ___ Yes ___ No

(d) Publicly available source _X__Yes ___ No

(e) Other_____

11. Please check the box(es) that apply(ies) to the samples/data that you will receive.

(a) ____ Samples and/or data will be anonymized/unlinked. (The samples/data cannot be linked to individual subjects by you or your collaborators at other sites.)

(b) ___ Samples and/or data will be coded, however that code cannot be used by either the sender or the receiver to identify specific individuals.

(c) __X_ Samples and/or data will be coded so that the provider of the samples/data can link them to specific individuals but the receiver will not be able to do so.

12. Will you send results back to the provider(s) (listed in question 2 of this form)?

(a) __X_ No, I will not send results back to the provider(s).

(b) ___ Yes, I will send aggregate results to the provider(s).

(c) ___ Yes, I will send results to the provider(s) that are linked to identifiable individuals.

If yes, does the provider intend to link your data to identifiable individuals?
_____Yes _____No

13. Has the research activity <u>that you are proposing in this form</u> been approved by an Institutional Review Board (IRB) elsewhere?

_____ Yes, the NIH research activity has been reviewed by the following IRB (s) (Please provide the following information for each IRB):

_____ Name of institution that provided the review

_____ Address of reviewing institution

_____ Name of PI for the IRB approved protocol

_____ Title of IRB approved protocol and protocol #

_____ Federal Wide Assurance (FWA) number**

___X_____No IRB review of the research activity described in question #1 above has taken place

(**An FWA is a contract between the U.S. Department of Health and Human Services (DHHS) and an entity receiving DHHS funds to conduct clinical research that the latter will follow ethical guidelines and federal regulations for the protection of human subjects. For a list of domestic and international institutions go to http://ohrp.cit.nih.gov/search/asearch.asp#ASUR

14. Per NIH guidance*, have conflicts of interest by NIH employees, if any, been resolved?**

__X___Yes _____No no conflicts of interest

If your answer is no, please see your Clinical Director about this matter before proceeding with this research.

***The January 5, 2005 NIH Guide to Preventing Conflict of Interest applies to all research conducted at NIH, http://ohsr.od.nih.gov/New/mpafwa_docs.html

ADVANCED BIOSCIENCE RESOURCES, INC

OVERVIEW

ADVANCED BIOSCIENCE RESOURCES is a non-profit corporate foundation established in 1989 under California law to provide biomedical researchers with access to human tissues. ABR was formed exclusively for biomedical, scientific, and educational purposes and is devoted to providing services in connection with the procurement of human organs and tissues for medical and scientific research. ABR specializes in the procurement, preservation and distribution of both human fetal tissues and full term umbilical cord blood for research, and provides a highly individualized, reliable and easily accessible service.

TISSUE COLLECTION AND DISTRIBUTION: The purpose of ABR is to promote cooperative efforts to collect and distribute human tissues and to thereby facilitate research utilizing those tissues. Trained personnel coordinate the retrieval, preservation and delivery of each specimen.

Tissues obtained through ABR are retrieved from routinely performed surgical procedures including first and second trimester induced abortions, and full term deliveries, either natural or caesarian section. Tissues that were once discarded are now available to scientists worldwide through the efforts of ABR. Researchers may specify tissue characteristics, preservation methods, and delivery times.

PRESERVATION METHODS: Each specimen is collected, preserved, and shipped according to the investigator's individual protocol.

QUALITY CONTROL: ABR practices strict quality control procedures and adheres to stringent guidelines for tissue collection and preservation. Consent is obtained in accordance with UAGA and NOTA guidelines. Tissue specimens are identified, dissected, and transferred to the specified medium. A control number is then assigned to each sample to ensure confidentiality of patient identity.

To assure proper processing of the tissue, every researcher selects a collection/preservation protocol tailored specifically to his needs. In the collection and distribution of these tissues, every effort is made to exercise the highest standards of medical and laboratory practice. ABR specializes in direct communication with each investigator from the initial application to specimen delivery.

INVESTIGATOR APPROVAL: ABR will provide tissue to researchers who provide information on current research funding, and a short summary of their research intent. Investigators must agree to accept responsibility for the potential biohazard of the tissue and to appropriately train laboratory personnel in the proper handling of the tissue. In addition, the researcher must agree to use the tissue solely for research purpose and to acknowledge ABR in any publications resulting from the use of ABR provided tissue.

APPLICATION PROCESS: To request human tissue for research, an application must be completed and submitted to ABR. The application will be reviewed for feasibility and priority. A protocol will be developed to meet individual research needs as identified in the application.

SERVICE AND PROCESSING FEES: Participating medical facilities that enable ABR to enact its tissue acquisition and distribution programs may be paid a nominal fee for such services. A minimal processing / preservation / shipment fee is also assessed for services provided to research facilities.

1516 Oak Street # 303 / Alameda, CA 94501 / 510-865-5872 / Fax 510-865-4090 / email abr@abr-inc.com

Recent advancements in medical research have been developed through the use of human tissues in scientific study. Diseases such as diabetes, hemophilia, Parkinson's disease, cancer, AIDS, heart and lung disease, as well as genetic and,neonatal disorders, are being investigated for the development of cures through the use of human fetal tissues. Any tissue donated may be distributed to medical institutions and private research groups in the United States and internationally to enhance the development of cures and therapies for disease.

PERMISSION FOR DONATION OF TISSUE
OBTAINED AT THE TIME OF ABORTION

I have previously decided to have an abortion and have previously consented to having such abortion.

I hereby donate the aborted material and/or a sample of my blood as an anatomical gift for the purposes of education, research, or for the advancement of medical science. I understand that my donation may be used by research facilities in the United States and abroad.

I also agree that a sample of my blood may be taken after the abortion and that it may be used for research and routine testing for AIDS, hepatitis, or other infectious agents. I understand that, if there is testing, the results will be confidential unless the law requires that they be disclosed.

I understand that the aborted material may be used to derive human pluripotent stem cells for medical research and possibly human transplantation research, and that these cells may be kept for many years. I also understand that my donation may be used for cosmetic purposes. I understand that there is no information associated with aborted material that could link me with my donation. I agree that this donation is made without any restriction or direction regarding the potential recipients of the cells derived from the aborted material and that I have not been informed of the identity of any potential recipients.

I understand that there will be no payment to me and I agree that, although the results of the research on the aborted material may have commercial value, I will have no property or other commercial or financial rights in the aborted material or any product, process, or service which may result from this donation.

I understand that my donation will not result in any direct medical benefit to me.

I understand that my donation is voluntary, and I may refuse to donate aborted material and this will not affect my medical care or my relationship with my physician.

I understand that, if I have any questions about my donation, I can contact ABR at 510-865-5872.

_____ _____
Signature Date

I choose not to participate.

_____ _____
Signature Date

_____ _____
Witness Date

ADVANCED BIOSCIENCE RESOURCES, INC.

APPLICATION FOR THE ACQUISITION OF

HUMAN FETAL TISSUE FOR RESEARCH

All requests for human fetal tissue are reviewed for feasibility of procurement and preparation. When approved, an individual protocol will be developed for the procurement, preparation and delivery of tissue samples, based on the information provided in this application and any subsequent communication.

I. APPLICANT INFORMATION

NAME: Kim J Hasenkrug

TITLE: Senior Investigator

COMPANY: NIAID, NIH

ADDRESS: Rocky Mountain Lab

ADDRESS: 903 S. 4th St

CITY,ST,ZIP: Hamilton, MT 59840

PHONE #: 406-363-9310

ALT. #:

FAX #: 406-363-9286

EMAIL: khasenkrug@nih.gov

DELIVERY OPTIONS:

__X__ Same Day: Commercial carrier, hand delivered
Maximizes cell viability (*geographical limits*)

_____ Next Day: Pickup, delivery Mon-Sat daytime
Economical for fresh, frozen specimens

Applicant will be charged for delivery fees.

Applicant may designate preferred carrier:

Carrier Name: FEDEX

Account #: (b)(4)

BILLING INFORMATION:

BILL TO: Kim J Hasenkrug

COMPANY: Rocky Mountain Labs

ADDRESS: 903 S. 4th St.

ADDRESS:

CITY,ST,ZIP: Hamilton, MT 59840

ACCOUNTING DEPT. PHONE #: 406-363-9438

P.O. # (if required by your company):

P.O. # is not required to submit application

Credit Card #:

Name on CC:

Expiration Date: VISA/MC

SHIP TO: Kim J Hasenkrug
Rocky Mountain Labs
903 S. 4th St
Hamilton, MT 59840

Please indicate how you heard about ABR: (b)(6)

II. HUMAN FETAL TISSUE

Tissue specimens requested: thymus, liver, cord blood

Preferred gestational age (6-24 weeks): 17-19 wks

Proposed starting date: May, 2010

CONTAGIOUS DISEASE SCREENING: Availability of test results varies from 24 hours to 7 days after procurement. Applicant requires the following tests to be performed by ABR:

__X__ No testing required

_____ HIV _____ HSV
_____ HBSAG _____ RPR
_____ CMV _____ HCV

OTHER_____

III. PRESERVATION

ABR uses *BioWhittaker RPMI-1640 With L-Glutamine* for tissue preparation, preservation and shipment. Applicant may supply ABR with other media specific to research needs. Please indicate preference below.

PRESERVATION METHODS AVAILABLE:

__X__ Fresh; shipped on wet ice
_____ Passive freezing on dry ice; shipped on dry ice
_____ "Snap" freezing in LN2; shipped on dry ice
_____ Media provided by applicant
_____ Media provided by ABR (RPMI)

IV. DONOR INFORMATION

CONSENT VERIFICATION: Consent for tissue donation is obtained prior to specimen procurement. The consent is extremely confidential in nature and shall not be communicated to the researcher.

SPECIFIC DONOR INFORMATION: Charts are routinely examined for patient medical histories. Please identify any specific information sought and indicate contraindications to specimen procurement:

_____HIV+ status contraindicates procurement_____

_____

_____

V. RESEARCH DATA

TITLE OF RESEARCH PROJECT: ___The role of virus-specific CD4+__T cells, CD8+ T cells and antibody in vaccine protection against HIV-1 in humanized mice_____

ABR will provide tissue to researchers who provide information on current research funding, and a short summary of their research intent. **(Please attach a brief synopsis of the research project named above.)** Researchers must agree to use the tissue solely for research purposes and to acknowledge ABR in any publications resulting from the use of ABR provided tissue. Updates on research progress will be requested at six-month intervals. Researchers agree to publish the results of the research as promptly after the completion of the research as is reasonably possible without jeopardizing the sponsor's right to secure patents or copyrights necessary to protect its ownership or control of the results of the research. Researchers agree to inform ABR of the name of the publication and the date of the issue in which the results will be published. It is the intent of this requirement to make the results available to the general public through acceptable means of publication.

VI. SOURCE OF FUNDING

Please identify the primary source of funding for this project.

NIH _X___ Other Federal or State Grants _____ Foundation Grants _____ Other (specify) _____

If this application is approved by ABR, ABR shall provide services to the applicant in accordance with the terms and the other conditions on the reverse side, and the signature of the applicant shall constitute acceptance of all such terms and conditions by applicant. The entire agreement between ABR and applicant relating to the services provided by ABR is expressly set forth herein, and any modification of or addition thereto shall be of no force or effect unless it is in writing and signed on behalf of ABR by a duly authorized representative.

BY SIGNING BELOW, THE APPLICANT ACKNOWLEDGES HAVING READ THE TERMS AND CONDITIONS ON THE FOLLOWING PAGE AND AGREES TO SUCH TERMS AND CONDITIONS.

Kim J Havenhuys

____ _____

_Senior Investigator_____
SIGNATURE and TITLE of APPLICANT

DATE 11/2/2009

Please return to:

ADVANCED BIOSCIENCE RESOURCES, INC.
1516 OAK STREET, SUITE 303
ALAMEDA, CALIFORNIA 94501
Telephone: 510-865-5872
Fax: 510-865-4090
Email: abr@abr-inc.com

TERMS AND CONDITIONS OF SERVICES

1. Services

1.1 During the term of this agreement, and pursuant to the terms and conditions hereinafter set forth, ABR will use its best efforts to provide services in connection with supplying researcher with the types of human tissues set forth in this application, as approved

by ABR, suitable for researcher requirements and in the amounts requested based upon ongoing discussions between researcher and ABR pursuant to the information sent by ABR.

1.2 Researcher acknowledges and agrees that ABR will provide the following types of services:

Removing tissue.
Preserving and processing tissue to a form suitable to the researcher needs.
Seeking consent for tissue donations from appropriate individuals, obtaining validly executed consent forms, and maintaining records of such consents in accordance.
Obtaining, labeling, storing, and delivering samples of donor or other required serum, and maintaining a system for matching such samples to specific tissue donations.
Preserving tissue viability and cleanliness during removal, processing, preservation, storage and transportation.
Storing tissue and transporting it to researcher in accordance with section 5.

1.3 In the event that tissues of the type specified in the application become unavailable to ABR, such that ABR is unable to perform the contemplated services, ABR shall have no obligation to perform such services.

2. Representations and Warranties. ABR hereby represents and warrants to researcher that (i) ABR will make no payments to anyone for any tissue transferred in connection with this agreement, and (ii) ABR will verify for each tissue delivery that appropriate consent was obtained for use of such tissue and any associated serum samples, and that adequate records of such consent are maintained; provided, however, that the parties hereto acknowledge and agree that such consents are extremely confidential in nature and shall not, in any case, be communicated to researcher. Researcher hereby represents and warrants to ABR that (i) researcher will neither sell nor transfer for valuable consideration any tissue received through ABR to anyone, (ii) researcher will use the tissue only to satisfy its objectives, which are, as acknowledged and agreed hereto, [research and clinical use], (iii) researcher agrees to inform ABR of any changes in clinical or research use of specimens received from ABR, or in any specifications, constraints, etc. in a timely manner, and (iv) researcher understands the bio-hazardous nature of human tissue and agrees to take proper precautionary measures at all times when handling tissue specimen.

3. Terms. The terms of this agreement shall be for one (1) year, beginning from the date hereof, and terminating one (1) year thereafter, unless either of the parties hereto shall have given to the other thirty (30) days written notice of its intention to terminate this agreement, whereupon same shall terminate thirty (30) days after date of said notice.

In default of notice as aforesaid from either party hereto, this agreement shall continue for further successive terms of one (1) year thereafter and in default of thirty (30) days written notice before the end of an annual term by either of the parties of its intention not to renew, whereupon this agreement shall terminate at the end of said term.

4. Payments. Researcher agrees to pay to ADR a fee for costs incurred by ABR in providing services in connection with the acquisition of each sample of tissue requested by researcher, to be mutually agreed upon by ABR and researcher upon approval of this agreement by ABR.

5. Shipment services.

5.1 All shipments will be made as soon as possible after request has been received by ABR from researcher.

5.2 Researcher acknowledges that networks of tissue availability are neither permanent nor dependable, but rather they fluctuate. However, ABR shall use its best efforts to transfer the tissue in the amounts requested by researcher.

5.3 Shipment will be made in the best possible manner so as to preserve the quality of the tissues. It is understood that the fragility of human tissue is such that damage may occur during shipment. ABR will use its best efforts to comply with the handling and shipment protocols provided by researcher.

5.4 ABR will package the tissue appropriately and, if so requested by researcher, will insure the shipment. Researcher agrees to bear all costs associated with insurance and shipment of any tissue.

5.5 The risk of loss and damage of any tissue or organs shall pass immediately to researcher when the shipment of such tissue or organs is deposited with a carrier for transportation at the F.O.B. point.

6. Limitation of liability. ABR shall not be responsible or liable under any section of this agreement or under any contract, negligence, strict liability or other legal or equitable theory, for the cost of procurement of substitutive services, or any indirect, incidental or consequential damages including, but not limited to loss of revenues and loss of profits. Any liability of ABR under any theory whatsoever will be limited exclusively to the provision of equivalent services by ABR or, if unenforceable, to payment of an amount not greater than any amount actually received by ABR from researcher on account of this agreement.

7. No warranties. It is understood that human tissue is by nature neither permanent nor dependable. Except as expressly set forth in this agreement, ABR makes no representation of any kind, expressed or implied, including any representation with respect to the safety, efficacy or merchantability or the fitness for any purpose with respect to the tissue transferred to researcher in connection with this agreement.

8. Indemnification. Researcher shall indemnify, defend and hold ABR harmless from and against all claims, causes of actions, suits, damages and costs arising out of, resulting from, or otherwise in respect of, the use of tissue transferred in connection with this agreement, except where such claims are the result of negligence of ABR, its employees, staff or agents to (i) comply with any governmental requirements, or (ii) adhere to the terms of this agreement.

9. General. This agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of law. This agreement may not be assigned by either party without the prior written consent of the other.

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Monday, November 23, 2009 10:43 AM
To: Hasenkrug, Kim (NIH/NIAID) [E]
Subject: Request for Review Rec'd-OHSR 4980

Good morning Dr. Hasenkrug,

This email is to verify that OHSR has received your Request for Review of Research and it is currently being processed as OHSR #4980. Please use this number in any future correspondence regarding this study. We will contact you via email if any additional information is needed. If you have not heard from OHSR within 7 business days, please contact us.

Protocol Title: Study of HIV infection and vaccine protection in mice reconstituted with a human immune system

Thank you.

OHSR:
Ph: 301.402.3444
Fax: 301.402.3443

Thank you.

Sincerely,

(b)(6)

OHSR (NIH/DDIR)

From: Hasenkrug, Kim (NIH/NIAID) [E]
Sent: Wednesday, December 09, 2009 5:41 PM
To: OHSR (NIH/DDIR)
Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up
Flag Status: Green

Attachments: IRB Letter with letterhead nonidentity.doc

IRB Letter with letterhead non...

Here is the letter on official ABR letterhead for you

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
Laboratory of Persistent Viral Diseases
Rocky Mountain Laboratories
National Institute of Allergy and Infectious Diseases National Institutes of Health
903 S. 4th Street
Hamilton, MT 59840
phone (406)363-9310
FAX (406)363-9286
khasenkrug@nih.gov

> From: "OHSR (NIH/DDIR)" <ohsr_nih_ddir@od.nih.gov>
> Date: Tue, 24 Nov 2009 10:27:55 -0500
> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
> Conversation: HasenkrugK_NIAID_4980_CY2009
> Subject: HasenkrugK_NIAID_4980_CY2009
>
> Good Afternoon Dr. Hasenkrug:
>
> Thank you for the opportunity to review your research project: Study
> of HIV infection & Vaccine Protection.. Since the work you are doing
> at the NIH provides little or no risk to human subjects off-site, OHSR
> has decided the appropriate action for you to take is the following:
>
> * Provide documentation that you will not seek the identity of the
> subjects who have provided the samples you will receive as well as
> documentation from ABR that under no circumstances will the identity
> or link to the identifiers of the subjects be released to you.
>
> An e-mail from you and from ABR holding the key to the code is
> sufficient documentation.
>
> This action is based on guidance issued on Aug. 10, 2004 by the HHS
> Office of Human Research Protections, the regulatory office for the
> protection of human subjects.

> Best regards,
>
>
>
> OHSR - National Institutes of Health
> Bldg 10, Suite 2C146
> Bethesda, MD 20892
> Office Telephone: 301-402-3444
> Office Fax: 301-402-3443
>
> The NIH is committed to maintaining the highest standards for the
> protection of human subjects.
> P Please consider the environment before printing this e-mail
>

ADVANCED BIOSCIENCE RESOURCES, INC

December 14, 2009

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
903 S. 4th Street
Hamilton, MT 59840

Dear Kim,

This letter verifies that ABR, a non-profit tissue procurement organization, supplies requesting and approved scientific investigators with the types of human fetal tissues required for specific bio-medical research. When requested and as availability allows, human fetal tissue specimens will be retrieved from products of conception from induced first and second trimester abortions. Tissue will be distributed according to established protocols. Specimens are not collected for directed donation. .

ABR warrants that maternal consent from patients aged over eighteen years is obtained for the use of fetal tissue specimens for research purposes, including the consent for the potential of stem cell research utilizing such tissues, and that adequate records of such consent are maintained for future verification. Donor identification is coded and scientific investigators have no access to donor identification. ABR also warrants that maternal consent is obtained for phlebotomy and blood testing for a variety of disease entities.

ABR warrants that no payments will be made to any third party for the conduct of or the product of an abortion, including without limitation any parent(s) of any unborn fetus. ABR, to the best of its knowledge, also warrants that all tissue provided will have been obtained in compliance with local, state and federal laws and regulations governing the procurement and distribution of human tissue.

Sincerely,

Perrin Larton

Perrin Larton, CTBS
Procurement Manager

Federal E.I.N.: 94-3110160
California E.I.N.: 370-20518
FDA FEI: 3005208435

1516 Oak Street # 303 / Alameda, CA 94501 / 510-865-5872 / Fax 510-865-4090 / email abr@abr-inc.com

OHSR (NIH/DDIR)

From: Hasenkrug, Kim (NIH/NIAID) [E]
Sent: Monday, November 30, 2009 5:24 PM
To: OHSR (NIH/DDIR)
Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up
Flag Status: Green

Attachments: Re: HFT Application

Re: HFT Application

HasenkrugK_NIAID_4980_CY2009

Attached please find the requested email from ABR stating that no personally identifiable information will be released to me. Furthermore, I will not seek any such information from ABR.

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
Laboratory of Persistent Viral Diseases
Rocky Mountain Laboratories
National Institute of Allergy and Infectious Diseases National Institutes of Health
903 S. 4th Street
Hamilton, MT 59840
phone (406)363-9310
FAX (406)363-9286
khasenkrug@nih.gov

> From: "OHSR (NIH/DDIR)" <ohsr_nih_ddir@od.nih.gov>
> Date: Tue, 24 Nov 2009 10:27:55 -0500
> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
> Conversation: HasenkrugK_NIAID_4980_CY2009
> Subject: HasenkrugK_NIAID_4980_CY2009
>
> Good Afternoon Dr. Hasenkrug:
>
> Thank you for the opportunity to review your research project: Study
> of HIV infection & Vaccine Protection.. Since the work you are doing
> at the NIH provides little or no risk to human subjects off-site, OHSR
> has decided the appropriate action for you to take is the following:
>
> * Provide documentation that you will not seek the identity of the
> subjects who have provided the samples you will receive as well as
> documentation from ABR that under no circumstances will the identity
> or link to the identifiers of the subjects be released to you.
>
> An e-mail from you and from ABR holding the key to the code is
> sufficient documentation.

>
> This action is based on guidance issued on Aug. 10, 2004 by the HHS
> Office of Human Research Protections, the regulatory office for the
> protection of human subjects.
>
> Best regards,
>
>
>
> OHSR - National Institutes of Health
> Bldg 10, Suite 2C146
> Bethesda, MD 20892
> Office Telephone: 301-402-3444
> Office Fax: 301-402-3443
>
> The NIH is committed to maintaining the highest standards for the
> protection of human subjects.
> P Please consider the environment before printing this e-mail
>

OHSR (NIH/DDIR)

From: Perrin Larton (b)(6)
Sent: Monday, November 30, 2009 5:10 PM
To: Hasenkrug, Kim (NIH/NIAID) [E]
Cc: (b)(6)
Subject: Re: HFT Application

Hi Kim,

All tissue is numerically coded and the personally identifiable information is never available. In other NIH applications we've had requests for letters that state NO information is available to researchers. I can send you a letter to that effect...but tissue cannot be tracked back to a specific patient. We guarantee anonymity to the patients donating tissue.

Perrin

> Dear Perrin, the Office of Human Subjects Research is asking me for a
> letter
> from you stating that personally identifiable information regarding the
> fetal tissue will be revealed to me. Would you kindly send me a letter
> stating such so that I can forward it to them? It would be greatly
> appreciated and let us begin our experiments. I attached a copy your
> letter
> regarding approval of our application for your information. Thank you
> very
> much, Perrin.
>
> Kim
>
> Kim J Hasenkrug, Ph.D.
> Senior Investigator
> Chief, Retroviral Immunology Section
> Laboratory of Persistent Viral Diseases
> Rocky Mountain Laboratories
> National Institute of Allergy and Infectious Diseases
> National Institutes of Health
> 903 S. 4th Street
> Hamilton, MT 59840
> phone (406)363-9310
> FAX (406)363-9286
> khasenkrug@nih.gov
>
> Disclaimer:
> The information in this e-mail and any of its attachments is confidential
> and may contain sensitive information. It should not be used by anyone who
> is not the original intended recipient. If you have received this e-mail
> in
> error please inform the sender and delete it from your mailbox or any
> other
> storage devices. National Institute of Allergy and Infectious Diseases
> shall
> not accept liability for any statements made that are sender's own and not
> expressly made on behalf of the NIAID by one of its representatives

>
>
>> From: Perrin Larton (b)(6)
>> Reply-To: (b)(6)
>> Date: Mon, 2 Nov 2009 13:40:51 -0500
>> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
>> Conversation: HFT Application
>> Subject: HFT Application
>>
>> Dear Kim,
>>
>> Attached you'll find the documents we just discussed. What I'll need
>> back
>> from you is the two page application as well as a short synopsis of the
>> work you'll be doing. As soon as I get the completed application from
>> you
>> it will go to our Scientific Advisory Board for review and approval. If
>> they have questions, I'll give you a call. Approval usually takes 5-10
>> working days from the time I receive the application from you.
>>
>> Please send your application back to my e-mail address
>> (b)(6)
>> or FAX to 510-865-4090.
>>
>> Thanks so much for your interest in the services supplied by Advanced
>> Bioscience Resources. I apologize again for taking such a long time to
>> respond to your query.
>>
>> Perrin Larton CTBS
>> Procurement Manager
>> Advanced Bioscience Resources
>
>

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Tuesday, November 24, 2009 10:28 AM
To: Hasenkrug, Kim (NIH/NIAID) [E]
Subject: HasenkrugK_NIAID_4980_CY2009

Good Afternoon Dr. Hasenkrug:

Thank you for the opportunity to review your research project: ***Study of HIV infection & Vaccine Protection..*** Since the work you are doing at the NIH provides little or no risk to human subjects off-site, OHSR has decided the appropriate action for you to take is the following:

- Provide documentation that you will not seek the identity of the subjects who have provided the samples you will receive as well as documentation from ABR that under no circumstances will the identity or link to the identifiers of the subjects be released to you.

An e-mail from you and from ABR holding the key to the code is sufficient documentation.

This action is based on guidance issued on Aug. 10, 2004 by the HHS Office of Human Research Protections, the regulatory office for the protection of human subjects.

Best regards,

OHSR - National Institutes of Health
Bldg 10, Suite 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

The NIH is committed to maintaining the highest standards for the protection of human subjects.


Please consider the environment before printing this e-mail

ADVANCED BIOSCIENCE RESOURCES, INC.

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
1/4/2017	(b)(6)	1033083
	TERMS	CUSTOMER #
	Due Upon Receipt	0522

BILL TO

Rocky Mountain Labs
NIH/NIAID
Kim J. Hasenkrug
903 S. 4th Street
Hamilton, MT 59840

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
1/4/2017	740401	5072	18	Thymus, 2nd Trimester	HASENKRUG	(b)(4)
1/4/2017	740401	5073	18	Liver, 2nd Trimester	HASENKRUG	
				01/10/17 PAID (b)(6)		
				Request by Kim Hasenkrug.		

ADVANCED BIOSCIENCE RESOURCES
1516 OAK ST STE 303
SITE 303
ALAMEDA, CA 94501
(510) 865-5872

Sale

VISA Entry Method: Manual

Total: $ 680.00

01/10/17 15:48:30
Inv #: 0000005 Appr Code: 015591
Approvd: Online Batch#: 010001
AVS Code: ZIP MATCH Z
CVV2 Code: MATCH M

Total	**$680.00**

SEQ: 1825906	PO#: (b)(6)	Requester: Messer, Ronald

CAN: 8335424 FY: 17 Owner: (b)(6)
Order Total: 680.00 Project: 107833
Date Needed: 12/02/2016 Emergency: Yes Order Type: Purchase Card
Requestor Phone: +1 406 363 9276 Order Status: Archive

Vendor Advanced Bioscience Resources,1516 Oak Street, Suite 303, Alameda, CA 94501
Phone: 510-865-5872 SmlBs: No FSS:
EIN: BPA: GSA:
Site: Clerk:
E-mail:

#	Description	CAN	Catalog	OC Code	Category	Qty at Price	Total
1	Tissue, 2nd Trimester (1 each of liver and thymus)	8335424	none	2613	6509	(b)(4)	680.00
2	shipping	8335424		2613	6509	1 each at $0	.00

Order Total: 680.00

Ship To: Ronald Messer,3220 ,RML CNTRL REC,RMTLAB

QUOTES

Vendor	Price	Good Until	Available
There are no quotes in the order			

JUSTIFICATION

These tissues, liver and thymus, are required Ron Messer for ongoing studies of HIV in the Hasenkrug Lab. Our mice will be ready for reconstitution soon. Please let me know when I can contact Perrin Larton at ABR to place our request on their schedule. Please contact the vendor at 510-865-5872 ext (b)(6) -give her the PO number Thanks, Ron. *** I certify that I have checked the sources of supply and services listed in FAR 8.002. ( ) I have purchased from the highest priority source available. (X) I did not purchase from a priority source because none could satisfy the requirement of the government either in product/service specifications, quality or required delivery time. **********NOTE to Purchasing Agent: Call vendor at 510-865-5872 ext (b)(6) (b)(6) -give her the PO number and credit card information.

Alternate Sources:

NIH Surplus: No	UNICOR: No	GSA Stock Catalog: No	GSA Self Service: No	Federal Supply: No	Open Market: Yes

AGENT

Purchase Order #: (b)(6)
Custodial Code: 30102
Order Reference: (b)(6)
FSS:
NBS Ref Order #: 4416699

Estimated Ship Date:
Date Entered into NBS: 12/02/2016
Expected Delivery Date: 12/06/2016
Select Agents: No
Clearance Requested: No

SF-37 Code:

Notes

There are no notes in the order

IT Clearance

Never seen by IT officer

ROUTE HISTORY

Role Summary

User Role	Name
Requester	Messer, Ronald
Releaser	Messer, Ronald
Admin Officer	(b)(6)
Lead Admin Officer	
Purchase Agent	(b)(6)
Lead Agent	
IT Clearance Officer	
Releaser1	
Releaser2	
NBS	
Receiving Official	

Dates

Description	Date
Needed By	12/02/2016
Submitted to NBS	12/02/2016
NBS Confirmation	12/03/2016
Award Created	12/02/2016
Award Received	12/02/2016
Estimated Ship Date	
Received	12/30/2016
Canceled	

Routing History

Name	Role	Date In	STATUS IN	ACTION
(b)(6)	Requester	12/01/2016	New order	Approved
	Administrative Officer	12/01/2016	Released	Approved
	Purchasing Agent	12/02/2016	Approved	Approved
NBS, NBS	NBS	12/02/2016	Sent to NBS	Approved
Messer, Ronald (b)(6)	Requester for receiving	12/02/2016	Pending receiving	Take
(b)(6)	Requester for receiving	12/30/2016	Pending receiving	Approved
	Archive	12/30/2016	Archive	(N/A)

Receiving Report

#	Description	Total Qty Ordered	Total Qty Received	Date Received
1	Tissue, 2nd Trimester (1 each of liver and thymus)	2	2	12/30/2016
2	shipping	1	1	12/30/2016

OHSR RESPONSE TO REQUEST FOR REVIEW OF RESEARCH ACTIVITY
INVOLVING HUMAN SUBJECTS

FAX:

Exempt: #: 4980

To: Hasenkrug, Kim
NIAID
RML - Rocky Mountain Laboratories, 3/218

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
Recent reports have demonstrated that immunodeficient mice reconstituted with 17-19 week old human fetal tissue develop a human immune system and are susceptible to HIV infection and disease. The goal of this project proposal is to create such humanized mice to study the role of immune cell subsets and virus-neutralizing antibodies in vaccine protection. The experiments will entail the development of a cohort of mice all reconstituted with the same human cells so as to be histocompatible. This will require transplantation of

Original Request Received in OHSR on: 11/19/2009

Responsible NIH Research Investigator(s): Kim Hasenkrug, NIAID

OHSR review of your request dated Thu, Nov 19, 2009 has determined that:

☒ Federal regulations for the protection of human subjects do not apply to above named activity. The OHSR determination of Not Human Subjects Research is based on the interpretation of 45 CFR 46 under "Research Involving Coded Private Information or Biological Specimens" (OHRP, Revised October 16, 2008) and Guidance on Engagement of Institutions in Human Subjects Research (October 16, 2008). NOTIFY OHSR VIA AN E-MAIL AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESEARCH ACTIVITY.

☐ The activity is designated **EXEMPT**, and has been entered in the OHSR database. PLEASE NOTIFY OHSR OF ANY **SIGNIFICANT** CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.

☐ **NOT EXEMPT**. OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additional information in order to determine whether expedited or full review is appropriate.

☐ Confidentiality Agreement

☐ Reliance

☐ Amendment

☐ Other

Office Person LB Admin Assist. CB

Note:
(b)(6)

CIP

for Charlotte Holden, JD — Acting Director, OHSR — 12/14/2009
Signature — Title — Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: Yes

OHSR Use Only
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

#4980

REQUEST FOR REVIEW OF RESEARCH ACTIVITY INVOLVING HUMAN SUBJECTS

INSTRUCTIONS: Please type directly on this form. You can expand the document if you need more space. If your research involves a survey or questionnaire, please attach it to this completed form.

Completed forms (with all required signatures) may be sent to OHSR by FAX (301-402-3443), email to ohsr_nih_ddir@od.nih.gov, or by mail (2C146). If you have any questions, call OHSR at (301) 402-3444.

Date: 11/19/2009

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146

From: Kim J Hasenkrug
(Signature)

Through: (b)(6) (acting)
(Signature of appropriate Official for IC, e.g., Lab/Branch Chief)

Protocol Title: Study of HIV infection and vaccine protection in mice reconstituted with a human immune system

Name of NIH Principal Investigator(s): Kim J Hasenkrug, Senior Investigator

IC NIAID Laboratory/Branch LPVD Building & Room No. RML 3218
Tel. No. 406-363-9310 FAX No. 406-363-9286
Is the Principal investigator an NIH employee? x **Yes** ____ **No**

If no, please explain: ____

1. What is the proposed research activity that you intend to perform at NIH (please use lay terms):
Recent reports have demonstrated that immunodeficient mice reconstituted with 17-19 week old human fetal tissue develop a human immune system and are susceptible to HIV infection and disease. The goal of this project proposal is to create such humanized mice to study the role of immune cell subsets and virus-neutralizing antibodies in vaccine protection. The experiments will entail the development of a cohort of mice all reconstituted with the same human cells so as to be histocompatible. This will require transplantation of the mice with 1 mm^3 pieces of fetal thymus as well as reconstitution with stem cells isolated from cord blood and liver. Once the humanized mice have been established some will be vaccinated to prime distinct subsets of immune cells. Immune cell subsets from vaccinated mice will be adoptively transferred into naïve mice, which will then be infected with HIV to

test the antiviral activity of the immune cells. The goal of these experiments is to establish correlates of immunity against HIV.

2. If applicable, list your non-NIH Collaborating Investigator(s).

Name Institution Address Tel. # FAX #

3. Proposed start date of your research __April, 2010_____
Proposed completion date _April, 2013_____

4. Will you be _____these samples or data?

Collecting Yes/(No)
Receiving (Yes)/No
Sending Yes/(No)

5. Do the samples or data:
(a) Already exist?___Yes _x__No

(b) Or are they being collected for the express purpose of this study? _X__Yes __No
If "yes," please describe:_

17-19 week fetal cells and tissue will be obtained from Advanced Bioscience Resources, Inc., a non-profit foundation established under California law to provide biomedical researchers access to human tissues in compliance with state, federal, and NIH guidelines. Consent to donate is obtained in accordance with UAGA and NOTA guidelines. Related documents including the consent form are attached._____

(c) Or a combination of (a) and (b)? ____Yes _____No

6. What role will you have in this research project? (Check all that apply)

___ Analyze samples/data only.

___ Consultant/advisor to collaborator(s) listed above.

___ Author of the protocol that is being implemented by your collaborating investigator (identified in question #2).

___ Co-authorship on publication(s)/manuscript(s) pertaining to this research.

___ You or NIH hold an IND for this research.

__X_ Decisional authority over the design or implementation of the research at the IRB approved site? If so, please explain.

I am the PI and lead investigator on this project which will take place in my laboratory and the animal care facilities at Rocky Mountain Labs, NIAID, NIH.

___Other (If necessary, use this space to describe your role in this research).

7. Where are the subjects of this research activity located?
The material for this research is obtained from natural or induced abortions from females in California. Thus the tissues and cells involved will not be from living humans.

8. If human subjects are located elsewhere (not at NIH), will you have direct contact or intervention with them? (Examples: as subject's physician; in obtaining samples directly from the subject; by interviewing the subject?) ____ Yes __x__No

9. What kind of human samples (e.g., tissue, blood) or data (e.g., private information, responses to questionnaires) will be involved in your research?
_Samples will include cord blood, fetal blood, thymus, liver, and bone marrow. No private information will be involved._____

---

10. If the samples, data do not come from an IRB approved protocol, do they come from:

(a) Repository ____Yes ___ No

(b) Pathological waste ___ Yes _____No

(c) Autopsy material ___ Yes ___ No

(d) Publicly available source _X__Yes ___ No

(e) Other_____

11. Please check the box(es) that apply(ies) to the samples/data that you will receive.

(a) ____ Samples and/or data will be anonymized/unlinked. (The samples/data cannot be linked to individual subjects by you or your collaborators at other sites.)

(b) ___ Samples and/or data will be coded, however that code cannot be used by either the sender or the receiver to identify specific individuals.

(c) __X_ Samples and/or data will be coded so that the provider of the samples/data can link them to specific individuals but the receiver will not be able to do so.

12. Will you send results back to the provider(s) (listed in question 2 of this form)?

(a) __X_ No, I will not send results back to the provider(s).

(b) ___ Yes, I will send aggregate results to the provider(s).

(c) ___ Yes, I will send results to the provider(s) that are linked to identifiable individuals.

If yes, does the provider intend to link your data to identifiable individuals?
_____Yes _____No

13. Has the research activity <u>that you are proposing in this form</u> been approved by an Institutional Review Board (IRB) elsewhere?

_____ Yes, the NIH research activity has been reviewed by the following IRB (s) (Please provide the following information for each IRB):

_____ Name of institution that provided the review

_____ Address of reviewing institution

_____ Name of PI for the IRB approved protocol

_____ Title of IRB approved protocol and protocol #

_____ Federal Wide Assurance (FWA) number**

___X_____No IRB review of the research activity described in question #1 above has taken place

(**An FWA is a contract between the U.S. Department of Health and Human Services (DHHS) and an entity receiving DHHS funds to conduct clinical research that the latter will follow ethical guidelines and federal regulations for the protection of human subjects. For a list of domestic and international institutions go to http://ohrp.cit.nih.gov/search/asearch.asp#ASUR

14. Per NIH guidance*, have conflicts of interest by NIH employees, if any, been resolved?**

__X___Yes _____No no conflicts of interest

If your answer is no, please see your Clinical Director about this matter before proceeding with this research.

***The January 5, 2005 NIH Guide to Preventing Conflict of Interest applies to all research conducted at NIH, http://ohsr.od.nih.gov/New/mpafwa_docs.html

ADVANCED BIOSCIENCE RESOURCES, INC

OVERVIEW

ADVANCED BIOSCIENCE RESOURCES is a non-profit corporate foundation established in 1989 under California law to provide biomedical researchers with access to human tissues. ABR was formed exclusively for biomedical, scientific, and educational purposes and is devoted to providing services in connection with the procurement of human organs and tissues for medical and scientific research. ABR specializes in the procurement, preservation and distribution of both human fetal tissues and full term umbilical cord blood for research, and provides a highly individualized, reliable and easily accessible service.

TISSUE COLLECTION AND DISTRIBUTION: The purpose of ABR is to promote cooperative efforts to collect and distribute human tissues and to thereby facilitate research utilizing those tissues. Trained personnel coordinate the retrieval, preservation and delivery of each specimen.

Tissues obtained through ABR are retrieved from routinely performed surgical procedures including first and second trimester induced abortions, and full term deliveries, either natural or caesarian section. Tissues that were once discarded are now available to scientists worldwide through the efforts of ABR. Researchers may specify tissue characteristics, preservation methods, and delivery times.

PRESERVATION METHODS: Each specimen is collected, preserved, and shipped according to the investigator's individual protocol.

QUALITY CONTROL: ABR practices strict quality control procedures and adheres to stringent guidelines for tissue collection and preservation. Consent is obtained in accordance with UAGA and NOTA guidelines. Tissue specimens are identified, dissected, and transferred to the specified medium. A control number is then assigned to each sample to ensure confidentiality of patient identity.

To assure proper processing of the tissue, every researcher selects a collection/preservation protocol tailored specifically to his needs. In the collection and distribution of these tissues, every effort is made to exercise the highest standards of medical and laboratory practice. ABR specializes in direct communication with each investigator from the initial application to specimen delivery.

INVESTIGATOR APPROVAL: ABR will provide tissue to researchers who provide information on current research funding, and a short summary of their research intent. Investigators must agree to accept responsibility for the potential biohazard of the tissue and to appropriately train laboratory personnel in the proper handling of the tissue. In addition, the researcher must agree to use the tissue solely for research purpose and to acknowledge ABR in any publications resulting from the use of ABR provided tissue.

APPLICATION PROCESS: To request human tissue for research, an application must be completed and submitted to ABR. The application will be reviewed for feasibility and priority. A protocol will be developed to meet individual research needs as identified in the application.

SERVICE AND PROCESSING FEES: Participating medical facilities that enable ABR to enact its tissue acquisition and distribution programs may be paid a nominal fee for such services. A minimal processing / preservation / shipment fee is also assessed for services provided to research facilities.

1516 Oak Street # 303 / Alameda, CA 94501 / 510-865-5872 / Fax 510-865-4090 / email abr@abr-inc.com

Recent advancements in medical research have been developed through the use of human tissues in scientific study. Diseases such as diabetes, hemophilia, Parkinson's disease, cancer, AIDS, heart and lung disease, as well as genetic and,neonatal disorders, are being investigated for the development of cures through the use of human fetal tissues. Any tissue donated may be distributed to medical institutions and private research groups in the United States and internationally to enhance the development of cures and therapies for disease.

PERMISSION FOR DONATION OF TISSUE
OBTAINED AT THE TIME OF ABORTION

I have previously decided to have an abortion and have previously consented to having such abortion.

I hereby donate the aborted material and/or a sample of my blood as an anatomical gift for the purposes of education, research, or for the advancement of medical science. I understand that my donation may be used by research facilities in the United States and abroad.

I also agree that a sample of my blood may be taken after the abortion and that it may be used for research and routine testing for AIDS, hepatitis, or other infectious agents. I understand that, if there is testing, the results will be confidential unless the law requires that they be disclosed.

I understand that the aborted material may be used to derive human pluripotent stem cells for medical research and possibly human transplantation research, and that these cells may be kept for many years. I also understand that my donation may be used for cosmetic purposes. I understand that there is no information associated with aborted material that could link me with my donation. I agree that this donation is made without any restriction or direction regarding the potential recipients of the cells derived from the aborted material and that I have not been informed of the identity of any potential recipients.

I understand that there will be no payment to me and I agree that, although the results of the research on the aborted material may have commercial value, I will have no property or other commercial or financial rights in the aborted material or any product, process, or service which may result from this donation.

I understand that my donation will not result in any direct medical benefit to me.

I understand that my donation is voluntary, and I may refuse to donate aborted material and this will not affect my medical care or my relationship with my physician.

I understand that, if I have any questions about my donation, I can contact ABR at 510-865-5872.

_____ _____
Signature Date

I choose not to participate.

_____ _____
Signature Date

_____ _____
Witness Date

ADVANCED BIOSCIENCE RESOURCES, INC.

APPLICATION FOR THE ACQUISITION OF

HUMAN FETAL TISSUE FOR RESEARCH

All requests for human fetal tissue are reviewed for feasibility of procurement and preparation. When approved, an individual protocol will be developed for the procurement, preparation and delivery of tissue samples, based on the information provided in this application and any subsequent communication.

I. APPLICANT INFORMATION

NAME: Kim J Hasenkrug

TITLE: Senior Investigator

COMPANY: NIAID, NIH

ADDRESS: Rocky Mountain Lab

ADDRESS: 903 S. 4th St

CITY,ST,ZIP: Hamilton, MT 59840

PHONE #: 406-363-9310

ALT. #:

FAX #: 406-363-9286

EMAIL: khasenkrug@nih.gov

DELIVERY OPTIONS:

__X__ Same Day: Commercial carrier, hand delivered
Maximizes cell viability (*geographical limits*)

_____ Next Day: Pickup, delivery Mon-Sat daytime
Economical for fresh, frozen specimens

Applicant will be charged for delivery fees.

Applicant may designate preferred carrier:

Carrier Name: FEDEX

Account #: (b)(4)

BILLING INFORMATION:

BILL TO: Kim J Hasenkrug

COMPANY: Rocky Mountain Labs

ADDRESS: 903 S. 4th St.

ADDRESS:

CITY,ST,ZIP: Hamilton, MT 59840

ACCOUNTING DEPT. PHONE #: 406-363-9438

P.O. # (if required by your company):

P.O. # is not required to submit application

Credit Card #:

Name on CC:

Expiration Date: VISA/MC

SHIP TO: Kim J Hasenkrug
Rocky Mountain Labs
903 S. 4th St
Hamilton, MT 59840

Please indicate how you heard about ABR: (b)(6)

II. HUMAN FETAL TISSUE

Tissue specimens requested: thymus, liver, cord blood

Preferred gestational age (6-24 weeks): 17-19 wks

Proposed starting date: May, 2010

CONTAGIOUS DISEASE SCREENING: Availability of test results varies from 24 hours to 7 days after procurement. Applicant requires the following tests to be performed by ABR:

__X__ No testing required

_____ HIV _____ HSV
_____ HBSAG _____ RPR
_____ CMV _____ HCV

OTHER_____

III. PRESERVATION

ABR uses *BioWhittaker RPMI-1640 With L-Glutamine* for tissue preparation, preservation and shipment. Applicant may supply ABR with other media specific to research needs. Please indicate preference below.

PRESERVATION METHODS AVAILABLE:

__X__ Fresh; shipped on wet ice
_____ Passive freezing on dry ice; shipped on dry ice
_____ "Snap" freezing in LN2; shipped on dry ice
_____ Media provided by applicant
_____ Media provided by ABR (RPMI)

IV. DONOR INFORMATION

CONSENT VERIFICATION: Consent for tissue donation is obtained prior to specimen procurement. The consent is extremely confidential in nature and shall not be communicated to the researcher.

SPECIFIC DONOR INFORMATION: Charts are routinely examined for patient medical histories. Please identify any specific information sought and indicate contraindications to specimen procurement:

_____HIV+ status contraindicates procurement_____

_____

_____

V. RESEARCH DATA

TITLE OF RESEARCH PROJECT: ___The role of virus-specific CD4+__T cells, CD8+ T cells and antibody in vaccine protection against HIV-1 in humanized mice_____

ABR will provide tissue to researchers who provide information on current research funding, and a short summary of their research intent. **(Please attach a brief synopsis of the research project named above.)** Researchers must agree to use the tissue solely for research purposes and to acknowledge ABR in any publications resulting from the use of ABR provided tissue. Updates on research progress will be requested at six-month intervals. Researchers agree to publish the results of the research as promptly after the completion of the research as is reasonably possible without jeopardizing the sponsor's right to secure patents or copyrights necessary to protect its ownership or control of the results of the research. Researchers agree to inform ABR of the name of the publication and the date of the issue in which the results will be published. It is the intent of this requirement to make the results available to the general public through acceptable means of publication.

VI. SOURCE OF FUNDING

Please identify the primary source of funding for this project.

NIH _X___ Other Federal or State Grants _____ Foundation Grants _____ Other (specify) _____

If this application is approved by ABR, ABR shall provide services to the applicant in accordance with the terms and the other conditions on the reverse side, and the signature of the applicant shall constitute acceptance of all such terms and conditions by applicant. The entire agreement between ABR and applicant relating to the services provided by ABR is expressly set forth herein, and any modification of or addition thereto shall be of no force or effect unless it is in writing and signed on behalf of ABR by a duly authorized representative.

BY SIGNING BELOW, THE APPLICANT ACKNOWLEDGES HAVING READ THE TERMS AND CONDITIONS ON THE FOLLOWING PAGE AND AGREES TO SUCH TERMS AND CONDITIONS.

Kim J Havenhuys

____ _____

_Senior Investigator_____
SIGNATURE and TITLE of APPLICANT

DATE 11/2/2009

Please return to:

ADVANCED BIOSCIENCE RESOURCES, INC.
1516 OAK STREET, SUITE 303
ALAMEDA, CALIFORNIA 94501
Telephone: 510-865-5872
Fax: 510-865-4090
Email: abr@abr-inc.com

TERMS AND CONDITIONS OF SERVICES

1. Services

1.1 During the term of this agreement, and pursuant to the terms and conditions hereinafter set forth, ABR will use its best efforts to provide services in connection with supplying researcher with the types of human tissues set forth in this application, as approved

by ABR, suitable for researcher requirements and in the amounts requested based upon ongoing discussions between researcher and ABR pursuant to the information sent by ABR.

1.2 Researcher acknowledges and agrees that ABR will provide the following types of services:

Removing tissue.
Preserving and processing tissue to a form suitable to the researcher needs.
Seeking consent for tissue donations from appropriate individuals, obtaining validly executed consent forms, and maintaining records of such consents in accordance.
Obtaining, labeling, storing, and delivering samples of donor or other required serum, and maintaining a system for matching such samples to specific tissue donations.
Preserving tissue viability and cleanliness during removal, processing, preservation, storage and transportation.
Storing tissue and transporting it to researcher in accordance with section 5.

1.3 In the event that tissues of the type specified in the application become unavailable to ABR, such that ABR is unable to perform the contemplated services, ABR shall have no obligation to perform such services.

2. Representations and Warranties. ABR hereby represents and warrants to researcher that (i) ABR will make no payments to anyone for any tissue transferred in connection with this agreement, and (ii) ABR will verify for each tissue delivery that appropriate consent was obtained for use of such tissue and any associated serum samples, and that adequate records of such consent are maintained; provided, however, that the parties hereto acknowledge and agree that such consents are extremely confidential in nature and shall not, in any case, be communicated to researcher. Researcher hereby represents and warrants to ABR that (i) researcher will neither sell nor transfer for valuable consideration any tissue received through ABR to anyone, (ii) researcher will use the tissue only to satisfy its objectives, which are, as acknowledged and agreed hereto, [research and clinical use], (iii) researcher agrees to inform ABR of any changes in clinical or research use of specimens received from ABR, or in any specifications, constraints, etc. in a timely manner, and (iv) researcher understands the bio-hazardous nature of human tissue and agrees to take proper precautionary measures at all times when handling tissue specimen.

3. Terms. The terms of this agreement shall be for one (1) year, beginning from the date hereof, and terminating one (1) year thereafter, unless either of the parties hereto shall have given to the other thirty (30) days written notice of its intention to terminate this agreement, whereupon same shall terminate thirty (30) days after date of said notice.

In default of notice as aforesaid from either party hereto, this agreement shall continue for further successive terms of one (1) year thereafter and in default of thirty (30) days written notice before the end of an annual term by either of the parties of its intention not to renew, whereupon this agreement shall terminate at the end of said term.

4. Payments. Researcher agrees to pay to ADR a fee for costs incurred by ABR in providing services in connection with the acquisition of each sample of tissue requested by researcher, to be mutually agreed upon by ABR and researcher upon approval of this agreement by ABR.

5. Shipment services.

5.1 All shipments will be made as soon as possible after request has been received by ABR from researcher.

5.2 Researcher acknowledges that networks of tissue availability are neither permanent nor dependable, but rather they fluctuate. However, ABR shall use its best efforts to transfer the tissue in the amounts requested by researcher.

5.3 Shipment will be made in the best possible manner so as to preserve the quality of the tissues. It is understood that the fragility of human tissue is such that damage may occur during shipment. ABR will use its best efforts to comply with the handling and shipment protocols provided by researcher.

5.4 ABR will package the tissue appropriately and, if so requested by researcher, will insure the shipment. Researcher agrees to bear all costs associated with insurance and shipment of any tissue.

5.5 The risk of loss and damage of any tissue or organs shall pass immediately to researcher when the shipment of such tissue or organs is deposited with a carrier for transportation at the F.O.B. point.

6. Limitation of liability. ABR shall not be responsible or liable under any section of this agreement or under any contract, negligence, strict liability or other legal or equitable theory, for the cost of procurement of substitutive services, or any indirect, incidental or consequential damages including, but not limited to loss of revenues and loss of profits. Any liability of ABR under any theory whatsoever will be limited exclusively to the provision of equivalent services by ABR or, if unenforceable, to payment of an amount not greater than any amount actually received by ABR from researcher on account of this agreement.

7. No warranties. It is understood that human tissue is by nature neither permanent nor dependable. Except as expressly set forth in this agreement, ABR makes no representation of any kind, expressed or implied, including any representation with respect to the safety, efficacy or merchantability or the fitness for any purpose with respect to the tissue transferred to researcher in connection with this agreement.

8. Indemnification. Researcher shall indemnify, defend and hold ABR harmless from and against all claims, causes of actions, suits, damages and costs arising out of, resulting from, or otherwise in respect of, the use of tissue transferred in connection with this agreement, except where such claims are the result of negligence of ABR, its employees, staff or agents to (i) comply with any governmental requirements, or (ii) adhere to the terms of this agreement.

9. General. This agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of law. This agreement may not be assigned by either party without the prior written consent of the other.

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Monday, November 23, 2009 10:43 AM
To: Hasenkrug, Kim (NIH/NIAID) [E]
Subject: Request for Review Rec'd-OHSR 4980

Good morning Dr. Hasenkrug,

This email is to verify that OHSR has received your Request for Review of Research and it is currently being processed as OHSR #4980. Please use this number in any future correspondence regarding this study. We will contact you via email if any additional information is needed. If you have not heard from OHSR within 7 business days, please contact us.

Protocol Title: Study of HIV infection and vaccine protection in mice reconstituted with a human immune system

Thank you.

OHSR:
Ph: 301.402.3444
Fax: 301.402.3443

Thank you.

Sincerely,

(b)(6)

OHSR (NIH/DDIR)

From: Hasenkrug, Kim (NIH/NIAID) [E]
Sent: Wednesday, December 09, 2009 5:41 PM
To: OHSR (NIH/DDIR)
Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up
Flag Status: Green

Attachments: IRB Letter with letterhead nonidentity.doc

IRB Letter with letterhead non...

Here is the letter on official ABR letterhead for you

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
Laboratory of Persistent Viral Diseases
Rocky Mountain Laboratories
National Institute of Allergy and Infectious Diseases National Institutes of Health
903 S. 4th Street
Hamilton, MT 59840
phone (406)363-9310
FAX (406)363-9286
khasenkrug@nih.gov

> From: "OHSR (NIH/DDIR)" <ohsr_nih_ddir@od.nih.gov>
> Date: Tue, 24 Nov 2009 10:27:55 -0500
> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
> Conversation: HasenkrugK_NIAID_4980_CY2009
> Subject: HasenkrugK_NIAID_4980_CY2009
>
> Good Afternoon Dr. Hasenkrug:
>
> Thank you for the opportunity to review your research project: Study
> of HIV infection & Vaccine Protection.. Since the work you are doing
> at the NIH provides little or no risk to human subjects off-site, OHSR
> has decided the appropriate action for you to take is the following:
>
> * Provide documentation that you will not seek the identity of the
> subjects who have provided the samples you will receive as well as
> documentation from ABR that under no circumstances will the identity
> or link to the identifiers of the subjects be released to you.
>
> An e-mail from you and from ABR holding the key to the code is
> sufficient documentation.
>
> This action is based on guidance issued on Aug. 10, 2004 by the HHS
> Office of Human Research Protections, the regulatory office for the
> protection of human subjects.

> Best regards,
>
>
>
> OHSR - National Institutes of Health
> Bldg 10, Suite 2C146
> Bethesda, MD 20892
> Office Telephone: 301-402-3444
> Office Fax: 301-402-3443
>
> The NIH is committed to maintaining the highest standards for the
> protection of human subjects.
> P Please consider the environment before printing this e-mail
>

ADVANCED BIOSCIENCE RESOURCES, INC

December 14, 2009

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
903 S. 4th Street
Hamilton, MT 59840

Dear Kim,

This letter verifies that ABR, a non-profit tissue procurement organization, supplies requesting and approved scientific investigators with the types of human fetal tissues required for specific bio-medical research. When requested and as availability allows, human fetal tissue specimens will be retrieved from products of conception from induced first and second trimester abortions. Tissue will be distributed according to established protocols. Specimens are not collected for directed donation. .

ABR warrants that maternal consent from patients aged over eighteen years is obtained for the use of fetal tissue specimens for research purposes, including the consent for the potential of stem cell research utilizing such tissues, and that adequate records of such consent are maintained for future verification. Donor identification is coded and scientific investigators have no access to donor identification. ABR also warrants that maternal consent is obtained for phlebotomy and blood testing for a variety of disease entities.

ABR warrants that no payments will be made to any third party for the conduct of or the product of an abortion, including without limitation any parent(s) of any unborn fetus. ABR, to the best of its knowledge, also warrants that all tissue provided will have been obtained in compliance with local, state and federal laws and regulations governing the procurement and distribution of human tissue.

Sincerely,

Perrin Larton

Perrin Larton, CTBS
Procurement Manager

Federal E.I.N.: 94-3110160
California E.I.N.: 370-20518
FDA FEI: 3005208435

1516 Oak Street # 303 / Alameda, CA 94501 / 510-865-5872 / Fax 510-865-4090 / email abr@abr-inc.com

OHSR (NIH/DDIR)

From: Hasenkrug, Kim (NIH/NIAID) [E]
Sent: Monday, November 30, 2009 5:24 PM
To: OHSR (NIH/DDIR)
Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up
Flag Status: Green

Attachments: Re: HFT Application

Re: HFT Application

HasenkrugK_NIAID_4980_CY2009

Attached please find the requested email from ABR stating that no personally identifiable information will be released to me. Furthermore, I will not seek any such information from ABR.

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
Laboratory of Persistent Viral Diseases
Rocky Mountain Laboratories
National Institute of Allergy and Infectious Diseases National Institutes of Health
903 S. 4th Street
Hamilton, MT 59840
phone (406)363-9310
FAX (406)363-9286
khasenkrug@nih.gov

> From: "OHSR (NIH/DDIR)" <ohsr_nih_ddir@od.nih.gov>
> Date: Tue, 24 Nov 2009 10:27:55 -0500
> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
> Conversation: HasenkrugK_NIAID_4980_CY2009
> Subject: HasenkrugK_NIAID_4980_CY2009
>
> Good Afternoon Dr. Hasenkrug:
>
> Thank you for the opportunity to review your research project: Study
> of HIV infection & Vaccine Protection.. Since the work you are doing
> at the NIH provides little or no risk to human subjects off-site, OHSR
> has decided the appropriate action for you to take is the following:
>
> * Provide documentation that you will not seek the identity of the
> subjects who have provided the samples you will receive as well as
> documentation from ABR that under no circumstances will the identity
> or link to the identifiers of the subjects be released to you.
>
> An e-mail from you and from ABR holding the key to the code is
> sufficient documentation.

>
> This action is based on guidance issued on Aug. 10, 2004 by the HHS
> Office of Human Research Protections, the regulatory office for the
> protection of human subjects.
>
> Best regards,
>
>
>
> OHSR - National Institutes of Health
> Bldg 10, Suite 2C146
> Bethesda, MD 20892
> Office Telephone: 301-402-3444
> Office Fax: 301-402-3443
>
> The NIH is committed to maintaining the highest standards for the
> protection of human subjects.
> P Please consider the environment before printing this e-mail
>

OHSR (NIH/DDIR)

From: Perrin Larton (b)(6)

Sent: Monday, November 30, 2009 5:10 PM

To: Hasenkrug, Kim (NIH/NIAID) [E]

Cc: (b)(6)

Subject: Re: HFT Application

Hi Kim,

All tissue is numerically coded and the personally identifiable information is never available. In other NIH applications we've had requests for letters that state NO information is available to researchers. I can send you a letter to that effect...but tissue cannot be tracked back to a specific patient. We guarantee anonymity to the patients donating tissue.

Perrin

> Dear Perrin, the Office of Human Subjects Research is asking me for a
> letter
> from you stating that personally identifiable information regarding the
> fetal tissue will be revealed to me. Would you kindly send me a letter
> stating such so that I can forward it to them? It would be greatly
> appreciated and let us begin our experiments. I attached a copy your
> letter
> regarding approval of our application for your information. Thank you
> very
> much, Perrin.
>
> Kim
>
> Kim J Hasenkrug, Ph.D.
> Senior Investigator
> Chief, Retroviral Immunology Section
> Laboratory of Persistent Viral Diseases
> Rocky Mountain Laboratories
> National Institute of Allergy and Infectious Diseases
> National Institutes of Health
> 903 S. 4th Street
> Hamilton, MT 59840
> phone (406)363-9310
> FAX (406)363-9286
> khasenkrug@nih.gov
>
> Disclaimer:
> The information in this e-mail and any of its attachments is confidential
> and may contain sensitive information. It should not be used by anyone who
> is not the original intended recipient. If you have received this e-mail
> in
> error please inform the sender and delete it from your mailbox or any
> other
> storage devices. National Institute of Allergy and Infectious Diseases
> shall
> not accept liability for any statements made that are sender's own and not
> expressly made on behalf of the NIAID by one of its representatives

>
>
>> From: Perrin Larton (b)(6)
>> Reply-To: (b)(6)
>> Date: Mon, 2 Nov 2009 13:40:51 -0500
>> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
>> Conversation: HFT Application
>> Subject: HFT Application
>>
>> Dear Kim,
>>
>> Attached you'll find the documents we just discussed. What I'll need
>> back
>> from you is the two page application as well as a short synopsis of the
>> work you'll be doing. As soon as I get the completed application from
>> you
>> it will go to our Scientific Advisory Board for review and approval. If
>> they have questions, I'll give you a call. Approval usually takes 5-10
>> working days from the time I receive the application from you.
>>
>> Please send your application back to my e-mail address
>> (b)(6)
>> or FAX to 510-865-4090.
>>
>> Thanks so much for your interest in the services supplied by Advanced
>> Bioscience Resources. I apologize again for taking such a long time to
>> respond to your query.
>>
>> Perrin Larton CTBS
>> Procurement Manager
>> Advanced Bioscience Resources
>
>

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Tuesday, November 24, 2009 10:28 AM
To: Hasenkrug, Kim (NIH/NIAID) [E]
Subject: HasenkrugK_NIAID_4980_CY2009

Good Afternoon Dr. Hasenkrug:

Thank you for the opportunity to review your research project: ***Study of HIV infection & Vaccine Protection..*** Since the work you are doing at the NIH provides little or no risk to human subjects off-site, OHSR has decided the appropriate action for you to take is the following:

- Provide documentation that you will not seek the identity of the subjects who have provided the samples you will receive as well as documentation from ABR that under no circumstances will the identity or link to the identifiers of the subjects be released to you.

An e-mail from you and from ABR holding the key to the code is sufficient documentation.

This action is based on guidance issued on Aug. 10, 2004 by the HHS Office of Human Research Protections, the regulatory office for the protection of human subjects.

Best regards,

OHSR - National Institutes of Health
Bldg 10, Suite 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

The NIH is committed to maintaining the highest standards for the protection of human subjects.


Please consider the environment before printing this e-mail

ADVANCED BIOSCIENCE RESOURCES, INC.

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
1/11/2017	(b)(6)	1033105
	TERMS	CUSTOMER #
	Due Upon Receipt	0522

BILL TO

Rocky Mountain Labs
NIH/NIAID
Kim J. Hasenkrug
903 S. 4th Street
Hamilton, MT 59840

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
1/11/2017	671104	6418	20	Thymus, 2nd Trimester	KIM	(b)(4)
1/11/2017	671104	6419	20	Liver, 2nd Trimester	KIM	
				01/25/17 PAID (b)(6)		
				Request by Kim Hasenkrug.		

ADVANCED BIOSCIENCE RESOURCES
1516 Oak St Ste 303
Ste 303
Alameda, CA 94501
(510) 865-5872

Sale

VISA Entry Method: Manual

Total: $ 680.00

01/25/17 15:56:54
Inv #: 0000066 Appr Code: 016306
Approved: Online Batch#: 025001
AVS Code: ZIP MATCH Z
CVV2 Code: MATCH M

Total $680.00

SEQ: 1829765	PO#: (b)(6)	Requester: Messer, Ronald

CAN: 8335424 FY: 17 Owner: (b)(6)
Order Total: 680.00 Project: 107833
Date Needed: 01/03/2017 Emergency: Yes Order Type: Purchase Card
Requestor Phone: +1 406 363 9276 Order Status: Archive

Vendor Advanced Bioscience Resources,1516 Oak Street, Suite 303, Alameda, CA 94501
Phone: 510-865-5872 SmlBs: No FSS:
EIN: BPA: GSA:
Site: Clerk:
E-mail:

#	Description	CAN	Catalog	OC Code	Category	Qty at Price	Total
1	Tissue, 2nd Trimester (1 each of liver and thymus)	8335424	none	2613	6509	(b)(4)	680.00
2	shipping	8335424		2613	6509	1 each at $0	.00

Order Total: 680.00

Ship To: Ronald Messer,3220 ,RML CNTRL REC,RMTLAB

QUOTES

Vendor	Price	Good Until	Available
There are no quotes in the order			

JUSTIFICATION

These tissues, liver and thymus, are required Ron Messer for ongoing studies of HIV in the Hasenkrug Lab. Our mice will be ready for reconstitution soon. Please let me know when I can contact Perrin Larton at ABR to place our request on their schedule. Please contact the vendor at 510-865-5872 ext (b)(6) -give her the PO number Thanks, Ron. *** I certify that I have checked the sources of supply and services listed in FAR 8.002. ( ) I have purchased from the highest priority source available. (X) I did not purchase from a priority source because none could satisfy the requirement of the government either in product/service specifications, quality or required delivery time. **********NOTE to Purchasing Agent: Call vendor at 510-865-5872 ext (b)(6) (b)(6) -give her the PO number and credit card information.

Alternate Sources:

NIH Surplus: No | UNICOR: No | GSA Stock Catalog: No | GSA Self Service: No | Federal Supply: No | Open Market: Yes

AGENT

Purchase Order #: (b)(6)
Custodial Code: 30102
Order Reference: (b)(6)
FSS:
NBS Ref Order #: 4443715

Estimated Ship Date:
Date Entered into NBS: 12/30/2016
Expected Delivery Date: 01/06/2017
Select Agents: No
Clearance Requested: No

SF-37 Code:

Notes

There are no notes in the order

IT Clearance

Never seen by IT officer

ROUTE HISTORY

Role Summary

User Role	Name
Requester	Messer, Ronald
Releaser	Messer, Ronald
Admin Officer	(b)(6)
Lead Admin Officer	
Purchase Agent	(b)(6)
Lead Agent	
IT Clearance Officer	
Releaser1	
Releaser2	
NBS	
Receiving Official	

Dates

Description	Date
Needed By	01/03/2017
Submitted to NBS	12/30/2016
NBS Confirmation	12/31/2016
Award Created	12/30/2016
Award Received	12/30/2016
Estimated Ship Date	
Received	02/10/2017
Canceled	

Routing History

Name	Role	Date In	STATUS IN	ACTION
Messer, Ronald	Requester	12/30/2016	New order	Approved
(b)(6)	Administrative Officer	12/30/2016	Released	Approved
	Purchasing Agent	12/30/2016	Approved	Approved
NBS, NBS	NBS	12/30/2016	Sent to NBS	Approved
Messer, Ronald (b)(6)	Requester for receiving	12/30/2016	Pending receiving	Take
(b)(6)	Requester for receiving	02/10/2017	Pending receiving	Approved
	Archive	02/10/2017	Archive	(N/A)

Receiving Report

#	Description	Total Qty Ordered	Total Qty Received	Date Received
1	Tissue, 2nd Trimester (1 each of liver and thymus)	2	2	02/10/2017
2	shipping	1	1	02/10/2017

OHSR RESPONSE TO REQUEST FOR REVIEW OF RESEARCH ACTIVITY
INVOLVING HUMAN SUBJECTS

FAX:

Exempt: #: 4980

To: Hasenkrug, Kim
NIAID
RML - Rocky Mountain Laboratories, 3/218

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
Recent reports have demonstrated that immunodeficient mice reconstituted with 17-19 week old human fetal tissue develop a human immune system and are susceptible to HIV infection and disease. The goal of this project proposal is to create such humanized mice to study the role of immune cell subsets and virus-neutralizing antibodies in vaccine protection. The experiments will entail the development of a cohort of mice all reconstituted with the same human cells so as to be histocompatible. This will require transplantation of

Original Request Received in OHSR on: 11/19/2009

Responsible NIH Research Investigator(s): Kim Hasenkrug, NIAID

OHSR review of your request dated Thu, Nov 19, 2009 has determined that:

☒ Federal regulations for the protection of human subjects do not apply to above named activity. The OHSR determination of Not Human Subjects Research is based on the interpretation of 45 CFR 46 under "Research Involving Coded Private Information or Biological Specimens" (OHRP, Revised October 16, 2008) and Guidance on Engagement of Institutions in Human Subjects Research (October 16, 2008). NOTIFY OHSR VIA AN E-MAIL AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESEARCH ACTIVITY.

☐ The activity is designated **EXEMPT**, and has been entered in the OHSR database. PLEASE NOTIFY OHSR OF ANY **SIGNIFICANT** CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.

☐ **NOT EXEMPT**. OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additional information in order to determine whether expedited or full review is appropriate.

☐ Confidentiality Agreement

☐ Reliance

☐ Amendment

☐ Other

Office Person LB Admin Assist. CB

Note:
(b)(6)

CIP

for Charlotte Holden, JD — Acting Director, OHSR — 12/14/2009
Signature — Title — Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: Yes

OHSR Use Only
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

#4980

REQUEST FOR REVIEW OF RESEARCH ACTIVITY INVOLVING HUMAN SUBJECTS

INSTRUCTIONS: Please type directly on this form. You can expand the document if you need more space. If your research involves a survey or questionnaire, please attach it to this completed form.

Completed forms (with all required signatures) may be sent to OHSR by FAX (301-402-3443), email to ohsr_nih_ddir@od.nih.gov, or by mail (2C146). If you have any questions, call OHSR at (301) 402-3444.

Date: 11/19/2009

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146

From: Kim J Hasenkrug
(Signature)

Through: (b)(6) (acting)
(Signature of appropriate Official for IC, e.g., Lab/Branch Chief)

Protocol Title: Study of HIV infection and vaccine protection in mice reconstituted with a human immune system

Name of NIH Principal Investigator(s): Kim J Hasenkrug, Senior Investigator

IC NIAID Laboratory/Branch LPVD Building & Room No. RML 3218
Tel. No. 406-363-9310 FAX No. 406-363-9286
Is the Principal investigator an NIH employee? x **Yes** ____ **No**

If no, please explain: ____

1. What is the proposed research activity that you intend to perform at NIH (please use lay terms):

Recent reports have demonstrated that immunodeficient mice reconstituted with 17-19 week old human fetal tissue develop a human immune system and are susceptible to HIV infection and disease. The goal of this project proposal is to create such humanized mice to study the role of immune cell subsets and virus-neutralizing antibodies in vaccine protection. The experiments will entail the development of a cohort of mice all reconstituted with the same human cells so as to be histocompatible. This will require transplantation of the mice with 1 mm^3 pieces of fetal thymus as well as reconstitution with stem cells isolated from cord blood and liver. Once the humanized mice have been established some will be vaccinated to prime distinct subsets of immune cells. Immune cell subsets from vaccinated mice will be adoptively transferred into naïve mice, which will then be infected with HIV to

test the antiviral activity of the immune cells. The goal of these experiments is to establish correlates of immunity against HIV.

2. If applicable, list your non-NIH Collaborating Investigator(s).

Name Institution Address Tel. # FAX #

3. Proposed start date of your research __April, 2010_____
Proposed completion date _April, 2013_____

4. Will you be _____these samples or data?

Collecting Yes/(No)
Receiving (Yes)/No
Sending Yes/(No)

5. Do the samples or data:
(a) Already exist?___Yes _x__No

(b) Or are they being collected for the express purpose of this study? _X__Yes __No
If "yes," please describe:_

17-19 week fetal cells and tissue will be obtained from Advanced Bioscience Resources, Inc., a non-profit foundation established under California law to provide biomedical researchers access to human tissues in compliance with state, federal, and NIH guidelines. Consent to donate is obtained in accordance with UAGA and NOTA guidelines. Related documents including the consent form are attached._____

(c) Or a combination of (a) and (b)? ____Yes _____No

6. What role will you have in this research project? (Check all that apply)

___ Analyze samples/data only.

___ Consultant/advisor to collaborator(s) listed above.

___ Author of the protocol that is being implemented by your collaborating investigator (identified in question #2).

___ Co-authorship on publication(s)/manuscript(s) pertaining to this research.

___ You or NIH hold an IND for this research.

__X_ Decisional authority over the design or implementation of the research at the IRB approved site? If so, please explain.

I am the PI and lead investigator on this project which will take place in my laboratory and the animal care facilities at Rocky Mountain Labs, NIAID, NIH.

___Other (If necessary, use this space to describe your role in this research).

7. Where are the subjects of this research activity located?
The material for this research is obtained from natural or induced abortions from females in California. Thus the tissues and cells involved will not be from living humans.

8. If human subjects are located elsewhere (not at NIH), will you have direct contact or intervention with them? (Examples: as subject's physician; in obtaining samples directly from the subject; by interviewing the subject?) ____ Yes __x__No

9. What kind of human samples (e.g., tissue, blood) or data (e.g., private information, responses to questionnaires) will be involved in your research?
_Samples will include cord blood, fetal blood, thymus, liver, and bone marrow. No private information will be involved._____

---

10. If the samples, data do not come from an IRB approved protocol, do they come from:

(a) Repository ____Yes ___ No

(b) Pathological waste ___ Yes _____No

(c) Autopsy material ___ Yes ___ No

(d) Publicly available source _X__Yes ___ No

(e) Other_____

11. Please check the box(es) that apply(ies) to the samples/data that you will receive.

(a) ____ Samples and/or data will be anonymized/unlinked. (The samples/data cannot be linked to individual subjects by you or your collaborators at other sites.)

(b) ___ Samples and/or data will be coded, however that code cannot be used by either the sender or the receiver to identify specific individuals.

(c) __X_ Samples and/or data will be coded so that the provider of the samples/data can link them to specific individuals but the receiver will not be able to do so.

12. Will you send results back to the provider(s) (listed in question 2 of this form)?

(a) __X_ No, I will not send results back to the provider(s).

(b) ___ Yes, I will send aggregate results to the provider(s).

(c) ___ Yes, I will send results to the provider(s) that are linked to identifiable individuals.

If yes, does the provider intend to link your data to identifiable individuals?
_____Yes _____No

13. Has the research activity <u>that you are proposing in this form</u> been approved by an Institutional Review Board (IRB) elsewhere?

_____ Yes, the NIH research activity has been reviewed by the following IRB (s) (Please provide the following information for each IRB):

_____ Name of institution that provided the review

_____ Address of reviewing institution

_____ Name of PI for the IRB approved protocol

_____ Title of IRB approved protocol and protocol #

_____ Federal Wide Assurance (FWA) number**

___X_____No IRB review of the research activity described in question #1 above has taken place

(**An FWA is a contract between the U.S. Department of Health and Human Services (DHHS) and an entity receiving DHHS funds to conduct clinical research that the latter will follow ethical guidelines and federal regulations for the protection of human subjects. For a list of domestic and international institutions go to http://ohrp.cit.nih.gov/search/asearch.asp#ASUR

14. Per NIH guidance*, have conflicts of interest by NIH employees, if any, been resolved?**

__X___Yes _____No no conflicts of interest

If your answer is no, please see your Clinical Director about this matter before proceeding with this research.

***The January 5, 2005 NIH Guide to Preventing Conflict of Interest applies to all research conducted at NIH, http://ohsr.od.nih.gov/New/mpafwa_docs.html

ADVANCED BIOSCIENCE RESOURCES, INC

OVERVIEW

ADVANCED BIOSCIENCE RESOURCES is a non-profit corporate foundation established in 1989 under California law to provide biomedical researchers with access to human tissues. ABR was formed exclusively for biomedical, scientific, and educational purposes and is devoted to providing services in connection with the procurement of human organs and tissues for medical and scientific research. ABR specializes in the procurement, preservation and distribution of both human fetal tissues and full term umbilical cord blood for research, and provides a highly individualized, reliable and easily accessible service.

TISSUE COLLECTION AND DISTRIBUTION: The purpose of ABR is to promote cooperative efforts to collect and distribute human tissues and to thereby facilitate research utilizing those tissues. Trained personnel coordinate the retrieval, preservation and delivery of each specimen.

Tissues obtained through ABR are retrieved from routinely performed surgical procedures including first and second trimester induced abortions, and full term deliveries, either natural or caesarian section. Tissues that were once discarded are now available to scientists worldwide through the efforts of ABR. Researchers may specify tissue characteristics, preservation methods, and delivery times.

PRESERVATION METHODS: Each specimen is collected, preserved, and shipped according to the investigator's individual protocol.

QUALITY CONTROL: ABR practices strict quality control procedures and adheres to stringent guidelines for tissue collection and preservation. Consent is obtained in accordance with UAGA and NOTA guidelines. Tissue specimens are identified, dissected, and transferred to the specified medium. A control number is then assigned to each sample to ensure confidentiality of patient identity.

To assure proper processing of the tissue, every researcher selects a collection/preservation protocol tailored specifically to his needs. In the collection and distribution of these tissues, every effort is made to exercise the highest standards of medical and laboratory practice. ABR specializes in direct communication with each investigator from the initial application to specimen delivery.

INVESTIGATOR APPROVAL: ABR will provide tissue to researchers who provide information on current research funding, and a short summary of their research intent. Investigators must agree to accept responsibility for the potential biohazard of the tissue and to appropriately train laboratory personnel in the proper handling of the tissue. In addition, the researcher must agree to use the tissue solely for research purpose and to acknowledge ABR in any publications resulting from the use of ABR provided tissue.

APPLICATION PROCESS: To request human tissue for research, an application must be completed and submitted to ABR. The application will be reviewed for feasibility and priority. A protocol will be developed to meet individual research needs as identified in the application.

SERVICE AND PROCESSING FEES: Participating medical facilities that enable ABR to enact its tissue acquisition and distribution programs may be paid a nominal fee for such services. A minimal processing / preservation / shipment fee is also assessed for services provided to research facilities.

1516 Oak Street # 303 / Alameda, CA 94501 / 510-865-5872 / Fax 510-865-4090 / email abr@abr-inc.com

Recent advancements in medical research have been developed through the use of human tissues in scientific study. Diseases such as diabetes, hemophilia, Parkinson's disease, cancer, AIDS, heart and lung disease, as well as genetic and,neonatal disorders, are being investigated for the development of cures through the use of human fetal tissues. Any tissue donated may be distributed to medical institutions and private research groups in the United States and internationally to enhance the development of cures and therapies for disease.

PERMISSION FOR DONATION OF TISSUE
OBTAINED AT THE TIME OF ABORTION

I have previously decided to have an abortion and have previously consented to having such abortion.

I hereby donate the aborted material and/or a sample of my blood as an anatomical gift for the purposes of education, research, or for the advancement of medical science. I understand that my donation may be used by research facilities in the United States and abroad.

I also agree that a sample of my blood may be taken after the abortion and that it may be used for research and routine testing for AIDS, hepatitis, or other infectious agents. I understand that, if there is testing, the results will be confidential unless the law requires that they be disclosed.

I understand that the aborted material may be used to derive human pluripotent stem cells for medical research and possibly human transplantation research, and that these cells may be kept for many years. I also understand that my donation may be used for cosmetic purposes. I understand that there is no information associated with aborted material that could link me with my donation. I agree that this donation is made without any restriction or direction regarding the potential recipients of the cells derived from the aborted material and that I have not been informed of the identity of any potential recipients.

I understand that there will be no payment to me and I agree that, although the results of the research on the aborted material may have commercial value, I will have no property or other commercial or financial rights in the aborted material or any product, process, or service which may result from this donation.

I understand that my donation will not result in any direct medical benefit to me.

I understand that my donation is voluntary, and I may refuse to donate aborted material and this will not affect my medical care or my relationship with my physician.

I understand that, if I have any questions about my donation, I can contact ABR at 510-865-5872.

_____ _____
Signature Date

I choose not to participate.

_____ _____
Signature Date

_____ _____
Witness Date

ADVANCED BIOSCIENCE RESOURCES, INC.

APPLICATION FOR THE ACQUISITION OF

HUMAN FETAL TISSUE FOR RESEARCH

All requests for human fetal tissue are reviewed for feasibility of procurement and preparation. When approved, an individual protocol will be developed for the procurement, preparation and delivery of tissue samples, based on the information provided in this application and any subsequent communication.

I. APPLICANT INFORMATION

NAME: Kim J Hasenkrug

TITLE: Senior Investigator

COMPANY: NIAID, NIH

ADDRESS: Rocky Mountain Lab

ADDRESS: 903 S. 4th St

CITY,ST,ZIP: Hamilton, MT 59840

PHONE #: 406-363-9310

ALT. #:

FAX #: 406-363-9286

EMAIL: khasenkrug@nih.gov

DELIVERY OPTIONS:

__X__ Same Day: Commercial carrier, hand delivered
Maximizes cell viability (*geographical limits*)

_____ Next Day: Pickup, delivery Mon-Sat daytime
Economical for fresh, frozen specimens

Applicant will be charged for delivery fees.

Applicant may designate preferred carrier:

Carrier Name: FEDEX

Account #: (b)(4)

BILLING INFORMATION:

BILL TO: Kim J Hasenkrug

COMPANY: Rocky Mountain Labs

ADDRESS: 903 S. 4th St.

ADDRESS:

CITY,ST,ZIP: Hamilton, MT 59840

ACCOUNTING DEPT. PHONE #: 406-363-9438

P.O. # (if required by your company):

P.O. # is not required to submit application

Credit Card #:

Name on CC:

Expiration Date: VISA/MC

SHIP TO: Kim J Hasenkrug
Rocky Mountain Labs
903 S. 4th St
Hamilton, MT 59840

Please indicate how you heard about ABR: (b)(6)

II. HUMAN FETAL TISSUE

Tissue specimens requested: thymus, liver, cord blood

Preferred gestational age (6-24 weeks): 17-19 wks

Proposed starting date: May, 2010

CONTAGIOUS DISEASE SCREENING: Availability of test results varies from 24 hours to 7 days after procurement. Applicant requires the following tests to be performed by ABR:

__X__ No testing required

_____ HIV _____ HSV
_____ HBSAG _____ RPR
_____ CMV _____ HCV

OTHER_____

III. PRESERVATION

ABR uses *BioWhittaker RPMI-1640 With L-Glutamine* for tissue preparation, preservation and shipment. Applicant may supply ABR with other media specific to research needs. Please indicate preference below.

PRESERVATION METHODS AVAILABLE:

__X__ Fresh; shipped on wet ice
_____ Passive freezing on dry ice; shipped on dry ice
_____ "Snap" freezing in LN2; shipped on dry ice
_____ Media provided by applicant
_____ Media provided by ABR (RPMI)

IV. DONOR INFORMATION

CONSENT VERIFICATION: Consent for tissue donation is obtained prior to specimen procurement. The consent is extremely confidential in nature and shall not be communicated to the researcher.

SPECIFIC DONOR INFORMATION: Charts are routinely examined for patient medical histories. Please identify any specific information sought and indicate contraindications to specimen procurement:

_____HIV+ status contraindicates procurement_____

_____

_____

V. RESEARCH DATA

TITLE OF RESEARCH PROJECT: ___The role of virus-specific CD4+__T cells, CD8+ T cells and antibody in vaccine protection against HIV-1 in humanized mice_____

ABR will provide tissue to researchers who provide information on current research funding, and a short summary of their research intent. **(Please attach a brief synopsis of the research project named above.)** Researchers must agree to use the tissue solely for research purposes and to acknowledge ABR in any publications resulting from the use of ABR provided tissue. Updates on research progress will be requested at six-month intervals. Researchers agree to publish the results of the research as promptly after the completion of the research as is reasonably possible without jeopardizing the sponsor's right to secure patents or copyrights necessary to protect its ownership or control of the results of the research. Researchers agree to inform ABR of the name of the publication and the date of the issue in which the results will be published. It is the intent of this requirement to make the results available to the general public through acceptable means of publication.

VI. SOURCE OF FUNDING

Please identify the primary source of funding for this project.

NIH _X___ Other Federal or State Grants _____ Foundation Grants _____ Other (specify) _____

If this application is approved by ABR, ABR shall provide services to the applicant in accordance with the terms and the other conditions on the reverse side, and the signature of the applicant shall constitute acceptance of all such terms and conditions by applicant. The entire agreement between ABR and applicant relating to the services provided by ABR is expressly set forth herein, and any modification of or addition thereto shall be of no force or effect unless it is in writing and signed on behalf of ABR by a duly authorized representative.

BY SIGNING BELOW, THE APPLICANT ACKNOWLEDGES HAVING READ THE TERMS AND CONDITIONS ON THE FOLLOWING PAGE AND AGREES TO SUCH TERMS AND CONDITIONS.

Kim J Havenhuys

____ _____

_Senior Investigator_____
SIGNATURE and TITLE of APPLICANT

DATE 11/2/2009

Please return to:

ADVANCED BIOSCIENCE RESOURCES, INC.
1516 OAK STREET, SUITE 303
ALAMEDA, CALIFORNIA 94501
Telephone: 510-865-5872
Fax: 510-865-4090
Email: abr@abr-inc.com

TERMS AND CONDITIONS OF SERVICES

1. Services

1.1 During the term of this agreement, and pursuant to the terms and conditions hereinafter set forth, ABR will use its best efforts to provide services in connection with supplying researcher with the types of human tissues set forth in this application, as approved

by ABR, suitable for researcher requirements and in the amounts requested based upon ongoing discussions between researcher and ABR pursuant to the information sent by ABR.

1.2 Researcher acknowledges and agrees that ABR will provide the following types of services:

Removing tissue.
Preserving and processing tissue to a form suitable to the researcher needs.
Seeking consent for tissue donations from appropriate individuals, obtaining validly executed consent forms, and maintaining records of such consents in accordance.
Obtaining, labeling, storing, and delivering samples of donor or other required serum, and maintaining a system for matching such samples to specific tissue donations.
Preserving tissue viability and cleanliness during removal, processing, preservation, storage and transportation.
Storing tissue and transporting it to researcher in accordance with section 5.

1.3 In the event that tissues of the type specified in the application become unavailable to ABR, such that ABR is unable to perform the contemplated services, ABR shall have no obligation to perform such services.

2. Representations and Warranties. ABR hereby represents and warrants to researcher that (i) ABR will make no payments to anyone for any tissue transferred in connection with this agreement, and (ii) ABR will verify for each tissue delivery that appropriate consent was obtained for use of such tissue and any associated serum samples, and that adequate records of such consent are maintained; provided, however, that the parties hereto acknowledge and agree that such consents are extremely confidential in nature and shall not, in any case, be communicated to researcher. Researcher hereby represents and warrants to ABR that (i) researcher will neither sell nor transfer for valuable consideration any tissue received through ABR to anyone, (ii) researcher will use the tissue only to satisfy its objectives, which are, as acknowledged and agreed hereto, [research and clinical use], (iii) researcher agrees to inform ABR of any changes in clinical or research use of specimens received from ABR, or in any specifications, constraints, etc. in a timely manner, and (iv) researcher understands the bio-hazardous nature of human tissue and agrees to take proper precautionary measures at all times when handling tissue specimen.

3. Terms. The terms of this agreement shall be for one (1) year, beginning from the date hereof, and terminating one (1) year thereafter, unless either of the parties hereto shall have given to the other thirty (30) days written notice of its intention to terminate this agreement, whereupon same shall terminate thirty (30) days after date of said notice.

In default of notice as aforesaid from either party hereto, this agreement shall continue for further successive terms of one (1) year thereafter and in default of thirty (30) days written notice before the end of an annual term by either of the parties of its intention not to renew, whereupon this agreement shall terminate at the end of said term.

4. Payments. Researcher agrees to pay to ADR a fee for costs incurred by ABR in providing services in connection with the acquisition of each sample of tissue requested by researcher, to be mutually agreed upon by ABR and researcher upon approval of this agreement by ABR.

5. Shipment services.

5.1 All shipments will be made as soon as possible after request has been received by ABR from researcher.

5.2 Researcher acknowledges that networks of tissue availability are neither permanent nor dependable, but rather they fluctuate. However, ABR shall use its best efforts to transfer the tissue in the amounts requested by researcher.

5.3 Shipment will be made in the best possible manner so as to preserve the quality of the tissues. It is understood that the fragility of human tissue is such that damage may occur during shipment. ABR will use its best efforts to comply with the handling and shipment protocols provided by researcher.

5.4 ABR will package the tissue appropriately and, if so requested by researcher, will insure the shipment. Researcher agrees to bear all costs associated with insurance and shipment of any tissue.

5.5 The risk of loss and damage of any tissue or organs shall pass immediately to researcher when the shipment of such tissue or organs is deposited with a carrier for transportation at the F.O.B. point.

6. Limitation of liability. ABR shall not be responsible or liable under any section of this agreement or under any contract, negligence, strict liability or other legal or equitable theory, for the cost of procurement of substitutive services, or any indirect, incidental or consequential damages including, but not limited to loss of revenues and loss of profits. Any liability of ABR under any theory whatsoever will be limited exclusively to the provision of equivalent services by ABR or, if unenforceable, to payment of an amount not greater than any amount actually received by ABR from researcher on account of this agreement.

7. No warranties. It is understood that human tissue is by nature neither permanent nor dependable. Except as expressly set forth in this agreement, ABR makes no representation of any kind, expressed or implied, including any representation with respect to the safety, efficacy or merchantability or the fitness for any purpose with respect to the tissue transferred to researcher in connection with this agreement.

8. Indemnification. Researcher shall indemnify, defend and hold ABR harmless from and against all claims, causes of actions, suits, damages and costs arising out of, resulting from, or otherwise in respect of, the use of tissue transferred in connection with this agreement, except where such claims are the result of negligence of ABR, its employees, staff or agents to (i) comply with any governmental requirements, or (ii) adhere to the terms of this agreement.

9. General. This agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of law. This agreement may not be assigned by either party without the prior written consent of the other.

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Monday, November 23, 2009 10:43 AM
To: Hasenkrug, Kim (NIH/NIAID) [E]
Subject: Request for Review Rec'd-OHSR 4980

Good morning Dr. Hasenkrug,

This email is to verify that OHSR has received your Request for Review of Research and it is currently being processed as OHSR #4980. Please use this number in any future correspondence regarding this study. We will contact you via email if any additional information is needed. If you have not heard from OHSR within 7 business days, please contact us.

Protocol Title: Study of HIV infection and vaccine protection in mice reconstituted with a human immune system

Thank you.

OHSR:
Ph: 301.402.3444
Fax: 301.402.3443

Thank you.

Sincerely,

(b)(6)

OHSR (NIH/DDIR)

From: Hasenkrug, Kim (NIH/NIAID) [E]
Sent: Wednesday, December 09, 2009 5:41 PM
To: OHSR (NIH/DDIR)
Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up
Flag Status: Green

Attachments: IRB Letter with letterhead nonidentity.doc

IRB Letter with letterhead non...

Here is the letter on official ABR letterhead for you

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
Laboratory of Persistent Viral Diseases
Rocky Mountain Laboratories
National Institute of Allergy and Infectious Diseases National Institutes of Health
903 S. 4th Street
Hamilton, MT 59840
phone (406)363-9310
FAX (406)363-9286
khasenkrug@nih.gov

> From: "OHSR (NIH/DDIR)" <ohsr_nih_ddir@od.nih.gov>
> Date: Tue, 24 Nov 2009 10:27:55 -0500
> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
> Conversation: HasenkrugK_NIAID_4980_CY2009
> Subject: HasenkrugK_NIAID_4980_CY2009
>
> Good Afternoon Dr. Hasenkrug:
>
> Thank you for the opportunity to review your research project: Study
> of HIV infection & Vaccine Protection.. Since the work you are doing
> at the NIH provides little or no risk to human subjects off-site, OHSR
> has decided the appropriate action for you to take is the following:
>
> * Provide documentation that you will not seek the identity of the
> subjects who have provided the samples you will receive as well as
> documentation from ABR that under no circumstances will the identity
> or link to the identifiers of the subjects be released to you.
>
> An e-mail from you and from ABR holding the key to the code is
> sufficient documentation.
>
> This action is based on guidance issued on Aug. 10, 2004 by the HHS
> Office of Human Research Protections, the regulatory office for the
> protection of human subjects.

> Best regards,
>
>
>
> OHSR - National Institutes of Health
> Bldg 10, Suite 2C146
> Bethesda, MD 20892
> Office Telephone: 301-402-3444
> Office Fax: 301-402-3443
>
> The NIH is committed to maintaining the highest standards for the
> protection of human subjects.
> P Please consider the environment before printing this e-mail
>

ADVANCED BIOSCIENCE RESOURCES, INC

December 14, 2009

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
903 S. 4th Street
Hamilton, MT 59840

Dear Kim,

This letter verifies that ABR, a non-profit tissue procurement organization, supplies requesting and approved scientific investigators with the types of human fetal tissues required for specific bio-medical research. When requested and as availability allows, human fetal tissue specimens will be retrieved from products of conception from induced first and second trimester abortions. Tissue will be distributed according to established protocols. Specimens are not collected for directed donation. .

ABR warrants that maternal consent from patients aged over eighteen years is obtained for the use of fetal tissue specimens for research purposes, including the consent for the potential of stem cell research utilizing such tissues, and that adequate records of such consent are maintained for future verification. Donor identification is coded and scientific investigators have no access to donor identification. ABR also warrants that maternal consent is obtained for phlebotomy and blood testing for a variety of disease entities.

ABR warrants that no payments will be made to any third party for the conduct of or the product of an abortion, including without limitation any parent(s) of any unborn fetus. ABR, to the best of its knowledge, also warrants that all tissue provided will have been obtained in compliance with local, state and federal laws and regulations governing the procurement and distribution of human tissue.

Sincerely,

Perrin Larton

Perrin Larton, CTBS
Procurement Manager

Federal E.I.N.: 94-3110160
California E.I.N.: 370-20518
FDA FEI: 3005208435

1516 Oak Street # 303 / Alameda, CA 94501 / 510-865-5872 / Fax 510-865-4090 / email abr@abr-inc.com

OHSR (NIH/DDIR)

From: Hasenkrug, Kim (NIH/NIAID) [E]
Sent: Monday, November 30, 2009 5:24 PM
To: OHSR (NIH/DDIR)
Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up
Flag Status: Green

Attachments: Re: HFT Application

Re: HFT Application

HasenkrugK_NIAID_4980_CY2009

Attached please find the requested email from ABR stating that no personally identifiable information will be released to me. Furthermore, I will not seek any such information from ABR.

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
Laboratory of Persistent Viral Diseases
Rocky Mountain Laboratories
National Institute of Allergy and Infectious Diseases National Institutes of Health
903 S. 4th Street
Hamilton, MT 59840
phone (406)363-9310
FAX (406)363-9286
khasenkrug@nih.gov

> From: "OHSR (NIH/DDIR)" <ohsr_nih_ddir@od.nih.gov>
> Date: Tue, 24 Nov 2009 10:27:55 -0500
> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
> Conversation: HasenkrugK_NIAID_4980_CY2009
> Subject: HasenkrugK_NIAID_4980_CY2009
>
> Good Afternoon Dr. Hasenkrug:
>
> Thank you for the opportunity to review your research project: Study
> of HIV infection & Vaccine Protection.. Since the work you are doing
> at the NIH provides little or no risk to human subjects off-site, OHSR
> has decided the appropriate action for you to take is the following:
>
> * Provide documentation that you will not seek the identity of the
> subjects who have provided the samples you will receive as well as
> documentation from ABR that under no circumstances will the identity
> or link to the identifiers of the subjects be released to you.
>
> An e-mail from you and from ABR holding the key to the code is
> sufficient documentation.

>
> This action is based on guidance issued on Aug. 10, 2004 by the HHS
> Office of Human Research Protections, the regulatory office for the
> protection of human subjects.
>
> Best regards,
>
>
>
> OHSR - National Institutes of Health
> Bldg 10, Suite 2C146
> Bethesda, MD 20892
> Office Telephone: 301-402-3444
> Office Fax: 301-402-3443
>
> The NIH is committed to maintaining the highest standards for the
> protection of human subjects.
> P Please consider the environment before printing this e-mail
>

OHSR (NIH/DDIR)

From: Perrin Larton (b)(6)
Sent: Monday, November 30, 2009 5:10 PM
To: Hasenkrug, Kim (NIH/NIAID) [E]
Cc: (b)(6)
Subject: Re: HFT Application

Hi Kim,

All tissue is numerically coded and the personally identifiable information is never available. In other NIH applications we've had requests for letters that state NO information is available to researchers. I can send you a letter to that effect...but tissue cannot be tracked back to a specific patient. We guarantee anonymity to the patients donating tissue.

Perrin

> Dear Perrin, the Office of Human Subjects Research is asking me for a
> letter
> from you stating that personally identifiable information regarding the
> fetal tissue will be revealed to me. Would you kindly send me a letter
> stating such so that I can forward it to them? It would be greatly
> appreciated and let us begin our experiments. I attached a copy your
> letter
> regarding approval of our application for your information. Thank you
> very
> much, Perrin.
>
> Kim
>
> Kim J Hasenkrug, Ph.D.
> Senior Investigator
> Chief, Retroviral Immunology Section
> Laboratory of Persistent Viral Diseases
> Rocky Mountain Laboratories
> National Institute of Allergy and Infectious Diseases
> National Institutes of Health
> 903 S. 4th Street
> Hamilton, MT 59840
> phone (406)363-9310
> FAX (406)363-9286
> khasenkrug@nih.gov
>
> Disclaimer:
> The information in this e-mail and any of its attachments is confidential
> and may contain sensitive information. It should not be used by anyone who
> is not the original intended recipient. If you have received this e-mail
> in
> error please inform the sender and delete it from your mailbox or any
> other
> storage devices. National Institute of Allergy and Infectious Diseases
> shall
> not accept liability for any statements made that are sender's own and not
> expressly made on behalf of the NIAID by one of its representatives

>
>
>> From: Perrin Larton (b)(6)
>> Reply-To: (b)(6)
>> Date: Mon, 2 Nov 2009 13:40:51 -0500
>> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
>> Conversation: HFT Application
>> Subject: HFT Application
>>
>> Dear Kim,
>>
>> Attached you'll find the documents we just discussed. What I'll need
>> back
>> from you is the two page application as well as a short synopsis of the
>> work you'll be doing. As soon as I get the completed application from
>> you
>> it will go to our Scientific Advisory Board for review and approval. If
>> they have questions, I'll give you a call. Approval usually takes 5-10
>> working days from the time I receive the application from you.
>>
>> Please send your application back to my e-mail address
>> (b)(6)
>> or FAX to 510-865-4090.
>>
>> Thanks so much for your interest in the services supplied by Advanced
>> Bioscience Resources. I apologize again for taking such a long time to
>> respond to your query.
>>
>> Perrin Larton CTBS
>> Procurement Manager
>> Advanced Bioscience Resources
>
>

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Tuesday, November 24, 2009 10:28 AM
To: Hasenkrug, Kim (NIH/NIAID) [E]
Subject: HasenkrugK_NIAID_4980_CY2009

Good Afternoon Dr. Hasenkrug:

Thank you for the opportunity to review your research project: ***Study of HIV infection & Vaccine Protection..*** Since the work you are doing at the NIH provides little or no risk to human subjects off-site, OHSR has decided the appropriate action for you to take is the following:

- Provide documentation that you will not seek the identity of the subjects who have provided the samples you will receive as well as documentation from ABR that under no circumstances will the identity or link to the identifiers of the subjects be released to you.

An e-mail from you and from ABR holding the key to the code is sufficient documentation.

This action is based on guidance issued on Aug. 10, 2004 by the HHS Office of Human Research Protections, the regulatory office for the protection of human subjects.

Best regards,

OHSR - National Institutes of Health
Bldg 10, Suite 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

The NIH is committed to maintaining the highest standards for the protection of human subjects.


Please consider the environment before printing this e-mail

ADVANCED BIOSCIENCE RESOURCES, INC.

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
1/25/2017	(b)(6)	1033174
	TERMS	CUSTOMER #
	Due Upon Receipt	0522

BILL TO

Rocky Mountain Labs
NIH/NIAID
Kim J. Hasenkrug
903 S. 4th Street
Hamilton, MT 59840

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
1/25/2017	312502	6330	18	Thymus, 2nd Trimester	HASENKRUG	(b)(4)
1/25/2017	312502	6331	18	Liver, 2nd Trimester	HASENKRUG	
				02/08/17 PAID via VISA (b)(6) Request by Kim Hasenkrug.		

ADVANCED BIOSCIENCE RESOURCES
1516 OAK ST STE 303
STE 303
ALAMEDA, CA 94501
(510) 865-5872

Sale

VISA Entry Method: Manual
Total: $ 680.00

02/08/17 14:55:13
Inv #: 0000004 Appr Code: 006874
Approvd: Online Batch#: 039001
AVS Code: ZIP MATCH 7
CVV2 Code: MATCH M

ENCRYPTED TRANSACTION

Total	**$680.00**

1516 Oak Street, Suite 303 / Alameda, California 94501 USA / Phn (510) 865-5872 / Fax (510) 865-4090 / email: abr@abr-inc.com

SEQ: 1829768	PO#: (b)(6)	Requester: Messer, Ronald

CAN: 8335424 FY: 17 Owner: (b)(6)
Order Total: 680.00 Project: 107833
Date Needed: 01/03/2017 Emergency: Yes Order Type: Purchase Card
Requestor Phone: +1 406 363 9276 Order Status: Archive

Vendor Advanced Bioscience Resources,1516 Oak Street, Suite 303, Alameda, CA 94501
Phone: 510-865-5872 SmlBs: No FSS:
EIN: BPA: GSA:
Site: Clerk:
E-mail:

#	Description	CAN	Catalog	OC Code	Category	Qty at Price	Total
1	Tissue, 2nd Trimester (1 each of liver and thymus)	8335424	none	2613	6509	(b)(4)	680.00
2	shipping	8335424		2613	6509	1 each at $0	.00

Order Total: 680.00

Ship To: Ronald Messer,3220 ,RML CNTRL REC,RMTLAB

QUOTES

Vendor	Price	Good Until	Available
There are no quotes in the order			

JUSTIFICATION

These tissues, liver and thymus, are required Ron Messer for ongoing studies of HIV in the Hasenkrug Lab. Our mice will be ready for reconstitution soon. Please let me know when I can contact Perrin Larton at ABR to place our request on their schedule. Please contact the vendor at 510-865-5872 ext (b)(6) -give her the PO number Thanks, Ron. *** I certify that I have checked the sources of supply and services listed in FAR 8.002. ( ) I have purchased from the highest priority source available. (X) I did not purchase from a priority source because none could satisfy the requirement of the government either in product/service specifications, quality or required delivery time. **********NOTE to Purchasing Agent: Call vendor at 510-865-5872 ext (b)(6) (b)(6) -give her the PO number and credit card information.

Alternate Sources:

NIH Surplus: No UNICOR: No GSA Stock Catalog: No GSA Self Service: No Federal Supply: No Open Market: Yes

AGENT

Purchase Order #: (b)(6)
Custodial Code: 30102
Order Reference: (b)(6)
FSS:
NBS Ref Order #: 4443716

Estimated Ship Date:
Date Entered into NBS: 12/30/2016
Expected Delivery Date: 01/06/2017
Select Agents: No
Clearance Requested: No

SF-37 Code:

Notes

There are no notes in the order

IT Clearance

Never seen by IT officer

ROUTE HISTORY

Role Summary

User Role	Name
Requester	Messer, Ronald
Releaser	Messer, Ronald
Admin Officer	(b)(6)
Lead Admin Officer	
Purchase Agent	(b)(6)
Lead Agent	
IT Clearance Officer	
Releaser1	
Releaser2	
NBS	
Receiving Official	

Dates

Description	Date
Needed By	01/03/2017
Submitted to NBS	12/30/2016
NBS Confirmation	12/31/2016
Award Created	12/30/2016
Award Received	12/30/2016
Estimated Ship Date	
Received	02/10/2017
Canceled	

Routing History

Name	Role	Date In	STATUS IN	ACTION
Messer, Ronald	Requester	12/30/2016	New order	Approved
(b)(6)	Administrative Officer	12/30/2016	Released	Approved
	Purchasing Agent	12/30/2016	Approved	Approved
NBS, NBS	NBS	12/30/2016	Sent to NBS	Approved
Messer, Ronald (b)(6)	Requester for receiving	12/30/2016	Pending receiving	Take
(b)(6)	Requester for receiving	02/10/2017	Pending receiving	Approved
	Archive	02/10/2017	Archive	(N/A)

Receiving Report

#	Description	Total Qty Ordered	Total Qty Received	Date Received
1	Tissue, 2nd Trimester (1 each of liver and thymus)	2	2	02/10/2017
2	shipping	1	1	02/10/2017

OHSR RESPONSE TO REQUEST FOR REVIEW OF RESEARCH ACTIVITY
INVOLVING HUMAN SUBJECTS

FAX:

Exempt: #: 4980

To: Hasenkrug, Kim
NIAID
RML - Rocky Mountain Laboratories, 3/218

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
Recent reports have demonstrated that immunodeficient mice reconstituted with 17-19 week old human fetal tissue develop a human immune system and are susceptible to HIV infection and disease. The goal of this project proposal is to create such humanized mice to study the role of immune cell subsets and virus-neutralizing antibodies in vaccine protection. The experiments will entail the development of a cohort of mice all reconstituted with the same human cells so as to be histocompatible. This will require transplantation of

Original Request Received in OHSR on: 11/19/2009

Responsible NIH Research Investigator(s): Kim Hasenkrug, NIAID

OHSR review of your request dated Thu, Nov 19, 2009 has determined that:

☒ Federal regulations for the protection of human subjects do not apply to above named activity. The OHSR determination of Not Human Subjects Research is based on the interpretation of 45 CFR 46 under "Research Involving Coded Private Information or Biological Specimens" (OHRP, Revised October 16, 2008) and Guidance on Engagement of Institutions in Human Subjects Research (October 16, 2008). NOTIFY OHSR VIA AN E-MAIL AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESEARCH ACTIVITY.

☐ The activity is designated **EXEMPT**, and has been entered in the OHSR database. PLEASE NOTIFY OHSR OF ANY **SIGNIFICANT** CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.

☐ **NOT EXEMPT**. OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additional information in order to determine whether expedited or full review is appropriate.

☐ Confidentiality Agreement

☐ Reliance

☐ Amendment

☐ Other

Office Person LB Admin Assist. CB

Note:
(b)(6)

CIP

for Charlotte Holden, JD — Acting Director, OHSR — 12/14/2009
Signature — Title — Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: Yes

OHSR Use Only
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

#4980

REQUEST FOR REVIEW OF RESEARCH ACTIVITY INVOLVING HUMAN SUBJECTS

INSTRUCTIONS: Please type directly on this form. You can expand the document if you need more space. If your research involves a survey or questionnaire, please attach it to this completed form.

Completed forms (with all required signatures) may be sent to OHSR by FAX (301-402-3443), email to ohsr_nih_ddir@od.nih.gov, or by mail (2C146). If you have any questions, call OHSR at (301) 402-3444.

Date: 11/19/2009

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146

From: Kim J Hasenkrug
(Signature)

(b)(6)

Through: (acting)
(Signature of appropriate Official for IC, e.g., Lab/Branch Chief)

Protocol Title: Study of HIV infection and vaccine protection in mice reconstituted with a human immune system

Name of NIH Principal Investigator(s): Kim J Hasenkrug, Senior Investigator

IC NIAID Laboratory/Branch LPVD Building & Room No. RML 3218
Tel. No. 406-363-9310 FAX No. 406-363-9286
Is the Principal investigator an NIH employee? x **Yes** ____ **No**

If no, please explain: ____

1. What is the proposed research activity that you intend to perform at NIH (please use lay terms):
Recent reports have demonstrated that immunodeficient mice reconstituted with 17-19 week old human fetal tissue develop a human immune system and are susceptible to HIV infection and disease. The goal of this project proposal is to create such humanized mice to study the role of immune cell subsets and virus-neutralizing antibodies in vaccine protection. The experiments will entail the development of a cohort of mice all reconstituted with the same human cells so as to be histocompatible. This will require transplantation of the mice with 1 mm^3 pieces of fetal thymus as well as reconstitution with stem cells isolated from cord blood and liver. Once the humanized mice have been established some will be vaccinated to prime distinct subsets of immune cells. Immune cell subsets from vaccinated mice will be adoptively transferred into naïve mice, which will then be infected with HIV to

test the antiviral activity of the immune cells. The goal of these experiments is to establish correlates of immunity against HIV.

_

2. If applicable, list your non-NIH Collaborating Investigator(s).

Name Institution Address Tel. # FAX #

_____

_____

_____

3. Proposed start date of your research __April, 2010_____
Proposed completion date _April, 2013_____

4. Will you be _____these samples or data?

Collecting Yes/(No)
Receiving (Yes)/No
Sending Yes/(No)

5. Do the samples or data:
(a) Already exist?___Yes _x__No

(b) Or are they being collected for the express purpose of this study? _X__Yes __No
If "yes," please describe:_

17-19 week fetal cells and tissue will be obtained from Advanced Bioscience Resources, Inc., a non-profit foundation established under California law to provide biomedical researchers access to human tissues in compliance with state, federal, and NIH guidelines. Consent to donate is obtained in accordance with UAGA and NOTA guidelines. Related documents including the consent form are attached._____

(c) Or a combination of (a) and (b)? ____Yes _____No

6. What role will you have in this research project? (Check all that apply)

___ Analyze samples/data only.

___ Consultant/advisor to collaborator(s) listed above.

___ Author of the protocol that is being implemented by your collaborating investigator (identified in question #2).

___ Co-authorship on publication(s)/manuscript(s) pertaining to this research.

___ You or NIH hold an IND for this research.

__X_ Decisional authority over the design or implementation of the research at the IRB approved site? If so, please explain.

I am the PI and lead investigator on this project which will take place in my laboratory and the animal care facilities at Rocky Mountain Labs, NIAID, NIH.

___Other (If necessary, use this space to describe your role in this research).

7. Where are the subjects of this research activity located?
The material for this research is obtained from natural or induced abortions from females in California. Thus the tissues and cells involved will not be from living humans.

8. If human subjects are located elsewhere (not at NIH), will you have direct contact or intervention with them? (Examples: as subject's physician; in obtaining samples directly from the subject; by interviewing the subject?) ____ Yes __x__No

9. What kind of human samples (e.g., tissue, blood) or data (e.g., private information, responses to questionnaires) will be involved in your research?
_Samples will include cord blood, fetal blood, thymus, liver, and bone marrow. No private information will be involved._____

---

10. If the samples, data do not come from an IRB approved protocol, do they come from:

(a) Repository ____Yes ___ No

(b) Pathological waste ___ Yes _____No

(c) Autopsy material ___ Yes ___ No

(d) Publicly available source _X__Yes ___ No

(e) Other_____

11. Please check the box(es) that apply(ies) to the samples/data that you will receive.

(a) ____ Samples and/or data will be anonymized/unlinked. (The samples/data cannot be linked to individual subjects by you or your collaborators at other sites.)

(b) ___ Samples and/or data will be coded, however that code cannot be used by either the sender or the receiver to identify specific individuals.

(c) __X_ Samples and/or data will be coded so that the provider of the samples/data can link them to specific individuals but the receiver will not be able to do so.

12. Will you send results back to the provider(s) (listed in question 2 of this form)?

(a) __X_ No, I will not send results back to the provider(s).

(b) ___ Yes, I will send aggregate results to the provider(s).

(c) ___ Yes, I will send results to the provider(s) that are linked to identifiable individuals.

If yes, does the provider intend to link your data to identifiable individuals?
_____Yes _____No

13. Has the research activity <u>that you are proposing in this form</u> been approved by an Institutional Review Board (IRB) elsewhere?

_____ Yes, the NIH research activity has been reviewed by the following IRB (s) (Please provide the following information for each IRB):

_____ Name of institution that provided the review

_____ Address of reviewing institution

_____ Name of PI for the IRB approved protocol

_____ Title of IRB approved protocol and protocol #

_____ Federal Wide Assurance (FWA) number**

___X_____No IRB review of the research activity described in question #1 above has taken place

(**An FWA is a contract between the U.S. Department of Health and Human Services (DHHS) and an entity receiving DHHS funds to conduct clinical research that the latter will follow ethical guidelines and federal regulations for the protection of human subjects. For a list of domestic and international institutions go to http://ohrp.cit.nih.gov/search/asearch.asp#ASUR

14. Per NIH guidance*, have conflicts of interest by NIH employees, if any, been resolved?**

__X___Yes _____No no conflicts of interest

If your answer is no, please see your Clinical Director about this matter before proceeding with this research.

***The January 5, 2005 NIH Guide to Preventing Conflict of Interest applies to all research conducted at NIH, http://ohsr.od.nih.gov/New/mpafwa_docs.html

ADVANCED BIOSCIENCE RESOURCES, INC

OVERVIEW

ADVANCED BIOSCIENCE RESOURCES is a non-profit corporate foundation established in 1989 under California law to provide biomedical researchers with access to human tissues. ABR was formed exclusively for biomedical, scientific, and educational purposes and is devoted to providing services in connection with the procurement of human organs and tissues for medical and scientific research. ABR specializes in the procurement, preservation and distribution of both human fetal tissues and full term umbilical cord blood for research, and provides a highly individualized, reliable and easily accessible service.

TISSUE COLLECTION AND DISTRIBUTION: The purpose of ABR is to promote cooperative efforts to collect and distribute human tissues and to thereby facilitate research utilizing those tissues. Trained personnel coordinate the retrieval, preservation and delivery of each specimen.

Tissues obtained through ABR are retrieved from routinely performed surgical procedures including first and second trimester induced abortions, and full term deliveries, either natural or caesarian section. Tissues that were once discarded are now available to scientists worldwide through the efforts of ABR. Researchers may specify tissue characteristics, preservation methods, and delivery times.

PRESERVATION METHODS: Each specimen is collected, preserved, and shipped according to the investigator's individual protocol.

QUALITY CONTROL: ABR practices strict quality control procedures and adheres to stringent guidelines for tissue collection and preservation. Consent is obtained in accordance with UAGA and NOTA guidelines. Tissue specimens are identified, dissected, and transferred to the specified medium. A control number is then assigned to each sample to ensure confidentiality of patient identity.

To assure proper processing of the tissue, every researcher selects a collection/preservation protocol tailored specifically to his needs. In the collection and distribution of these tissues, every effort is made to exercise the highest standards of medical and laboratory practice. ABR specializes in direct communication with each investigator from the initial application to specimen delivery.

INVESTIGATOR APPROVAL: ABR will provide tissue to researchers who provide information on current research funding, and a short summary of their research intent. Investigators must agree to accept responsibility for the potential biohazard of the tissue and to appropriately train laboratory personnel in the proper handling of the tissue. In addition, the researcher must agree to use the tissue solely for research purpose and to acknowledge ABR in any publications resulting from the use of ABR provided tissue.

APPLICATION PROCESS: To request human tissue for research, an application must be completed and submitted to ABR. The application will be reviewed for feasibility and priority. A protocol will be developed to meet individual research needs as identified in the application.

SERVICE AND PROCESSING FEES: Participating medical facilities that enable ABR to enact its tissue acquisition and distribution programs may be paid a nominal fee for such services. A minimal processing / preservation / shipment fee is also assessed for services provided to research facilities.

1516 Oak Street # 303 / Alameda, CA 94501 / 510-865-5872 / Fax 510-865-4090 / email abr@abr-inc.com

Recent advancements in medical research have been developed through the use of human tissues in scientific study. Diseases such as diabetes, hemophilia, Parkinson's disease, cancer, AIDS, heart and lung disease, as well as genetic and,neonatal disorders, are being investigated for the development of cures through the use of human fetal tissues. Any tissue donated may be distributed to medical institutions and private research groups in the United States and internationally to enhance the development of cures and therapies for disease.

PERMISSION FOR DONATION OF TISSUE
OBTAINED AT THE TIME OF ABORTION

I have previously decided to have an abortion and have previously consented to having such abortion.

I hereby donate the aborted material and/or a sample of my blood as an anatomical gift for the purposes of education, research, or for the advancement of medical science. I understand that my donation may be used by research facilities in the United States and abroad.

I also agree that a sample of my blood may be taken after the abortion and that it may be used for research and routine testing for AIDS, hepatitis, or other infectious agents. I understand that, if there is testing, the results will be confidential unless the law requires that they be disclosed.

I understand that the aborted material may be used to derive human pluripotent stem cells for medical research and possibly human transplantation research, and that these cells may be kept for many years. I also understand that my donation may be used for cosmetic purposes. I understand that there is no information associated with aborted material that could link me with my donation. I agree that this donation is made without any restriction or direction regarding the potential recipients of the cells derived from the aborted material and that I have not been informed of the identity of any potential recipients.

I understand that there will be no payment to me and I agree that, although the results of the research on the aborted material may have commercial value, I will have no property or other commercial or financial rights in the aborted material or any product, process, or service which may result from this donation.

I understand that my donation will not result in any direct medical benefit to me.

I understand that my donation is voluntary, and I may refuse to donate aborted material and this will not affect my medical care or my relationship with my physician.

I understand that, if I have any questions about my donation, I can contact ABR at 510-865-5872.

_____ _____
Signature Date

I choose not to participate.

_____ _____
Signature Date

_____ _____
Witness Date

ADVANCED BIOSCIENCE RESOURCES, INC.

APPLICATION FOR THE ACQUISITION OF

HUMAN FETAL TISSUE FOR RESEARCH

All requests for human fetal tissue are reviewed for feasibility of procurement and preparation. When approved, an individual protocol will be developed for the procurement, preparation and delivery of tissue samples, based on the information provided in this application and any subsequent communication.

I. APPLICANT INFORMATION

NAME: Kim J Hasenkrug

TITLE: Senior Investigator

COMPANY: NIAID, NIH

ADDRESS: Rocky Mountain Lab

ADDRESS: 903 S. 4th St

CITY,ST,ZIP: Hamilton, MT 59840

PHONE #: 406-363-9310

ALT. #:

FAX #: 406-363-9286

EMAIL: khasenkrug@nih.gov

DELIVERY OPTIONS:

__X__ Same Day: Commercial carrier, hand delivered
Maximizes cell viability (*geographical limits*)

_____ Next Day: Pickup, delivery Mon-Sat daytime
Economical for fresh, frozen specimens

Applicant will be charged for delivery fees.

Applicant may designate preferred carrier:

Carrier Name: FEDEX

Account #: (b)(4)

BILLING INFORMATION:

BILL TO: Kim J Hasenkrug

COMPANY: Rocky Mountain Labs

ADDRESS: 903 S. 4th St.

ADDRESS:

CITY,ST,ZIP: Hamilton, MT 59840

ACCOUNTING DEPT. PHONE #: 406-363-9438

P.O. # (if required by your company):

P.O. # is not required to submit application

Credit Card #:

Name on CC:

Expiration Date: VISA/MC

SHIP TO: Kim J Hasenkrug
Rocky Mountain Labs
903 S. 4th St
Hamilton, MT 59840

Please indicate how you heard about ABR: (b)(6)

II. HUMAN FETAL TISSUE

Tissue specimens requested: thymus, liver, cord blood

Preferred gestational age (6-24 weeks): 17-19 wks

Proposed starting date: May, 2010

CONTAGIOUS DISEASE SCREENING: Availability of test results varies from 24 hours to 7 days after procurement. Applicant requires the following tests to be performed by ABR:

__X__ No testing required

_____ HIV _____ HSV
_____ HBSAG _____ RPR
_____ CMV _____ HCV

OTHER_____

III. PRESERVATION

ABR uses *BioWhittaker RPMI-1640 With L-Glutamine* for tissue preparation, preservation and shipment. Applicant may supply ABR with other media specific to research needs. Please indicate preference below.

PRESERVATION METHODS AVAILABLE:

__X__ Fresh; shipped on wet ice
_____ Passive freezing on dry ice; shipped on dry ice
_____ "Snap" freezing in LN2; shipped on dry ice
_____ Media provided by applicant
_____ Media provided by ABR (RPMI)

IV. DONOR INFORMATION

CONSENT VERIFICATION: Consent for tissue donation is obtained prior to specimen procurement. The consent is extremely confidential in nature and shall not be communicated to the researcher.

SPECIFIC DONOR INFORMATION: Charts are routinely examined for patient medical histories. Please identify any specific information sought and indicate contraindications to specimen procurement:

_____HIV+ status contraindicates procurement_____

_____

_____

V. RESEARCH DATA

TITLE OF RESEARCH PROJECT: ___The role of virus-specific CD4+__T cells, CD8+ T cells and antibody in vaccine protection against HIV-1 in humanized mice_____

ABR will provide tissue to researchers who provide information on current research funding, and a short summary of their research intent. **(Please attach a brief synopsis of the research project named above.)** Researchers must agree to use the tissue solely for research purposes and to acknowledge ABR in any publications resulting from the use of ABR provided tissue. Updates on research progress will be requested at six-month intervals. Researchers agree to publish the results of the research as promptly after the completion of the research as is reasonably possible without jeopardizing the sponsor's right to secure patents or copyrights necessary to protect its ownership or control of the results of the research. Researchers agree to inform ABR of the name of the publication and the date of the issue in which the results will be published. It is the intent of this requirement to make the results available to the general public through acceptable means of publication.

VI. SOURCE OF FUNDING

Please identify the primary source of funding for this project.

NIH _X___ Other Federal or State Grants _____ Foundation Grants _____ Other (specify) _____

If this application is approved by ABR, ABR shall provide services to the applicant in accordance with the terms and the other conditions on the reverse side, and the signature of the applicant shall constitute acceptance of all such terms and conditions by applicant. The entire agreement between ABR and applicant relating to the services provided by ABR is expressly set forth herein, and any modification of or addition thereto shall be of no force or effect unless it is in writing and signed on behalf of ABR by a duly authorized representative.

BY SIGNING BELOW, THE APPLICANT ACKNOWLEDGES HAVING READ THE TERMS AND CONDITIONS ON THE FOLLOWING PAGE AND AGREES TO SUCH TERMS AND CONDITIONS.

Kim J Havenhuys

____ _____

_Senior Investigator_____
SIGNATURE and TITLE of APPLICANT

DATE 11/2/2009

Please return to:

ADVANCED BIOSCIENCE RESOURCES, INC.
1516 OAK STREET, SUITE 303
ALAMEDA, CALIFORNIA 94501
Telephone: 510-865-5872
Fax: 510-865-4090
Email: abr@abr-inc.com

TERMS AND CONDITIONS OF SERVICES

1. Services

1.1 During the term of this agreement, and pursuant to the terms and conditions hereinafter set forth, ABR will use its best efforts to provide services in connection with supplying researcher with the types of human tissues set forth in this application, as approved

by ABR, suitable for researcher requirements and in the amounts requested based upon ongoing discussions between researcher and ABR pursuant to the information sent by ABR.

1.2 Researcher acknowledges and agrees that ABR will provide the following types of services:

Removing tissue.
Preserving and processing tissue to a form suitable to the researcher needs.
Seeking consent for tissue donations from appropriate individuals, obtaining validly executed consent forms, and maintaining records of such consents in accordance.
Obtaining, labeling, storing, and delivering samples of donor or other required serum, and maintaining a system for matching such samples to specific tissue donations.
Preserving tissue viability and cleanliness during removal, processing, preservation, storage and transportation.
Storing tissue and transporting it to researcher in accordance with section 5.

1.3 In the event that tissues of the type specified in the application become unavailable to ABR, such that ABR is unable to perform the contemplated services, ABR shall have no obligation to perform such services.

2. Representations and Warranties. ABR hereby represents and warrants to researcher that (i) ABR will make no payments to anyone for any tissue transferred in connection with this agreement, and (ii) ABR will verify for each tissue delivery that appropriate consent was obtained for use of such tissue and any associated serum samples, and that adequate records of such consent are maintained; provided, however, that the parties hereto acknowledge and agree that such consents are extremely confidential in nature and shall not, in any case, be communicated to researcher. Researcher hereby represents and warrants to ABR that (i) researcher will neither sell nor transfer for valuable consideration any tissue received through ABR to anyone, (ii) researcher will use the tissue only to satisfy its objectives, which are, as acknowledged and agreed hereto, [research and clinical use], (iii) researcher agrees to inform ABR of any changes in clinical or research use of specimens received from ABR, or in any specifications, constraints, etc. in a timely manner, and (iv) researcher understands the bio-hazardous nature of human tissue and agrees to take proper precautionary measures at all times when handling tissue specimen.

3. Terms. The terms of this agreement shall be for one (1) year, beginning from the date hereof, and terminating one (1) year thereafter, unless either of the parties hereto shall have given to the other thirty (30) days written notice of its intention to terminate this agreement, whereupon same shall terminate thirty (30) days after date of said notice.

In default of notice as aforesaid from either party hereto, this agreement shall continue for further successive terms of one (1) year thereafter and in default of thirty (30) days written notice before the end of an annual term by either of the parties of its intention not to renew, whereupon this agreement shall terminate at the end of said term.

4. Payments. Researcher agrees to pay to ADR a fee for costs incurred by ABR in providing services in connection with the acquisition of each sample of tissue requested by researcher, to be mutually agreed upon by ABR and researcher upon approval of this agreement by ABR.

5. Shipment services.

5.1 All shipments will be made as soon as possible after request has been received by ABR from researcher.

5.2 Researcher acknowledges that networks of tissue availability are neither permanent nor dependable, but rather they fluctuate. However, ABR shall use its best efforts to transfer the tissue in the amounts requested by researcher.

5.3 Shipment will be made in the best possible manner so as to preserve the quality of the tissues. It is understood that the fragility of human tissue is such that damage may occur during shipment. ABR will use its best efforts to comply with the handling and shipment protocols provided by researcher.

5.4 ABR will package the tissue appropriately and, if so requested by researcher, will insure the shipment. Researcher agrees to bear all costs associated with insurance and shipment of any tissue.

5.5 The risk of loss and damage of any tissue or organs shall pass immediately to researcher when the shipment of such tissue or organs is deposited with a carrier for transportation at the F.O.B. point.

6. Limitation of liability. ABR shall not be responsible or liable under any section of this agreement or under any contract, negligence, strict liability or other legal or equitable theory, for the cost of procurement of substitutive services, or any indirect, incidental or consequential damages including, but not limited to loss of revenues and loss of profits. Any liability of ABR under any theory whatsoever will be limited exclusively to the provision of equivalent services by ABR or, if unenforceable, to payment of an amount not greater than any amount actually received by ABR from researcher on account of this agreement.

7. No warranties. It is understood that human tissue is by nature neither permanent nor dependable. Except as expressly set forth in this agreement, ABR makes no representation of any kind, expressed or implied, including any representation with respect to the safety, efficacy or merchantability or the fitness for any purpose with respect to the tissue transferred to researcher in connection with this agreement.

8. Indemnification. Researcher shall indemnify, defend and hold ABR harmless from and against all claims, causes of actions, suits, damages and costs arising out of, resulting from, or otherwise in respect of, the use of tissue transferred in connection with this agreement, except where such claims are the result of negligence of ABR, its employees, staff or agents to (i) comply with any governmental requirements, or (ii) adhere to the terms of this agreement.

9. General. This agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of law. This agreement may not be assigned by either party without the prior written consent of the other.

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Monday, November 23, 2009 10:43 AM
To: Hasenkrug, Kim (NIH/NIAID) [E]
Subject: Request for Review Rec'd-OHSR 4980

Good morning Dr. Hasenkrug,

This email is to verify that OHSR has received your Request for Review of Research and it is currently being processed as OHSR #4980. Please use this number in any future correspondence regarding this study. We will contact you via email if any additional information is needed. If you have not heard from OHSR within 7 business days, please contact us.

Protocol Title: Study of HIV infection and vaccine protection in mice reconstituted with a human immune system

Thank you.

OHSR:
Ph: 301.402.3444
Fax: 301.402.3443

Thank you.

Sincerely,

(b)(6)

OHSR (NIH/DDIR)

From: Hasenkrug, Kim (NIH/NIAID) [E]
Sent: Wednesday, December 09, 2009 5:41 PM
To: OHSR (NIH/DDIR)
Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up
Flag Status: Green

Attachments: IRB Letter with letterhead nonidentity.doc

IRB Letter with letterhead non...

Here is the letter on official ABR letterhead for you

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
Laboratory of Persistent Viral Diseases
Rocky Mountain Laboratories
National Institute of Allergy and Infectious Diseases National Institutes of Health
903 S. 4th Street
Hamilton, MT 59840
phone (406)363-9310
FAX (406)363-9286
khasenkrug@nih.gov

> From: "OHSR (NIH/DDIR)" <ohsr_nih_ddir@od.nih.gov>
> Date: Tue, 24 Nov 2009 10:27:55 -0500
> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
> Conversation: HasenkrugK_NIAID_4980_CY2009
> Subject: HasenkrugK_NIAID_4980_CY2009
>
> Good Afternoon Dr. Hasenkrug:
>
> Thank you for the opportunity to review your research project: Study
> of HIV infection & Vaccine Protection.. Since the work you are doing
> at the NIH provides little or no risk to human subjects off-site, OHSR
> has decided the appropriate action for you to take is the following:
>
> * Provide documentation that you will not seek the identity of the
> subjects who have provided the samples you will receive as well as
> documentation from ABR that under no circumstances will the identity
> or link to the identifiers of the subjects be released to you.
>
> An e-mail from you and from ABR holding the key to the code is
> sufficient documentation.
>
> This action is based on guidance issued on Aug. 10, 2004 by the HHS
> Office of Human Research Protections, the regulatory office for the
> protection of human subjects.

> Best regards,
>
>
>
> OHSR - National Institutes of Health
> Bldg 10, Suite 2C146
> Bethesda, MD 20892
> Office Telephone: 301-402-3444
> Office Fax: 301-402-3443
>
> The NIH is committed to maintaining the highest standards for the
> protection of human subjects.
> P Please consider the environment before printing this e-mail
>

ADVANCED BIOSCIENCE RESOURCES, INC

December 14, 2009

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
903 S. 4th Street
Hamilton, MT 59840

Dear Kim,

This letter verifies that ABR, a non-profit tissue procurement organization, supplies requesting and approved scientific investigators with the types of human fetal tissues required for specific bio-medical research. When requested and as availability allows, human fetal tissue specimens will be retrieved from products of conception from induced first and second trimester abortions. Tissue will be distributed according to established protocols. Specimens are not collected for directed donation. .

ABR warrants that maternal consent from patients aged over eighteen years is obtained for the use of fetal tissue specimens for research purposes, including the consent for the potential of stem cell research utilizing such tissues, and that adequate records of such consent are maintained for future verification. Donor identification is coded and scientific investigators have no access to donor identification. ABR also warrants that maternal consent is obtained for phlebotomy and blood testing for a variety of disease entities.

ABR warrants that no payments will be made to any third party for the conduct of or the product of an abortion, including without limitation any parent(s) of any unborn fetus. ABR, to the best of its knowledge, also warrants that all tissue provided will have been obtained in compliance with local, state and federal laws and regulations governing the procurement and distribution of human tissue.

Sincerely,

Perrin Larton

Perrin Larton, CTBS
Procurement Manager

Federal E.I.N.: 94-3110160
California E.I.N.: 370-20518
FDA FEI: 3005208435

1516 Oak Street # 303 / Alameda, CA 94501 / 510-865-5872 / Fax 510-865-4090 / email abr@abr-inc.com

OHSR (NIH/DDIR)

From: Hasenkrug, Kim (NIH/NIAID) [E]
Sent: Monday, November 30, 2009 5:24 PM
To: OHSR (NIH/DDIR)
Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up
Flag Status: Green

Attachments: Re: HFT Application

Re: HFT Application

HasenkrugK_NIAID_4980_CY2009

Attached please find the requested email from ABR stating that no personally identifiable information will be released to me. Furthermore, I will not seek any such information from ABR.

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
Laboratory of Persistent Viral Diseases
Rocky Mountain Laboratories
National Institute of Allergy and Infectious Diseases National Institutes of Health
903 S. 4th Street
Hamilton, MT 59840
phone (406)363-9310
FAX (406)363-9286
khasenkrug@nih.gov

> From: "OHSR (NIH/DDIR)" <ohsr_nih_ddir@od.nih.gov>
> Date: Tue, 24 Nov 2009 10:27:55 -0500
> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
> Conversation: HasenkrugK_NIAID_4980_CY2009
> Subject: HasenkrugK_NIAID_4980_CY2009
>
> Good Afternoon Dr. Hasenkrug:
>
> Thank you for the opportunity to review your research project: Study
> of HIV infection & Vaccine Protection.. Since the work you are doing
> at the NIH provides little or no risk to human subjects off-site, OHSR
> has decided the appropriate action for you to take is the following:
>
> * Provide documentation that you will not seek the identity of the
> subjects who have provided the samples you will receive as well as
> documentation from ABR that under no circumstances will the identity
> or link to the identifiers of the subjects be released to you.
>
> An e-mail from you and from ABR holding the key to the code is
> sufficient documentation.

>
> This action is based on guidance issued on Aug. 10, 2004 by the HHS
> Office of Human Research Protections, the regulatory office for the
> protection of human subjects.
>
> Best regards,
>
>
>
> OHSR - National Institutes of Health
> Bldg 10, Suite 2C146
> Bethesda, MD 20892
> Office Telephone: 301-402-3444
> Office Fax: 301-402-3443
>
> The NIH is committed to maintaining the highest standards for the
> protection of human subjects.
> P Please consider the environment before printing this e-mail
>

OHSR (NIH/DDIR)

From: Perrin Larton (b)(6)

Sent: Monday, November 30, 2009 5:10 PM

To: Hasenkrug, Kim (NIH/NIAID) [E]

Cc: (b)(6)

Subject: Re: HFT Application

Hi Kim,

All tissue is numerically coded and the personally identifiable information is never available. In other NIH applications we've had requests for letters that state NO information is available to researchers. I can send you a letter to that effect...but tissue cannot be tracked back to a specific patient. We guarantee anonymity to the patients donating tissue.

Perrin

> Dear Perrin, the Office of Human Subjects Research is asking me for a
> letter
> from you stating that personally identifiable information regarding the
> fetal tissue will be revealed to me. Would you kindly send me a letter
> stating such so that I can forward it to them? It would be greatly
> appreciated and let us begin our experiments. I attached a copy your
> letter
> regarding approval of our application for your information. Thank you
> very
> much, Perrin.
>
> Kim
>
> Kim J Hasenkrug, Ph.D.
> Senior Investigator
> Chief, Retroviral Immunology Section
> Laboratory of Persistent Viral Diseases
> Rocky Mountain Laboratories
> National Institute of Allergy and Infectious Diseases
> National Institutes of Health
> 903 S. 4th Street
> Hamilton, MT 59840
> phone (406)363-9310
> FAX (406)363-9286
> khasenkrug@nih.gov
>
> Disclaimer:
> The information in this e-mail and any of its attachments is confidential
> and may contain sensitive information. It should not be used by anyone who
> is not the original intended recipient. If you have received this e-mail
> in
> error please inform the sender and delete it from your mailbox or any
> other
> storage devices. National Institute of Allergy and Infectious Diseases
> shall
> not accept liability for any statements made that are sender's own and not
> expressly made on behalf of the NIAID by one of its representatives

>
>
>> From: Perrin Larton (b)(6)
>> Reply-To: (b)(6)
>> Date: Mon, 2 Nov 2009 13:40:51 -0500
>> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
>> Conversation: HFT Application
>> Subject: HFT Application
>>
>> Dear Kim,
>>
>> Attached you'll find the documents we just discussed. What I'll need
>> back
>> from you is the two page application as well as a short synopsis of the
>> work you'll be doing. As soon as I get the completed application from
>> you
>> it will go to our Scientific Advisory Board for review and approval. If
>> they have questions, I'll give you a call. Approval usually takes 5-10
>> working days from the time I receive the application from you.
>>
>> Please send your application back to my e-mail address
>> (b)(6)
>> or FAX to 510-865-4090.
>>
>> Thanks so much for your interest in the services supplied by Advanced
>> Bioscience Resources. I apologize again for taking such a long time to
>> respond to your query.
>>
>> Perrin Larton CTBS
>> Procurement Manager
>> Advanced Bioscience Resources
>
>

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Tuesday, November 24, 2009 10:28 AM
To: Hasenkrug, Kim (NIH/NIAID) [E]
Subject: HasenkrugK_NIAID_4980_CY2009

Good Afternoon Dr. Hasenkrug:

Thank you for the opportunity to review your research project: ***Study of HIV infection & Vaccine Protection..*** Since the work you are doing at the NIH provides little or no risk to human subjects off-site, OHSR has decided the appropriate action for you to take is the following:

- Provide documentation that you will not seek the identity of the subjects who have provided the samples you will receive as well as documentation from ABR that under no circumstances will the identity or link to the identifiers of the subjects be released to you.

An e-mail from you and from ABR holding the key to the code is sufficient documentation.

This action is based on guidance issued on Aug. 10, 2004 by the HHS Office of Human Research Protections, the regulatory office for the protection of human subjects.

Best regards,

OHSR - National Institutes of Health
Bldg 10, Suite 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

The NIH is committed to maintaining the highest standards for the protection of human subjects.


Please consider the environment before printing this e-mail

ADVANCED BIOSCIENCE RESOURCES, INC.

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
2/8/2017	(b)(6)	1033232
	TERMS	CUSTOMER #
	Due Upon Receipt	0522

BILL TO

Rocky Mountain Labs
NIH/NIAID
Kim J. Hasenkrug
903 S. 4th Street
Hamilton, MT 59840

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
2/8/2017	670802	6483	21	Thymus, 2nd Trimester	HASENKRUG	(b)(4)
2/8/2017	670802	6484	21	Liver, 2nd Trimester	HASENKRUG	
				02/15/17 PAID via VISA (b)(6) Request by Kim Hasenkrug.		

ADVANCED BIOSCIENCE RESOURCES
1516 OAK ST STE 303
ALAMEDA, CA 94501
(510) 865-5872

Sale

Entry Method: Manual

VISA Total: $ 680.00

02/15/17 12:13:52
Inv #: 6000005 Appr Code: 054654
Approved: Online Batch#: 046001
AVS Code: ZIP MATCH 2
CVV2 Code: MATCH M

Total $680.00

SEQ: 1833955	PO#: (b)(6)	Requester: Messer, Ronald

CAN: 8335424 FY: 17 Owner: (b)(6)
Order Total: 680.00 Project: 107833
Date Needed: 01/31/2017 Emergency: No Order Type: Purchase Card
Requestor Phone: +1 406 363 9276 Order Status: Archive

Vendor Advanced Bioscience Resources,1516 Oak Street, Suite 303, Alameda, CA 94501
Phone: 510-865-5872 SmlBs: No FSS:
EIN: BPA: GSA:
Site: Clerk:
E-mail:

#	Description	CAN	Catalog	OC Code	Category	Qty at Price	Total
1	Tissue, 2nd Trimester (1 each of liver and thymus)	8335424	none	2613	6509	(b)(4)	680.00
2	shipping	8335424		2613	6509	1 each at $0	.00
Order Total: 680.00							

Ship To: Ronald Messer,3220 ,RML CNTRL REC,RMTLAB

QUOTES

Vendor	Price	Good Until	Available
There are no quotes in the order			

JUSTIFICATION

These tissues, liver and thymus, are required by Ron Messer for ongoing studies of HIV in the Hasenkrug Lab. Our mice will be ready for reconstitution soon. Please let me know when I can contact Perrin Larton at ABR to place our request on their schedule. Please contact the vendor at 510-865-5872 ext (b)(6) -give her the PO number Thanks, Ron. *** I certify that I have checked the sources of supply and services listed in FAR 8.002. ( ) I have purchased from the highest priority source available. (X) I did not purchase from a priority source because none could satisfy the requirement of the government either in product/service specifications, quality or required delivery time. **********NOTE to Purchasing Agent: Call vendor at 510-865-5872 ext (b)(6) (b)(6) give her the PO number and credit card information.

Alternate Sources:

NIH Surplus: No | UNICOR: No | GSA Stock Catalog: No | GSA Self Service: No | Federal Supply: No | Open Market: Yes

AGENT

Purchase Order #: (b)(6)
Custodial Code: 30102
Order Reference: em'd (b)(6)
FSS:
NBS Ref Order #: 4472919

Estimated Ship Date:
Date Entered into NBS: 01/30/2017
Expected Delivery Date: 02/08/2017
Select Agents: No
Clearance Requested: No

SF-37 Code:

Notes

There are no notes in the order

IT Clearance

Never seen by IT officer

ROUTE HISTORY

Role Summary

User Role	Name
Requester	Messer, Ronald
Releaser	Messer, Ronald
Admin Officer	(b)(6)
Lead Admin Officer	
Purchase Agent	(b)(6)
Lead Agent	
IT Clearance Officer	
Releaser1	
Releaser2	
NBS	
Receiving Official	

Dates

Description	Date
Needed By	01/31/2017
Submitted to NBS	01/30/2017
NBS Confirmation	01/31/2017
Award Created	01/30/2017
Award Received	01/30/2017
Estimated Ship Date	
Received	03/29/2017
Canceled	

Routing History

Name	Role	Date In	STATUS IN	ACTION
Messer, Ronald	Requester	01/30/2017	New order	Approved
(b)(6)	Administrative Officer	01/30/2017	Released	Approved
	Purchasing Agent	01/30/2017	Approved	Approved
NBS, NBS	NBS	01/30/2017	Sent to NBS	Approved
Messer, Ronald (b)(6)	Requester for receiving	01/30/2017	Pending receiving	Take
(b)(6)	Requester for receiving	03/29/2017	Pending receiving	Approved
	Archive	03/29/2017	Archive	(N/A)

Receiving Report

#	Description	Total Qty Ordered	Total Qty Received	Date Received
1	Tissue, 2nd Trimester (1 each of liver and thymus)	2	2	03/29/2017
2	shipping	1	1	03/29/2017

OHSR RESPONSE TO REQUEST FOR REVIEW OF RESEARCH ACTIVITY
INVOLVING HUMAN SUBJECTS

FAX:

Exempt: #: 4980

To: Hasenkrug, Kim
NIAID
RML - Rocky Mountain Laboratories, 3/218

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
Recent reports have demonstrated that immunodeficient mice reconstituted with 17-19 week old human fetal tissue develop a human immune system and are susceptible to HIV infection and disease. The goal of this project proposal is to create such humanized mice to study the role of immune cell subsets and virus-neutralizing antibodies in vaccine protection. The experiments will entail the development of a cohort of mice all reconstituted with the same human cells so as to be histocompatible. This will require transplantation of

Original Request Received in OHSR on: 11/19/2009

Responsible NIH Research Investigator(s): Kim Hasenkrug, NIAID

OHSR review of your request dated Thu, Nov 19, 2009 has determined that:

☒ Federal regulations for the protection of human subjects do not apply to above named activity. The OHSR determination of Not Human Subjects Research is based on the interpretation of 45 CFR 46 under "Research Involving Coded Private Information or Biological Specimens" (OHRP, Revised October 16, 2008) and Guidance on Engagement of Institutions in Human Subjects Research (October 16, 2008). NOTIFY OHSR VIA AN E-MAIL AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESEARCH ACTIVITY.

☐ The activity is designated **EXEMPT**, and has been entered in the OHSR database. PLEASE NOTIFY OHSR OF ANY **SIGNIFICANT** CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.

☐ **NOT EXEMPT**. OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additional information in order to determine whether expedited or full review is appropriate.

☐ Confidentiality Agreement

☐ Reliance

☐ Amendment

☐ Other

Office Person LB Admin Assist. CB

Note:
(b)(6)

CIP

for Charlotte Holden, JD — Acting Director, OHSR — 12/14/2009
Signature — Title — Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: Yes

OHSR Use Only
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

#4980

REQUEST FOR REVIEW OF RESEARCH ACTIVITY INVOLVING HUMAN SUBJECTS

INSTRUCTIONS: Please type directly on this form. You can expand the document if you need more space. If your research involves a survey or questionnaire, please attach it to this completed form.

Completed forms (with all required signatures) may be sent to OHSR by FAX (301-402-3443), email to ohsr_nih_ddir@od.nih.gov, or by mail (2C146). If you have any questions, call OHSR at (301) 402-3444.

Date: 11/19/2009

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146

From: Kim J Hasenkrug
(Signature)

(b)(6)

Through: (acting)
(Signature of appropriate Official for IC, e.g., Lab/Branch Chief)

Protocol Title: Study of HIV infection and vaccine protection in mice reconstituted with a human immune system

Name of NIH Principal Investigator(s): Kim J Hasenkrug, Senior Investigator

IC NIAID Laboratory/Branch LPVD Building & Room No. RML 3218
Tel. No. 406-363-9310 FAX No. 406-363-9286
Is the Principal investigator an NIH employee? x **Yes** ____ **No**

If no, please explain: ____

1. What is the proposed research activity that you intend to perform at NIH (please use lay terms):

Recent reports have demonstrated that immunodeficient mice reconstituted with 17-19 week old human fetal tissue develop a human immune system and are susceptible to HIV infection and disease. The goal of this project proposal is to create such humanized mice to study the role of immune cell subsets and virus-neutralizing antibodies in vaccine protection. The experiments will entail the development of a cohort of mice all reconstituted with the same human cells so as to be histocompatible. This will require transplantation of the mice with 1 mm^3 pieces of fetal thymus as well as reconstitution with stem cells isolated from cord blood and liver. Once the humanized mice have been established some will be vaccinated to prime distinct subsets of immune cells. Immune cell subsets from vaccinated mice will be adoptively transferred into naïve mice, which will then be infected with HIV to

test the antiviral activity of the immune cells. The goal of these experiments is to establish correlates of immunity against HIV.

2. If applicable, list your non-NIH Collaborating Investigator(s).

Name Institution Address Tel. # FAX #

3. Proposed start date of your research __April, 2010_____
Proposed completion date _April, 2013_____

4. Will you be _____these samples or data?

Collecting Yes/(No)
Receiving (Yes)/No
Sending Yes/(No)

5. Do the samples or data:
(a) Already exist?___Yes _x__No

(b) Or are they being collected for the express purpose of this study? _X__Yes __No
If "yes," please describe:_

17-19 week fetal cells and tissue will be obtained from Advanced Bioscience Resources, Inc., a non-profit foundation established under California law to provide biomedical researchers access to human tissues in compliance with state, federal, and NIH guidelines. Consent to donate is obtained in accordance with UAGA and NOTA guidelines. Related documents including the consent form are attached._____

(c) Or a combination of (a) and (b)? ____Yes _____No

6. What role will you have in this research project? (Check all that apply)

___ Analyze samples/data only.

___ Consultant/advisor to collaborator(s) listed above.

___ Author of the protocol that is being implemented by your collaborating investigator (identified in question #2).

___ Co-authorship on publication(s)/manuscript(s) pertaining to this research.

___ You or NIH hold an IND for this research.

__X_ Decisional authority over the design or implementation of the research at the IRB approved site? If so, please explain.

I am the PI and lead investigator on this project which will take place in my laboratory and the animal care facilities at Rocky Mountain Labs, NIAID, NIH.

___Other (If necessary, use this space to describe your role in this research).

7. Where are the subjects of this research activity located?
The material for this research is obtained from natural or induced abortions from females in California. Thus the tissues and cells involved will not be from living humans.

8. If human subjects are located elsewhere (not at NIH), will you have direct contact or intervention with them? (Examples: as subject's physician; in obtaining samples directly from the subject; by interviewing the subject?) ____ Yes __x__No

9. What kind of human samples (e.g., tissue, blood) or data (e.g., private information, responses to questionnaires) will be involved in your research?
_Samples will include cord blood, fetal blood, thymus, liver, and bone marrow. No private information will be involved._____

---

10. If the samples, data do not come from an IRB approved protocol, do they come from:

(a) Repository ____Yes ___ No

(b) Pathological waste ___ Yes _____No

(c) Autopsy material ___ Yes ___ No

(d) Publicly available source _X__Yes ___ No

(e) Other_____

11. Please check the box(es) that apply(ies) to the samples/data that you will receive.

(a) ____ Samples and/or data will be anonymized/unlinked. (The samples/data cannot be linked to individual subjects by you or your collaborators at other sites.)

(b) ___ Samples and/or data will be coded, however that code cannot be used by either the sender or the receiver to identify specific individuals.

(c) __X_ Samples and/or data will be coded so that the provider of the samples/data can link them to specific individuals but the receiver will not be able to do so.

12. Will you send results back to the provider(s) (listed in question 2 of this form)?

(a) __X_ No, I will not send results back to the provider(s).

(b) ___ Yes, I will send aggregate results to the provider(s).

(c) ___ Yes, I will send results to the provider(s) that are linked to identifiable individuals.

If yes, does the provider intend to link your data to identifiable individuals?
_____Yes _____No

13. Has the research activity <u>that you are proposing in this form</u> been approved by an Institutional Review Board (IRB) elsewhere?

_____ Yes, the NIH research activity has been reviewed by the following IRB (s) (Please provide the following information for each IRB):

_____ Name of institution that provided the review

_____ Address of reviewing institution

_____ Name of PI for the IRB approved protocol

_____ Title of IRB approved protocol and protocol #

_____ Federal Wide Assurance (FWA) number**

___X_____No IRB review of the research activity described in question #1 above has taken place

(**An FWA is a contract between the U.S. Department of Health and Human Services (DHHS) and an entity receiving DHHS funds to conduct clinical research that the latter will follow ethical guidelines and federal regulations for the protection of human subjects. For a list of domestic and international institutions go to http://ohrp.cit.nih.gov/search/asearch.asp#ASUR

14. Per NIH guidance*, have conflicts of interest by NIH employees, if any, been resolved?**

__X___Yes _____No no conflicts of interest

If your answer is no, please see your Clinical Director about this matter before proceeding with this research.

***The January 5, 2005 NIH Guide to Preventing Conflict of Interest applies to all research conducted at NIH, http://ohsr.od.nih.gov/New/mpafwa_docs.html

ADVANCED BIOSCIENCE RESOURCES, INC

OVERVIEW

ADVANCED BIOSCIENCE RESOURCES is a non-profit corporate foundation established in 1989 under California law to provide biomedical researchers with access to human tissues. ABR was formed exclusively for biomedical, scientific, and educational purposes and is devoted to providing services in connection with the procurement of human organs and tissues for medical and scientific research. ABR specializes in the procurement, preservation and distribution of both human fetal tissues and full term umbilical cord blood for research, and provides a highly individualized, reliable and easily accessible service.

TISSUE COLLECTION AND DISTRIBUTION: The purpose of ABR is to promote cooperative efforts to collect and distribute human tissues and to thereby facilitate research utilizing those tissues. Trained personnel coordinate the retrieval, preservation and delivery of each specimen.

Tissues obtained through ABR are retrieved from routinely performed surgical procedures including first and second trimester induced abortions, and full term deliveries, either natural or caesarian section. Tissues that were once discarded are now available to scientists worldwide through the efforts of ABR. Researchers may specify tissue characteristics, preservation methods, and delivery times.

PRESERVATION METHODS: Each specimen is collected, preserved, and shipped according to the investigator's individual protocol.

QUALITY CONTROL: ABR practices strict quality control procedures and adheres to stringent guidelines for tissue collection and preservation. Consent is obtained in accordance with UAGA and NOTA guidelines. Tissue specimens are identified, dissected, and transferred to the specified medium. A control number is then assigned to each sample to ensure confidentiality of patient identity.

To assure proper processing of the tissue, every researcher selects a collection/preservation protocol tailored specifically to his needs. In the collection and distribution of these tissues, every effort is made to exercise the highest standards of medical and laboratory practice. ABR specializes in direct communication with each investigator from the initial application to specimen delivery.

INVESTIGATOR APPROVAL: ABR will provide tissue to researchers who provide information on current research funding, and a short summary of their research intent. Investigators must agree to accept responsibility for the potential biohazard of the tissue and to appropriately train laboratory personnel in the proper handling of the tissue. In addition, the researcher must agree to use the tissue solely for research purpose and to acknowledge ABR in any publications resulting from the use of ABR provided tissue.

APPLICATION PROCESS: To request human tissue for research, an application must be completed and submitted to ABR. The application will be reviewed for feasibility and priority. A protocol will be developed to meet individual research needs as identified in the application.

SERVICE AND PROCESSING FEES: Participating medical facilities that enable ABR to enact its tissue acquisition and distribution programs may be paid a nominal fee for such services. A minimal processing / preservation / shipment fee is also assessed for services provided to research facilities.

1516 Oak Street # 303 / Alameda, CA 94501 / 510-865-5872 / Fax 510-865-4090 / email abr@abr-inc.com

Recent advancements in medical research have been developed through the use of human tissues in scientific study. Diseases such as diabetes, hemophilia, Parkinson's disease, cancer, AIDS, heart and lung disease, as well as genetic and,neonatal disorders, are being investigated for the development of cures through the use of human fetal tissues. Any tissue donated may be distributed to medical institutions and private research groups in the United States and internationally to enhance the development of cures and therapies for disease.

PERMISSION FOR DONATION OF TISSUE
OBTAINED AT THE TIME OF ABORTION

I have previously decided to have an abortion and have previously consented to having such abortion.

I hereby donate the aborted material and/or a sample of my blood as an anatomical gift for the purposes of education, research, or for the advancement of medical science. I understand that my donation may be used by research facilities in the United States and abroad.

I also agree that a sample of my blood may be taken after the abortion and that it may be used for research and routine testing for AIDS, hepatitis, or other infectious agents. I understand that, if there is testing, the results will be confidential unless the law requires that they be disclosed.

I understand that the aborted material may be used to derive human pluripotent stem cells for medical research and possibly human transplantation research, and that these cells may be kept for many years. I also understand that my donation may be used for cosmetic purposes. I understand that there is no information associated with aborted material that could link me with my donation. I agree that this donation is made without any restriction or direction regarding the potential recipients of the cells derived from the aborted material and that I have not been informed of the identity of any potential recipients.

I understand that there will be no payment to me and I agree that, although the results of the research on the aborted material may have commercial value, I will have no property or other commercial or financial rights in the aborted material or any product, process, or service which may result from this donation.

I understand that my donation will not result in any direct medical benefit to me.

I understand that my donation is voluntary, and I may refuse to donate aborted material and this will not affect my medical care or my relationship with my physician.

I understand that, if I have any questions about my donation, I can contact ABR at 510-865-5872.

_____ _____
Signature Date

I choose not to participate.

_____ _____
Signature Date

_____ _____
Witness Date

ADVANCED BIOSCIENCE RESOURCES, INC.

APPLICATION FOR THE ACQUISITION OF

HUMAN FETAL TISSUE FOR RESEARCH

All requests for human fetal tissue are reviewed for feasibility of procurement and preparation. When approved, an individual protocol will be developed for the procurement, preparation and delivery of tissue samples, based on the information provided in this application and any subsequent communication.

I. APPLICANT INFORMATION

NAME: Kim J Hasenkrug

TITLE: Senior Investigator

COMPANY: NIAID, NIH

ADDRESS: Rocky Mountain Lab

ADDRESS: 903 S. 4th St

CITY,ST,ZIP: Hamilton, MT 59840

PHONE #: 406-363-9310

ALT. #:

FAX #: 406-363-9286

EMAIL: khasenkrug@nih.gov

DELIVERY OPTIONS:

__X__ Same Day: Commercial carrier, hand delivered
Maximizes cell viability (*geographical limits*)

_____ Next Day: Pickup, delivery Mon-Sat daytime
Economical for fresh, frozen specimens

Applicant will be charged for delivery fees.

Applicant may designate preferred carrier:

Carrier Name: FEDEX

Account #: (b)(4)

BILLING INFORMATION:

BILL TO: Kim J Hasenkrug

COMPANY: Rocky Mountain Labs

ADDRESS: 903 S. 4th St.

ADDRESS:

CITY,ST,ZIP: Hamilton, MT 59840

ACCOUNTING DEPT. PHONE #: 406-363-9438

P.O. # (if required by your company):

P.O. # is not required to submit application

Credit Card #:

Name on CC:

Expiration Date: VISA/MC

SHIP TO: Kim J Hasenkrug
Rocky Mountain Labs
903 S. 4th St
Hamilton, MT 59840

Please indicate how you heard about ABR: (b)(6)

II. HUMAN FETAL TISSUE

Tissue specimens requested: thymus, liver, cord blood

Preferred gestational age (6-24 weeks): 17-19 wks

Proposed starting date: May, 2010

CONTAGIOUS DISEASE SCREENING: Availability of test results varies from 24 hours to 7 days after procurement. Applicant requires the following tests to be performed by ABR:

__X__ No testing required

_____ HIV _____ HSV
_____ HBSAG _____ RPR
_____ CMV _____ HCV

OTHER_____

III. PRESERVATION

ABR uses *BioWhittaker RPMI-1640 With L-Glutamine* for tissue preparation, preservation and shipment. Applicant may supply ABR with other media specific to research needs. Please indicate preference below.

PRESERVATION METHODS AVAILABLE:

__X__ Fresh; shipped on wet ice
_____ Passive freezing on dry ice; shipped on dry ice
_____ "Snap" freezing in LN2; shipped on dry ice
_____ Media provided by applicant
_____ Media provided by ABR (RPMI)

IV. DONOR INFORMATION

CONSENT VERIFICATION: Consent for tissue donation is obtained prior to specimen procurement. The consent is extremely confidential in nature and shall not be communicated to the researcher.

SPECIFIC DONOR INFORMATION: Charts are routinely examined for patient medical histories. Please identify any specific information sought and indicate contraindications to specimen procurement:

_____HIV+ status contraindicates procurement_____

_____

_____

V. RESEARCH DATA

TITLE OF RESEARCH PROJECT: ___The role of virus-specific CD4+__T cells, CD8+ T cells and antibody in vaccine protection against HIV-1 in humanized mice_____

ABR will provide tissue to researchers who provide information on current research funding, and a short summary of their research intent. **(Please attach a brief synopsis of the research project named above.)** Researchers must agree to use the tissue solely for research purposes and to acknowledge ABR in any publications resulting from the use of ABR provided tissue. Updates on research progress will be requested at six-month intervals. Researchers agree to publish the results of the research as promptly after the completion of the research as is reasonably possible without jeopardizing the sponsor's right to secure patents or copyrights necessary to protect its ownership or control of the results of the research. Researchers agree to inform ABR of the name of the publication and the date of the issue in which the results will be published. It is the intent of this requirement to make the results available to the general public through acceptable means of publication.

VI. SOURCE OF FUNDING

Please identify the primary source of funding for this project.

NIH _X___ Other Federal or State Grants _____ Foundation Grants _____ Other (specify) _____

If this application is approved by ABR, ABR shall provide services to the applicant in accordance with the terms and the other conditions on the reverse side, and the signature of the applicant shall constitute acceptance of all such terms and conditions by applicant. The entire agreement between ABR and applicant relating to the services provided by ABR is expressly set forth herein, and any modification of or addition thereto shall be of no force or effect unless it is in writing and signed on behalf of ABR by a duly authorized representative.

BY SIGNING BELOW, THE APPLICANT ACKNOWLEDGES HAVING READ THE TERMS AND CONDITIONS ON THE FOLLOWING PAGE AND AGREES TO SUCH TERMS AND CONDITIONS.

Kim J Havenhuys

____ _____

_Senior Investigator_____
SIGNATURE and TITLE of APPLICANT

DATE 11/2/2009

Please return to:

ADVANCED BIOSCIENCE RESOURCES, INC.
1516 OAK STREET, SUITE 303
ALAMEDA, CALIFORNIA 94501
Telephone: 510-865-5872
Fax: 510-865-4090
Email: abr@abr-inc.com

TERMS AND CONDITIONS OF SERVICES

1. Services

1.1 During the term of this agreement, and pursuant to the terms and conditions hereinafter set forth, ABR will use its best efforts to provide services in connection with supplying researcher with the types of human tissues set forth in this application, as approved

by ABR, suitable for researcher requirements and in the amounts requested based upon ongoing discussions between researcher and ABR pursuant to the information sent by ABR.

1.2 Researcher acknowledges and agrees that ABR will provide the following types of services:

Removing tissue.
Preserving and processing tissue to a form suitable to the researcher needs.
Seeking consent for tissue donations from appropriate individuals, obtaining validly executed consent forms, and maintaining records of such consents in accordance.
Obtaining, labeling, storing, and delivering samples of donor or other required serum, and maintaining a system for matching such samples to specific tissue donations.
Preserving tissue viability and cleanliness during removal, processing, preservation, storage and transportation.
Storing tissue and transporting it to researcher in accordance with section 5.

1.3 In the event that tissues of the type specified in the application become unavailable to ABR, such that ABR is unable to perform the contemplated services, ABR shall have no obligation to perform such services.

2. Representations and Warranties. ABR hereby represents and warrants to researcher that (i) ABR will make no payments to anyone for any tissue transferred in connection with this agreement, and (ii) ABR will verify for each tissue delivery that appropriate consent was obtained for use of such tissue and any associated serum samples, and that adequate records of such consent are maintained; provided, however, that the parties hereto acknowledge and agree that such consents are extremely confidential in nature and shall not, in any case, be communicated to researcher. Researcher hereby represents and warrants to ABR that (i) researcher will neither sell nor transfer for valuable consideration any tissue received through ABR to anyone, (ii) researcher will use the tissue only to satisfy its objectives, which are, as acknowledged and agreed hereto, [research and clinical use], (iii) researcher agrees to inform ABR of any changes in clinical or research use of specimens received from ABR, or in any specifications, constraints, etc. in a timely manner, and (iv) researcher understands the bio-hazardous nature of human tissue and agrees to take proper precautionary measures at all times when handling tissue specimen.

3. Terms. The terms of this agreement shall be for one (1) year, beginning from the date hereof, and terminating one (1) year thereafter, unless either of the parties hereto shall have given to the other thirty (30) days written notice of its intention to terminate this agreement, whereupon same shall terminate thirty (30) days after date of said notice.

In default of notice as aforesaid from either party hereto, this agreement shall continue for further successive terms of one (1) year thereafter and in default of thirty (30) days written notice before the end of an annual term by either of the parties of its intention not to renew, whereupon this agreement shall terminate at the end of said term.

4. Payments. Researcher agrees to pay to ADR a fee for costs incurred by ABR in providing services in connection with the acquisition of each sample of tissue requested by researcher, to be mutually agreed upon by ABR and researcher upon approval of this agreement by ABR.

5. Shipment services.

5.1 All shipments will be made as soon as possible after request has been received by ABR from researcher.

5.2 Researcher acknowledges that networks of tissue availability are neither permanent nor dependable, but rather they fluctuate. However, ABR shall use its best efforts to transfer the tissue in the amounts requested by researcher.

5.3 Shipment will be made in the best possible manner so as to preserve the quality of the tissues. It is understood that the fragility of human tissue is such that damage may occur during shipment. ABR will use its best efforts to comply with the handling and shipment protocols provided by researcher.

5.4 ABR will package the tissue appropriately and, if so requested by researcher, will insure the shipment. Researcher agrees to bear all costs associated with insurance and shipment of any tissue.

5.5 The risk of loss and damage of any tissue or organs shall pass immediately to researcher when the shipment of such tissue or organs is deposited with a carrier for transportation at the F.O.B. point.

6. Limitation of liability. ABR shall not be responsible or liable under any section of this agreement or under any contract, negligence, strict liability or other legal or equitable theory, for the cost of procurement of substitutive services, or any indirect, incidental or consequential damages including, but not limited to loss of revenues and loss of profits. Any liability of ABR under any theory whatsoever will be limited exclusively to the provision of equivalent services by ABR or, if unenforceable, to payment of an amount not greater than any amount actually received by ABR from researcher on account of this agreement.

7. No warranties. It is understood that human tissue is by nature neither permanent nor dependable. Except as expressly set forth in this agreement, ABR makes no representation of any kind, expressed or implied, including any representation with respect to the safety, efficacy or merchantability or the fitness for any purpose with respect to the tissue transferred to researcher in connection with this agreement.

8. Indemnification. Researcher shall indemnify, defend and hold ABR harmless from and against all claims, causes of actions, suits, damages and costs arising out of, resulting from, or otherwise in respect of, the use of tissue transferred in connection with this agreement, except where such claims are the result of negligence of ABR, its employees, staff or agents to (i) comply with any governmental requirements, or (ii) adhere to the terms of this agreement.

9. General. This agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of law. This agreement may not be assigned by either party without the prior written consent of the other.

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Monday, November 23, 2009 10:43 AM
To: Hasenkrug, Kim (NIH/NIAID) [E]
Subject: Request for Review Rec'd-OHSR 4980

Good morning Dr. Hasenkrug,

This email is to verify that OHSR has received your Request for Review of Research and it is currently being processed as OHSR #4980. Please use this number in any future correspondence regarding this study. We will contact you via email if any additional information is needed. If you have not heard from OHSR within 7 business days, please contact us.

Protocol Title: Study of HIV infection and vaccine protection in mice reconstituted with a human immune system

Thank you.

OHSR:
Ph: 301.402.3444
Fax: 301.402.3443

Thank you.

Sincerely,

(b)(6)

OHSR (NIH/DDIR)

From: Hasenkrug, Kim (NIH/NIAID) [E]
Sent: Wednesday, December 09, 2009 5:41 PM
To: OHSR (NIH/DDIR)
Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up
Flag Status: Green

Attachments: IRB Letter with letterhead nonidentity.doc

IRB Letter with letterhead non...

Here is the letter on official ABR letterhead for you

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
Laboratory of Persistent Viral Diseases
Rocky Mountain Laboratories
National Institute of Allergy and Infectious Diseases National Institutes of Health
903 S. 4th Street
Hamilton, MT 59840
phone (406)363-9310
FAX (406)363-9286
khasenkrug@nih.gov

> From: "OHSR (NIH/DDIR)" <ohsr_nih_ddir@od.nih.gov>
> Date: Tue, 24 Nov 2009 10:27:55 -0500
> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
> Conversation: HasenkrugK_NIAID_4980_CY2009
> Subject: HasenkrugK_NIAID_4980_CY2009
>
> Good Afternoon Dr. Hasenkrug:
>
> Thank you for the opportunity to review your research project: Study
> of HIV infection & Vaccine Protection.. Since the work you are doing
> at the NIH provides little or no risk to human subjects off-site, OHSR
> has decided the appropriate action for you to take is the following:
>
> * Provide documentation that you will not seek the identity of the
> subjects who have provided the samples you will receive as well as
> documentation from ABR that under no circumstances will the identity
> or link to the identifiers of the subjects be released to you.
>
> An e-mail from you and from ABR holding the key to the code is
> sufficient documentation.
>
> This action is based on guidance issued on Aug. 10, 2004 by the HHS
> Office of Human Research Protections, the regulatory office for the
> protection of human subjects.

> Best regards,
>
>
>
> OHSR - National Institutes of Health
> Bldg 10, Suite 2C146
> Bethesda, MD 20892
> Office Telephone: 301-402-3444
> Office Fax: 301-402-3443
>
> The NIH is committed to maintaining the highest standards for the
> protection of human subjects.
> P Please consider the environment before printing this e-mail
>

ADVANCED BIOSCIENCE RESOURCES, INC

December 14, 2009

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
903 S. 4th Street
Hamilton, MT 59840

Dear Kim,

This letter verifies that ABR, a non-profit tissue procurement organization, supplies requesting and approved scientific investigators with the types of human fetal tissues required for specific bio-medical research. When requested and as availability allows, human fetal tissue specimens will be retrieved from products of conception from induced first and second trimester abortions. Tissue will be distributed according to established protocols. Specimens are not collected for directed donation. .

ABR warrants that maternal consent from patients aged over eighteen years is obtained for the use of fetal tissue specimens for research purposes, including the consent for the potential of stem cell research utilizing such tissues, and that adequate records of such consent are maintained for future verification. Donor identification is coded and scientific investigators have no access to donor identification. ABR also warrants that maternal consent is obtained for phlebotomy and blood testing for a variety of disease entities.

ABR warrants that no payments will be made to any third party for the conduct of or the product of an abortion, including without limitation any parent(s) of any unborn fetus. ABR, to the best of its knowledge, also warrants that all tissue provided will have been obtained in compliance with local, state and federal laws and regulations governing the procurement and distribution of human tissue.

Sincerely,

Perrin Larton

Perrin Larton, CTBS
Procurement Manager

Federal E.I.N.: 94-3110160
California E.I.N.: 370-20518
FDA FEI: 3005208435

1516 Oak Street # 303 / Alameda, CA 94501 / 510-865-5872 / Fax 510-865-4090 / email abr@abr-inc.com

OHSR (NIH/DDIR)

From: Hasenkrug, Kim (NIH/NIAID) [E]
Sent: Monday, November 30, 2009 5:24 PM
To: OHSR (NIH/DDIR)
Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up
Flag Status: Green

Attachments: Re: HFT Application

Re: HFT Application

HasenkrugK_NIAID_4980_CY2009

Attached please find the requested email from ABR stating that no personally identifiable information will be released to me. Furthermore, I will not seek any such information from ABR.

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
Laboratory of Persistent Viral Diseases
Rocky Mountain Laboratories
National Institute of Allergy and Infectious Diseases National Institutes of Health
903 S. 4th Street
Hamilton, MT 59840
phone (406)363-9310
FAX (406)363-9286
khasenkrug@nih.gov

> From: "OHSR (NIH/DDIR)" <ohsr_nih_ddir@od.nih.gov>
> Date: Tue, 24 Nov 2009 10:27:55 -0500
> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
> Conversation: HasenkrugK_NIAID_4980_CY2009
> Subject: HasenkrugK_NIAID_4980_CY2009
>
> Good Afternoon Dr. Hasenkrug:
>
> Thank you for the opportunity to review your research project: Study
> of HIV infection & Vaccine Protection.. Since the work you are doing
> at the NIH provides little or no risk to human subjects off-site, OHSR
> has decided the appropriate action for you to take is the following:
>
> * Provide documentation that you will not seek the identity of the
> subjects who have provided the samples you will receive as well as
> documentation from ABR that under no circumstances will the identity
> or link to the identifiers of the subjects be released to you.
>
> An e-mail from you and from ABR holding the key to the code is
> sufficient documentation.

>
> This action is based on guidance issued on Aug. 10, 2004 by the HHS
> Office of Human Research Protections, the regulatory office for the
> protection of human subjects.
>
> Best regards,
>
>
>
> OHSR - National Institutes of Health
> Bldg 10, Suite 2C146
> Bethesda, MD 20892
> Office Telephone: 301-402-3444
> Office Fax: 301-402-3443
>
> The NIH is committed to maintaining the highest standards for the
> protection of human subjects.
> P Please consider the environment before printing this e-mail
>

OHSR (NIH/DDIR)

From: Perrin Larton (b)(6)

Sent: Monday, November 30, 2009 5:10 PM

To: Hasenkrug, Kim (NIH/NIAID) [E]

Cc: (b)(6)

Subject: Re: HFT Application

Hi Kim,

All tissue is numerically coded and the personally identifiable information is never available. In other NIH applications we've had requests for letters that state NO information is available to researchers. I can send you a letter to that effect...but tissue cannot be tracked back to a specific patient. We guarantee anonymity to the patients donating tissue.

Perrin

> Dear Perrin, the Office of Human Subjects Research is asking me for a
> letter
> from you stating that personally identifiable information regarding the
> fetal tissue will be revealed to me. Would you kindly send me a letter
> stating such so that I can forward it to them? It would be greatly
> appreciated and let us begin our experiments. I attached a copy your
> letter
> regarding approval of our application for your information. Thank you
> very
> much, Perrin.
>
> Kim
>
> Kim J Hasenkrug, Ph.D.
> Senior Investigator
> Chief, Retroviral Immunology Section
> Laboratory of Persistent Viral Diseases
> Rocky Mountain Laboratories
> National Institute of Allergy and Infectious Diseases
> National Institutes of Health
> 903 S. 4th Street
> Hamilton, MT 59840
> phone (406)363-9310
> FAX (406)363-9286
> khasenkrug@nih.gov
>
> Disclaimer:
> The information in this e-mail and any of its attachments is confidential
> and may contain sensitive information. It should not be used by anyone who
> is not the original intended recipient. If you have received this e-mail
> in
> error please inform the sender and delete it from your mailbox or any
> other
> storage devices. National Institute of Allergy and Infectious Diseases
> shall
> not accept liability for any statements made that are sender's own and not
> expressly made on behalf of the NIAID by one of its representatives

>
>
>> From: Perrin Larton (b)(6)
>> Reply-To: (b)(6)
>> Date: Mon, 2 Nov 2009 13:40:51 -0500
>> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
>> Conversation: HFT Application
>> Subject: HFT Application
>>
>> Dear Kim,
>>
>> Attached you'll find the documents we just discussed. What I'll need
>> back
>> from you is the two page application as well as a short synopsis of the
>> work you'll be doing. As soon as I get the completed application from
>> you
>> it will go to our Scientific Advisory Board for review and approval. If
>> they have questions, I'll give you a call. Approval usually takes 5-10
>> working days from the time I receive the application from you.
>>
>> Please send your application back to my e-mail address
>> (b)(6)
>> or FAX to 510-865-4090.
>>
>> Thanks so much for your interest in the services supplied by Advanced
>> Bioscience Resources. I apologize again for taking such a long time to
>> respond to your query.
>>
>> Perrin Larton CTBS
>> Procurement Manager
>> Advanced Bioscience Resources
>
>

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Tuesday, November 24, 2009 10:28 AM
To: Hasenkrug, Kim (NIH/NIAID) [E]
Subject: HasenkrugK_NIAID_4980_CY2009

Good Afternoon Dr. Hasenkrug:

Thank you for the opportunity to review your research project: ***Study of HIV infection & Vaccine Protection..*** Since the work you are doing at the NIH provides little or no risk to human subjects off-site, OHSR has decided the appropriate action for you to take is the following:

- Provide documentation that you will not seek the identity of the subjects who have provided the samples you will receive as well as documentation from ABR that under no circumstances will the identity or link to the identifiers of the subjects be released to you.

An e-mail from you and from ABR holding the key to the code is sufficient documentation.

This action is based on guidance issued on Aug. 10, 2004 by the HHS Office of Human Research Protections, the regulatory office for the protection of human subjects.

Best regards,

OHSR - National Institutes of Health
Bldg 10, Suite 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

The NIH is committed to maintaining the highest standards for the protection of human subjects.


Please consider the environment before printing this e-mail

ADVANCED BIOSCIENCE RESOURCES, INC.

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
3/9/2017	(b)(6)	1033372
	TERMS	CUSTOMER #
	Due Upon Receipt	0522

BILL TO

Rocky Mountain Labs
NIH/NIAID
Kim J. Hasenkrug
903 S. 4th Street
Hamilton, MT 59840

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
3/9/2017	730901	5162	19	Thymus, 2nd Trimester	HASENKRUG	(b)(4)
3/9/2017	730901	5163	19	Liver, 2nd Trimester	HASENKRUG	
				03/24/17 PAID via VISA (b)(6) Request by Kim Hasenkrug.		

ADVANCED BIOSCIENCE RESOURCES
1516 Oak St Ste 303
Alameda, CA 94501
(510) 865-5872

Sale

Entry Method: Manual

VISA Total: $ 680.00

03-24-17 13:19:20
Inv #: 000006 Appr Code: 083677
Approval: Online Batch#: 083001
AVS Code: ZIP MATCH Z
CVV2 Code: MATCH M

Total $680.00

SEQ: 1838455	PO#: (b)(6)	Requester: Messer, Ronald

CAN: 8335424 FY: 17 Owner: (b)(6)
Order Total: 680.00 Project: 107833
Date Needed: 02/28/2017 Emergency: No Order Type: Purchase Card
Requestor Phone: +1 406 363 9276 Order Status: Archive

Vendor Advanced Bioscience Resources,1516 Oak Street, Suite 303, Alameda, CA 94501
Phone: 510-865-5872 SmlBs: No FSS:
EIN: BPA: GSA:
Site: Clerk:
E-mail:

#	Description	CAN	Catalog	OC Code	Category	Qty at Price	Total
1	Tissue, 2nd Trimester (1 each of liver and thymus)	8335424	none	2613	6509	(b)(4)	680.00
2	shipping	8335424		2613	6509	1 each at $0	.00
Order Total: 680.00							

Ship To: Ronald Messer,3220 ,RML CNTRL REC,RMTLAB

QUOTES

Vendor	Price	Good Until	Available
There are no quotes in the order			

JUSTIFICATION

These tissues, liver and thymus, are required by Ron Messer for ongoing studies of HIV in the Hasenkrug Lab. Our mice will be ready for reconstitution soon. Please let me know when I can contact Perrin Larton at ABR to place our request on their schedule. Please contact the vendor at 510-865-5872 ext (b)(6) -give her the PO number Thanks, Ron. *** I certify that I have checked the sources of supply and services listed in FAR 8.002. ( ) I have purchased from the highest priority source available. (X) I did not purchase from a priority source because none could satisfy the requirement of the government either in product/service specifications, quality or required delivery time. **********NOTE to Purchasing Agent: Call vendor at 510-865-5872 ext (b)(6) (b)(6) give her the PO number and credit card information.

Alternate Sources:

NIH Surplus: No	UNICOR: No	GSA Stock Catalog: No	GSA Self Service: No	Federal Supply: No	Open Market: Yes

AGENT

Purchase Order #: (b)(6)
Custodial Code: 30102
Order Reference: em'd (b)(6)
FSS:
NBS Ref Order #: 4506062

Estimated Ship Date:
Date Entered into NBS: 02/28/2017
Expected Delivery Date: 03/03/2017
Select Agents: No
Clearance Requested: No

SF-37 Code:

Notes

There are no notes in the order

IT Clearance

Never seen by IT officer

ROUTE HISTORY

Role Summary

User Role	Name
Requester	Messer, Ronald
Releaser	Messer, Ronald
Admin Officer	(b)(6)
Lead Admin Officer	
Purchase Agent	(b)(6)
Lead Agent	
IT Clearance Officer	
Releaser1	
Releaser2	
NBS	
Receiving Official	

Dates

Description	Date
Needed By	02/28/2017
Submitted to NBS	02/28/2017
NBS Confirmation	03/01/2017
Award Created	02/28/2017
Award Received	02/28/2017
Estimated Ship Date	
Received	03/23/2017
Canceled	

Routing History

Name	Role	Date In	STATUS IN	ACTION
Messer, Ronald	Requester	02/24/2017	New order	Approved
(b)(6)	Administrative Officer	02/24/2017	Released	Approved
	Purchasing Agent	02/27/2017	Approved	Approved
NBS, NBS	NBS	02/28/2017	Sent to NBS	Approved
Messer, Ronald (b)(6)	Requester for receiving	02/28/2017	Pending receiving	Take
(b)(6)	Requester for receiving	03/23/2017	Pending receiving	Approved
	Archive	03/23/2017	Archive	(N/A)

Receiving Report

#	Description	Total Qty Ordered	Total Qty Received	Date Received
1	Tissue, 2nd Trimester (1 each of liver and thymus)	2	2	03/23/2017
2	shipping	1	1	03/23/2017

OHSR RESPONSE TO REQUEST FOR REVIEW OF RESEARCH ACTIVITY
INVOLVING HUMAN SUBJECTS

FAX:

Exempt: #: 4980

To: Hasenkrug, Kim
NIAID
RML - Rocky Mountain Laboratories, 3/218

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
Recent reports have demonstrated that immunodeficient mice reconstituted with 17-19 week old human fetal tissue develop a human immune system and are susceptible to HIV infection and disease. The goal of this project proposal is to create such humanized mice to study the role of immune cell subsets and virus-neutralizing antibodies in vaccine protection. The experiments will entail the development of a cohort of mice all reconstituted with the same human cells so as to be histocompatible. This will require transplantation of

Original Request Received in OHSR on: 11/19/2009

Responsible NIH Research Investigator(s): Kim Hasenkrug, NIAID

OHSR review of your request dated Thu, Nov 19, 2009 has determined that:

☒ Federal regulations for the protection of human subjects do not apply to above named activity. The OHSR determination of Not Human Subjects Research is based on the interpretation of 45 CFR 46 under "Research Involving Coded Private Information or Biological Specimens" (OHRP, Revised October 16, 2008) and Guidance on Engagement of Institutions in Human Subjects Research (October 16, 2008). NOTIFY OHSR VIA AN E-MAIL AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESEARCH ACTIVITY.

☐ The activity is designated **EXEMPT**, and has been entered in the OHSR database. PLEASE NOTIFY OHSR OF ANY **SIGNIFICANT** CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.

☐ **NOT EXEMPT**. OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additional information in order to determine whether expedited or full review is appropriate.

☐ Confidentiality Agreement

☐ Reliance

☐ Amendment

☐ Other

Office Person LB Admin Assist. CB

Note:
(b)(6)

CIP

for Charlotte Holden, JD — Acting Director, OHSR — 12/14/2009
Signature — Title — Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: Yes

OHSR Use Only
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

#4980

REQUEST FOR REVIEW OF RESEARCH ACTIVITY INVOLVING HUMAN SUBJECTS

INSTRUCTIONS: Please type directly on this form. You can expand the document if you need more space. If your research involves a survey or questionnaire, please attach it to this completed form.

Completed forms (with all required signatures) may be sent to OHSR by FAX (301-402-3443), email to ohsr_nih_ddir@od.nih.gov, or by mail (2C146). If you have any questions, call OHSR at (301) 402-3444.

Date: 11/19/2009

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146

From: Kim J Hasenkrug
(Signature)

Through: (b)(6) (acting)
(Signature of appropriate Official for IC, e.g., Lab/Branch Chief)

Protocol Title: Study of HIV infection and vaccine protection in mice reconstituted with a human immune system

Name of NIH Principal Investigator(s): Kim J Hasenkrug, Senior Investigator

IC NIAID Laboratory/Branch LPVD Building & Room No. RML 3218
Tel. No. 406-363-9310 FAX No. 406-363-9286
Is the Principal investigator an NIH employee? x **Yes** ____ **No**

If no, please explain: ____

1. What is the proposed research activity that you intend to perform at NIH (please use lay terms):

Recent reports have demonstrated that immunodeficient mice reconstituted with 17-19 week old human fetal tissue develop a human immune system and are susceptible to HIV infection and disease. The goal of this project proposal is to create such humanized mice to study the role of immune cell subsets and virus-neutralizing antibodies in vaccine protection. The experiments will entail the development of a cohort of mice all reconstituted with the same human cells so as to be histocompatible. This will require transplantation of the mice with 1 mm^3 pieces of fetal thymus as well as reconstitution with stem cells isolated from cord blood and liver. Once the humanized mice have been established some will be vaccinated to prime distinct subsets of immune cells. Immune cell subsets from vaccinated mice will be adoptively transferred into naïve mice, which will then be infected with HIV to

test the antiviral activity of the immune cells. The goal of these experiments is to establish correlates of immunity against HIV.

2. If applicable, list your non-NIH Collaborating Investigator(s).

Name Institution Address Tel. # FAX #

3. Proposed start date of your research __April, 2010_____
Proposed completion date _April, 2013_____

4. Will you be _____these samples or data?

Collecting Yes/(No)
Receiving (Yes)/No
Sending Yes/(No)

5. Do the samples or data:
(a) Already exist?___Yes _x__No

(b) Or are they being collected for the express purpose of this study? _X__Yes __No
If "yes," please describe:_

17-19 week fetal cells and tissue will be obtained from Advanced Bioscience Resources, Inc., a non-profit foundation established under California law to provide biomedical researchers access to human tissues in compliance with state, federal, and NIH guidelines. Consent to donate is obtained in accordance with UAGA and NOTA guidelines. Related documents including the consent form are attached._____

(c) Or a combination of (a) and (b)? ____Yes _____No

6. What role will you have in this research project? (Check all that apply)

___ Analyze samples/data only.

___ Consultant/advisor to collaborator(s) listed above.

___ Author of the protocol that is being implemented by your collaborating investigator (identified in question #2).

___ Co-authorship on publication(s)/manuscript(s) pertaining to this research.

___ You or NIH hold an IND for this research.

__X_ Decisional authority over the design or implementation of the research at the IRB approved site? If so, please explain.

I am the PI and lead investigator on this project which will take place in my laboratory and the animal care facilities at Rocky Mountain Labs, NIAID, NIH.

___Other (If necessary, use this space to describe your role in this research).

7. Where are the subjects of this research activity located?
The material for this research is obtained from natural or induced abortions from females in California. Thus the tissues and cells involved will not be from living humans.

8. If human subjects are located elsewhere (not at NIH), will you have direct contact or intervention with them? (Examples: as subject's physician; in obtaining samples directly from the subject; by interviewing the subject?) ____ Yes __x__No

9. What kind of human samples (e.g., tissue, blood) or data (e.g., private information, responses to questionnaires) will be involved in your research?
_Samples will include cord blood, fetal blood, thymus, liver, and bone marrow. No private information will be involved._____

---

10. If the samples, data do not come from an IRB approved protocol, do they come from:

(a) Repository ____Yes ___ No

(b) Pathological waste ___ Yes _____No

(c) Autopsy material ___ Yes ___ No

(d) Publicly available source _X__Yes ___ No

(e) Other_____

11. Please check the box(es) that apply(ies) to the samples/data that you will receive.

(a) ____ Samples and/or data will be anonymized/unlinked. (The samples/data cannot be linked to individual subjects by you or your collaborators at other sites.)

(b) ___ Samples and/or data will be coded, however that code cannot be used by either the sender or the receiver to identify specific individuals.

(c) __X_ Samples and/or data will be coded so that the provider of the samples/data can link them to specific individuals but the receiver will not be able to do so.

12. Will you send results back to the provider(s) (listed in question 2 of this form)?

(a) __X_ No, I will not send results back to the provider(s).

(b) ___ Yes, I will send aggregate results to the provider(s).

(c) ___ Yes, I will send results to the provider(s) that are linked to identifiable individuals.

If yes, does the provider intend to link your data to identifiable individuals?
_____Yes _____No

13. Has the research activity <u>that you are proposing in this form</u> been approved by an Institutional Review Board (IRB) elsewhere?

_____ Yes, the NIH research activity has been reviewed by the following IRB (s) (Please provide the following information for each IRB):

_____ Name of institution that provided the review

_____ Address of reviewing institution

_____ Name of PI for the IRB approved protocol

_____ Title of IRB approved protocol and protocol #

_____ Federal Wide Assurance (FWA) number**

___X_____No IRB review of the research activity described in question #1 above has taken place

(**An FWA is a contract between the U.S. Department of Health and Human Services (DHHS) and an entity receiving DHHS funds to conduct clinical research that the latter will follow ethical guidelines and federal regulations for the protection of human subjects. For a list of domestic and international institutions go to http://ohrp.cit.nih.gov/search/asearch.asp#ASUR

14. Per NIH guidance*, have conflicts of interest by NIH employees, if any, been resolved?**

__X___Yes _____No no conflicts of interest

If your answer is no, please see your Clinical Director about this matter before proceeding with this research.

***The January 5, 2005 NIH Guide to Preventing Conflict of Interest applies to all research conducted at NIH, http://ohsr.od.nih.gov/New/mpafwa_docs.html

ADVANCED BIOSCIENCE RESOURCES, INC

OVERVIEW

ADVANCED BIOSCIENCE RESOURCES is a non-profit corporate foundation established in 1989 under California law to provide biomedical researchers with access to human tissues. ABR was formed exclusively for biomedical, scientific, and educational purposes and is devoted to providing services in connection with the procurement of human organs and tissues for medical and scientific research. ABR specializes in the procurement, preservation and distribution of both human fetal tissues and full term umbilical cord blood for research, and provides a highly individualized, reliable and easily accessible service.

TISSUE COLLECTION AND DISTRIBUTION: The purpose of ABR is to promote cooperative efforts to collect and distribute human tissues and to thereby facilitate research utilizing those tissues. Trained personnel coordinate the retrieval, preservation and delivery of each specimen.

Tissues obtained through ABR are retrieved from routinely performed surgical procedures including first and second trimester induced abortions, and full term deliveries, either natural or caesarian section. Tissues that were once discarded are now available to scientists worldwide through the efforts of ABR. Researchers may specify tissue characteristics, preservation methods, and delivery times.

PRESERVATION METHODS: Each specimen is collected, preserved, and shipped according to the investigator's individual protocol.

QUALITY CONTROL: ABR practices strict quality control procedures and adheres to stringent guidelines for tissue collection and preservation. Consent is obtained in accordance with UAGA and NOTA guidelines. Tissue specimens are identified, dissected, and transferred to the specified medium. A control number is then assigned to each sample to ensure confidentiality of patient identity.

To assure proper processing of the tissue, every researcher selects a collection/preservation protocol tailored specifically to his needs. In the collection and distribution of these tissues, every effort is made to exercise the highest standards of medical and laboratory practice. ABR specializes in direct communication with each investigator from the initial application to specimen delivery.

INVESTIGATOR APPROVAL: ABR will provide tissue to researchers who provide information on current research funding, and a short summary of their research intent. Investigators must agree to accept responsibility for the potential biohazard of the tissue and to appropriately train laboratory personnel in the proper handling of the tissue. In addition, the researcher must agree to use the tissue solely for research purpose and to acknowledge ABR in any publications resulting from the use of ABR provided tissue.

APPLICATION PROCESS: To request human tissue for research, an application must be completed and submitted to ABR. The application will be reviewed for feasibility and priority. A protocol will be developed to meet individual research needs as identified in the application.

SERVICE AND PROCESSING FEES: Participating medical facilities that enable ABR to enact its tissue acquisition and distribution programs may be paid a nominal fee for such services. A minimal processing / preservation / shipment fee is also assessed for services provided to research facilities.

1516 Oak Street # 303 / Alameda, CA 94501 / 510-865-5872 / Fax 510-865-4090 / email abr@abr-inc.com

Recent advancements in medical research have been developed through the use of human tissues in scientific study. Diseases such as diabetes, hemophilia, Parkinson's disease, cancer, AIDS, heart and lung disease, as well as genetic and,neonatal disorders, are being investigated for the development of cures through the use of human fetal tissues. Any tissue donated may be distributed to medical institutions and private research groups in the United States and internationally to enhance the development of cures and therapies for disease.

PERMISSION FOR DONATION OF TISSUE
OBTAINED AT THE TIME OF ABORTION

I have previously decided to have an abortion and have previously consented to having such abortion.

I hereby donate the aborted material and/or a sample of my blood as an anatomical gift for the purposes of education, research, or for the advancement of medical science. I understand that my donation may be used by research facilities in the United States and abroad.

I also agree that a sample of my blood may be taken after the abortion and that it may be used for research and routine testing for AIDS, hepatitis, or other infectious agents. I understand that, if there is testing, the results will be confidential unless the law requires that they be disclosed.

I understand that the aborted material may be used to derive human pluripotent stem cells for medical research and possibly human transplantation research, and that these cells may be kept for many years. I also understand that my donation may be used for cosmetic purposes. I understand that there is no information associated with aborted material that could link me with my donation. I agree that this donation is made without any restriction or direction regarding the potential recipients of the cells derived from the aborted material and that I have not been informed of the identity of any potential recipients.

I understand that there will be no payment to me and I agree that, although the results of the research on the aborted material may have commercial value, I will have no property or other commercial or financial rights in the aborted material or any product, process, or service which may result from this donation.

I understand that my donation will not result in any direct medical benefit to me.

I understand that my donation is voluntary, and I may refuse to donate aborted material and this will not affect my medical care or my relationship with my physician.

I understand that, if I have any questions about my donation, I can contact ABR at 510-865-5872.

_____ _____
Signature Date

I choose not to participate.

_____ _____
Signature Date

_____ _____
Witness Date

ADVANCED BIOSCIENCE RESOURCES, INC.

APPLICATION FOR THE ACQUISITION OF

HUMAN FETAL TISSUE FOR RESEARCH

All requests for human fetal tissue are reviewed for feasibility of procurement and preparation. When approved, an individual protocol will be developed for the procurement, preparation and delivery of tissue samples, based on the information provided in this application and any subsequent communication.

I. APPLICANT INFORMATION

NAME: Kim J Hasenkrug
TITLE: Senior Investigator
COMPANY: NIAID, NIH
ADDRESS: Rocky Mountain Lab
ADDRESS: 903 S. 4th St
CITY,ST,ZIP: Hamilton, MT 59840
PHONE #: 406-363-9310
ALT. #:
FAX #: 406-363-9286

EMAIL: khasenkrug@nih.gov

DELIVERY OPTIONS:

__X__ Same Day: Commercial carrier, hand delivered
Maximizes cell viability (*geographical limits*)
_____ Next Day: Pickup, delivery Mon-Sat daytime
Economical for fresh, frozen specimens

Applicant will be charged for delivery fees.

Applicant may designate preferred carrier:

Carrier Name: FEDEX
Account #: (b)(4)

BILLING INFORMATION:
BILL TO: Kim J Hasenkrug
COMPANY: Rocky Mountain Labs
ADDRESS: 903 S. 4th St.
ADDRESS:
CITY,ST,ZIP: Hamilton, MT 59840
ACCOUNTING DEPT. PHONE #: 406-363-9438
P.O. # (if required by your company):

P.O. # is not required to submit application
Credit Card #:
Name on CC:
Expiration Date: VISA/MC

SHIP TO: Kim J Hasenkrug
Rocky Mountain Labs
903 S. 4th St
Hamilton, MT 59840

Please indicate how you heard about ABR: (b)(6)

II. HUMAN FETAL TISSUE

Tissue specimens requested: thymus, liver, cord blood

Preferred gestational age (6-24 weeks): 17-19 wks
Proposed starting date: May, 2010

CONTAGIOUS DISEASE SCREENING: Availability of test results varies from 24 hours to 7 days after procurement. Applicant requires the following tests to be performed by ABR:

__X__ No testing required

_____ HIV _____ HSV
_____ HBSAG _____ RPR
_____ CMV _____ HCV OTHER_____

III. PRESERVATION

ABR uses *BioWhittaker RPMI-1640 With L-Glutamine* for tissue preparation, preservation and shipment. Applicant may supply ABR with other media specific to research needs. Please indicate preference below.

PRESERVATION METHODS AVAILABLE:

__X__ Fresh; shipped on wet ice
_____ Passive freezing on dry ice; shipped on dry ice
_____ "Snap" freezing in LN2; shipped on dry ice
_____ Media provided by applicant
_____ Media provided by ABR (RPMI)

IV. DONOR INFORMATION

CONSENT VERIFICATION: Consent for tissue donation is obtained prior to specimen procurement. The consent is extremely confidential in nature and shall not be communicated to the researcher.

SPECIFIC DONOR INFORMATION: Charts are routinely examined for patient medical histories. Please identify any specific information sought and indicate contraindications to specimen procurement:

_____HIV+ status contraindicates procurement_____

_____

_____

V. RESEARCH DATA

TITLE OF RESEARCH PROJECT: ___The role of virus-specific CD4+__T cells, CD8+ T cells and antibody in vaccine protection against HIV-1 in humanized mice_____

ABR will provide tissue to researchers who provide information on current research funding, and a short summary of their research intent. **(Please attach a brief synopsis of the research project named above.)** Researchers must agree to use the tissue solely for research purposes and to acknowledge ABR in any publications resulting from the use of ABR provided tissue. Updates on research progress will be requested at six-month intervals. Researchers agree to publish the results of the research as promptly after the completion of the research as is reasonably possible without jeopardizing the sponsor's right to secure patents or copyrights necessary to protect its ownership or control of the results of the research. Researchers agree to inform ABR of the name of the publication and the date of the issue in which the results will be published. It is the intent of this requirement to make the results available to the general public through acceptable means of publication.

VI. SOURCE OF FUNDING

Please identify the primary source of funding for this project.

NIH _X___ Other Federal or State Grants _____ Foundation Grants _____ Other (specify) _____

If this application is approved by ABR, ABR shall provide services to the applicant in accordance with the terms and the other conditions on the reverse side, and the signature of the applicant shall constitute acceptance of all such terms and conditions by applicant. The entire agreement between ABR and applicant relating to the services provided by ABR is expressly set forth herein, and any modification of or addition thereto shall be of no force or effect unless it is in writing and signed on behalf of ABR by a duly authorized representative.

BY SIGNING BELOW, THE APPLICANT ACKNOWLEDGES HAVING READ THE TERMS AND CONDITIONS ON THE FOLLOWING PAGE AND AGREES TO SUCH TERMS AND CONDITIONS.

Kim J Havenhuys

____ _____

_Senior Investigator_____
SIGNATURE and TITLE of APPLICANT

DATE 11/2/2009

Please return to:

ADVANCED BIOSCIENCE RESOURCES, INC.
1516 OAK STREET, SUITE 303
ALAMEDA, CALIFORNIA 94501
Telephone: 510-865-5872
Fax: 510-865-4090
Email: abr@abr-inc.com

TERMS AND CONDITIONS OF SERVICES

1. Services

1.1 During the term of this agreement, and pursuant to the terms and conditions hereinafter set forth, ABR will use its best efforts to provide services in connection with supplying researcher with the types of human tissues set forth in this application, as approved

by ABR, suitable for researcher requirements and in the amounts requested based upon ongoing discussions between researcher and ABR pursuant to the information sent by ABR.

1.2 Researcher acknowledges and agrees that ABR will provide the following types of services:

Removing tissue.
Preserving and processing tissue to a form suitable to the researcher needs.
Seeking consent for tissue donations from appropriate individuals, obtaining validly executed consent forms, and maintaining records of such consents in accordance.
Obtaining, labeling, storing, and delivering samples of donor or other required serum, and maintaining a system for matching such samples to specific tissue donations.
Preserving tissue viability and cleanliness during removal, processing, preservation, storage and transportation.
Storing tissue and transporting it to researcher in accordance with section 5.

1.3 In the event that tissues of the type specified in the application become unavailable to ABR, such that ABR is unable to perform the contemplated services, ABR shall have no obligation to perform such services.

2. Representations and Warranties. ABR hereby represents and warrants to researcher that (i) ABR will make no payments to anyone for any tissue transferred in connection with this agreement, and (ii) ABR will verify for each tissue delivery that appropriate consent was obtained for use of such tissue and any associated serum samples, and that adequate records of such consent are maintained; provided, however, that the parties hereto acknowledge and agree that such consents are extremely confidential in nature and shall not, in any case, be communicated to researcher. Researcher hereby represents and warrants to ABR that (i) researcher will neither sell nor transfer for valuable consideration any tissue received through ABR to anyone, (ii) researcher will use the tissue only to satisfy its objectives, which are, as acknowledged and agreed hereto, [research and clinical use], (iii) researcher agrees to inform ABR of any changes in clinical or research use of specimens received from ABR, or in any specifications, constraints, etc. in a timely manner, and (iv) researcher understands the bio-hazardous nature of human tissue and agrees to take proper precautionary measures at all times when handling tissue specimen.

3. Terms. The terms of this agreement shall be for one (1) year, beginning from the date hereof, and terminating one (1) year thereafter, unless either of the parties hereto shall have given to the other thirty (30) days written notice of its intention to terminate this agreement, whereupon same shall terminate thirty (30) days after date of said notice.

In default of notice as aforesaid from either party hereto, this agreement shall continue for further successive terms of one (1) year thereafter and in default of thirty (30) days written notice before the end of an annual term by either of the parties of its intention not to renew, whereupon this agreement shall terminate at the end of said term.

4. Payments. Researcher agrees to pay to ADR a fee for costs incurred by ABR in providing services in connection with the acquisition of each sample of tissue requested by researcher, to be mutually agreed upon by ABR and researcher upon approval of this agreement by ABR.

5. Shipment services.

5.1 All shipments will be made as soon as possible after request has been received by ABR from researcher.

5.2 Researcher acknowledges that networks of tissue availability are neither permanent nor dependable, but rather they fluctuate. However, ABR shall use its best efforts to transfer the tissue in the amounts requested by researcher.

5.3 Shipment will be made in the best possible manner so as to preserve the quality of the tissues. It is understood that the fragility of human tissue is such that damage may occur during shipment. ABR will use its best efforts to comply with the handling and shipment protocols provided by researcher.

5.4 ABR will package the tissue appropriately and, if so requested by researcher, will insure the shipment. Researcher agrees to bear all costs associated with insurance and shipment of any tissue.

5.5 The risk of loss and damage of any tissue or organs shall pass immediately to researcher when the shipment of such tissue or organs is deposited with a carrier for transportation at the F.O.B. point.

6. Limitation of liability. ABR shall not be responsible or liable under any section of this agreement or under any contract, negligence, strict liability or other legal or equitable theory, for the cost of procurement of substitutive services, or any indirect, incidental or consequential damages including, but not limited to loss of revenues and loss of profits. Any liability of ABR under any theory whatsoever will be limited exclusively to the provision of equivalent services by ABR or, if unenforceable, to payment of an amount not greater than any amount actually received by ABR from researcher on account of this agreement.

7. No warranties. It is understood that human tissue is by nature neither permanent nor dependable. Except as expressly set forth in this agreement, ABR makes no representation of any kind, expressed or implied, including any representation with respect to the safety, efficacy or merchantability or the fitness for any purpose with respect to the tissue transferred to researcher in connection with this agreement.

8. Indemnification. Researcher shall indemnify, defend and hold ABR harmless from and against all claims, causes of actions, suits, damages and costs arising out of, resulting from, or otherwise in respect of, the use of tissue transferred in connection with this agreement, except where such claims are the result of negligence of ABR, its employees, staff or agents to (i) comply with any governmental requirements, or (ii) adhere to the terms of this agreement.

9. General. This agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of law. This agreement may not be assigned by either party without the prior written consent of the other.

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Monday, November 23, 2009 10:43 AM
To: Hasenkrug, Kim (NIH/NIAID) [E]
Subject: Request for Review Rec'd-OHSR 4980

Good morning Dr. Hasenkrug,

This email is to verify that OHSR has received your Request for Review of Research and it is currently being processed as OHSR #4980. Please use this number in any future correspondence regarding this study. We will contact you via email if any additional information is needed. If you have not heard from OHSR within 7 business days, please contact us.

Protocol Title: Study of HIV infection and vaccine protection in mice reconstituted with a human immune system

Thank you.

OHSR:
Ph: 301.402.3444
Fax: 301.402.3443

Thank you.

Sincerely,

(b)(6)

OHSR (NIH/DDIR)

From: Hasenkrug, Kim (NIH/NIAID) [E]
Sent: Wednesday, December 09, 2009 5:41 PM
To: OHSR (NIH/DDIR)
Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up
Flag Status: Green

Attachments: IRB Letter with letterhead nonidentity.doc

IRB Letter with letterhead non...

Here is the letter on official ABR letterhead for you

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
Laboratory of Persistent Viral Diseases
Rocky Mountain Laboratories
National Institute of Allergy and Infectious Diseases National Institutes of Health
903 S. 4th Street
Hamilton, MT 59840
phone (406)363-9310
FAX (406)363-9286
khasenkrug@nih.gov

> From: "OHSR (NIH/DDIR)" <ohsr_nih_ddir@od.nih.gov>
> Date: Tue, 24 Nov 2009 10:27:55 -0500
> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
> Conversation: HasenkrugK_NIAID_4980_CY2009
> Subject: HasenkrugK_NIAID_4980_CY2009
>
> Good Afternoon Dr. Hasenkrug:
>
> Thank you for the opportunity to review your research project: Study
> of HIV infection & Vaccine Protection.. Since the work you are doing
> at the NIH provides little or no risk to human subjects off-site, OHSR
> has decided the appropriate action for you to take is the following:
>
> * Provide documentation that you will not seek the identity of the
> subjects who have provided the samples you will receive as well as
> documentation from ABR that under no circumstances will the identity
> or link to the identifiers of the subjects be released to you.
>
> An e-mail from you and from ABR holding the key to the code is
> sufficient documentation.
>
> This action is based on guidance issued on Aug. 10, 2004 by the HHS
> Office of Human Research Protections, the regulatory office for the
> protection of human subjects.

> Best regards,
>
>
>
> OHSR - National Institutes of Health
> Bldg 10, Suite 2C146
> Bethesda, MD 20892
> Office Telephone: 301-402-3444
> Office Fax: 301-402-3443
>
> The NIH is committed to maintaining the highest standards for the
> protection of human subjects.
> P Please consider the environment before printing this e-mail
>

ADVANCED BIOSCIENCE RESOURCES, INC

December 14, 2009

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
903 S. 4th Street
Hamilton, MT 59840

Dear Kim,

This letter verifies that ABR, a non-profit tissue procurement organization, supplies requesting and approved scientific investigators with the types of human fetal tissues required for specific bio-medical research. When requested and as availability allows, human fetal tissue specimens will be retrieved from products of conception from induced first and second trimester abortions. Tissue will be distributed according to established protocols. Specimens are not collected for directed donation. .

ABR warrants that maternal consent from patients aged over eighteen years is obtained for the use of fetal tissue specimens for research purposes, including the consent for the potential of stem cell research utilizing such tissues, and that adequate records of such consent are maintained for future verification. Donor identification is coded and scientific investigators have no access to donor identification. ABR also warrants that maternal consent is obtained for phlebotomy and blood testing for a variety of disease entities.

ABR warrants that no payments will be made to any third party for the conduct of or the product of an abortion, including without limitation any parent(s) of any unborn fetus. ABR, to the best of its knowledge, also warrants that all tissue provided will have been obtained in compliance with local, state and federal laws and regulations governing the procurement and distribution of human tissue.

Sincerely,

Perrin Larton

Perrin Larton, CTBS
Procurement Manager

Federal E.I.N.: 94-3110160
California E.I.N.: 370-20518
FDA FEI: 3005208435

1516 Oak Street # 303 / Alameda, CA 94501 / 510-865-5872 / Fax 510-865-4090 / email abr@abr-inc.com

OHSR (NIH/DDIR)

From: Hasenkrug, Kim (NIH/NIAID) [E]
Sent: Monday, November 30, 2009 5:24 PM
To: OHSR (NIH/DDIR)
Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up
Flag Status: Green

Attachments: Re: HFT Application

Re: HFT Application

HasenkrugK_NIAID_4980_CY2009

Attached please find the requested email from ABR stating that no personally identifiable information will be released to me. Furthermore, I will not seek any such information from ABR.

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
Laboratory of Persistent Viral Diseases
Rocky Mountain Laboratories
National Institute of Allergy and Infectious Diseases National Institutes of Health
903 S. 4th Street
Hamilton, MT 59840
phone (406)363-9310
FAX (406)363-9286
khasenkrug@nih.gov

> From: "OHSR (NIH/DDIR)" <ohsr_nih_ddir@od.nih.gov>
> Date: Tue, 24 Nov 2009 10:27:55 -0500
> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
> Conversation: HasenkrugK_NIAID_4980_CY2009
> Subject: HasenkrugK_NIAID_4980_CY2009
>
> Good Afternoon Dr. Hasenkrug:
>
> Thank you for the opportunity to review your research project: Study
> of HIV infection & Vaccine Protection.. Since the work you are doing
> at the NIH provides little or no risk to human subjects off-site, OHSR
> has decided the appropriate action for you to take is the following:
>
> * Provide documentation that you will not seek the identity of the
> subjects who have provided the samples you will receive as well as
> documentation from ABR that under no circumstances will the identity
> or link to the identifiers of the subjects be released to you.
>
> An e-mail from you and from ABR holding the key to the code is
> sufficient documentation.

>
> This action is based on guidance issued on Aug. 10, 2004 by the HHS
> Office of Human Research Protections, the regulatory office for the
> protection of human subjects.
>
> Best regards,
>
>
>
> OHSR - National Institutes of Health
> Bldg 10, Suite 2C146
> Bethesda, MD 20892
> Office Telephone: 301-402-3444
> Office Fax: 301-402-3443
>
> The NIH is committed to maintaining the highest standards for the
> protection of human subjects.
> P Please consider the environment before printing this e-mail
>

OHSR (NIH/DDIR)

From: Perrin Larton (b)(6)

Sent: Monday, November 30, 2009 5:10 PM

To: Hasenkrug, Kim (NIH/NIAID) [E]

Cc: (b)(6)

Subject: Re: HFT Application

Hi Kim,

All tissue is numerically coded and the personally identifiable information is never available. In other NIH applications we've had requests for letters that state NO information is available to researchers. I can send you a letter to that effect...but tissue cannot be tracked back to a specific patient. We guarantee anonymity to the patients donating tissue.

Perrin

> Dear Perrin, the Office of Human Subjects Research is asking me for a
> letter
> from you stating that personally identifiable information regarding the
> fetal tissue will be revealed to me. Would you kindly send me a letter
> stating such so that I can forward it to them? It would be greatly
> appreciated and let us begin our experiments. I attached a copy your
> letter
> regarding approval of our application for your information. Thank you
> very
> much, Perrin.
>
> Kim
>
> Kim J Hasenkrug, Ph.D.
> Senior Investigator
> Chief, Retroviral Immunology Section
> Laboratory of Persistent Viral Diseases
> Rocky Mountain Laboratories
> National Institute of Allergy and Infectious Diseases
> National Institutes of Health
> 903 S. 4th Street
> Hamilton, MT 59840
> phone (406)363-9310
> FAX (406)363-9286
> khasenkrug@nih.gov
>
> Disclaimer:
> The information in this e-mail and any of its attachments is confidential
> and may contain sensitive information. It should not be used by anyone who
> is not the original intended recipient. If you have received this e-mail
> in
> error please inform the sender and delete it from your mailbox or any
> other
> storage devices. National Institute of Allergy and Infectious Diseases
> shall
> not accept liability for any statements made that are sender's own and not
> expressly made on behalf of the NIAID by one of its representatives

>
>
>> From: Perrin Larton (b)(6)
>> Reply-To: (b)(6)
>> Date: Mon, 2 Nov 2009 13:40:51 -0500
>> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
>> Conversation: HFT Application
>> Subject: HFT Application
>>
>> Dear Kim,
>>
>> Attached you'll find the documents we just discussed. What I'll need
>> back
>> from you is the two page application as well as a short synopsis of the
>> work you'll be doing. As soon as I get the completed application from
>> you
>> it will go to our Scientific Advisory Board for review and approval. If
>> they have questions, I'll give you a call. Approval usually takes 5-10
>> working days from the time I receive the application from you.
>>
>> Please send your application back to my e-mail address
>> (b)(6)
>> or FAX to 510-865-4090.
>>
>> Thanks so much for your interest in the services supplied by Advanced
>> Bioscience Resources. I apologize again for taking such a long time to
>> respond to your query.
>>
>> Perrin Larton CTBS
>> Procurement Manager
>> Advanced Bioscience Resources
>
>

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Tuesday, November 24, 2009 10:28 AM
To: Hasenkrug, Kim (NIH/NIAID) [E]
Subject: HasenkrugK_NIAID_4980_CY2009

Good Afternoon Dr. Hasenkrug:

Thank you for the opportunity to review your research project: ***Study of HIV infection & Vaccine Protection..*** Since the work you are doing at the NIH provides little or no risk to human subjects off-site, OHSR has decided the appropriate action for you to take is the following:

- Provide documentation that you will not seek the identity of the subjects who have provided the samples you will receive as well as documentation from ABR that under no circumstances will the identity or link to the identifiers of the subjects be released to you.

An e-mail from you and from ABR holding the key to the code is sufficient documentation.

This action is based on guidance issued on Aug. 10, 2004 by the HHS Office of Human Research Protections, the regulatory office for the protection of human subjects.

Best regards,

OHSR - National Institutes of Health
Bldg 10, Suite 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

The NIH is committed to maintaining the highest standards for the protection of human subjects.


Please consider the environment before printing this e-mail

ADVANCED BIOSCIENCE RESOURCES, INC.

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
3/30/2017	(b)(6)	1033450
	TERMS	CUSTOMER #
	Due Upon Receipt	0522

PAID

BILL TO

Rocky Mountain Labs
NIH/NIAID
Kim J. Hasenkrug
903 S. 4th Street
Hamilton, MT 59840

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
3/30/2017	643003	8600	17	Thymus, 2nd Tri-N/C Delivery Delay	HASENKRUG	0.00
3/30/2017	643003	8601	17	Liver, 2nd Tri-N/C Delivery Delay	HASENKRUG	0.00

Total $0.00

1516 Oak Street, Suite 303 / Alameda, California 94501 USA / Phn (510) 865-5872 / Fax (510) 865-4090 / email: abr@abr-inc.com

SEQ: 1841763	PO#: (b)(6)		Requester: Messer, Ronald

CAN: 8335424 FY: 17 Owner: (b)(6)
Order Total: 680.00 Project: 107833
Date Needed: 03/17/2017 Emergency: Yes Order Type: Purchase Card
Requestor Phone: +1 406 363 9276 Order Status: Archive

Vendor Advanced Bioscience Resources,1516 Oak Street, Suite 303, Alameda, CA 94501
Phone: 510-865-5872 SmlBs: No FSS:
EIN: BPA: GSA:
Site: Clerk:
E-mail:

#	Description	CAN	Catalog	OC Code	Category	Qty at Price	Total
1	Tissue, 2nd Trimester (1 each of liver and thymus)	8335424	none	2613	6509	(b)(4)	680.00
2	shipping	8335424		2613	6509	1 each at $0	.00
Order Total: 680.00							

Ship To: Ronald Messer,3220 ,RML CNTRL REC,RMTLAB

QUOTES

Vendor	Price	Good Until	Available
There are no quotes in the order			

JUSTIFICATION

These tissues, liver and thymus, are required by Ron Messer for ongoing studies of HIV in the Hasenkrug Lab. Our mice will be ready for reconstitution soon. Please let me know when I can contact Perrin Larton at ABR to place our request on their schedule. Please contact the vendor at 510-865-5872 ext (b)(6) -give her the PO number Thanks, Ron. *** I certify that I have checked the sources of supply and services listed in FAR 8.002. ( ) I have purchased from the highest priority source available. (X) I did not purchase from a priority source because none could satisfy the requirement of the government either in product/service specifications, quality or required delivery time. **********NOTE to Purchasing Agent: Call vendor at 510-865-5872 ext (b)(6) (b)(6) give her the PO number and credit card information.

Alternate Sources:

NIH Surplus: No UNICOR: No GSA Stock Catalog: No GSA Self Service: No Federal Supply: No Open Market: Yes

AGENT

Purchase Order #: (b)(6)
Custodial Code: 30102
Order Reference: em'd (b)(6)
FSS:
NBS Ref Order #: 4526195

Estimated Ship Date:
Date Entered into NBS: 03/16/2017
Expected Delivery Date: 03/23/2017
Select Agents: No
Clearance Requested: No

SF-37 Code:

Notes

There are no notes in the order

IT Clearance

Never seen by IT officer

ROUTE HISTORY

Role Summary

User Role	Name
Requester	Messer, Ronald
Releaser	Messer, Ronald
Admin Officer	(b)(6)
Lead Admin Officer	
Purchase Agent	(b)(6)
Lead Agent	
IT Clearance Officer	
Releaser1	
Releaser2	
NBS	
Receiving Official	

Dates

Description	Date
Needed By	03/17/2017
Submitted to NBS	03/16/2017
NBS Confirmation	03/17/2017
Award Created	03/16/2017
Award Received	03/16/2017
Estimated Ship Date	
Received	04/19/2017
Canceled	

Routing History

Name	Role	Date In	STATUS IN	ACTION
Messer, Ronald	Requester	03/16/2017	New order	Approved
(b)(6)	Administrative Officer	03/16/2017	Released	Approved
	Purchasing Agent	03/16/2017	Approved	Approved
NBS, NBS	NBS	03/16/2017	Sent to NBS	Approved
Messer, Ronald (b)(6)	Requester for receiving	03/16/2017	Pending receiving	Take
(b)(6)	Requester for receiving	04/19/2017	Pending receiving	Approved
	Archive	04/19/2017	Archive	(N/A)

Receiving Report

#	Description	Total Qty Ordered	Total Qty Received	Date Received
1	Tissue, 2nd Trimester (1 each of liver and thymus)	2	2	04/19/2017
2	shipping	1	1	04/19/2017

OHSR RESPONSE TO REQUEST FOR REVIEW OF RESEARCH ACTIVITY
INVOLVING HUMAN SUBJECTS

FAX:

Exempt: #: 4980

To: Hasenkrug, Kim
NIAID
RML - Rocky Mountain Laboratories, 3/218

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
Recent reports have demonstrated that immunodeficient mice reconstituted with 17-19 week old human fetal tissue develop a human immune system and are susceptible to HIV infection and disease. The goal of this project proposal is to create such humanized mice to study the role of immune cell subsets and virus-neutralizing antibodies in vaccine protection. The experiments will entail the development of a cohort of mice all reconstituted with the same human cells so as to be histocompatible. This will require transplantation of

Original Request Received in OHSR on: 11/19/2009

Responsible NIH Research Investigator(s): Kim Hasenkrug, NIAID

OHSR review of your request dated Thu, Nov 19, 2009 has determined that:

☒ Federal regulations for the protection of human subjects do not apply to above named activity. The OHSR determination of Not Human Subjects Research is based on the interpretation of 45 CFR 46 under "Research Involving Coded Private Information or Biological Specimens" (OHRP, Revised October 16, 2008) and Guidance on Engagement of Institutions in Human Subjects Research (October 16, 2008). NOTIFY OHSR VIA AN E-MAIL AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESEARCH ACTIVITY.

☐ The activity is designated **EXEMPT**, and has been entered in the OHSR database. PLEASE NOTIFY OHSR OF ANY **SIGNIFICANT** CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.

☐ **NOT EXEMPT**. OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additional information in order to determine whether expedited or full review is appropriate.

☐ Confidentiality Agreement

☐ Reliance

☐ Amendment

☐ Other

Office Person LB Admin Assist. CB

Note:
(b)(6)

CIP

for Charlotte Holden, JD — Acting Director, OHSR — 12/14/2009
Signature — Title — Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: Yes

OHSR Use Only
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

#4980

REQUEST FOR REVIEW OF RESEARCH ACTIVITY INVOLVING HUMAN SUBJECTS

INSTRUCTIONS: Please type directly on this form. You can expand the document if you need more space. If your research involves a survey or questionnaire, please attach it to this completed form.

Completed forms (with all required signatures) may be sent to OHSR by FAX (301-402-3443), email to ohsr_nih_ddir@od.nih.gov, or by mail (2C146). If you have any questions, call OHSR at (301) 402-3444.

Date: 11/19/2009

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146

From: Kim J Hasenkrug
(Signature)

Through: (b)(6) (acting)
(Signature of appropriate Official for IC, e.g., Lab/Branch Chief)

Protocol Title: Study of HIV infection and vaccine protection in mice reconstituted with a human immune system

Name of NIH Principal Investigator(s): Kim J Hasenkrug, Senior Investigator

IC NIAID Laboratory/Branch LPVD Building & Room No. RML 3218
Tel. No. 406-363-9310 FAX No. 406-363-9286
Is the Principal investigator an NIH employee? x **Yes** ____ **No**

If no, please explain: ____

1. What is the proposed research activity that you intend to perform at NIH (please use lay terms):
Recent reports have demonstrated that immunodeficient mice reconstituted with 17-19 week old human fetal tissue develop a human immune system and are susceptible to HIV infection and disease. The goal of this project proposal is to create such humanized mice to study the role of immune cell subsets and virus-neutralizing antibodies in vaccine protection. The experiments will entail the development of a cohort of mice all reconstituted with the same human cells so as to be histocompatible. This will require transplantation of the mice with 1 mm^3 pieces of fetal thymus as well as reconstitution with stem cells isolated from cord blood and liver. Once the humanized mice have been established some will be vaccinated to prime distinct subsets of immune cells. Immune cell subsets from vaccinated mice will be adoptively transferred into naïve mice, which will then be infected with HIV to

test the antiviral activity of the immune cells. The goal of these experiments is to establish correlates of immunity against HIV.

2. If applicable, list your non-NIH Collaborating Investigator(s).

Name Institution Address Tel. # FAX #

3. Proposed start date of your research __April, 2010_____
Proposed completion date _April, 2013_____

4. Will you be _____these samples or data?

Collecting Yes/(No)
Receiving (Yes)/No
Sending Yes/(No)

5. Do the samples or data:
(a) Already exist?___Yes _x__No

(b) Or are they being collected for the express purpose of this study? _X__Yes __No
If "yes," please describe:_

17-19 week fetal cells and tissue will be obtained from Advanced Bioscience Resources, Inc., a non-profit foundation established under California law to provide biomedical researchers access to human tissues in compliance with state, federal, and NIH guidelines. Consent to donate is obtained in accordance with UAGA and NOTA guidelines. Related documents including the consent form are attached._____

(c) Or a combination of (a) and (b)? ____Yes _____No

6. What role will you have in this research project? (Check all that apply)

___ Analyze samples/data only.

___ Consultant/advisor to collaborator(s) listed above.

___ Author of the protocol that is being implemented by your collaborating investigator (identified in question #2).

___ Co-authorship on publication(s)/manuscript(s) pertaining to this research.

___ You or NIH hold an IND for this research.

__X_ Decisional authority over the design or implementation of the research at the IRB approved site? If so, please explain.

I am the PI and lead investigator on this project which will take place in my laboratory and the animal care facilities at Rocky Mountain Labs, NIAID, NIH.

___Other (If necessary, use this space to describe your role in this research).

7. Where are the subjects of this research activity located?
The material for this research is obtained from natural or induced abortions from females in California. Thus the tissues and cells involved will not be from living humans.

8. If human subjects are located elsewhere (not at NIH), will you have direct contact or intervention with them? (Examples: as subject's physician; in obtaining samples directly from the subject; by interviewing the subject?) ____ Yes __x__No

9. What kind of human samples (e.g., tissue, blood) or data (e.g., private information, responses to questionnaires) will be involved in your research?
_Samples will include cord blood, fetal blood, thymus, liver, and bone marrow. No private information will be involved._____

---

10. If the samples, data do not come from an IRB approved protocol, do they come from:

(a) Repository ____Yes ___ No

(b) Pathological waste ___ Yes _____No

(c) Autopsy material ___ Yes ___ No

(d) Publicly available source _X__Yes ___ No

(e) Other_____

11. Please check the box(es) that apply(ies) to the samples/data that you will receive.

(a) ____ Samples and/or data will be anonymized/unlinked. (The samples/data cannot be linked to individual subjects by you or your collaborators at other sites.)

(b) ___ Samples and/or data will be coded, however that code cannot be used by either the sender or the receiver to identify specific individuals.

(c) __X_ Samples and/or data will be coded so that the provider of the samples/data can link them to specific individuals but the receiver will not be able to do so.

12. Will you send results back to the provider(s) (listed in question 2 of this form)?

(a) __X_ No, I will not send results back to the provider(s).

(b) ___ Yes, I will send aggregate results to the provider(s).

(c) ___ Yes, I will send results to the provider(s) that are linked to identifiable individuals.

If yes, does the provider intend to link your data to identifiable individuals?
_____Yes _____No

13. Has the research activity <u>that you are proposing in this form</u> been approved by an Institutional Review Board (IRB) elsewhere?

_____ Yes, the NIH research activity has been reviewed by the following IRB (s) (Please provide the following information for each IRB):

_____ Name of institution that provided the review

_____ Address of reviewing institution

_____ Name of PI for the IRB approved protocol

_____ Title of IRB approved protocol and protocol #

_____ Federal Wide Assurance (FWA) number**

___X_____No IRB review of the research activity described in question #1 above has taken place

(**An FWA is a contract between the U.S. Department of Health and Human Services (DHHS) and an entity receiving DHHS funds to conduct clinical research that the latter will follow ethical guidelines and federal regulations for the protection of human subjects. For a list of domestic and international institutions go to http://ohrp.cit.nih.gov/search/asearch.asp#ASUR

14. Per NIH guidance*, have conflicts of interest by NIH employees, if any, been resolved?**

__X___Yes _____No no conflicts of interest

If your answer is no, please see your Clinical Director about this matter before proceeding with this research.

***The January 5, 2005 NIH Guide to Preventing Conflict of Interest applies to all research conducted at NIH, http://ohsr.od.nih.gov/New/mpafwa_docs.html

ADVANCED BIOSCIENCE RESOURCES, INC

OVERVIEW

ADVANCED BIOSCIENCE RESOURCES is a non-profit corporate foundation established in 1989 under California law to provide biomedical researchers with access to human tissues. ABR was formed exclusively for biomedical, scientific, and educational purposes and is devoted to providing services in connection with the procurement of human organs and tissues for medical and scientific research. ABR specializes in the procurement, preservation and distribution of both human fetal tissues and full term umbilical cord blood for research, and provides a highly individualized, reliable and easily accessible service.

TISSUE COLLECTION AND DISTRIBUTION: The purpose of ABR is to promote cooperative efforts to collect and distribute human tissues and to thereby facilitate research utilizing those tissues. Trained personnel coordinate the retrieval, preservation and delivery of each specimen.

Tissues obtained through ABR are retrieved from routinely performed surgical procedures including first and second trimester induced abortions, and full term deliveries, either natural or caesarian section. Tissues that were once discarded are now available to scientists worldwide through the efforts of ABR. Researchers may specify tissue characteristics, preservation methods, and delivery times.

PRESERVATION METHODS: Each specimen is collected, preserved, and shipped according to the investigator's individual protocol.

QUALITY CONTROL: ABR practices strict quality control procedures and adheres to stringent guidelines for tissue collection and preservation. Consent is obtained in accordance with UAGA and NOTA guidelines. Tissue specimens are identified, dissected, and transferred to the specified medium. A control number is then assigned to each sample to ensure confidentiality of patient identity.

To assure proper processing of the tissue, every researcher selects a collection/preservation protocol tailored specifically to his needs. In the collection and distribution of these tissues, every effort is made to exercise the highest standards of medical and laboratory practice. ABR specializes in direct communication with each investigator from the initial application to specimen delivery.

INVESTIGATOR APPROVAL: ABR will provide tissue to researchers who provide information on current research funding, and a short summary of their research intent. Investigators must agree to accept responsibility for the potential biohazard of the tissue and to appropriately train laboratory personnel in the proper handling of the tissue. In addition, the researcher must agree to use the tissue solely for research purpose and to acknowledge ABR in any publications resulting from the use of ABR provided tissue.

APPLICATION PROCESS: To request human tissue for research, an application must be completed and submitted to ABR. The application will be reviewed for feasibility and priority. A protocol will be developed to meet individual research needs as identified in the application.

SERVICE AND PROCESSING FEES: Participating medical facilities that enable ABR to enact its tissue acquisition and distribution programs may be paid a nominal fee for such services. A minimal processing / preservation / shipment fee is also assessed for services provided to research facilities.

1516 Oak Street # 303 / Alameda, CA 94501 / 510-865-5872 / Fax 510-865-4090 / email abr@abr-inc.com

Recent advancements in medical research have been developed through the use of human tissues in scientific study. Diseases such as diabetes, hemophilia, Parkinson's disease, cancer, AIDS, heart and lung disease, as well as genetic and,neonatal disorders, are being investigated for the development of cures through the use of human fetal tissues. Any tissue donated may be distributed to medical institutions and private research groups in the United States and internationally to enhance the development of cures and therapies for disease.

PERMISSION FOR DONATION OF TISSUE
OBTAINED AT THE TIME OF ABORTION

I have previously decided to have an abortion and have previously consented to having such abortion.

I hereby donate the aborted material and/or a sample of my blood as an anatomical gift for the purposes of education, research, or for the advancement of medical science. I understand that my donation may be used by research facilities in the United States and abroad.

I also agree that a sample of my blood may be taken after the abortion and that it may be used for research and routine testing for AIDS, hepatitis, or other infectious agents. I understand that, if there is testing, the results will be confidential unless the law requires that they be disclosed.

I understand that the aborted material may be used to derive human pluripotent stem cells for medical research and possibly human transplantation research, and that these cells may be kept for many years. I also understand that my donation may be used for cosmetic purposes. I understand that there is no information associated with aborted material that could link me with my donation. I agree that this donation is made without any restriction or direction regarding the potential recipients of the cells derived from the aborted material and that I have not been informed of the identity of any potential recipients.

I understand that there will be no payment to me and I agree that, although the results of the research on the aborted material may have commercial value, I will have no property or other commercial or financial rights in the aborted material or any product, process, or service which may result from this donation.

I understand that my donation will not result in any direct medical benefit to me.

I understand that my donation is voluntary, and I may refuse to donate aborted material and this will not affect my medical care or my relationship with my physician.

I understand that, if I have any questions about my donation, I can contact ABR at 510-865-5872.

_____ _____
Signature Date

I choose not to participate.

_____ _____
Signature Date

_____ _____
Witness Date

ADVANCED BIOSCIENCE RESOURCES, INC.

APPLICATION FOR THE ACQUISITION OF

HUMAN FETAL TISSUE FOR RESEARCH

All requests for human fetal tissue are reviewed for feasibility of procurement and preparation. When approved, an individual protocol will be developed for the procurement, preparation and delivery of tissue samples, based on the information provided in this application and any subsequent communication.

I. APPLICANT INFORMATION

NAME: Kim J Hasenkrug

TITLE: Senior Investigator

COMPANY: NIAID, NIH

ADDRESS: Rocky Mountain Lab

ADDRESS: 903 S. 4th St

CITY,ST,ZIP: Hamilton, MT 59840

PHONE #: 406-363-9310

ALT. #:

FAX #: 406-363-9286

EMAIL: khasenkrug@nih.gov

DELIVERY OPTIONS:

__X__ Same Day: Commercial carrier, hand delivered
Maximizes cell viability (*geographical limits*)

_____ Next Day: Pickup, delivery Mon-Sat daytime
Economical for fresh, frozen specimens

Applicant will be charged for delivery fees.

Applicant may designate preferred carrier:

Carrier Name: FEDEX

Account #: (b)(4)

BILLING INFORMATION:

BILL TO: Kim J Hasenkrug

COMPANY: Rocky Mountain Labs

ADDRESS: 903 S. 4th St.

ADDRESS:

CITY,ST,ZIP: Hamilton, MT 59840

ACCOUNTING DEPT. PHONE #: 406-363-9438

P.O. # (if required by your company):

P.O. # is not required to submit application

Credit Card #:

Name on CC:

Expiration Date: VISA/MC

SHIP TO: Kim J Hasenkrug
Rocky Mountain Labs
903 S. 4th St
Hamilton, MT 59840

Please indicate how you heard about ABR: (b)(6)

II. HUMAN FETAL TISSUE

Tissue specimens requested: thymus, liver, cord blood

Preferred gestational age (6-24 weeks): 17-19 wks

Proposed starting date: May, 2010

CONTAGIOUS DISEASE SCREENING: Availability of test results varies from 24 hours to 7 days after procurement. Applicant requires the following tests to be performed by ABR:

__X__ No testing required

_____ HIV _____ HSV
_____ HBSAG _____ RPR
_____ CMV _____ HCV

OTHER_____

III. PRESERVATION

ABR uses *BioWhittaker RPMI-1640 With L-Glutamine* for tissue preparation, preservation and shipment. Applicant may supply ABR with other media specific to research needs. Please indicate preference below.

PRESERVATION METHODS AVAILABLE:

__X__ Fresh; shipped on wet ice
_____ Passive freezing on dry ice; shipped on dry ice
_____ "Snap" freezing in LN2; shipped on dry ice
_____ Media provided by applicant
_____ Media provided by ABR (RPMI)

IV. DONOR INFORMATION

CONSENT VERIFICATION: Consent for tissue donation is obtained prior to specimen procurement. The consent is extremely confidential in nature and shall not be communicated to the researcher.

SPECIFIC DONOR INFORMATION: Charts are routinely examined for patient medical histories. Please identify any specific information sought and indicate contraindications to specimen procurement:

_____HIV+ status contraindicates procurement_____

_____

_____

V. RESEARCH DATA

TITLE OF RESEARCH PROJECT: ___The role of virus-specific CD4+__T cells, CD8+ T cells and antibody in vaccine protection against HIV-1 in humanized mice_____

ABR will provide tissue to researchers who provide information on current research funding, and a short summary of their research intent. **(Please attach a brief synopsis of the research project named above.)** Researchers must agree to use the tissue solely for research purposes and to acknowledge ABR in any publications resulting from the use of ABR provided tissue. Updates on research progress will be requested at six-month intervals. Researchers agree to publish the results of the research as promptly after the completion of the research as is reasonably possible without jeopardizing the sponsor's right to secure patents or copyrights necessary to protect its ownership or control of the results of the research. Researchers agree to inform ABR of the name of the publication and the date of the issue in which the results will be published. It is the intent of this requirement to make the results available to the general public through acceptable means of publication.

VI. SOURCE OF FUNDING

Please identify the primary source of funding for this project.

NIH _X___ Other Federal or State Grants _____ Foundation Grants _____ Other (specify) _____

If this application is approved by ABR, ABR shall provide services to the applicant in accordance with the terms and the other conditions on the reverse side, and the signature of the applicant shall constitute acceptance of all such terms and conditions by applicant. The entire agreement between ABR and applicant relating to the services provided by ABR is expressly set forth herein, and any modification of or addition thereto shall be of no force or effect unless it is in writing and signed on behalf of ABR by a duly authorized representative.

BY SIGNING BELOW, THE APPLICANT ACKNOWLEDGES HAVING READ THE TERMS AND CONDITIONS ON THE FOLLOWING PAGE AND AGREES TO SUCH TERMS AND CONDITIONS.

Kim J Havenhuys

____ _____

_Senior Investigator_____
SIGNATURE and TITLE of APPLICANT

DATE 11/2/2009

Please return to:

ADVANCED BIOSCIENCE RESOURCES, INC.
1516 OAK STREET, SUITE 303
ALAMEDA, CALIFORNIA 94501
Telephone: 510-865-5872
Fax: 510-865-4090
Email: abr@abr-inc.com

TERMS AND CONDITIONS OF SERVICES

1. Services

1.1 During the term of this agreement, and pursuant to the terms and conditions hereinafter set forth, ABR will use its best efforts to provide services in connection with supplying researcher with the types of human tissues set forth in this application, as approved

by ABR, suitable for researcher requirements and in the amounts requested based upon ongoing discussions between researcher and ABR pursuant to the information sent by ABR.

1.2 Researcher acknowledges and agrees that ABR will provide the following types of services:

Removing tissue.
Preserving and processing tissue to a form suitable to the researcher needs.
Seeking consent for tissue donations from appropriate individuals, obtaining validly executed consent forms, and maintaining records of such consents in accordance.
Obtaining, labeling, storing, and delivering samples of donor or other required serum, and maintaining a system for matching such samples to specific tissue donations.
Preserving tissue viability and cleanliness during removal, processing, preservation, storage and transportation.
Storing tissue and transporting it to researcher in accordance with section 5.

1.3 In the event that tissues of the type specified in the application become unavailable to ABR, such that ABR is unable to perform the contemplated services, ABR shall have no obligation to perform such services.

2. Representations and Warranties. ABR hereby represents and warrants to researcher that (i) ABR will make no payments to anyone for any tissue transferred in connection with this agreement, and (ii) ABR will verify for each tissue delivery that appropriate consent was obtained for use of such tissue and any associated serum samples, and that adequate records of such consent are maintained; provided, however, that the parties hereto acknowledge and agree that such consents are extremely confidential in nature and shall not, in any case, be communicated to researcher. Researcher hereby represents and warrants to ABR that (i) researcher will neither sell nor transfer for valuable consideration any tissue received through ABR to anyone, (ii) researcher will use the tissue only to satisfy its objectives, which are, as acknowledged and agreed hereto, [research and clinical use], (iii) researcher agrees to inform ABR of any changes in clinical or research use of specimens received from ABR, or in any specifications, constraints, etc. in a timely manner, and (iv) researcher understands the bio-hazardous nature of human tissue and agrees to take proper precautionary measures at all times when handling tissue specimen.

3. Terms. The terms of this agreement shall be for one (1) year, beginning from the date hereof, and terminating one (1) year thereafter, unless either of the parties hereto shall have given to the other thirty (30) days written notice of its intention to terminate this agreement, whereupon same shall terminate thirty (30) days after date of said notice.

In default of notice as aforesaid from either party hereto, this agreement shall continue for further successive terms of one (1) year thereafter and in default of thirty (30) days written notice before the end of an annual term by either of the parties of its intention not to renew, whereupon this agreement shall terminate at the end of said term.

4. Payments. Researcher agrees to pay to ADR a fee for costs incurred by ABR in providing services in connection with the acquisition of each sample of tissue requested by researcher, to be mutually agreed upon by ABR and researcher upon approval of this agreement by ABR.

5. Shipment services.

5.1 All shipments will be made as soon as possible after request has been received by ABR from researcher.

5.2 Researcher acknowledges that networks of tissue availability are neither permanent nor dependable, but rather they fluctuate. However, ABR shall use its best efforts to transfer the tissue in the amounts requested by researcher.

5.3 Shipment will be made in the best possible manner so as to preserve the quality of the tissues. It is understood that the fragility of human tissue is such that damage may occur during shipment. ABR will use its best efforts to comply with the handling and shipment protocols provided by researcher.

5.4 ABR will package the tissue appropriately and, if so requested by researcher, will insure the shipment. Researcher agrees to bear all costs associated with insurance and shipment of any tissue.

5.5 The risk of loss and damage of any tissue or organs shall pass immediately to researcher when the shipment of such tissue or organs is deposited with a carrier for transportation at the F.O.B. point.

6. Limitation of liability. ABR shall not be responsible or liable under any section of this agreement or under any contract, negligence, strict liability or other legal or equitable theory, for the cost of procurement of substitutive services, or any indirect, incidental or consequential damages including, but not limited to loss of revenues and loss of profits. Any liability of ABR under any theory whatsoever will be limited exclusively to the provision of equivalent services by ABR or, if unenforceable, to payment of an amount not greater than any amount actually received by ABR from researcher on account of this agreement.

7. No warranties. It is understood that human tissue is by nature neither permanent nor dependable. Except as expressly set forth in this agreement, ABR makes no representation of any kind, expressed or implied, including any representation with respect to the safety, efficacy or merchantability or the fitness for any purpose with respect to the tissue transferred to researcher in connection with this agreement.

8. Indemnification. Researcher shall indemnify, defend and hold ABR harmless from and against all claims, causes of actions, suits, damages and costs arising out of, resulting from, or otherwise in respect of, the use of tissue transferred in connection with this agreement, except where such claims are the result of negligence of ABR, its employees, staff or agents to (i) comply with any governmental requirements, or (ii) adhere to the terms of this agreement.

9. General. This agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of law. This agreement may not be assigned by either party without the prior written consent of the other.

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Monday, November 23, 2009 10:43 AM
To: Hasenkrug, Kim (NIH/NIAID) [E]
Subject: Request for Review Rec'd-OHSR 4980

Good morning Dr. Hasenkrug,

This email is to verify that OHSR has received your Request for Review of Research and it is currently being processed as OHSR #4980. Please use this number in any future correspondence regarding this study. We will contact you via email if any additional information is needed. If you have not heard from OHSR within 7 business days, please contact us.

Protocol Title: Study of HIV infection and vaccine protection in mice reconstituted with a human immune system

Thank you.

OHSR:
Ph: 301.402.3444
Fax: 301.402.3443

Thank you.

Sincerely,

(b)(6)

OHSR (NIH/DDIR)

From: Hasenkrug, Kim (NIH/NIAID) [E]
Sent: Wednesday, December 09, 2009 5:41 PM
To: OHSR (NIH/DDIR)
Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up
Flag Status: Green

Attachments: IRB Letter with letterhead nonidentity.doc

IRB Letter with letterhead non...

Here is the letter on official ABR letterhead for you

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
Laboratory of Persistent Viral Diseases
Rocky Mountain Laboratories
National Institute of Allergy and Infectious Diseases National Institutes of Health
903 S. 4th Street
Hamilton, MT 59840
phone (406)363-9310
FAX (406)363-9286
khasenkrug@nih.gov

> From: "OHSR (NIH/DDIR)" <ohsr_nih_ddir@od.nih.gov>
> Date: Tue, 24 Nov 2009 10:27:55 -0500
> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
> Conversation: HasenkrugK_NIAID_4980_CY2009
> Subject: HasenkrugK_NIAID_4980_CY2009
>
> Good Afternoon Dr. Hasenkrug:
>
> Thank you for the opportunity to review your research project: Study
> of HIV infection & Vaccine Protection.. Since the work you are doing
> at the NIH provides little or no risk to human subjects off-site, OHSR
> has decided the appropriate action for you to take is the following:
>
> * Provide documentation that you will not seek the identity of the
> subjects who have provided the samples you will receive as well as
> documentation from ABR that under no circumstances will the identity
> or link to the identifiers of the subjects be released to you.
>
> An e-mail from you and from ABR holding the key to the code is
> sufficient documentation.
>
> This action is based on guidance issued on Aug. 10, 2004 by the HHS
> Office of Human Research Protections, the regulatory office for the
> protection of human subjects.

> Best regards,
>
>
>
> OHSR - National Institutes of Health
> Bldg 10, Suite 2C146
> Bethesda, MD 20892
> Office Telephone: 301-402-3444
> Office Fax: 301-402-3443
>
> The NIH is committed to maintaining the highest standards for the
> protection of human subjects.
> P Please consider the environment before printing this e-mail
>

ADVANCED BIOSCIENCE RESOURCES, INC

December 14, 2009

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
903 S. 4th Street
Hamilton, MT 59840

Dear Kim,

This letter verifies that ABR, a non-profit tissue procurement organization, supplies requesting and approved scientific investigators with the types of human fetal tissues required for specific bio-medical research. When requested and as availability allows, human fetal tissue specimens will be retrieved from products of conception from induced first and second trimester abortions. Tissue will be distributed according to established protocols. Specimens are not collected for directed donation. .

ABR warrants that maternal consent from patients aged over eighteen years is obtained for the use of fetal tissue specimens for research purposes, including the consent for the potential of stem cell research utilizing such tissues, and that adequate records of such consent are maintained for future verification. Donor identification is coded and scientific investigators have no access to donor identification. ABR also warrants that maternal consent is obtained for phlebotomy and blood testing for a variety of disease entities.

ABR warrants that no payments will be made to any third party for the conduct of or the product of an abortion, including without limitation any parent(s) of any unborn fetus. ABR, to the best of its knowledge, also warrants that all tissue provided will have been obtained in compliance with local, state and federal laws and regulations governing the procurement and distribution of human tissue.

Sincerely,

Perrin Larton

Perrin Larton, CTBS
Procurement Manager

Federal E.I.N.: 94-3110160
California E.I.N.: 370-20518
FDA FEI: 3005208435

1516 Oak Street # 303 / Alameda, CA 94501 / 510-865-5872 / Fax 510-865-4090 / email abr@abr-inc.com

OHSR (NIH/DDIR)

From: Hasenkrug, Kim (NIH/NIAID) [E]
Sent: Monday, November 30, 2009 5:24 PM
To: OHSR (NIH/DDIR)
Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up
Flag Status: Green

Attachments: Re: HFT Application

Re: HFT Application

HasenkrugK_NIAID_4980_CY2009

Attached please find the requested email from ABR stating that no personally identifiable information will be released to me. Furthermore, I will not seek any such information from ABR.

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
Laboratory of Persistent Viral Diseases
Rocky Mountain Laboratories
National Institute of Allergy and Infectious Diseases National Institutes of Health
903 S. 4th Street
Hamilton, MT 59840
phone (406)363-9310
FAX (406)363-9286
khasenkrug@nih.gov

> From: "OHSR (NIH/DDIR)" <ohsr_nih_ddir@od.nih.gov>
> Date: Tue, 24 Nov 2009 10:27:55 -0500
> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
> Conversation: HasenkrugK_NIAID_4980_CY2009
> Subject: HasenkrugK_NIAID_4980_CY2009
>
> Good Afternoon Dr. Hasenkrug:
>
> Thank you for the opportunity to review your research project: Study
> of HIV infection & Vaccine Protection.. Since the work you are doing
> at the NIH provides little or no risk to human subjects off-site, OHSR
> has decided the appropriate action for you to take is the following:
>
> * Provide documentation that you will not seek the identity of the
> subjects who have provided the samples you will receive as well as
> documentation from ABR that under no circumstances will the identity
> or link to the identifiers of the subjects be released to you.
>
> An e-mail from you and from ABR holding the key to the code is
> sufficient documentation.

>
> This action is based on guidance issued on Aug. 10, 2004 by the HHS
> Office of Human Research Protections, the regulatory office for the
> protection of human subjects.
>
> Best regards,
>
>
>
> OHSR - National Institutes of Health
> Bldg 10, Suite 2C146
> Bethesda, MD 20892
> Office Telephone: 301-402-3444
> Office Fax: 301-402-3443
>
> The NIH is committed to maintaining the highest standards for the
> protection of human subjects.
> P Please consider the environment before printing this e-mail
>

OHSR (NIH/DDIR)

From: Perrin Larton (b)(6)
Sent: Monday, November 30, 2009 5:10 PM
To: Hasenkrug, Kim (NIH/NIAID) [E]
Cc: (b)(6)
Subject: Re: HFT Application

Hi Kim,

All tissue is numerically coded and the personally identifiable information is never available. In other NIH applications we've had requests for letters that state NO information is available to researchers. I can send you a letter to that effect...but tissue cannot be tracked back to a specific patient. We guarantee anonymity to the patients donating tissue.

Perrin

> Dear Perrin, the Office of Human Subjects Research is asking me for a
> letter
> from you stating that personally identifiable information regarding the
> fetal tissue will be revealed to me. Would you kindly send me a letter
> stating such so that I can forward it to them? It would be greatly
> appreciated and let us begin our experiments. I attached a copy your
> letter
> regarding approval of our application for your information. Thank you
> very
> much, Perrin.
>
> Kim
>
> Kim J Hasenkrug, Ph.D.
> Senior Investigator
> Chief, Retroviral Immunology Section
> Laboratory of Persistent Viral Diseases
> Rocky Mountain Laboratories
> National Institute of Allergy and Infectious Diseases
> National Institutes of Health
> 903 S. 4th Street
> Hamilton, MT 59840
> phone (406)363-9310
> FAX (406)363-9286
> khasenkrug@nih.gov
>
> Disclaimer:
> The information in this e-mail and any of its attachments is confidential
> and may contain sensitive information. It should not be used by anyone who
> is not the original intended recipient. If you have received this e-mail
> in
> error please inform the sender and delete it from your mailbox or any
> other
> storage devices. National Institute of Allergy and Infectious Diseases
> shall
> not accept liability for any statements made that are sender's own and not
> expressly made on behalf of the NIAID by one of its representatives

>
>
>> From: Perrin Larton (b)(6)
>> Reply-To: (b)(6)
>> Date: Mon, 2 Nov 2009 13:40:51 -0500
>> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
>> Conversation: HFT Application
>> Subject: HFT Application
>>
>> Dear Kim,
>>
>> Attached you'll find the documents we just discussed. What I'll need
>> back
>> from you is the two page application as well as a short synopsis of the
>> work you'll be doing. As soon as I get the completed application from
>> you
>> it will go to our Scientific Advisory Board for review and approval. If
>> they have questions, I'll give you a call. Approval usually takes 5-10
>> working days from the time I receive the application from you.
>>
>> Please send your application back to my e-mail address
>> (b)(6)
>> or FAX to 510-865-4090.
>>
>> Thanks so much for your interest in the services supplied by Advanced
>> Bioscience Resources. I apologize again for taking such a long time to
>> respond to your query.
>>
>> Perrin Larton CTBS
>> Procurement Manager
>> Advanced Bioscience Resources
>
>

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Tuesday, November 24, 2009 10:28 AM
To: Hasenkrug, Kim (NIH/NIAID) [E]
Subject: HasenkrugK_NIAID_4980_CY2009

Good Afternoon Dr. Hasenkrug:

Thank you for the opportunity to review your research project: ***Study of HIV infection & Vaccine Protection..*** Since the work you are doing at the NIH provides little or no risk to human subjects off-site, OHSR has decided the appropriate action for you to take is the following:

- Provide documentation that you will not seek the identity of the subjects who have provided the samples you will receive as well as documentation from ABR that under no circumstances will the identity or link to the identifiers of the subjects be released to you.

An e-mail from you and from ABR holding the key to the code is sufficient documentation.

This action is based on guidance issued on Aug. 10, 2004 by the HHS Office of Human Research Protections, the regulatory office for the protection of human subjects.

Best regards,

OHSR - National Institutes of Health
Bldg 10, Suite 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

The NIH is committed to maintaining the highest standards for the protection of human subjects.


Please consider the environment before printing this e-mail

ADVANCED BIOSCIENCE RESOURCES, INC.

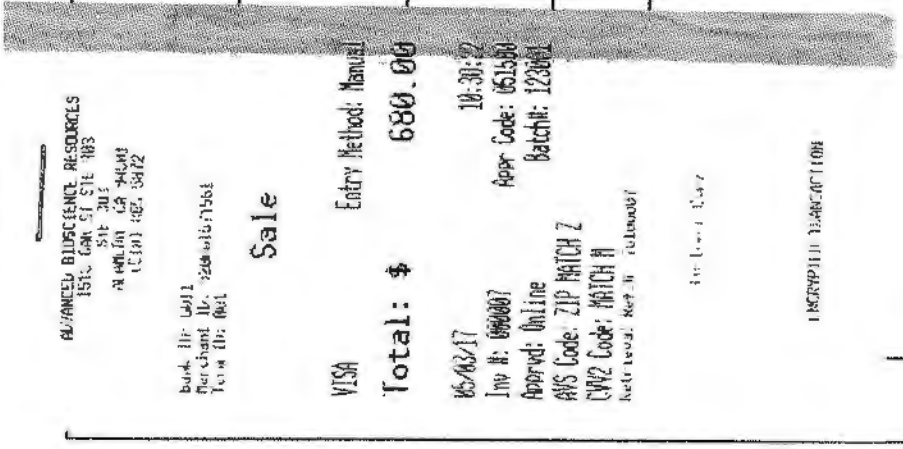
TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
4/20/2017	(b)(6)	1033535
	TERMS	CUSTOMER #
	Due Upon Receipt	0522

BILL TO

Rocky Mountain Labs
NIH/NIAID
Kim J. Hasenkrug
903 S. 4th Street
Hamilton, MT 59840

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
4/20/2017	642002	8627	17	Thymus, 2nd Trimester	KIM	(b)(4)
4/20/2017	642002	8628	17	Liver, 2nd Trimester	KIM	
				05/03/17 PAID via VISA (b)(6) Request by Kim Hasenkrug.		



Total **$680.00**

SEQ: 1844479	PO#: (b)(6)	Requester: Messer, Ronald

CAN: 8335424 FY: 17 Owner: (b)(6)
Order Total: 680.00 Project: 107833
Date Needed: 03/31/2017 Emergency: Yes Order Type: Purchase Card
Requestor Phone: +1 406 363 9276 Order Status: Archive

Vendor Advanced Bioscience Resources,1516 Oak Street, Suite 303, Alameda, CA 94501
Phone: 510-865-5872 SmlBs: No FSS:
EIN: BPA: GSA:
Site: Clerk:
E-mail:

#	Description	CAN	Catalog	OC Code	Category	Qty at Price	Total
1	Tissue, 2nd Trimester (1 each of liver and thymus)	8335424	none	2613	6509	(b)(4)	680.00
2	shipping	8335424		2613	6509	1 each at $0	.00
Order Total: 680.00							

Ship To: Ronald Messer,3220 ,RML CNTRL REC,RMTLAB

QUOTES

Vendor	Price	Good Until	Available
There are no quotes in the order			

JUSTIFICATION

These tissues, liver and thymus, are required by Ron Messer for ongoing studies of HIV in the Hasenkrug Lab. Our mice are ready for reconstitution. Please let me know when I can contact Perrin Larton at ABR to place our request on their schedule. Please contact the vendor at 510-865-5872 ext (b)(6) -give her the PO number Thanks, Ron. *** I certify that I have checked the sources of supply and services listed in FAR 8.002. ( ) I have purchased from the highest priority source available. (X) I did not purchase from a priority source because none could satisfy the requirement of the government either in product/service specifications, quality or required delivery time. **********NOTE to Purchasing Agent: Call vendor at 510-865-5872 ext (b)(6) - give her the PO number and credit card information.

Alternate Sources:

NIH Surplus: No UNICOR: No GSA Stock Catalog: No GSA Self Service: No Federal Supply: No Open Market: Yes

AGENT

Purchase Order #: (b)(6)
Custodial Code: 30102
Order Reference: em'd
FSS:
NBS Ref Order #: 4543155

Estimated Ship Date:
Date Entered into NBS: 03/31/2017
Expected Delivery Date: 04/07/2017
Select Agents: No
Clearance Requested: No

SF-37 Code:

Notes

There are no notes in the order

IT Clearance

Never seen by IT officer

ROUTE HISTORY

Role Summary

User Role	Name
Requester	Messer, Ronald
Releaser	Messer, Ronald
Admin Officer	(b)(6)
Lead Admin Officer	
Purchase Agent	(b)(6)
Lead Agent	
IT Clearance Officer	
Releaser1	
Releaser2	
NBS	
Receiving Official	

Dates

Description	Date
Needed By	03/31/2017
Submitted to NBS	03/31/2017
NBS Confirmation	04/01/2017
Award Created	03/31/2017
Award Received	03/31/2017
Estimated Ship Date	
Received	04/19/2017
Canceled	

Routing History

Name	Role	Date In	STATUS IN	ACTION
Messer, Ronald	Requester	03/31/2017	New order	Approved
(b)(6)	Administrative Officer	03/31/2017	Released	Approved
	Purchasing Agent	03/31/2017	Approved	Approved
NBS, NBS	NBS	03/31/2017	Sent to NBS	Approved
Messer, Ronald (taken by (b)(6)	Requester for receiving	03/31/2017	Pending receiving	Take
(b)(6)	Requester for receiving	04/19/2017	Pending receiving	Approved
	Archive	04/19/2017	Archive	(N/A)

Receiving Report

#	Description	Total Qty Ordered	Total Qty Received	Date Received
1	Tissue, 2nd Trimester (1 each of liver and thymus)	2	2	04/19/2017
2	shipping	1	1	04/19/2017

OHSR RESPONSE TO REQUEST FOR REVIEW OF RESEARCH ACTIVITY
INVOLVING HUMAN SUBJECTS

FAX:

Exempt: #: 4980

To: Hasenkrug, Kim
NIAID
RML - Rocky Mountain Laboratories, 3/218

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
Recent reports have demonstrated that immunodeficient mice reconstituted with 17-19 week old human fetal tissue develop a human immune system and are susceptible to HIV infection and disease. The goal of this project proposal is to create such humanized mice to study the role of immune cell subsets and virus-neutralizing antibodies in vaccine protection. The experiments will entail the development of a cohort of mice all reconstituted with the same human cells so as to be histocompatible. This will require transplantation of

Original Request Received in OHSR on: 11/19/2009

Responsible NIH Research Investigator(s): Kim Hasenkrug, NIAID

OHSR review of your request dated Thu, Nov 19, 2009 has determined that:

☒ Federal regulations for the protection of human subjects do not apply to above named activity. The OHSR determination of Not Human Subjects Research is based on the interpretation of 45 CFR 46 under "Research Involving Coded Private Information or Biological Specimens" (OHRP, Revised October 16, 2008) and Guidance on Engagement of Institutions in Human Subjects Research (October 16, 2008). NOTIFY OHSR VIA AN E-MAIL AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESEARCH ACTIVITY.

☐ The activity is designated **EXEMPT**, and has been entered in the OHSR database. PLEASE NOTIFY OHSR OF ANY **SIGNIFICANT** CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.

☐ **NOT EXEMPT**. OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additional information in order to determine whether expedited or full review is appropriate.

☐ Confidentiality Agreement

☐ Reliance

☐ Amendment

☐ Other

Office Person LB Admin Assist. CB

Note:
(b)(6)

CIP

for Charlotte Holden, JD — Acting Director, OHSR — 12/14/2009
Signature — Title — Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: Yes

OHSR Use Only
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

#4980

REQUEST FOR REVIEW OF RESEARCH ACTIVITY INVOLVING HUMAN SUBJECTS

INSTRUCTIONS: Please type directly on this form. You can expand the document if you need more space. If your research involves a survey or questionnaire, please attach it to this completed form.

Completed forms (with all required signatures) may be sent to OHSR by FAX (301-402-3443), email to ohsr_nih_ddir@od.nih.gov, or by mail (2C146). If you have any questions, call OHSR at (301) 402-3444.

Date: 11/19/2009

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146

From: Kim J Hasenkrug
(Signature)

Through: (b)(6) (acting)
(Signature of appropriate Official for IC, e.g., Lab/Branch Chief)

Protocol Title: Study of HIV infection and vaccine protection in mice reconstituted with a human immune system

Name of NIH Principal Investigator(s): Kim J Hasenkrug, Senior Investigator

IC NIAID Laboratory/Branch LPVD Building & Room No. RML 3218
Tel. No. 406-363-9310 FAX No. 406-363-9286
Is the Principal investigator an NIH employee? x **Yes** ____ **No**

If no, please explain: ____

1. What is the proposed research activity that you intend to perform at NIH (please use lay terms):

Recent reports have demonstrated that immunodeficient mice reconstituted with 17-19 week old human fetal tissue develop a human immune system and are susceptible to HIV infection and disease. The goal of this project proposal is to create such humanized mice to study the role of immune cell subsets and virus-neutralizing antibodies in vaccine protection. The experiments will entail the development of a cohort of mice all reconstituted with the same human cells so as to be histocompatible. This will require transplantation of the mice with 1 mm^3 pieces of fetal thymus as well as reconstitution with stem cells isolated from cord blood and liver. Once the humanized mice have been established some will be vaccinated to prime distinct subsets of immune cells. Immune cell subsets from vaccinated mice will be adoptively transferred into naïve mice, which will then be infected with HIV to

test the antiviral activity of the immune cells. The goal of these experiments is to establish correlates of immunity against HIV.

2. If applicable, list your non-NIH Collaborating Investigator(s).

Name Institution Address Tel. # FAX #

3. Proposed start date of your research __April, 2010_____
Proposed completion date _April, 2013_____

4. Will you be _____these samples or data?

Collecting Yes/(No)
Receiving (Yes)/No
Sending Yes/(No)

5. Do the samples or data:
(a) Already exist?___Yes _x__No

(b) Or are they being collected for the express purpose of this study? _X__Yes __No
If "yes," please describe:_

17-19 week fetal cells and tissue will be obtained from Advanced Bioscience Resources, Inc., a non-profit foundation established under California law to provide biomedical researchers access to human tissues in compliance with state, federal, and NIH guidelines. Consent to donate is obtained in accordance with UAGA and NOTA guidelines. Related documents including the consent form are attached._____

(c) Or a combination of (a) and (b)? ____Yes _____No

6. What role will you have in this research project? (Check all that apply)

___ Analyze samples/data only.

___ Consultant/advisor to collaborator(s) listed above.

___ Author of the protocol that is being implemented by your collaborating investigator (identified in question #2).

___ Co-authorship on publication(s)/manuscript(s) pertaining to this research.

___ You or NIH hold an IND for this research.

__X_ Decisional authority over the design or implementation of the research at the IRB approved site? If so, please explain.

I am the PI and lead investigator on this project which will take place in my laboratory and the animal care facilities at Rocky Mountain Labs, NIAID, NIH.

___Other (If necessary, use this space to describe your role in this research).

7. Where are the subjects of this research activity located?
The material for this research is obtained from natural or induced abortions from females in California. Thus the tissues and cells involved will not be from living humans.

8. If human subjects are located elsewhere (not at NIH), will you have direct contact or intervention with them? (Examples: as subject's physician; in obtaining samples directly from the subject; by interviewing the subject?) ____ Yes __x__No

9. What kind of human samples (e.g., tissue, blood) or data (e.g., private information, responses to questionnaires) will be involved in your research?
_Samples will include cord blood, fetal blood, thymus, liver, and bone marrow. No private information will be involved._____

---

10. If the samples, data do not come from an IRB approved protocol, do they come from:

(a) Repository ____Yes ___ No

(b) Pathological waste ___ Yes _____No

(c) Autopsy material ___ Yes ___ No

(d) Publicly available source _X__Yes ___ No

(e) Other_____

11. Please check the box(es) that apply(ies) to the samples/data that you will receive.

(a) ____ Samples and/or data will be anonymized/unlinked. (The samples/data cannot be linked to individual subjects by you or your collaborators at other sites.)

(b) ___ Samples and/or data will be coded, however that code cannot be used by either the sender or the receiver to identify specific individuals.

(c) __X_ Samples and/or data will be coded so that the provider of the samples/data can link them to specific individuals but the receiver will not be able to do so.

12. Will you send results back to the provider(s) (listed in question 2 of this form)?

(a) __X_ No, I will not send results back to the provider(s).

(b) ___ Yes, I will send aggregate results to the provider(s).

(c) ___ Yes, I will send results to the provider(s) that are linked to identifiable individuals.

If yes, does the provider intend to link your data to identifiable individuals?
_____Yes _____No

13. Has the research activity <u>that you are proposing in this form</u> been approved by an Institutional Review Board (IRB) elsewhere?

_____ Yes, the NIH research activity has been reviewed by the following IRB (s) (Please provide the following information for each IRB):

_____ Name of institution that provided the review

_____ Address of reviewing institution

_____ Name of PI for the IRB approved protocol

_____ Title of IRB approved protocol and protocol #

_____ Federal Wide Assurance (FWA) number**

___X_____No IRB review of the research activity described in question #1 above has taken place

(**An FWA is a contract between the U.S. Department of Health and Human Services (DHHS) and an entity receiving DHHS funds to conduct clinical research that the latter will follow ethical guidelines and federal regulations for the protection of human subjects. For a list of domestic and international institutions go to http://ohrp.cit.nih.gov/search/asearch.asp#ASUR

14. Per NIH guidance*, have conflicts of interest by NIH employees, if any, been resolved?**

__X___Yes _____No no conflicts of interest

If your answer is no, please see your Clinical Director about this matter before proceeding with this research.

***The January 5, 2005 NIH Guide to Preventing Conflict of Interest applies to all research conducted at NIH, http://ohsr.od.nih.gov/New/mpafwa_docs.html

ADVANCED BIOSCIENCE RESOURCES, INC

OVERVIEW

ADVANCED BIOSCIENCE RESOURCES is a non-profit corporate foundation established in 1989 under California law to provide biomedical researchers with access to human tissues. ABR was formed exclusively for biomedical, scientific, and educational purposes and is devoted to providing services in connection with the procurement of human organs and tissues for medical and scientific research. ABR specializes in the procurement, preservation and distribution of both human fetal tissues and full term umbilical cord blood for research, and provides a highly individualized, reliable and easily accessible service.

TISSUE COLLECTION AND DISTRIBUTION: The purpose of ABR is to promote cooperative efforts to collect and distribute human tissues and to thereby facilitate research utilizing those tissues. Trained personnel coordinate the retrieval, preservation and delivery of each specimen.

Tissues obtained through ABR are retrieved from routinely performed surgical procedures including first and second trimester induced abortions, and full term deliveries, either natural or caesarian section. Tissues that were once discarded are now available to scientists worldwide through the efforts of ABR. Researchers may specify tissue characteristics, preservation methods, and delivery times.

PRESERVATION METHODS: Each specimen is collected, preserved, and shipped according to the investigator's individual protocol.

QUALITY CONTROL: ABR practices strict quality control procedures and adheres to stringent guidelines for tissue collection and preservation. Consent is obtained in accordance with UAGA and NOTA guidelines. Tissue specimens are identified, dissected, and transferred to the specified medium. A control number is then assigned to each sample to ensure confidentiality of patient identity.

To assure proper processing of the tissue, every researcher selects a collection/preservation protocol tailored specifically to his needs. In the collection and distribution of these tissues, every effort is made to exercise the highest standards of medical and laboratory practice. ABR specializes in direct communication with each investigator from the initial application to specimen delivery.

INVESTIGATOR APPROVAL: ABR will provide tissue to researchers who provide information on current research funding, and a short summary of their research intent. Investigators must agree to accept responsibility for the potential biohazard of the tissue and to appropriately train laboratory personnel in the proper handling of the tissue. In addition, the researcher must agree to use the tissue solely for research purpose and to acknowledge ABR in any publications resulting from the use of ABR provided tissue.

APPLICATION PROCESS: To request human tissue for research, an application must be completed and submitted to ABR. The application will be reviewed for feasibility and priority. A protocol will be developed to meet individual research needs as identified in the application.

SERVICE AND PROCESSING FEES: Participating medical facilities that enable ABR to enact its tissue acquisition and distribution programs may be paid a nominal fee for such services. A minimal processing / preservation / shipment fee is also assessed for services provided to research facilities.

1516 Oak Street # 303 / Alameda, CA 94501 / 510-865-5872 / Fax 510-865-4090 / email abr@abr-inc.com

Recent advancements in medical research have been developed through the use of human tissues in scientific study. Diseases such as diabetes, hemophilia, Parkinson's disease, cancer, AIDS, heart and lung disease, as well as genetic and,neonatal disorders, are being investigated for the development of cures through the use of human fetal tissues. Any tissue donated may be distributed to medical institutions and private research groups in the United States and internationally to enhance the development of cures and therapies for disease.

PERMISSION FOR DONATION OF TISSUE
OBTAINED AT THE TIME OF ABORTION

I have previously decided to have an abortion and have previously consented to having such abortion.

I hereby donate the aborted material and/or a sample of my blood as an anatomical gift for the purposes of education, research, or for the advancement of medical science. I understand that my donation may be used by research facilities in the United States and abroad.

I also agree that a sample of my blood may be taken after the abortion and that it may be used for research and routine testing for AIDS, hepatitis, or other infectious agents. I understand that, if there is testing, the results will be confidential unless the law requires that they be disclosed.

I understand that the aborted material may be used to derive human pluripotent stem cells for medical research and possibly human transplantation research, and that these cells may be kept for many years. I also understand that my donation may be used for cosmetic purposes. I understand that there is no information associated with aborted material that could link me with my donation. I agree that this donation is made without any restriction or direction regarding the potential recipients of the cells derived from the aborted material and that I have not been informed of the identity of any potential recipients.

I understand that there will be no payment to me and I agree that, although the results of the research on the aborted material may have commercial value, I will have no property or other commercial or financial rights in the aborted material or any product, process, or service which may result from this donation.

I understand that my donation will not result in any direct medical benefit to me.

I understand that my donation is voluntary, and I may refuse to donate aborted material and this will not affect my medical care or my relationship with my physician.

I understand that, if I have any questions about my donation, I can contact ABR at 510-865-5872.

_____ _____
Signature Date

I choose not to participate.

_____ _____
Signature Date

_____ _____
Witness Date

ADVANCED BIOSCIENCE RESOURCES, INC.

APPLICATION FOR THE ACQUISITION OF

HUMAN FETAL TISSUE FOR RESEARCH

All requests for human fetal tissue are reviewed for feasibility of procurement and preparation. When approved, an individual protocol will be developed for the procurement, preparation and delivery of tissue samples, based on the information provided in this application and any subsequent communication.

I. APPLICANT INFORMATION

NAME: Kim J Hasenkrug

TITLE: Senior Investigator

COMPANY: NIAID, NIH

ADDRESS: Rocky Mountain Lab

ADDRESS: 903 S. 4th St

CITY,ST,ZIP: Hamilton, MT 59840

PHONE #: 406-363-9310

ALT. #:

FAX #: 406-363-9286

EMAIL: khasenkrug@nih.gov

DELIVERY OPTIONS:

__X__ Same Day: Commercial carrier, hand delivered
Maximizes cell viability (*geographical limits*)

_____ Next Day: Pickup, delivery Mon-Sat daytime
Economical for fresh, frozen specimens

Applicant will be charged for delivery fees.

Applicant may designate preferred carrier:

Carrier Name: FEDEX

Account #: (b)(4)

BILLING INFORMATION:

BILL TO: Kim J Hasenkrug

COMPANY: Rocky Mountain Labs

ADDRESS: 903 S. 4th St.

ADDRESS:

CITY,ST,ZIP: Hamilton, MT 59840

ACCOUNTING DEPT. PHONE #: 406-363-9438

P.O. # (if required by your company):

P.O. # is not required to submit application

Credit Card #:

Name on CC:

Expiration Date: VISA/MC

SHIP TO: Kim J Hasenkrug
Rocky Mountain Labs
903 S. 4th St
Hamilton, MT 59840

Please indicate how you heard about ABR: (b)(6)

II. HUMAN FETAL TISSUE

Tissue specimens requested: thymus, liver, cord blood

Preferred gestational age (6-24 weeks): 17-19 wks

Proposed starting date: May, 2010

CONTAGIOUS DISEASE SCREENING: Availability of test results varies from 24 hours to 7 days after procurement. Applicant requires the following tests to be performed by ABR:

__X__ No testing required

_____ HIV _____ HSV
_____ HBSAG _____ RPR
_____ CMV _____ HCV

OTHER_____

III. PRESERVATION

ABR uses *BioWhittaker RPMI-1640 With L-Glutamine* for tissue preparation, preservation and shipment. Applicant may supply ABR with other media specific to research needs. Please indicate preference below.

PRESERVATION METHODS AVAILABLE:

__X__ Fresh; shipped on wet ice
_____ Passive freezing on dry ice; shipped on dry ice
_____ "Snap" freezing in LN2; shipped on dry ice
_____ Media provided by applicant
_____ Media provided by ABR (RPMI)

IV. DONOR INFORMATION

CONSENT VERIFICATION: Consent for tissue donation is obtained prior to specimen procurement. The consent is extremely confidential in nature and shall not be communicated to the researcher.

SPECIFIC DONOR INFORMATION: Charts are routinely examined for patient medical histories. Please identify any specific information sought and indicate contraindications to specimen procurement:

_____HIV+ status contraindicates procurement_____

_____

_____

V. RESEARCH DATA

TITLE OF RESEARCH PROJECT: ___The role of virus-specific CD4+__T cells, CD8+ T cells and antibody in vaccine protection against HIV-1 in humanized mice_____

ABR will provide tissue to researchers who provide information on current research funding, and a short summary of their research intent. **(Please attach a brief synopsis of the research project named above.)** Researchers must agree to use the tissue solely for research purposes and to acknowledge ABR in any publications resulting from the use of ABR provided tissue. Updates on research progress will be requested at six-month intervals. Researchers agree to publish the results of the research as promptly after the completion of the research as is reasonably possible without jeopardizing the sponsor's right to secure patents or copyrights necessary to protect its ownership or control of the results of the research. Researchers agree to inform ABR of the name of the publication and the date of the issue in which the results will be published. It is the intent of this requirement to make the results available to the general public through acceptable means of publication.

VI. SOURCE OF FUNDING

Please identify the primary source of funding for this project.

NIH _X___ Other Federal or State Grants _____ Foundation Grants _____ Other (specify) _____

If this application is approved by ABR, ABR shall provide services to the applicant in accordance with the terms and the other conditions on the reverse side, and the signature of the applicant shall constitute acceptance of all such terms and conditions by applicant. The entire agreement between ABR and applicant relating to the services provided by ABR is expressly set forth herein, and any modification of or addition thereto shall be of no force or effect unless it is in writing and signed on behalf of ABR by a duly authorized representative.

BY SIGNING BELOW, THE APPLICANT ACKNOWLEDGES HAVING READ THE TERMS AND CONDITIONS ON THE FOLLOWING PAGE AND AGREES TO SUCH TERMS AND CONDITIONS.

Kim J Havenhuys

____ _____

_Senior Investigator_____
SIGNATURE and TITLE of APPLICANT

DATE 11/2/2009

Please return to:

ADVANCED BIOSCIENCE RESOURCES, INC.
1516 OAK STREET, SUITE 303
ALAMEDA, CALIFORNIA 94501
Telephone: 510-865-5872
Fax: 510-865-4090
Email: abr@abr-inc.com

TERMS AND CONDITIONS OF SERVICES

1. Services

1.1 During the term of this agreement, and pursuant to the terms and conditions hereinafter set forth, ABR will use its best efforts to provide services in connection with supplying researcher with the types of human tissues set forth in this application, as approved

by ABR, suitable for researcher requirements and in the amounts requested based upon ongoing discussions between researcher and ABR pursuant to the information sent by ABR.

1.2 Researcher acknowledges and agrees that ABR will provide the following types of services:

Removing tissue.
Preserving and processing tissue to a form suitable to the researcher needs.
Seeking consent for tissue donations from appropriate individuals, obtaining validly executed consent forms, and maintaining records of such consents in accordance.
Obtaining, labeling, storing, and delivering samples of donor or other required serum, and maintaining a system for matching such samples to specific tissue donations.
Preserving tissue viability and cleanliness during removal, processing, preservation, storage and transportation.
Storing tissue and transporting it to researcher in accordance with section 5.

1.3 In the event that tissues of the type specified in the application become unavailable to ABR, such that ABR is unable to perform the contemplated services, ABR shall have no obligation to perform such services.

2. Representations and Warranties. ABR hereby represents and warrants to researcher that (i) ABR will make no payments to anyone for any tissue transferred in connection with this agreement, and (ii) ABR will verify for each tissue delivery that appropriate consent was obtained for use of such tissue and any associated serum samples, and that adequate records of such consent are maintained; provided, however, that the parties hereto acknowledge and agree that such consents are extremely confidential in nature and shall not, in any case, be communicated to researcher. Researcher hereby represents and warrants to ABR that (i) researcher will neither sell nor transfer for valuable consideration any tissue received through ABR to anyone, (ii) researcher will use the tissue only to satisfy its objectives, which are, as acknowledged and agreed hereto, [research and clinical use], (iii) researcher agrees to inform ABR of any changes in clinical or research use of specimens received from ABR, or in any specifications, constraints, etc. in a timely manner, and (iv) researcher understands the bio-hazardous nature of human tissue and agrees to take proper precautionary measures at all times when handling tissue specimen.

3. Terms. The terms of this agreement shall be for one (1) year, beginning from the date hereof, and terminating one (1) year thereafter, unless either of the parties hereto shall have given to the other thirty (30) days written notice of its intention to terminate this agreement, whereupon same shall terminate thirty (30) days after date of said notice.

In default of notice as aforesaid from either party hereto, this agreement shall continue for further successive terms of one (1) year thereafter and in default of thirty (30) days written notice before the end of an annual term by either of the parties of its intention not to renew, whereupon this agreement shall terminate at the end of said term.

4. Payments. Researcher agrees to pay to ADR a fee for costs incurred by ABR in providing services in connection with the acquisition of each sample of tissue requested by researcher, to be mutually agreed upon by ABR and researcher upon approval of this agreement by ABR.

5. Shipment services.

5.1 All shipments will be made as soon as possible after request has been received by ABR from researcher.

5.2 Researcher acknowledges that networks of tissue availability are neither permanent nor dependable, but rather they fluctuate. However, ABR shall use its best efforts to transfer the tissue in the amounts requested by researcher.

5.3 Shipment will be made in the best possible manner so as to preserve the quality of the tissues. It is understood that the fragility of human tissue is such that damage may occur during shipment. ABR will use its best efforts to comply with the handling and shipment protocols provided by researcher.

5.4 ABR will package the tissue appropriately and, if so requested by researcher, will insure the shipment. Researcher agrees to bear all costs associated with insurance and shipment of any tissue.

5.5 The risk of loss and damage of any tissue or organs shall pass immediately to researcher when the shipment of such tissue or organs is deposited with a carrier for transportation at the F.O.B. point.

6. Limitation of liability. ABR shall not be responsible or liable under any section of this agreement or under any contract, negligence, strict liability or other legal or equitable theory, for the cost of procurement of substitutive services, or any indirect, incidental or consequential damages including, but not limited to loss of revenues and loss of profits. Any liability of ABR under any theory whatsoever will be limited exclusively to the provision of equivalent services by ABR or, if unenforceable, to payment of an amount not greater than any amount actually received by ABR from researcher on account of this agreement.

7. No warranties. It is understood that human tissue is by nature neither permanent nor dependable. Except as expressly set forth in this agreement, ABR makes no representation of any kind, expressed or implied, including any representation with respect to the safety, efficacy or merchantability or the fitness for any purpose with respect to the tissue transferred to researcher in connection with this agreement.

8. Indemnification. Researcher shall indemnify, defend and hold ABR harmless from and against all claims, causes of actions, suits, damages and costs arising out of, resulting from, or otherwise in respect of, the use of tissue transferred in connection with this agreement, except where such claims are the result of negligence of ABR, its employees, staff or agents to (i) comply with any governmental requirements, or (ii) adhere to the terms of this agreement.

9. General. This agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of law. This agreement may not be assigned by either party without the prior written consent of the other.

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Monday, November 23, 2009 10:43 AM
To: Hasenkrug, Kim (NIH/NIAID) [E]
Subject: Request for Review Rec'd-OHSR 4980

Good morning Dr. Hasenkrug,

This email is to verify that OHSR has received your Request for Review of Research and it is currently being processed as OHSR #4980. Please use this number in any future correspondence regarding this study. We will contact you via email if any additional information is needed. If you have not heard from OHSR within 7 business days, please contact us.

Protocol Title: Study of HIV infection and vaccine protection in mice reconstituted with a human immune system

Thank you.

OHSR:
Ph: 301.402.3444
Fax: 301.402.3443

Thank you.

Sincerely,

(b)(6)

OHSR (NIH/DDIR)

From: Hasenkrug, Kim (NIH/NIAID) [E]
Sent: Wednesday, December 09, 2009 5:41 PM
To: OHSR (NIH/DDIR)
Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up
Flag Status: Green

Attachments: IRB Letter with letterhead nonidentity.doc

IRB Letter with letterhead non...

Here is the letter on official ABR letterhead for you

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
Laboratory of Persistent Viral Diseases
Rocky Mountain Laboratories
National Institute of Allergy and Infectious Diseases National Institutes of Health
903 S. 4th Street
Hamilton, MT 59840
phone (406)363-9310
FAX (406)363-9286
khasenkrug@nih.gov

> From: "OHSR (NIH/DDIR)" <ohsr_nih_ddir@od.nih.gov>
> Date: Tue, 24 Nov 2009 10:27:55 -0500
> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
> Conversation: HasenkrugK_NIAID_4980_CY2009
> Subject: HasenkrugK_NIAID_4980_CY2009
>
> Good Afternoon Dr. Hasenkrug:
>
> Thank you for the opportunity to review your research project: Study
> of HIV infection & Vaccine Protection.. Since the work you are doing
> at the NIH provides little or no risk to human subjects off-site, OHSR
> has decided the appropriate action for you to take is the following:
>
> * Provide documentation that you will not seek the identity of the
> subjects who have provided the samples you will receive as well as
> documentation from ABR that under no circumstances will the identity
> or link to the identifiers of the subjects be released to you.
>
> An e-mail from you and from ABR holding the key to the code is
> sufficient documentation.
>
> This action is based on guidance issued on Aug. 10, 2004 by the HHS
> Office of Human Research Protections, the regulatory office for the
> protection of human subjects.

> Best regards,
>
>
>
> OHSR - National Institutes of Health
> Bldg 10, Suite 2C146
> Bethesda, MD 20892
> Office Telephone: 301-402-3444
> Office Fax: 301-402-3443
>
> The NIH is committed to maintaining the highest standards for the
> protection of human subjects.
> P Please consider the environment before printing this e-mail
>

ADVANCED BIOSCIENCE RESOURCES, INC

December 14, 2009

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
903 S. 4th Street
Hamilton, MT 59840

Dear Kim,

This letter verifies that ABR, a non-profit tissue procurement organization, supplies requesting and approved scientific investigators with the types of human fetal tissues required for specific bio-medical research. When requested and as availability allows, human fetal tissue specimens will be retrieved from products of conception from induced first and second trimester abortions. Tissue will be distributed according to established protocols. Specimens are not collected for directed donation. .

ABR warrants that maternal consent from patients aged over eighteen years is obtained for the use of fetal tissue specimens for research purposes, including the consent for the potential of stem cell research utilizing such tissues, and that adequate records of such consent are maintained for future verification. Donor identification is coded and scientific investigators have no access to donor identification. ABR also warrants that maternal consent is obtained for phlebotomy and blood testing for a variety of disease entities.

ABR warrants that no payments will be made to any third party for the conduct of or the product of an abortion, including without limitation any parent(s) of any unborn fetus. ABR, to the best of its knowledge, also warrants that all tissue provided will have been obtained in compliance with local, state and federal laws and regulations governing the procurement and distribution of human tissue.

Sincerely,

Perrin Larton

Perrin Larton, CTBS
Procurement Manager

Federal E.I.N.: 94-3110160
California E.I.N.: 370-20518
FDA FEI: 3005208435

1516 Oak Street # 303 / Alameda, CA 94501 / 510-865-5872 / Fax 510-865-4090 / email abr@abr-inc.com

OHSR (NIH/DDIR)

From: Hasenkrug, Kim (NIH/NIAID) [E]
Sent: Monday, November 30, 2009 5:24 PM
To: OHSR (NIH/DDIR)
Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up
Flag Status: Green

Attachments: Re: HFT Application

Re: HFT Application

HasenkrugK_NIAID_4980_CY2009

Attached please find the requested email from ABR stating that no personally identifiable information will be released to me. Furthermore, I will not seek any such information from ABR.

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
Laboratory of Persistent Viral Diseases
Rocky Mountain Laboratories
National Institute of Allergy and Infectious Diseases National Institutes of Health
903 S. 4th Street
Hamilton, MT 59840
phone (406)363-9310
FAX (406)363-9286
khasenkrug@nih.gov

> From: "OHSR (NIH/DDIR)" <ohsr_nih_ddir@od.nih.gov>
> Date: Tue, 24 Nov 2009 10:27:55 -0500
> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
> Conversation: HasenkrugK_NIAID_4980_CY2009
> Subject: HasenkrugK_NIAID_4980_CY2009
>
> Good Afternoon Dr. Hasenkrug:
>
> Thank you for the opportunity to review your research project: Study
> of HIV infection & Vaccine Protection.. Since the work you are doing
> at the NIH provides little or no risk to human subjects off-site, OHSR
> has decided the appropriate action for you to take is the following:
>
> * Provide documentation that you will not seek the identity of the
> subjects who have provided the samples you will receive as well as
> documentation from ABR that under no circumstances will the identity
> or link to the identifiers of the subjects be released to you.
>
> An e-mail from you and from ABR holding the key to the code is
> sufficient documentation.

>
> This action is based on guidance issued on Aug. 10, 2004 by the HHS
> Office of Human Research Protections, the regulatory office for the
> protection of human subjects.
>
> Best regards,
>
>
>
> OHSR - National Institutes of Health
> Bldg 10, Suite 2C146
> Bethesda, MD 20892
> Office Telephone: 301-402-3444
> Office Fax: 301-402-3443
>
> The NIH is committed to maintaining the highest standards for the
> protection of human subjects.
> P Please consider the environment before printing this e-mail
>

OHSR (NIH/DDIR)

From: Perrin Larton (b)(6)

Sent: Monday, November 30, 2009 5:10 PM

To: Hasenkrug, Kim (NIH/NIAID) [E]

Cc: (b)(6)

Subject: Re: HFT Application

Hi Kim,

All tissue is numerically coded and the personally identifiable information is never available. In other NIH applications we've had requests for letters that state NO information is available to researchers. I can send you a letter to that effect...but tissue cannot be tracked back to a specific patient. We guarantee anonymity to the patients donating tissue.

Perrin

> Dear Perrin, the Office of Human Subjects Research is asking me for a
> letter
> from you stating that personally identifiable information regarding the
> fetal tissue will be revealed to me. Would you kindly send me a letter
> stating such so that I can forward it to them? It would be greatly
> appreciated and let us begin our experiments. I attached a copy your
> letter
> regarding approval of our application for your information. Thank you
> very
> much, Perrin.
>
> Kim
>
> Kim J Hasenkrug, Ph.D.
> Senior Investigator
> Chief, Retroviral Immunology Section
> Laboratory of Persistent Viral Diseases
> Rocky Mountain Laboratories
> National Institute of Allergy and Infectious Diseases
> National Institutes of Health
> 903 S. 4th Street
> Hamilton, MT 59840
> phone (406)363-9310
> FAX (406)363-9286
> khasenkrug@nih.gov
>
> Disclaimer:
> The information in this e-mail and any of its attachments is confidential
> and may contain sensitive information. It should not be used by anyone who
> is not the original intended recipient. If you have received this e-mail
> in
> error please inform the sender and delete it from your mailbox or any
> other
> storage devices. National Institute of Allergy and Infectious Diseases
> shall
> not accept liability for any statements made that are sender's own and not
> expressly made on behalf of the NIAID by one of its representatives

>
>
>> From: Perrin Larton (b)(6)
>> Reply-To: (b)(6)
>> Date: Mon, 2 Nov 2009 13:40:51 -0500
>> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
>> Conversation: HFT Application
>> Subject: HFT Application
>>
>> Dear Kim,
>>
>> Attached you'll find the documents we just discussed. What I'll need
>> back
>> from you is the two page application as well as a short synopsis of the
>> work you'll be doing. As soon as I get the completed application from
>> you
>> it will go to our Scientific Advisory Board for review and approval. If
>> they have questions, I'll give you a call. Approval usually takes 5-10
>> working days from the time I receive the application from you.
>>
>> Please send your application back to my e-mail address
>> (b)(6)
>> or FAX to 510-865-4090.
>>
>> Thanks so much for your interest in the services supplied by Advanced
>> Bioscience Resources. I apologize again for taking such a long time to
>> respond to your query.
>>
>> Perrin Larton CTBS
>> Procurement Manager
>> Advanced Bioscience Resources
>
>

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Tuesday, November 24, 2009 10:28 AM
To: Hasenkrug, Kim (NIH/NIAID) [E]
Subject: HasenkrugK_NIAID_4980_CY2009

Good Afternoon Dr. Hasenkrug:

Thank you for the opportunity to review your research project: ***Study of HIV infection & Vaccine Protection..*** Since the work you are doing at the NIH provides little or no risk to human subjects off-site, OHSR has decided the appropriate action for you to take is the following:

- Provide documentation that you will not seek the identity of the subjects who have provided the samples you will receive as well as documentation from ABR that under no circumstances will the identity or link to the identifiers of the subjects be released to you.

An e-mail from you and from ABR holding the key to the code is sufficient documentation.

This action is based on guidance issued on Aug. 10, 2004 by the HHS Office of Human Research Protections, the regulatory office for the protection of human subjects.

Best regards,

OHSR - National Institutes of Health
Bldg 10, Suite 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

The NIH is committed to maintaining the highest standards for the protection of human subjects.


Please consider the environment before printing this e-mail

ADVANCED BIOSCIENCE RESOURCES, INC.

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
5/17/2017	(b)(6)	1033628
	TERMS	CUSTOMER #
	Due Upon Receipt	0522

BILL TO

Rocky Mountain Labs
NIH/NIAID
Kim J. Hasenkrug
903 S. 4th Street
Hamilton, MT 59840

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
5/17/2017	311702	6559	21	Thymus, 2nd Trimester	HASENKRUG	(b)(4)
5/17/2017	311702	6560	21	Liver, 2nd Trimester	HASENKRUG	
				05/19/17 PAID via VISA (b)(6) Request by Kim Hasenkrug.		

Sale
Entry Method: Manual
VISA
Total: $ 680.00
05/19/17 15:05:13
Inv #: 000005 Appr Code: 065208
Approved: Online Batch#: 139001
AVS Code: ZIP MATCH 2
CVV2 Code: MATCH M

Total $680.00

1516 Oak Street, Suite 303 / Alameda, California 94501 USA / Phn (510) 865-5872 / Fax (510) 865-4090 / email: abr@abr-inc.com

SEQ: 1846665	PO#: (b)(6)		Requester: Messer, Ronald

CAN: 8335424 FY: 17 Owner: (b)(6)
Order Total: 680.00 Project: 107833
Date Needed: 04/17/2017 Emergency: No Order Type: Purchase Card
Requestor Phone: +1 406 363 9276 Order Status: Archive

Vendor Advanced Bioscience Resources,1516 Oak Street, Suite 303, Alameda, CA 94501
Phone: 510-865-5872 SmlBs: No FSS:
EIN: BPA: GSA:
Site: Clerk:
E-mail:

#	Description	CAN	Catalog	OC Code	Category	Qty at Price	Total
1	Tissue, 2nd Trimester (1 each of liver and thymus)	8335424	none	2613	6509	(b)(4)	680.00
2	shipping	8335424		2613	6509	1 each at $0	.00
Order Total: 680.00							

Ship To: Ronald Messer,3220 ,RML CNTRL REC,RMTLAB

QUOTES

Vendor	Price	Good Until	Available
There are no quotes in the order			

JUSTIFICATION

These tissues, liver and thymus, are required by Ron Messer for ongoing studies of HIV in the Hasenkrug Lab. Our mice are ready for reconstitution. Please let me know when I can contact Perrin Larton at ABR to place our request on their schedule. Please contact the vendor at 510-865-5872 ext (b)(6) -give her the PO number Thanks, Ron. *** I certify that I have checked the sources of supply and services listed in FAR 8.002. ( ) I have purchased from the highest priority source available. (X) I did not purchase from a priority source because none could satisfy the requirement of the government either in product/service specifications, quality or required delivery time. **********NOTE to Purchasing Agent: Call vendor at 510-865-5872 ext (b)(6) give her the PO number and credit card information.

Alternate Sources:

NIH Surplus: No	UNICOR: No	GSA Stock Catalog: No	GSA Self Service: No	Federal Supply: No	Open Market: Yes

AGENT

Purchase Order #: (b)(6) Estimated Ship Date:
Custodial Code: 30102 Date Entered into NBS: 04/19/2017
Order Reference: em'd (b)(6) Expected Delivery Date: 04/28/2017
FSS: Select Agents: No
NBS Ref Order #: 4563860 Clearance Requested: No

SF-37 Code:

Notes

There are no notes in the order

IT Clearance

Never seen by IT officer

ROUTE HISTORY

Role Summary

User Role	Name
Requester	Messer, Ronald
Releaser	Messer, Ronald
Admin Officer	(b)(6)
Lead Admin Officer	
Purchase Agent	(b)(6)
Lead Agent	
IT Clearance Officer	
Releaser1	
Releaser2	
NBS	
Receiving Official	

Dates

Description	Date
Needed By	04/17/2017
Submitted to NBS	04/19/2017
NBS Confirmation	04/20/2017
Award Created	04/19/2017
Award Received	04/19/2017
Estimated Ship Date	
Received	05/15/2017
Canceled	

Routing History

Name	Role	Date In	STATUS IN	ACTION
Messer, Ronald	Requester	04/13/2017	New order	Approved
(b)(6)	Administrative Officer	04/13/2017	Released	Approved
	Purchasing Agent	04/14/2017	Approved	Approved
NBS, NBS	NBS	04/19/2017	Sent to NBS	Approved
Messer, Ronald (b)(6)	Requester for receiving	04/19/2017	Pending receiving	Take
(b)(6)	Requester for receiving	05/15/2017	Pending receiving	Approved
	Archive	05/15/2017	Archive	(N/A)

Receiving Report

#	Description	Total Qty Ordered	Total Qty Received	Date Received
1	Tissue, 2nd Trimester (1 each of liver and thymus)	2	2	05/15/2017
2	shipping	1	1	05/15/2017

OHSR RESPONSE TO REQUEST FOR REVIEW OF RESEARCH ACTIVITY
INVOLVING HUMAN SUBJECTS

FAX:

Exempt: #: 4980

To: Hasenkrug, Kim
NIAID
RML - Rocky Mountain Laboratories, 3/218

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
Recent reports have demonstrated that immunodeficient mice reconstituted with 17-19 week old human fetal tissue develop a human immune system and are susceptible to HIV infection and disease. The goal of this project proposal is to create such humanized mice to study the role of immune cell subsets and virus-neutralizing antibodies in vaccine protection. The experiments will entail the development of a cohort of mice all reconstituted with the same human cells so as to be histocompatible. This will require transplantation of

Original Request Received in OHSR on: 11/19/2009

Responsible NIH Research Investigator(s): Kim Hasenkrug, NIAID

OHSR review of your request dated Thu, Nov 19, 2009 has determined that:

☒ Federal regulations for the protection of human subjects do not apply to above named activity. The OHSR determination of Not Human Subjects Research is based on the interpretation of 45 CFR 46 under "Research Involving Coded Private Information or Biological Specimens" (OHRP, Revised October 16, 2008) and Guidance on Engagement of Institutions in Human Subjects Research (October 16, 2008). NOTIFY OHSR VIA AN E-MAIL AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESEARCH ACTIVITY.

☐ The activity is designated **EXEMPT**, and has been entered in the OHSR database. PLEASE NOTIFY OHSR OF ANY **SIGNIFICANT** CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.

☐ **NOT EXEMPT**. OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additional information in order to determine whether expedited or full review is appropriate.

☐ Confidentiality Agreement

☐ Reliance

☐ Amendment

☐ Other

Office Person LB Admin Assist. CB

Note:
(b)(6)

CIP

for Charlotte Holden, JD — Acting Director, OHSR — 12/14/2009
Signature — Title — Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: Yes

OHSR Use Only
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

#4980

REQUEST FOR REVIEW OF RESEARCH ACTIVITY INVOLVING HUMAN SUBJECTS

INSTRUCTIONS: Please type directly on this form. You can expand the document if you need more space. If your research involves a survey or questionnaire, please attach it to this completed form.

Completed forms (with all required signatures) may be sent to OHSR by FAX (301-402-3443), email to ohsr_nih_ddir@od.nih.gov, or by mail (2C146). If you have any questions, call OHSR at (301) 402-3444.

Date: 11/19/2009

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146

From: Kim J Hasenkrug
(Signature)

Through: (b)(6) (acting)
(Signature of appropriate Official for IC, e.g., Lab/Branch Chief)

Protocol Title: Study of HIV infection and vaccine protection in mice reconstituted with a human immune system

Name of NIH Principal Investigator(s): Kim J Hasenkrug, Senior Investigator

IC NIAID Laboratory/Branch LPVD Building & Room No. RML 3218
Tel. No. 406-363-9310 FAX No. 406-363-9286
Is the Principal investigator an NIH employee? x **Yes** ____ **No**

If no, please explain: ____

1. What is the proposed research activity that you intend to perform at NIH (please use lay terms):

Recent reports have demonstrated that immunodeficient mice reconstituted with 17-19 week old human fetal tissue develop a human immune system and are susceptible to HIV infection and disease. The goal of this project proposal is to create such humanized mice to study the role of immune cell subsets and virus-neutralizing antibodies in vaccine protection. The experiments will entail the development of a cohort of mice all reconstituted with the same human cells so as to be histocompatible. This will require transplantation of the mice with 1 mm^3 pieces of fetal thymus as well as reconstitution with stem cells isolated from cord blood and liver. Once the humanized mice have been established some will be vaccinated to prime distinct subsets of immune cells. Immune cell subsets from vaccinated mice will be adoptively transferred into naïve mice, which will then be infected with HIV to

test the antiviral activity of the immune cells. The goal of these experiments is to establish correlates of immunity against HIV.

2. If applicable, list your non-NIH Collaborating Investigator(s).

Name Institution Address Tel. # FAX #

3. Proposed start date of your research __April, 2010_____
Proposed completion date _April, 2013_____

4. Will you be _____these samples or data?

Collecting Yes/(No)
Receiving (Yes)/No
Sending Yes/(No)

5. Do the samples or data:
(a) Already exist?___Yes _x__No

(b) Or are they being collected for the express purpose of this study? _X__Yes __No
If "yes," please describe:_

17-19 week fetal cells and tissue will be obtained from Advanced Bioscience Resources, Inc., a non-profit foundation established under California law to provide biomedical researchers access to human tissues in compliance with state, federal, and NIH guidelines. Consent to donate is obtained in accordance with UAGA and NOTA guidelines. Related documents including the consent form are attached._____

(c) Or a combination of (a) and (b)? ____Yes _____No

6. What role will you have in this research project? (Check all that apply)

___ Analyze samples/data only.

___ Consultant/advisor to collaborator(s) listed above.

___ Author of the protocol that is being implemented by your collaborating investigator (identified in question #2).

___ Co-authorship on publication(s)/manuscript(s) pertaining to this research.

___ You or NIH hold an IND for this research.

__X_ Decisional authority over the design or implementation of the research at the IRB approved site? If so, please explain.

I am the PI and lead investigator on this project which will take place in my laboratory and the animal care facilities at Rocky Mountain Labs, NIAID, NIH.

___Other (If necessary, use this space to describe your role in this research).

7. Where are the subjects of this research activity located?
The material for this research is obtained from natural or induced abortions from females in California. Thus the tissues and cells involved will not be from living humans.

8. If human subjects are located elsewhere (not at NIH), will you have direct contact or intervention with them? (Examples: as subject's physician; in obtaining samples directly from the subject; by interviewing the subject?) ____ Yes __x__No

9. What kind of human samples (e.g., tissue, blood) or data (e.g., private information, responses to questionnaires) will be involved in your research?
_Samples will include cord blood, fetal blood, thymus, liver, and bone marrow. No private information will be involved._____

---

10. If the samples, data do not come from an IRB approved protocol, do they come from:

(a) Repository ____Yes ___ No

(b) Pathological waste ___ Yes _____No

(c) Autopsy material ___ Yes ___ No

(d) Publicly available source _X__Yes ___ No

(e) Other_____

11. Please check the box(es) that apply(ies) to the samples/data that you will receive.

(a) ____ Samples and/or data will be anonymized/unlinked. (The samples/data cannot be linked to individual subjects by you or your collaborators at other sites.)

(b) ___ Samples and/or data will be coded, however that code cannot be used by either the sender or the receiver to identify specific individuals.

(c) __X_ Samples and/or data will be coded so that the provider of the samples/data can link them to specific individuals but the receiver will not be able to do so.

12. Will you send results back to the provider(s) (listed in question 2 of this form)?

(a) __X_ No, I will not send results back to the provider(s).

(b) ___ Yes, I will send aggregate results to the provider(s).

(c) ___ Yes, I will send results to the provider(s) that are linked to identifiable individuals.

If yes, does the provider intend to link your data to identifiable individuals?
_____Yes _____No

13. Has the research activity <u>that you are proposing in this form</u> been approved by an Institutional Review Board (IRB) elsewhere?

_____ Yes, the NIH research activity has been reviewed by the following IRB (s) (Please provide the following information for each IRB):

_____ Name of institution that provided the review

_____ Address of reviewing institution

_____ Name of PI for the IRB approved protocol

_____ Title of IRB approved protocol and protocol #

_____ Federal Wide Assurance (FWA) number**

___X_____No IRB review of the research activity described in question #1 above has taken place

(**An FWA is a contract between the U.S. Department of Health and Human Services (DHHS) and an entity receiving DHHS funds to conduct clinical research that the latter will follow ethical guidelines and federal regulations for the protection of human subjects. For a list of domestic and international institutions go to http://ohrp.cit.nih.gov/search/asearch.asp#ASUR

14. Per NIH guidance*, have conflicts of interest by NIH employees, if any, been resolved?**

__X___Yes _____No no conflicts of interest

If your answer is no, please see your Clinical Director about this matter before proceeding with this research.

***The January 5, 2005 NIH Guide to Preventing Conflict of Interest applies to all research conducted at NIH, http://ohsr.od.nih.gov/New/mpafwa_docs.html

ADVANCED BIOSCIENCE RESOURCES, INC

OVERVIEW

ADVANCED BIOSCIENCE RESOURCES is a non-profit corporate foundation established in 1989 under California law to provide biomedical researchers with access to human tissues. ABR was formed exclusively for biomedical, scientific, and educational purposes and is devoted to providing services in connection with the procurement of human organs and tissues for medical and scientific research. ABR specializes in the procurement, preservation and distribution of both human fetal tissues and full term umbilical cord blood for research, and provides a highly individualized, reliable and easily accessible service.

TISSUE COLLECTION AND DISTRIBUTION: The purpose of ABR is to promote cooperative efforts to collect and distribute human tissues and to thereby facilitate research utilizing those tissues. Trained personnel coordinate the retrieval, preservation and delivery of each specimen.

Tissues obtained through ABR are retrieved from routinely performed surgical procedures including first and second trimester induced abortions, and full term deliveries, either natural or caesarian section. Tissues that were once discarded are now available to scientists worldwide through the efforts of ABR. Researchers may specify tissue characteristics, preservation methods, and delivery times.

PRESERVATION METHODS: Each specimen is collected, preserved, and shipped according to the investigator's individual protocol.

QUALITY CONTROL: ABR practices strict quality control procedures and adheres to stringent guidelines for tissue collection and preservation. Consent is obtained in accordance with UAGA and NOTA guidelines. Tissue specimens are identified, dissected, and transferred to the specified medium. A control number is then assigned to each sample to ensure confidentiality of patient identity.

To assure proper processing of the tissue, every researcher selects a collection/preservation protocol tailored specifically to his needs. In the collection and distribution of these tissues, every effort is made to exercise the highest standards of medical and laboratory practice. ABR specializes in direct communication with each investigator from the initial application to specimen delivery.

INVESTIGATOR APPROVAL: ABR will provide tissue to researchers who provide information on current research funding, and a short summary of their research intent. Investigators must agree to accept responsibility for the potential biohazard of the tissue and to appropriately train laboratory personnel in the proper handling of the tissue. In addition, the researcher must agree to use the tissue solely for research purpose and to acknowledge ABR in any publications resulting from the use of ABR provided tissue.

APPLICATION PROCESS: To request human tissue for research, an application must be completed and submitted to ABR. The application will be reviewed for feasibility and priority. A protocol will be developed to meet individual research needs as identified in the application.

SERVICE AND PROCESSING FEES: Participating medical facilities that enable ABR to enact its tissue acquisition and distribution programs may be paid a nominal fee for such services. A minimal processing / preservation / shipment fee is also assessed for services provided to research facilities.

1516 Oak Street # 303 / Alameda, CA 94501 / 510-865-5872 / Fax 510-865-4090 / email abr@abr-inc.com

Recent advancements in medical research have been developed through the use of human tissues in scientific study. Diseases such as diabetes, hemophilia, Parkinson's disease, cancer, AIDS, heart and lung disease, as well as genetic and,neonatal disorders, are being investigated for the development of cures through the use of human fetal tissues. Any tissue donated may be distributed to medical institutions and private research groups in the United States and internationally to enhance the development of cures and therapies for disease.

PERMISSION FOR DONATION OF TISSUE
OBTAINED AT THE TIME OF ABORTION

I have previously decided to have an abortion and have previously consented to having such abortion.

I hereby donate the aborted material and/or a sample of my blood as an anatomical gift for the purposes of education, research, or for the advancement of medical science. I understand that my donation may be used by research facilities in the United States and abroad.

I also agree that a sample of my blood may be taken after the abortion and that it may be used for research and routine testing for AIDS, hepatitis, or other infectious agents. I understand that, if there is testing, the results will be confidential unless the law requires that they be disclosed.

I understand that the aborted material may be used to derive human pluripotent stem cells for medical research and possibly human transplantation research, and that these cells may be kept for many years. I also understand that my donation may be used for cosmetic purposes. I understand that there is no information associated with aborted material that could link me with my donation. I agree that this donation is made without any restriction or direction regarding the potential recipients of the cells derived from the aborted material and that I have not been informed of the identity of any potential recipients.

I understand that there will be no payment to me and I agree that, although the results of the research on the aborted material may have commercial value, I will have no property or other commercial or financial rights in the aborted material or any product, process, or service which may result from this donation.

I understand that my donation will not result in any direct medical benefit to me.

I understand that my donation is voluntary, and I may refuse to donate aborted material and this will not affect my medical care or my relationship with my physician.

I understand that, if I have any questions about my donation, I can contact ABR at 510-865-5872.

_____ _____
Signature Date

I choose not to participate.

_____ _____
Signature Date

_____ _____
Witness Date

ADVANCED BIOSCIENCE RESOURCES, INC.

APPLICATION FOR THE ACQUISITION OF

HUMAN FETAL TISSUE FOR RESEARCH

All requests for human fetal tissue are reviewed for feasibility of procurement and preparation. When approved, an individual protocol will be developed for the procurement, preparation and delivery of tissue samples, based on the information provided in this application and any subsequent communication.

I. APPLICANT INFORMATION

NAME: Kim J Hasenkrug

TITLE: Senior Investigator

COMPANY: NIAID, NIH

ADDRESS: Rocky Mountain Lab

ADDRESS: 903 S. 4th St

CITY,ST,ZIP: Hamilton, MT 59840

PHONE #: 406-363-9310

ALT. #:

FAX #: 406-363-9286

EMAIL: khasenkrug@nih.gov

DELIVERY OPTIONS:

__X__ Same Day: Commercial carrier, hand delivered
Maximizes cell viability (*geographical limits*)

_____ Next Day: Pickup, delivery Mon-Sat daytime
Economical for fresh, frozen specimens

Applicant will be charged for delivery fees.

Applicant may designate preferred carrier:

Carrier Name: FEDEX

Account #: (b)(4)

BILLING INFORMATION:

BILL TO: Kim J Hasenkrug

COMPANY: Rocky Mountain Labs

ADDRESS: 903 S. 4th St.

ADDRESS:

CITY,ST,ZIP: Hamilton, MT 59840

ACCOUNTING DEPT. PHONE #: 406-363-9438

P.O. # (if required by your company):

P.O. # is not required to submit application

Credit Card #:

Name on CC:

Expiration Date: VISA/MC

SHIP TO: Kim J Hasenkrug
Rocky Mountain Labs
903 S. 4th St
Hamilton, MT 59840

Please indicate how you heard about ABR: (b)(6)

II. HUMAN FETAL TISSUE

Tissue specimens requested: thymus, liver, cord blood

Preferred gestational age (6-24 weeks): 17-19 wks

Proposed starting date: May, 2010

CONTAGIOUS DISEASE SCREENING: Availability of test results varies from 24 hours to 7 days after procurement. Applicant requires the following tests to be performed by ABR:

__X__ No testing required

_____ HIV _____ HSV
_____ HBSAG _____ RPR
_____ CMV _____ HCV

OTHER_____

III. PRESERVATION

ABR uses *BioWhittaker RPMI-1640 With L-Glutamine* for tissue preparation, preservation and shipment. Applicant may supply ABR with other media specific to research needs. Please indicate preference below.

PRESERVATION METHODS AVAILABLE:

__X__ Fresh; shipped on wet ice
_____ Passive freezing on dry ice; shipped on dry ice
_____ "Snap" freezing in LN2; shipped on dry ice
_____ Media provided by applicant
_____ Media provided by ABR (RPMI)

IV. DONOR INFORMATION

CONSENT VERIFICATION: Consent for tissue donation is obtained prior to specimen procurement. The consent is extremely confidential in nature and shall not be communicated to the researcher.

SPECIFIC DONOR INFORMATION: Charts are routinely examined for patient medical histories. Please identify any specific information sought and indicate contraindications to specimen procurement:

_____HIV+ status contraindicates procurement_____

_____

_____

V. RESEARCH DATA

TITLE OF RESEARCH PROJECT: ___The role of virus-specific CD4+__T cells, CD8+ T cells and antibody in vaccine protection against HIV-1 in humanized mice_____

ABR will provide tissue to researchers who provide information on current research funding, and a short summary of their research intent. **(Please attach a brief synopsis of the research project named above.)** Researchers must agree to use the tissue solely for research purposes and to acknowledge ABR in any publications resulting from the use of ABR provided tissue. Updates on research progress will be requested at six-month intervals. Researchers agree to publish the results of the research as promptly after the completion of the research as is reasonably possible without jeopardizing the sponsor's right to secure patents or copyrights necessary to protect its ownership or control of the results of the research. Researchers agree to inform ABR of the name of the publication and the date of the issue in which the results will be published. It is the intent of this requirement to make the results available to the general public through acceptable means of publication.

VI. SOURCE OF FUNDING

Please identify the primary source of funding for this project.

NIH _X___ Other Federal or State Grants _____ Foundation Grants _____ Other (specify) _____

If this application is approved by ABR, ABR shall provide services to the applicant in accordance with the terms and the other conditions on the reverse side, and the signature of the applicant shall constitute acceptance of all such terms and conditions by applicant. The entire agreement between ABR and applicant relating to the services provided by ABR is expressly set forth herein, and any modification of or addition thereto shall be of no force or effect unless it is in writing and signed on behalf of ABR by a duly authorized representative.

BY SIGNING BELOW, THE APPLICANT ACKNOWLEDGES HAVING READ THE TERMS AND CONDITIONS ON THE FOLLOWING PAGE AND AGREES TO SUCH TERMS AND CONDITIONS.

Kim J Havenhuys

____ _____

_Senior Investigator_____
SIGNATURE and TITLE of APPLICANT

DATE 11/2/2009

Please return to:

ADVANCED BIOSCIENCE RESOURCES, INC.
1516 OAK STREET, SUITE 303
ALAMEDA, CALIFORNIA 94501
Telephone: 510-865-5872
Fax: 510-865-4090
Email: abr@abr-inc.com

TERMS AND CONDITIONS OF SERVICES

1. Services

1.1 During the term of this agreement, and pursuant to the terms and conditions hereinafter set forth, ABR will use its best efforts to provide services in connection with supplying researcher with the types of human tissues set forth in this application, as approved

by ABR, suitable for researcher requirements and in the amounts requested based upon ongoing discussions between researcher and ABR pursuant to the information sent by ABR.

1.2 Researcher acknowledges and agrees that ABR will provide the following types of services:

Removing tissue.
Preserving and processing tissue to a form suitable to the researcher needs.
Seeking consent for tissue donations from appropriate individuals, obtaining validly executed consent forms, and maintaining records of such consents in accordance.
Obtaining, labeling, storing, and delivering samples of donor or other required serum, and maintaining a system for matching such samples to specific tissue donations.
Preserving tissue viability and cleanliness during removal, processing, preservation, storage and transportation.
Storing tissue and transporting it to researcher in accordance with section 5.

1.3 In the event that tissues of the type specified in the application become unavailable to ABR, such that ABR is unable to perform the contemplated services, ABR shall have no obligation to perform such services.

2. Representations and Warranties. ABR hereby represents and warrants to researcher that (i) ABR will make no payments to anyone for any tissue transferred in connection with this agreement, and (ii) ABR will verify for each tissue delivery that appropriate consent was obtained for use of such tissue and any associated serum samples, and that adequate records of such consent are maintained; provided, however, that the parties hereto acknowledge and agree that such consents are extremely confidential in nature and shall not, in any case, be communicated to researcher. Researcher hereby represents and warrants to ABR that (i) researcher will neither sell nor transfer for valuable consideration any tissue received through ABR to anyone, (ii) researcher will use the tissue only to satisfy its objectives, which are, as acknowledged and agreed hereto, [research and clinical use], (iii) researcher agrees to inform ABR of any changes in clinical or research use of specimens received from ABR, or in any specifications, constraints, etc. in a timely manner, and (iv) researcher understands the bio-hazardous nature of human tissue and agrees to take proper precautionary measures at all times when handling tissue specimen.

3. Terms. The terms of this agreement shall be for one (1) year, beginning from the date hereof, and terminating one (1) year thereafter, unless either of the parties hereto shall have given to the other thirty (30) days written notice of its intention to terminate this agreement, whereupon same shall terminate thirty (30) days after date of said notice.

In default of notice as aforesaid from either party hereto, this agreement shall continue for further successive terms of one (1) year thereafter and in default of thirty (30) days written notice before the end of an annual term by either of the parties of its intention not to renew, whereupon this agreement shall terminate at the end of said term.

4. Payments. Researcher agrees to pay to ADR a fee for costs incurred by ABR in providing services in connection with the acquisition of each sample of tissue requested by researcher, to be mutually agreed upon by ABR and researcher upon approval of this agreement by ABR.

5. Shipment services.

5.1 All shipments will be made as soon as possible after request has been received by ABR from researcher.

5.2 Researcher acknowledges that networks of tissue availability are neither permanent nor dependable, but rather they fluctuate. However, ABR shall use its best efforts to transfer the tissue in the amounts requested by researcher.

5.3 Shipment will be made in the best possible manner so as to preserve the quality of the tissues. It is understood that the fragility of human tissue is such that damage may occur during shipment. ABR will use its best efforts to comply with the handling and shipment protocols provided by researcher.

5.4 ABR will package the tissue appropriately and, if so requested by researcher, will insure the shipment. Researcher agrees to bear all costs associated with insurance and shipment of any tissue.

5.5 The risk of loss and damage of any tissue or organs shall pass immediately to researcher when the shipment of such tissue or organs is deposited with a carrier for transportation at the F.O.B. point.

6. Limitation of liability. ABR shall not be responsible or liable under any section of this agreement or under any contract, negligence, strict liability or other legal or equitable theory, for the cost of procurement of substitutive services, or any indirect, incidental or consequential damages including, but not limited to loss of revenues and loss of profits. Any liability of ABR under any theory whatsoever will be limited exclusively to the provision of equivalent services by ABR or, if unenforceable, to payment of an amount not greater than any amount actually received by ABR from researcher on account of this agreement.

7. No warranties. It is understood that human tissue is by nature neither permanent nor dependable. Except as expressly set forth in this agreement, ABR makes no representation of any kind, expressed or implied, including any representation with respect to the safety, efficacy or merchantability or the fitness for any purpose with respect to the tissue transferred to researcher in connection with this agreement.

8. Indemnification. Researcher shall indemnify, defend and hold ABR harmless from and against all claims, causes of actions, suits, damages and costs arising out of, resulting from, or otherwise in respect of, the use of tissue transferred in connection with this agreement, except where such claims are the result of negligence of ABR, its employees, staff or agents to (i) comply with any governmental requirements, or (ii) adhere to the terms of this agreement.

9. General. This agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of law. This agreement may not be assigned by either party without the prior written consent of the other.

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Monday, November 23, 2009 10:43 AM
To: Hasenkrug, Kim (NIH/NIAID) [E]
Subject: Request for Review Rec'd-OHSR 4980

Good morning Dr. Hasenkrug,

This email is to verify that OHSR has received your Request for Review of Research and it is currently being processed as OHSR #4980. Please use this number in any future correspondence regarding this study. We will contact you via email if any additional information is needed. If you have not heard from OHSR within 7 business days, please contact us.

Protocol Title: Study of HIV infection and vaccine protection in mice reconstituted with a human immune system

Thank you.

OHSR:
Ph: 301.402.3444
Fax: 301.402.3443

Thank you.

Sincerely,

(b)(6)

OHSR (NIH/DDIR)

From: Hasenkrug, Kim (NIH/NIAID) [E]
Sent: Wednesday, December 09, 2009 5:41 PM
To: OHSR (NIH/DDIR)
Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up
Flag Status: Green

Attachments: IRB Letter with letterhead nonidentity.doc

IRB Letter with letterhead non...

Here is the letter on official ABR letterhead for you

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
Laboratory of Persistent Viral Diseases
Rocky Mountain Laboratories
National Institute of Allergy and Infectious Diseases National Institutes of Health
903 S. 4th Street
Hamilton, MT 59840
phone (406)363-9310
FAX (406)363-9286
khasenkrug@nih.gov

> From: "OHSR (NIH/DDIR)" <ohsr_nih_ddir@od.nih.gov>
> Date: Tue, 24 Nov 2009 10:27:55 -0500
> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
> Conversation: HasenkrugK_NIAID_4980_CY2009
> Subject: HasenkrugK_NIAID_4980_CY2009
>
> Good Afternoon Dr. Hasenkrug:
>
> Thank you for the opportunity to review your research project: Study
> of HIV infection & Vaccine Protection.. Since the work you are doing
> at the NIH provides little or no risk to human subjects off-site, OHSR
> has decided the appropriate action for you to take is the following:
>
> * Provide documentation that you will not seek the identity of the
> subjects who have provided the samples you will receive as well as
> documentation from ABR that under no circumstances will the identity
> or link to the identifiers of the subjects be released to you.
>
> An e-mail from you and from ABR holding the key to the code is
> sufficient documentation.
>
> This action is based on guidance issued on Aug. 10, 2004 by the HHS
> Office of Human Research Protections, the regulatory office for the
> protection of human subjects.

> Best regards,
>
>
>
> OHSR - National Institutes of Health
> Bldg 10, Suite 2C146
> Bethesda, MD 20892
> Office Telephone: 301-402-3444
> Office Fax: 301-402-3443
>
> The NIH is committed to maintaining the highest standards for the
> protection of human subjects.
> P Please consider the environment before printing this e-mail
>

ADVANCED BIOSCIENCE RESOURCES, INC

December 14, 2009

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
903 S. 4th Street
Hamilton, MT 59840

Dear Kim,

This letter verifies that ABR, a non-profit tissue procurement organization, supplies requesting and approved scientific investigators with the types of human fetal tissues required for specific bio-medical research. When requested and as availability allows, human fetal tissue specimens will be retrieved from products of conception from induced first and second trimester abortions. Tissue will be distributed according to established protocols. Specimens are not collected for directed donation. .

ABR warrants that maternal consent from patients aged over eighteen years is obtained for the use of fetal tissue specimens for research purposes, including the consent for the potential of stem cell research utilizing such tissues, and that adequate records of such consent are maintained for future verification. Donor identification is coded and scientific investigators have no access to donor identification. ABR also warrants that maternal consent is obtained for phlebotomy and blood testing for a variety of disease entities.

ABR warrants that no payments will be made to any third party for the conduct of or the product of an abortion, including without limitation any parent(s) of any unborn fetus. ABR, to the best of its knowledge, also warrants that all tissue provided will have been obtained in compliance with local, state and federal laws and regulations governing the procurement and distribution of human tissue.

Sincerely,

Perrin Larton

Perrin Larton, CTBS
Procurement Manager

Federal E.I.N.: 94-3110160
California E.I.N.: 370-20518
FDA FEI: 3005208435

1516 Oak Street # 303 / Alameda, CA 94501 / 510-865-5872 / Fax 510-865-4090 / email abr@abr-inc.com

OHSR (NIH/DDIR)

From: Hasenkrug, Kim (NIH/NIAID) [E]
Sent: Monday, November 30, 2009 5:24 PM
To: OHSR (NIH/DDIR)
Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up
Flag Status: Green

Attachments: Re: HFT Application

Re: HFT Application

HasenkrugK_NIAID_4980_CY2009

Attached please find the requested email from ABR stating that no personally identifiable information will be released to me. Furthermore, I will not seek any such information from ABR.

Kim J Hasenkrug, Ph.D.
Senior Investigator
Chief, Retroviral Immunology Section
Laboratory of Persistent Viral Diseases
Rocky Mountain Laboratories
National Institute of Allergy and Infectious Diseases National Institutes of Health
903 S. 4th Street
Hamilton, MT 59840
phone (406)363-9310
FAX (406)363-9286
khasenkrug@nih.gov

> From: "OHSR (NIH/DDIR)" <ohsr_nih_ddir@od.nih.gov>
> Date: Tue, 24 Nov 2009 10:27:55 -0500
> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
> Conversation: HasenkrugK_NIAID_4980_CY2009
> Subject: HasenkrugK_NIAID_4980_CY2009
>
> Good Afternoon Dr. Hasenkrug:
>
> Thank you for the opportunity to review your research project: Study
> of HIV infection & Vaccine Protection.. Since the work you are doing
> at the NIH provides little or no risk to human subjects off-site, OHSR
> has decided the appropriate action for you to take is the following:
>
> * Provide documentation that you will not seek the identity of the
> subjects who have provided the samples you will receive as well as
> documentation from ABR that under no circumstances will the identity
> or link to the identifiers of the subjects be released to you.
>
> An e-mail from you and from ABR holding the key to the code is
> sufficient documentation.

>
> This action is based on guidance issued on Aug. 10, 2004 by the HHS
> Office of Human Research Protections, the regulatory office for the
> protection of human subjects.
>
> Best regards,
>
>
>
> OHSR - National Institutes of Health
> Bldg 10, Suite 2C146
> Bethesda, MD 20892
> Office Telephone: 301-402-3444
> Office Fax: 301-402-3443
>
> The NIH is committed to maintaining the highest standards for the
> protection of human subjects.
> P Please consider the environment before printing this e-mail
>

OHSR (NIH/DDIR)

From: Perrin Larton (b)(6)
Sent: Monday, November 30, 2009 5:10 PM
To: Hasenkrug, Kim (NIH/NIAID) [E]
Cc: (b)(6)
Subject: Re: HFT Application

Hi Kim,

All tissue is numerically coded and the personally identifiable information is never available. In other NIH applications we've had requests for letters that state NO information is available to researchers. I can send you a letter to that effect...but tissue cannot be tracked back to a specific patient. We guarantee anonymity to the patients donating tissue.

Perrin

> Dear Perrin, the Office of Human Subjects Research is asking me for a
> letter
> from you stating that personally identifiable information regarding the
> fetal tissue will be revealed to me. Would you kindly send me a letter
> stating such so that I can forward it to them? It would be greatly
> appreciated and let us begin our experiments. I attached a copy your
> letter
> regarding approval of our application for your information. Thank you
> very
> much, Perrin.
>
> Kim
>
> Kim J Hasenkrug, Ph.D.
> Senior Investigator
> Chief, Retroviral Immunology Section
> Laboratory of Persistent Viral Diseases
> Rocky Mountain Laboratories
> National Institute of Allergy and Infectious Diseases
> National Institutes of Health
> 903 S. 4th Street
> Hamilton, MT 59840
> phone (406)363-9310
> FAX (406)363-9286
> khasenkrug@nih.gov
>
> Disclaimer:
> The information in this e-mail and any of its attachments is confidential
> and may contain sensitive information. It should not be used by anyone who
> is not the original intended recipient. If you have received this e-mail
> in
> error please inform the sender and delete it from your mailbox or any
> other
> storage devices. National Institute of Allergy and Infectious Diseases
> shall
> not accept liability for any statements made that are sender's own and not
> expressly made on behalf of the NIAID by one of its representatives

>
>
>> From: Perrin Larton (b)(6)
>> Reply-To: (b)(6)
>> Date: Mon, 2 Nov 2009 13:40:51 -0500
>> To: "Hasenkrug, Kim (NIH/NIAID) [E]" <KHASENKRUG@niaid.nih.gov>
>> Conversation: HFT Application
>> Subject: HFT Application
>>
>> Dear Kim,
>>
>> Attached you'll find the documents we just discussed. What I'll need
>> back
>> from you is the two page application as well as a short synopsis of the
>> work you'll be doing. As soon as I get the completed application from
>> you
>> it will go to our Scientific Advisory Board for review and approval. If
>> they have questions, I'll give you a call. Approval usually takes 5-10
>> working days from the time I receive the application from you.
>>
>> Please send your application back to my e-mail address
>> (b)(6)
>> or FAX to 510-865-4090.
>>
>> Thanks so much for your interest in the services supplied by Advanced
>> Bioscience Resources. I apologize again for taking such a long time to
>> respond to your query.
>>
>> Perrin Larton CTBS
>> Procurement Manager
>> Advanced Bioscience Resources
>
>

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Tuesday, November 24, 2009 10:28 AM
To: Hasenkrug, Kim (NIH/NIAID) [E]
Subject: HasenkrugK_NIAID_4980_CY2009

Good Afternoon Dr. Hasenkrug:

Thank you for the opportunity to review your research project: ***Study of HIV infection & Vaccine Protection..*** Since the work you are doing at the NIH provides little or no risk to human subjects off-site, OHSR has decided the appropriate action for you to take is the following:

- Provide documentation that you will not seek the identity of the subjects who have provided the samples you will receive as well as documentation from ABR that under no circumstances will the identity or link to the identifiers of the subjects be released to you.

An e-mail from you and from ABR holding the key to the code is sufficient documentation.

This action is based on guidance issued on Aug. 10, 2004 by the HHS Office of Human Research Protections, the regulatory office for the protection of human subjects.

Best regards,

OHSR - National Institutes of Health
Bldg 10, Suite 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

The NIH is committed to maintaining the highest standards for the protection of human subjects.


Please consider the environment before printing this e-mail

ADVANCED BIOSCIENCE RESOURCES, INC.

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6/28/2017	(b)(6)	1033788
	TERMS	CUSTOMER #
	Due Upon Receipt	0522

BILL TO

Rocky Mountain Labs
NIH/NIAID
Kim J. Hasenkrug
903 S. 4th Street
Hamilton, MT 59840

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6/28/2017	672804	6783	22	Thymus, 2nd Trimester	Kim	(b)(4)
6/28/2017	672804	6784	22	Liver, 2nd Trimester	Kim	

Total $680.00

1516 Oak Street, Suite 303 / Alameda, California 94501 USA / Phn (510) 865-5872 / Fax (510) 865-4090 / email: abr@abr-inc.com

SEQ: 1851291	PO#: (b)(6)	Requester: Messer, Ronald

CAN: 8335424 FY: 17 Owner: (b)(6)
Order Total: 680.00 Project: 107833
Date Needed: 05/12/2017 Emergency: Yes Order Type: Purchase Card
Requestor Phone: +1 406 363 9276 Order Status: Archive

Vendor Advanced Bioscience Resources,1516 Oak Street, Suite 303, Alameda, CA 94501
Phone: 510-865-5872 SmlBs: No FSS:
EIN: BPA: GSA:
Site: Clerk:
E-mail:

#	Description	CAN	Catalog	OC Code	Category	Qty at Price	Total
1	Tissue, 2nd Trimester (1 each of liver and thymus)	8335424	none	2613	6509	(b)(4)	680.00
2	shipping	8335424		2613	6509	1 each at $0	.00
Order Total: 680.00							

Ship To: Ronald Messer,3220 ,RML CNTRL REC,RMTLAB

QUOTES

Vendor	Price	Good Until	Available
There are no quotes in the order			

JUSTIFICATION

These tissues, liver and thymus, are required by Ron Messer for ongoing studies of HIV in the Hasenkrug Lab. Our mice are ready for reconstitution. Please let me know when I can contact Perrin Larton at ABR to place our request on their schedule. Please contact the vendor at 510-865-5872 ext (b)(6) -give her the PO number Thanks, Ron. *** I certify that I have checked the sources of supply and services listed in FAR 8.002. ( ) I have purchased from the highest priority source available. (X) I did not purchase from a priority source because none could satisfy the requirement of the government either in product/service specifications, quality or required delivery time. **********NOTE to Purchasing Agent: Call vendor at 510-865-5872 ext (b)(6) give her the PO number and credit card information.

Alternate Sources:

NIH Surplus: No UNICOR: No GSA Stock Catalog: No GSA Self Service: No Federal Supply: No Open Market: Yes

AGENT

Purchase Order #: (b)(6)
Custodial Code: 30102
Order Reference: (b)(6)
FSS:
NBS Ref Order #: 4589328

Estimated Ship Date:
Date Entered into NBS: 05/12/2017
Expected Delivery Date: 05/18/2017
Select Agents: No
Clearance Requested: No

SF-37 Code:

Notes

There are no notes in the order

IT Clearance

Never seen by IT officer

ROUTE HISTORY

Role Summary

User Role	Name
Requester	Messer, Ronald
Releaser	Messer, Ronald
Admin Officer	(b)(6)
Lead Admin Officer	
Purchase Agent	(b)(6)
Lead Agent	
IT Clearance Officer	
Releaser1	
Releaser2	
NBS	
Receiving Official	

Dates

Description	Date
Needed By	05/12/2017
Submitted to NBS	05/12/2017
NBS Confirmation	05/13/2017
Award Created	05/12/2017
Award Received	05/12/2017
Estimated Ship Date	
Received	05/30/2017
Canceled	

Routing History

Name	Role	Date In	STATUS IN	ACTION
Messer, Ronald	Requester	05/12/2017	New order	Approved
(b)(6)	Administrative Officer	05/12/2017	Released	Approved
	Purchasing Agent	05/12/2017	Approved	Take
	Purchasing Agent	05/12/2017	Approved	Approved
NBS, NBS	NBS	05/12/2017	Sent to NBS	Approved
Messer, Ronald (b)(6)	Requester for receiving	05/12/2017	Pending receiving	Take
(b)(6)	Requester for receiving	05/30/2017	Pending receiving	Approved
	Archive	05/30/2017	Archive	(N/A)

Receiving Report

#	Description	Total Qty Ordered	Total Qty Received	Date Received
1	Tissue, 2nd Trimester (1 each of liver and thymus)	2	2	05/30/2017
2	shipping	1	1	05/30/2017

OHSR RESPONSE TO REQUEST FOR REVIEW OF RESEARCH ACTIVITY
INVOLVING HUMAN SUBJECTS

FAX:

Exempt: #: 4980

To: Hasenkrug, Kim
NIAID
RML - Rocky Mountain Laboratories, 3/218

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
Recent reports have demonstrated that immunodeficient mice reconstituted with 17-19 week old human fetal tissue develop a human immune system and are susceptible to HIV infection and disease. The goal of this project proposal is to create such humanized mice to study the role of immune cell subsets and virus-neutralizing antibodies in vaccine protection. The experiments will entail the development of a cohort of mice all reconstituted with the same human cells so as to be histocompatible. This will require transplantation of

Original Request Received in OHSR on: 11/19/2009

Responsible NIH Research Investigator(s): Kim Hasenkrug, NIAID

OHSR review of your request dated Thu, Nov 19, 2009 has determined that:

☒ Federal regulations for the protection of human subjects do not apply to above named activity. The OHSR determination of Not Human Subjects Research is based on the interpretation of 45 CFR 46 under "Research Involving Coded Private Information or Biological Specimens" (OHRP, Revised October 16, 2008) and Guidance on Engagement of Institutions in Human Subjects Research (October 16, 2008). NOTIFY OHSR VIA AN E-MAIL AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESEARCH ACTIVITY.

☐ The activity is designated **EXEMPT**, and has been entered in the OHSR database. PLEASE NOTIFY OHSR OF ANY **SIGNIFICANT** CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.

☐ **NOT EXEMPT**. OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additional information in order to determine whether expedited or full review is appropriate.

☐ Confidentiality Agreement

☐ Reliance

☐ Amendment

☐ Other

Office Person LB Admin Assist. CB

Note:
(b)(6)

CIP

for Charlotte Holden, JD — Acting Director, OHSR — 12/14/2009
Signature — Title — Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: Yes

OHSR Use Only
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

#4980

REQUEST FOR REVIEW OF RESEARCH ACTIVITY INVOLVING HUMAN SUBJECTS

INSTRUCTIONS: Please type directly on this form. You can expand the document if you need more space. If your research involves a survey or questionnaire, please attach it to this completed form.

Completed forms (with all required signatures) may be sent to OHSR by FAX (301-402-3443), email to ohsr_nih_ddir@od.nih.gov, or by mail (2C146). If you have any questions, call OHSR at (301) 402-3444.

Date: 11/19/2009

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146

From: Kim J Hasenkrug
(Signature)

(b)(6)

Through: (acting)
(Signature of appropriate Official for IC, e.g., Lab/Branch Chief)

Protocol Title: Study of HIV infection and vaccine protection in mice reconstituted with a human immune system

Name of NIH Principal Investigator(s): Kim J Hasenkrug, Senior Investigator

IC NIAID Laboratory/Branch LPVD Building & Room No. RML 3218
Tel. No. 406-363-9310 FAX No. 406-363-9286
Is the Principal investigator an NIH employee? x **Yes** **No**

If no, please explain:

1. What is the proposed research activity that you intend to perform at NIH (please use lay terms):

Recent reports have demonstrated that immunodeficient mice reconstituted with 17-19 week old human fetal tissue develop a human immune system and are susceptible to HIV infection and disease. The goal of this project proposal is to create such humanized mice to study the role of immune cell subsets and virus-neutralizing antibodies in vaccine protection. The experiments will entail the development of a cohort of mice all reconstituted with the same human cells so as to be histocompatible. This will require transplantation of the mice with 1 mm^3 pieces of fetal thymus as well as reconstitution with stem cells isolated from cord blood and liver. Once the humanized mice have been established some will be vaccinated to prime distinct subsets of immune cells. Immune cell subsets from vaccinated mice will be adoptively transferred into naïve mice, which will then be infected with HIV to

test the antiviral activity of the immune cells. The goal of these experiments is to establish correlates of immunity against HIV.

2. If applicable, list your non-NIH Collaborating Investigator(s).

Name Institution Address Tel. # FAX #

3. Proposed start date of your research __April, 2010_____
Proposed completion date _April, 2013_____

4. Will you be _____these samples or data?

Collecting Yes/No
Receiving Yes/No
Sending Yes/No

5. Do the samples or data:
(a) Already exist?___Yes _x__No

(b) Or are they being collected for the express purpose of this study? _X__Yes __No
If "yes," please describe:_

17-19 week fetal cells and tissue will be obtained from Advanced Bioscience Resources, Inc., a non-profit foundation established under California law to provide biomedical researchers access to human tissues in compliance with state, federal, and NIH guidelines. Consent to donate is obtained in accordance with UAGA and NOTA guidelines. Related documents including the consent form are attached._____

(c) Or a combination of (a) and (b)? ____Yes _____No

6. What role will you have in this research project? (Check all that apply)

___ Analyze samples/data only.

___ Consultant/advisor to collaborator(s) listed above.

___ Author of the protocol that is being implemented by your collaborating investigator (identified in question #2).

___ Co-authorship on publication(s)/manuscript(s) pertaining to this research.

___ You or NIH hold an IND for this research.

__X_ Decisional authority over the design or implementation of the research at the IRB approved site? If so, please explain.

I am the PI and lead investigator on this project which will take place in my laboratory and the animal care facilities at Rocky Mountain Labs, NIAID, NIH.

___Other (If necessary, use this space to describe your role in this research).

7. Where are the subjects of this research activity located?
The material for this research is obtained from natural or induced abortions from females in California. Thus the tissues and cells involved will not be from living humans.

8. If human subjects are located elsewhere (not at NIH), will you have direct contact or intervention with them? (Examples: as subject's physician; in obtaining samples directly from the subject; by interviewing the subject?) ____ Yes __x__No