

DEPARTMENT OF HEALTH & HUMAN SERVICES

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: NIII 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/efoia.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.
- 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 IIIIS 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
 OGIS

 Stephanie Clipper
 National Archives and Records Admin.

 Building 31, Room 5B35
 8601 Adelphi Rd – OGIS

 31 Center Drive
 College Park, MD 20740-6001

 Bethesda, MD 20814
 202-741-5770 (phone)

 301-496-2411 (phone)
 1-877-684-6448 (toll-free)

 202-741-5760 (fore)
 202-741-5760 (fore)

301-402-0818 (fax) 202-741-5769 (fax) <u>nhlbieo@mail.nih.gov</u> (email) <u>ogis@nara.gov</u> (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



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	RESE	ARCHER FEE
12/21/2016 12/21/2016	672104 672104	6376 6377	21	Thymus, 2nd Trimester Liver, 2nd Trimester 01/10/17 PAID (b)(6) Request by Kim Hasenkrug.	KIM	(b)(4)
	e Entry Nethod: Namual 68ย. ชย	18:15:31 86:170: (86) 86:170: (86)		. 40:1		
STI 303 HAMILA, LE UNDO CERT OF CONTROL OT CONTROL OF C	Sale fatr	n.	AVS Code: 7JP MICH Z CVV2 Code: MICH II Retrieval Netter Servedort	inclosed for	Total	\$680.00

via FOIA by Judicial Watch, Inc PO# (b)(6) SEQ: 1823136 Requester: Messer, Ronald Owner: (b)(6) CAN: 8335424 FY: 17 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: OC # Description CAN Catalog Category Oty at Price Total Code (b)(4) Tissue, 2nd Trimester (1 each of liver and 6509 8335424 none 2613 680.00 thymus) 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) give her the PO number and credit card information. Alternate Sources: GSA Stock Catalog: GSA Self Service: Federal Supply: Open Market: UNICOR: NIH Surplus: No No No No 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

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
i i e	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

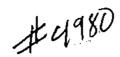
OHSR RESPONSE TO REQU**ESTIFOR REVIEW OF RESEARCH** ACTIVITY INVOLVING HUMAN SUBJECTS

FAX:			Exe	mpt: #:	4980	
To:	Hasenkrug, Kim					
	NIAID				;	
	RML - Rocky Mountain Lab	oratories, 3/218				
From	n: Office of Human Subjects R	esearch (OHSR)			·	
Re- tiss pro net all t	re of Research Activity: cent reports have demonstrated sue develop a human immune sy ject proposal is to create such h utralizing antibodies in vaccine p reconstituted with the same hum	stem and are susceptible to H umanized mice to study the ro rotection. The experiments wi nan cells so as to be histocomo	IIV infection and dise le of immune cell sul il entail the developn	ease. The good was and want of a co	goal of this virus- phort of mice	
Origi	nal Request Received in OHSR	on: 11/19/2009			·	
Resp	onsible NIH Research Investiga	tor(s): Kim Hasenkrug, NIA	/ID			
OHS	R review of your request dated	Thu, Nov 19, 2009 has determ	nined 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 Guidanc on Engagement of Institutions in Human Subjects Research (October 16, 2008). NOTIFY OHSR VIA AN E-MAI 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					
Note	a·)(6)	Office	Person LB	Admin Assi	st. CB	
Ì	,	CIP				
√Chā	arlotte Holden, JD	Acting Director, OHSR		12/14/20	09	
	nature	Title		Date		
Don	nestic/International:					
	nestic					
Hum	nan Subjects Data: Yes		OHSR Use Only		_	
	ogic Material: Yes		□1 □2 □3	□4 □	5 🗆 6	

Date:

11/19/2009

Obtained via FOIA by Judicial Watch, Inc.



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.

<u> </u>
To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146
From: KIM Jasen Kura
(Signature)
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 NoRML 3218_
Tel. No. 406-363-9310 FAX No. 406-363-9286
Is the Principal investigator an NIH employee?x_YesNo
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 mm³ 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 naive 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 #		
	i start date of your researchAp i completion date _April, 2013			
4. Will you	bethese samples or dat	a?		
	ng Yes/No Yes/No			
	amples or data: ady exist?Yes _xNo			
	re they being collected for the expre please describe:	ess purpose of this study? _XYesNo		
Resource biomedic NIH guid	cal researchers access to human tissudelines. Consent to donate is obtain uidelines. Related documents inclu-	blished under California law to provide ues in compliance with state, federal, and ned in accordance with UAGA and		
(c) Or a	combination of (a) and (b)?	YesNo		
6. What	role will you have in this research	project? (Check all that apply)		
Analyze	samples/data only.			
Consulte	ant/advisor to collaborator(s) listed a	above.		
	of the protocol that is being implement question #2).	ented by your collaborating investigator		
Co-auth	orship on publication(s)/manuscript	(s) pertaining to this research.		

Last revised 8/4/09

P. 002

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

Last revised 8/4/09

3

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) RepositoryYes No		
(b) Pathological waste YesNo		
(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? YesNo		

13. Has the research activity that you are an Institutional Review Board (IRB) elsew	
 _ :	as been reviewed by the following IRB (s)
(Please provide the following information for	r each IRB):
·	Name of institution that provided the review
	Address of reviewing institution
	Name of PI for the IRB approved protocol
Т	Citle of IRB approved protocol and protocol #
	Federal Wide Assurance (FWA) number**
(**An FWA is a contract between the U.S. I (DHHS) and an entity receiving DHHS funds will follow ethical guidelines and federal reg subjects. For a list of domestic and internation http://ohrp.cit.nih.gov/search/asearch.asp#AS	s to conduct clinical research that the latter ulations for the protection of human nal institutions go to
14. Per NIH guidance***, have conflicts of been resolved? XYesNo no conflicts of inte	
If your answer is no, please see your Clipproceeding with this research.	nical Director about this matter before
***The January 5, 2005 NIH Guide to Prever research conducted at NIH, http://ohsr.od.nih	

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.

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 theraples 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. APPI	ICANT INFORMATION	ſ				
NAME:	Kim J Hasenkrug			BILLING	INFORMATION:	
TITLB:	Senior Investigator		BILL TO:	Kim .	J Hasenkrug	
COMPANY:	NIAID, NIH		COMPANY:		y Mountain Labs	
ADDRESS:	Rocky Mountain Lab		ADDRESS:	903 S.	4th St	
ADDRESS:	_903 S. 4th St		ADDRESS:			
CITY,ST,ZIP: PHONE #: ALT. #:	_Hamilton, MT 59840 _406-363-9310		CITY, ST, ZIP: ACCOUNTING	Hami DEPT. P	lton, MT 59840_ HONE #:406-36	3-9438
	6-363-9286		P.O. # (if requi	red by yo	ur company):	
DELIVERY O		_	Credit Card #:	equired to	submit applicati	on
Mexim	Day: Commercial carrier, hand of izes cell viability (geographica ay: Pickup, delivery Mon-Sat of	al linsits)	Name on CC: Expiration Date	:		VJ8A/MC
Всопог	nical for fresh, fro zen s pecimen	15	SHIP TO:	_Kim J	Hasenkrug	
Applicant will	be charged for delivery fees.			_Rocky N	Mountain Labs	
Applicant may	designate preferred carrier:			903 S.	4th St	
Carrier Name:	PEDEX			_Hamilto	n, MT 59840	
Account #:	<u>(b)(4)</u>					
Piesse indicate	how you heard about ABR:	b)(6)			·—·—	
II. HUM	AN FETAL TISSUE				,	
Tissue specime	ns requested:thymus, liver,	, cord blood_				
Preferç Propos	ed gestational age (6-24 weeks) ed starting date:May,	: 17-19 w	/ks			
CONTAGIOUS Applicant requi	DISEASE SCREENING: Avaious the following tests to be pe	ilability of ter erformed by A	et results veries BR:	from 24 h	ours to 7 days afte	r procurement.
x	No testing required	H(V HB\$A CMV	a <u>—</u>	HSV RPR 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	y ice	_ Media provided by applicant _ Media provided by ABR (RPMI)
IV.	DONOR INFORMATION		
	SENT VERIFICATION: Consent for tissue donation is obtain nely confidential in nature and shall not be communicated to t		cimen procurement. The consent is
	CIFIC DONOR INFORMATION: Charts are routinely examing information sought and indicate contraindications to specin		
	HIV+ status contraindicates procurement		
v .	— RESEARCH DATA		
TITLE protecti	E OF RESEARCH PROJECT: The role of virus-specition against HIV-1 in humanized mice	fic CD4+T o	zells, CD8+ T cells and antibody in vaccine
research tissue s Updates as pron patents ABR o	will provide tissue to researchers who provide information of intent. (Please attach a brief synopsis of the research personal solely for research purposes and to acknowledge ABR in any less on research progress will be requested at six-month interval omptly after the completion of the research as is reasonably as or copyrights necessary to protect its ownership or control of the name of the publication and the date of the issue in we rement to make the results available to the general public through	project named publications resist. Researchers possible without the results of the results of the results.	above.) Researchers must agree to use the ulting from the use of ABR provided tissue, agree to publish the results of the research at jeopardizing the sponsor's right to secure the research. Researchers agree to inform a will be published. It is the intent of this
VI.	SOURCE OF FUNDING		
	e identify the primary source of funding for this project. X Other Federal or State Grants Foundation Gra	nis Oti	ner (specify)
other co condition express	s application is approved by ABR, ABR shall provide servi conditions on the reverse side, and the signature of the aptions by applicant. The entire agreement between ABR and say set forth herein, and any modification of or addition then don behalf of ABR by a duly authorized representative.	plicant shall c d applicant rel	onstitute acceptance of all such terms and ating to the services provided by ABR is
	IGNING BELOW, THE APPLICANT ACKNOWLEDGES HE FOLLOWING PAGE AND AGREES TO SUCH TER		
	kin D Hasenling		,
_Senio SIONA	or Investigator	DATE 11/2/2	009
CONI	Please return to: DITIONS OF SERVICES	1516 OAK ST ALAMBDA, (Telephone: 51 Fax: 51	BIOSCIENCE RESOURCES, INC. TREET, SUITE 303 CALIFORNIA 94501 0-865-5872 0-865-4090 r@abr-inc.coinTERMS AND

Services_

During the term of this agreement, and pursuant to the terms and conditions hereinofter set forth. ABR will use its bost offorts 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 engoing 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 tissuc.

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 zerum, 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 acction 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 itssue 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 self nor transfer for valuable consideration any lissue 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. Tarms. 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 heret 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 aforesald 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. <u>Paymenta.</u> 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 noither 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 itssues. 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 Hability. ABR shall not be responsible or Habie 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 setually received by ABR from researcher on account of this agreement.
- 7. No warrantles. It is understood that human tissue is by nature noither 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. <u>Indemnification</u>. Researcher shall indemnify, defend and hold ABR harmless from and against all claims, causes of actions, suits, demages 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. Qeneral. This agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of faw. 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,

(p)(p)			

OHSR (NIH/DDIR)

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

Sent: Wednesday, December 09, 2009 5:41 PM

To: OHSR (NIĤ/DDIR)

Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up Flag Status: Green

Attachments: IRB Letter with letterhead nonidentity.doc

> From: "OHSR (NIH/DDIR)" <ohsr nih ddir@od.nih.gov>

> Date: Tue, 24 Nov 2009 10:27:55 -0500



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

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

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> 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

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: Flag Status:

Follow up 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.

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

Kim J Hasenkrug, Ph.D.

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: "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
```

Re: HFT Application

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.

Рептіп

- > 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

Re: HFT Application

```
>
>
>> 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
>> 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 Projections, 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



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 1/4/2017	740401 740401	5072 5073	18	Thymus, 2nd Trimester Liver, 2nd Trimester 01/10/17 PAID Request by Kim Hasenkrug.		HASENKRUG HASENKRUG	(b)(4)
を	Sale Entry Method: Manual I: \$ 680.00	15:48:30 16:41 Appr Code: 916541 17:10 Batch8: 919961	RYS CODE: 1217 MILUM 2 CVV2 Code: MATCH M Kerrievsk kef.n: Gologousts	Conton Cont.			
Son H. G Bornani Lea Ho	vis Total:	Minterior (Medicial Investment)	CW2 Code		Total	\$680.	00

CAN: 8335424

CAN: 8335424

Order Total: 680.00

Date Needed: 12/02/2016

Requester: Messer, Ronald

Emergency: Yes

Order Type: Purchase Card

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
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

OUOTES

JUSTIFICATION

Alternate Sources:

NIH Surplus: No No

UNICOR: GSA Stock Catalog:

No

GSA Self Service: No Federal Supply:

Open Market:

No

Yes

AGENT

Purchase Order #: (b)(6)

Estimated Ship Date: Date Entered into NBS: 12/02/2016

Custodial Code: 30102

Expected Delivery Date: 12/06/2016

Order Reference: (b)(6)
ESS:

Select Agents: No

NBS Ref Order #: 4416699

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	
1 1	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

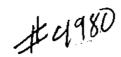
OHSR RESPONSE TO REQU**ESTIFOR REVIEW OF RESEARCH** ACTIVITY INVOLVING HUMAN SUBJECTS

FAX			Exempt: #:	4980	
To:	Hasenkrug, Kim				
	NIAID			1	
	RML - Rocky Mountain Laborat	ories, 3/218			
From	n: Office of Human Subjects Rese	arch (OHSR)			
Retiss	re of Research Activity: cent reports have demonstrated tha sue develop a human immune syste sject proposal is to create such huma utralizing antibodies in vaccine prote reconstituted with the same human	m and are susceptible to HIV in and are susceptible to HIV in anized mice to study the role oction. The experiments will er	nfection and disease. The of immune cell subsets and ntail the development of a	e goal of this d virus- cohort of mice	
Origi	nal Request Received in OHSR on:	11/19/2009			
Resp	oonsible NIH Research Investigator(s): Kim Hasenkrug, NIAID			
ОН	SR review of your request dated Thu	, Nov 19, 2009 has determine	d that:		
X	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.				
	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			!	
Note	⊋: ((6)	Office Per	son LB Admin As	sist. CB	
		P			
√Cha	arlotte Holden, JD	Acting Director, OHSR	12/14/2	2009	
Sig	nature	Title	 Date		
Don	nestic/International:				
Dor	nestic				
Hum	nan Subjects Data: Yes		OHSR Use Only	7 - 0 .	
	ogic Material: Yes	L	□1 □2 □3 □4 [⊥5 ∐6	

Date

11/19/2009

Obtained via FOIA by Judicial Watch, Inc.



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.

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146
From: KIM J Hasen Kung
(Signature)
Through:
(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 NoRML 3218_
Tel. No406-363-9310_FAX No. 406-363-9286
Is the Principal investigator an NIH employee?x_YesNo
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 mm³ 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 naive 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.

If applicable, list your non-NIH Collaborating Investigator(s).				
Name	Institution	Address Tel, # FAX #		
	osed start date of your research osed completion date _April, 201			
4. Will <u>y</u>	ou bethese samples o	r data?		
	ecting Yes/No iving Yes/No ing Yes/No			
	ne samples or data: Already exist?Yes _xNo			
	Or are they being collected for the es," please describe:	express purpose of this study? _X_YesNo		
Reso bion NIH	urces, Inc., a non-profit foundation edical researchers access to human guidelines. Consent to donate is a guidelines. Related documents	e obtained from Advanced Bioscience n established under California law to provide n tissues in compliance with state, federal, and obtained in accordance with UAGA and including the consent form are		
(c) (Or a combination of (a) and (b)?	YesNo		
6. W	hat role will you have in this reso	earch project? (Check all that apply)		
Ana	lyze samples/data only.	•		
Con	sultant/advisor to collaborator(s) li	sted above.		
	nor of the protocol that is being imped in question #2).	plemented by your collaborating investigator		
Co-	uthorship on publication(s)/manus	cript(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			

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) RepositoryYes No			
(b) Pathological waste YesNo			
(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? YesNo			

13. Has the research activity that you are an Institutional Review Board (IRB) elsew	
Yes, the NIH research activity hat (Please provide the following information for	as been reviewed by the following IRB (s)
(x tease provide the following information for	i enell (ICO).
1	Name of institution that provided the review
	Address of reviewing institution
1	Name of PI for the IRB approved protocol
т	Citle of IRB approved protocol and protocol #
	Federal Wide Assurance (FWA) number**
(**An FWA is a contract between the U.S. I (DHHS) and an entity receiving DHHS funds will follow ethical guidelines and federal reg subjects. For a list of domestic and internatio http://ohrp.cit.nih.gov/search/asearch.asp#AS	s to conduct clinical research that the latter ulations for the protection of human nal institutions go to
14. Per NIH guidance***, have conflicts of been resolved? XYesNo no conflicts of inte	
If your answer is no, please see your Cli proceeding with this research.	nical Director about this matter before
***The January 5, 2005 NIH Guide to Prever research conducted at NIH, http://ohsr.od.nih	

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.

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 theraples 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. APP	LICANT INFORMATION		
NAME:	Kim J Hasenkrug		BILLING INFORMATION:
TITLB:	Senior Investigator		Kinn J Hasenkrug
COMPANY:	NIAID, NIH		Rocky Mountain Labs
ADDRESS:	Rocky Mountain Lab		903 S. 4th St
ADDRESS:	_903 S. 4th St	ADDRESS:	
CITY,ST,ZIP PHONE #: _ ALT. #:	: _Hamilton, MT 59840 406-363-9310	CITY,ST,ZJP: ACCOUNTING	Hamilton, MT 59840
FAX #: 40	06-363-9286	P.O. # (if requi	red by your company):
DELIVERY		Credit Card #:	quired to submit application
Mexic	Day: Commercial carrier, hand delivered nizes cell viability (geographical limits) Day: Pickup, delivery Mon-Sat daytime	Name on CC: Expiration Date	:VJSA/MC
Всопа	mical for fresh, frozen specimens	SHIP TO:	Kim J Hasenkrug
Applicant wit	ll be charged for delivery fees.		_Rocky Mountain Labs
Applicant may	designate preferred carrier:		903 S. 4th St
Carrier Name:			_Hamilton, MT 59840
Account #:	(b)(4)		
Piesse indicat	e how you heard about ABR: (b)(6)		
II. HUM	ian fetal tissue		•
Tissue specim	ens requested:thymus, liver, cord bloo	d	·
Prefer Propo	red gestational age (6-24 weeks):17-1: sed starting date:May, 2010	9 wks	
CONTAGIOU Applicant requ	S DISEASE SCREENING: Availability of uires the following tests to be performed by	test results varies (from 24 hours to 7 days after procurement.
x	No testing required	DAS	HSV RPR 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	y ice	_ Media provided by applicant _ Media provided by ABR (RPMI)
IV.	DONOR INFORMATION		
	SENT VERIFICATION: Consent for tissue donation is obtain nely confidential in nature and shall not be communicated to t		cimen procurement. The consent is
	CIFIC DONOR INFORMATION: Charts are routinely examing information sought and indicate contraindications to specin		
	HIV+ status contraindicates procurement		
v .	— RESEARCH DATA		
TITLE protecti	E OF RESBARCH PROJECT:The role of virus-specition against HIV-1 in humanized mice	fic CD4+T o	zells, CD8+ T cells and antibody in vaccine
research tissue s Updates as pron patents ABR o	will provide tissue to researchers who provide information of intent. (Please attach a brief synopsis of the research personal solely for research purposes and to acknowledge ABR in any less on research progress will be requested at six-month interval omptly after the completion of the research as is reasonably as or copyrights necessary to protect its ownership or control of the name of the publication and the date of the issue in we rement to make the results available to the general public through	project named publications resist. Researchers possible without the results of the results of the results.	above.) Researchers must agree to use the ulting from the use of ABR provided tissue, agree to publish the results of the research at jeopardizing the sponsor's right to secure the research. Researchers agree to inform a will be published. It is the intent of this
VI.	SOURCE OF FUNDING		
	e identify the primary source of funding for this project. X Other Federal or State Grants Foundation Gra	nis Oti	ner (specify)
other co condition express	s application is approved by ABR, ABR shall provide servi conditions on the reverse side, and the signature of the aptions by applicant. The entire agreement between ABR and any sect forth herein, and any modification of or addition then don behalf of ABR by a duly authorized representative.	plicant shall c d applicant rel	onstitute acceptance of all such terms and ating to the services provided by ABR is
	IGNING BELOW, THE APPLICANT ACKNOWLEDGES HE FOLLOWING PAGE AND AGREES TO SUCH TER		
	kin D Hasenling		,
_Senio SIONA	or Investigator	DATE 11/2/2	009
CONI	Please return to: DITIONS OF SERVICES	1516 OAK ST ALAMBDA, (Telephone: 51 Fax: 51	BIOSCIENCE RESOURCES, INC. TREET, SUITE 303 CALIFORNIA 94501 0-865-5872 0-865-4090 r@abr-inc.coinTERMS AND

Services_

During the term of this agreement, and pursuant to the terms and conditions hereinofter set forth. ABR will use its bost offorts 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 engoing 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 tissuc.

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 zerum, 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 acction 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 itssue 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 self nor transfer for valuable consideration any lissue 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. Tarms. 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 heret 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 aforesald 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. <u>Paymenta.</u> 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 noither 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 itssues. 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 Hability. ABR shall not be responsible or Habie 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 setually received by ABR from researcher on account of this agreement.
- 7. No warrantles. It is understood that human tissue is by nature noither 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. <u>Indemnification</u>. Researcher shall indemnify, defend and hold ABR harmless from and against all claims, causes of actions, suits, demages 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. Qeneral. This agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of faw. 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)			
l				

OHSR (NIH/DDIR)

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

Sent: Wednesday, December 09, 2009 5:41 PM

To: OHSR (NIĤ/DDIR)

Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up Flag Status: Green

Attachments: IRB Letter with letterhead nonidentity.doc

> From: "OHSR (NIH/DDIR)" <ohsr nih ddir@od.nih.gov>

> Date: Tue, 24 Nov 2009 10:27:55 -0500



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

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

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> 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

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: Flag Status:

Follow up 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.

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

Kim J Hasenkrug, Ph.D.

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: "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.
```

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> 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
```

Re: HFT Application

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.

Рептіп

- > 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
- > vcry
- > 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

Re: HFT Application

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>
>
>> From: Perrin Larton (b)(6)
\Rightarrow 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
>> 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
>
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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 Projections, 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



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

							\$197 7
PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIP	TION	RESEARCHER	FEE
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15.16 insk 21 SR 20 SR 20 SR 2	tal: \$	81/25/17 Inv 8: 000005 Approd: Online	NS Code: ZIP INICH CVV2 Code: MACH II Retained And III III	Co.			
Sea	#IS	12/2 12/2 14/2 14/2 14/2 14/2 14/2 14/2	EEE		Total	\$680	.00

PO#: (b)(6) SEQ: 1829765 Requester: Messer, Ronald Owner: (b)(6) CAN: 8335424 FY: 17 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: OC # Description CAN Catalog Category Oty at Price Total Code Tissue, 2nd Trimester (1 each of liver and (b)(4) 6509 8335424 none 2613 680.00 thymus) 2 shipping 8335424 2613 6509 1 each at \$0 .00Order 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 give her the PO number and credit card information. Alternate Sources: GSA Stock Catalog: GSA Self Service: Federal Supply: Open Market: UNICOR: NIH Surplus: No No No No Yes AGENT Purchase Order #: (b)(6) Estimated Ship Date: Custodial Code: 30102 Date Entered into NBS: 12/30/2016

Expected Delivery Date: 01/06/2017

Select Agents: No

Clearance Requested: No

Order Reference: (b)(6)

NBS Ref Order #: 4443715

FSS:

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
Tissue, 2nd Trimester (1 each of liver and thymus)	2	2	02/10/2017
2 shipping	1	1	02/10/2017

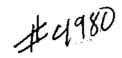
OHSR RESPONSE TO REQU**ESTIFOR REVIEW OF RESEARCH** ACTIVITY INVOLVING HUMAN SUBJECTS

FAX				E	Exempt: #:	4980
To:	Hasenkrug, Ki	im				
	NIAID					
	RML - Rocky I	Mountain Laboratorie	s. 3/218			
From	n: Office of Huma	an Subjects Research	n (OHSR)			
Re tiss pro net	sue develop a huma oject proposal is to o utralizing antibodies	demonstrated that imit an immune system ar create such humanize s in vaccine protection	munodeficient mice rea nd are susceptible to he ed mice to study the ro n. The experiments we see as to be histocom	HIV infection and only and onl	disease. The of subsets and volument of a co	goal of this virus- phort of mice
Origi	nal Request Receiv	ved in OHSR on:	11/19/2009			
Resp	oonsible NIH Resea	arch Investigator(s):	Kim Hasenkrug, NIA	AID		
OHS	SR review of your re	equest dated Thu, No	ov 19, 2009 has detern	nined that:		
	determination of N Involving Coded F on Engagement o	Not Human Subjects I Private Information or of Institutions in Huma	of human subjects do n Research is based on Biological Specimens In Subjects Research (BAT MAY ALTER THIS	the interpretation " (OHRP, Revised (October 16, 2008	of 45 CFR 46 d October 16, 2 d). NOTIFY OF	under "Research 2008) and Guidance
	The activity is des	signated <u>EXEMPT</u> , ar	nd has been entered in HAT MAY ALTER THE	the OHSR datab	ase. <u>PLEASE</u>	
			RB review. Please for mation in order to dete	•		- '
	Confidentiality Agr	reement				
	Reliance					
	Amendment			-		
	Other					!
NI_4.			Office	Person LB	Admin Assi	st. CB
Note	e: b)(6)					•
		CIP)			
√ <u>Chi</u>	arlotte Holden, JD		Acting Director, OHSR	<u> </u>	12/14/20	09
Sig	nature		Title		Date	
Don	nestic/International:	:				
Dor	nestic					
Hun	nan Subjects Data:	Yes		OHSR Use Or	-	1
	ogic Material:	Yes		∐1 ∐2 L]3 □4 □	5 ∐6

Date

11/19/2009

Obtained via FOIA by Judicial Watch, Inc.



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.

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146
From: Kim & tasen knig
(Signature)
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_
ICNIAID_Laboratory/Branch LPVD_Building & Room NoRML 3218_
Tel. No. 406-363-9310 FAX No. 406-363-9286
Is the Principal investigator an NIH employee?x_YesNo
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 mm³ 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 appl	icable, list your non-NIH Collal	porating Investigator(s).
Name	Institution	Address Tel. # FAX #
_	start date of your researchApcompletion date _April, 2013	·
4. Will you be	ethese samples or da	ta?
Collecting Receiving Sending	Yes/No Yes/No Yes/No	
	nples or data: ly exist?Yes _xNo	
	they being collected for the expre lease describe:_	ess purpose of this study? _X_YesNo
Resources, biomedica NIH guide NOTA gui	Inc., a non-profit foundation esta researchers access to human tiss	ained from Advanced Bioscience ablished under California law to provide ues in compliance with state, federal, and ned in accordance with UAGA and ading the consent form are
(c) Oraco	ombination of (a) and (b)?	_YesNo
6. What re	ole will you have in this researc	h project? (Check all that apply)
Analyze s	amples/data only.	
Consultan	t/advisor to collaborator(s) listed	above.
Author of (identified in c		ented by your collaborating investigator
Co-author	ship on publication(s)/manuscrip	t(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

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) RepositoryYes No		
(b) Pathological waste YesNo		
(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? YesNo		

13. Has the research activity that you are pan Institutional Review Board (IRB) elsew	
	s been reviewed by the following IRB (s)
(Please provide the following information for	eact (KB):
	Name of institution that provided the review
	Address of reviewing institution
	Name of PI for the IRB approved protocol
Т	itle of IRB approved protocol and protocol #
F	ederal Wide Assurance (FWA) number**
(**An FWA is a contract between the U.S. D (DHHS) and an entity receiving DHHS funds will follow ethical guidelines and federal regu subjects. For a list of domestic and internation http://ohrp.cit.nih.gov/search/asearch.asp#AS	to conduct clinical research that the latter allations for the protection of human nal institutions go to
14. Per NIH guidance***, have conflicts of been resolved? XYesNo no conflicts of inter	
If your answer is no, please see your Clin proceeding with this research.	nical Director about this matter before
***The January 5, 2005 NIH Guide to Prever research conducted at NIH, http://ohsr.od.nih.	

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.

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 theraples 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

Obtained via FOIA by Judicial Watch, Inc.

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	BILLING INFORMATION:
TITLE: _Senior Investigator	
COMPANY:NIAID, NIH	
ADDRESS: _Rocky Mountain Lab	
ADDRESS:903 S. 4th St	ADDRESS:
CITY,ST,ZIP: _Hamilton, MT 59840 PHONE #:406-363-9310 ALT. #:	CITY,ST,ZIP:Hamilton, MT 59840ACCOUNTING DEPT. PHONE #:406-363-9438
FAX #: 406-363-9286	P.O. # (if required by your company):
EMAIL: khasenkrug@nih.gov DELIVERY OPTIONS:	P.O. # is not required to submit application Credit Card #:
x Same Day: Commercial carrier, hand de Maximizes cell viability (geographical	Inits) Expiration Date: VISA/MC
Next Day: Pickup, delivery Mon-Sat da	time
Economical for fresh, frozen specimens	SHIP TO:Kim J Hasenkrug
Applicant will be charged for delivery fees.	_Rocky Mountain Labs
Applicant may designate preferred carrier:	903 S. 4th St
Carrier Name: PEDEX	Hamilton, MT 59840
Account #: _(b)(4)	
Please indicate how you heard about ABR:)
II. HUMAN FETAL TISSUE	
Tissue specimens requested:thymus, liver,	ord blood
Preferred gestational age (6-24 weeks): Proposed starting date:May, 2	17-19 wks
CONTAGIOUS DISEASE SCREENING: Avail Applicant requires the following tests to be per	pility of test results varies from 24 hours to 7 days after procurement ormed by ABR:
X No testing required	_ нгv нsv
	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	y ice	_ Media provided by applicant _ Media provided by ABR (RPMI)
IV.	DONOR INFORMATION		
	SENT VERIFICATION: Consent for tissue donation is obtain nely confidential in nature and shall not be communicated to t		cimen procurement. The consent is
	CIFIC DONOR INFORMATION: Charts are routinely examing information sought and indicate contraindications to specin		
	HIV+ status contraindicates procurement		
v .	— RESEARCH DATA		
TITLE protecti	E OF RESEARCH PROJECT:The role of virus-spection against HIV-1 in humanized mice	fic CD4+T o	ells, CD8+ T cells and antibody in vaccine
research tissue s Updates as pron patents ABR o	will provide tissue to researchers who provide information of intent. (Please attach a brief synopsis of the research personal solely for research purposes and to acknowledge ABR in any less on research progress will be requested at six-month interval omptly after the completion of the research as is reasonably as or copyrights necessary to protect its ownership or control of the name of the publication and the date of the issue in we rement to make the results available to the general public through	project named publications resist. Researchers possible without the results of the results of the results.	above.) Researchers must agree to use the ulting from the use of ABR provided tissue, agree to publish the results of the research at jeopardizing the sponsor's right to secure the research. Researchers agree to inform a will be published. It is the intent of this
VI.	SOURCE OF FUNDING		
	e identify the primary source of funding for this project. X Other Federal or State Grants Foundation Gra	nis Oti	ner (specify)
other co condition express	s application is approved by ABR, ABR shall provide servi conditions on the reverse side, and the signature of the ap tions by applicant. The entire agreement between ABR ar- astly set forth herein, and any modification of or addition then tion behalf of ABR by a duly authorized representative.	plicant shall c d applicant rel	onstitute acceptance of all such terms and ating to the services provided by ABR is
	IGNING BELOW, THE APPLICANT ACKNOWLEDGES HE FOLLOWING PAGE AND AGREES TO SUCH TER		
	kin D Hasenling		,
_Senio SIONA	or Investigator ATURE and TITLE of APPLICANT	DATE 11/2/2	009
CONI	Please return to: IDITIONS OF SERVICES	1516 OAK ST ALAMBDA, C Telephone: 51 Fax: 51	BIOSCIENCE RESOURCES, INC. TREET, SUITE 303 CALIFORNIA 94501 0-865-5872 0-865-4090 r@abr-inc.coinTERMS AND

Services_

During the term of this agreement, and pursuant to the terms and conditions hereinofter set forth. ABR will use its bost offorts 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 engoing 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 tissuc.

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 zerum, 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 acction 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 itssue 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 self nor transfer for valuable consideration any lissue 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. Tarms. 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 heret 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 aforesald 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. <u>Paymenta.</u> 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 noither 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 itssues. 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 Hability. ABR shall not be responsible or Habie 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 setually received by ABR from researcher on account of this agreement.
- 7. No warrantles. It is understood that human tissue is by nature noither 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. <u>Indemnification</u>. Researcher shall indemnify, defend and hold ABR harmless from and against all claims, causes of actions, suits, demages 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. Qeneral. This agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of faw. 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 (NIĤ/DDIR)

Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up Flag Status: Green

Attachments: IRB Letter with letterhead nonidentity.doc

> From: "OHSR (NIH/DDIR)" <ohsr nih ddir@od.nih.gov>

> Date: Tue, 24 Nov 2009 10:27:55 -0500



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

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

```
> 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

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: Flag Status:

Follow up 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.

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

Kim J Hasenkrug, Ph.D.

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: "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
```

Re: HFT Application

OHSR (NIH/DDIR)

Perrin Larton (b)(6) From:

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

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

(b)(6)Cc:

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
- > 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
- > 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

Re: HFT Application

```
>
>
>> 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
>> 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 Projections, 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



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 1/25/2017	312502 312502	6330 6331	18	Thymus, 2nd Trimester Liver, 2nd Trimester 02/08/17 PAID via VISA Request by Kim Hasenkrug.	HASENKRUG HASENKRUG	(b)(4)
10 still the Les structs 15 to 10 still the Les structs 15 to 10 still the Structs 16 structures 11 structs 16 structures 11 structures 12 structures 12 structures 12 structures 13 structures 14 structures 15 str	Sale	THE	ANS Code: ZIP MAICH ? CVVZ Code: NATCH M Metricolal Mail objudenz	Libratures Curv ENGRYPTE (* 1878/SACTION		
Bood He Fertham Jees IV	Wish Total:	62/68/17 Inv II: UBGGBH Approd: Online	EVE COA	-	Total S680).00

PO#: (b)(6) Requester: Messer, Ronald SEQ: 1829768 Owner: (b)(6) CAN: 8335424 FY: 17 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: OC # Description CAN Catalog Category Oty at Price Total Code (b)(4) Tissue, 2nd Trimester (1 each of liver and 6509 8335424 none 2613 680.00 thymus) 2 shipping 8335424 2613 6509 1 each at \$0 .00Order 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:

GSA Self Service:

No

GSA Stock Catalog:

No

AGENT

NIH Surplus: No

Purchase Order #: (b)(6)

UNICOR:

Order Reference: (b)(6)

FSS:

NBS Ref Order #: 4443716

Estimated Ship Date:

Yes

Date Entered into NBS: 12/30/2016 Expected Delivery Date: 01/06/2017

Federal Supply:

No

Select Agents: No Clearance Requested: No

Open Market:

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
Tissue, 2nd Trimester (1 each of liver and thymus)	2	2	02/10/2017
2 shipping	1	1	02/10/2017

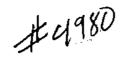
OHSR RESPONSE TO REQU**ESTIFOR REVIEW OF RESEARCH** ACTIVITY INVOLVING HUMAN SUBJECTS

FAX		Exempt: #:	4980			
To:	Hasenkrug, Kim					
	NIAID		;			
	RML - Rocky Mountain Laboratories, 3/218					
From	Office of Human Subjects Research (OHSR)					
Re tiss pro nei	e of Research Activity: cent reports have demonstrated that immunodeficient mice reconstitute ue develop a human immune system and are susceptible to HIV infecti ect proposal is to create such humanized mice to study the role of imm tralizing antibodies in vaccine protection. The experiments will entail the econstituted with the same human cells so as to be histocompatible. The	on and disease. The nune cell subsets and ne development of a c	goal of this virus- ohort of mice			
Origi	nal Request Received in OHSR on: 11/19/2009		·			
Resp	onsible NIH Research Investigator(s): Kim Hasenkrug, NIAID					
OHS	R review of your request dated Thu, Nov 19, 2009 has determined that	t:				
☒	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					
	OF ANY SIGNIFICANT CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.					
	may ask you to provide additional information in order to determine whappropriate.	•	- '			
	Confidentiality Agreement					
	Reliance					
	Amendment					
	Other		!			
	Office Person	LB Admin Ass	_{ist.} CB			
Note	(6)					
	CIP					
\sqrt{chi}	rlotte Holden, JD Acting Director, OHSR	12/14/20	009			
Sig	nature Title	Date				
Don	estic/International:					
Dor	nestic					
Hun	an Subjects Data: Ves	≀ Use Only	_			
	gic Material: Yes	□2 □3 □4 □]5 □6			

Date

11/19/2009

Obtained via FOIA by Judicial Watch, Inc.



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.

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146				
From: King Jasen kung				
(Signature)				
Through:				
(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 NoRML 3218_				
Tel. No. 406-363-9310 FAX No. 406-363-9286				
Is the Principal investigator an NIH employee?x_YesNo				
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 mm³ 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.	(f applicable, list your non-NIH Co	llaborating Investigator(s).	
Name	Institution	Address Tel, # FAX #	
	posed start date of your research _ posed completion date _April, 2013		
4. Will	you bethese samples or	data?	
Rec	lecting Yes/No eiving Yes/No ding Yes/No		
	the samples or data: Already exist?Yes _xNo		
	Or are they being collected for the exyes," please describe:	tpress purpose of this study? _XYesNo	
Res bio NII NO	medical researchers access to human t	established under California law to provide tissues in compliance with state, federal, and stained in accordance with UAGA and	
(c)	Or a combination of (a) and (b)?	YesNo	
6. V	Vhat role will you have in this resea	rch project? (Check all that apply)	
An	alyze samples/data only.	·	
Co	nsultant/advisor to collaborator(s) list	ed above.	
	thor of the protocol that is being implied in question #2).	emented by your collaborating investigator	
Co	-authorship on publication(s)/manusc	ript(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

Last revised 8/4/09

3

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) RepositoryYes No		
(b) Pathological waste YesNo		
(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? YesNo		

13. Has the research activity that you are an Institutional Review Board (IRB) elsew	
 _ :	as been reviewed by the following IRB (s)
(Please provide the following information for	r each IRB):
·	Name of institution that provided the review
	Address of reviewing institution
	Name of PI for the IRB approved protocol
Т	Citle of IRB approved protocol and protocol #
	Federal Wide Assurance (FWA) number**
(**An FWA is a contract between the U.S. I (DHHS) and an entity receiving DHHS funds will follow ethical guidelines and federal reg subjects. For a list of domestic and internation http://ohrp.cit.nih.gov/search/asearch.asp#AS	s to conduct clinical research that the latter ulations for the protection of human nal institutions go to
14. Per NIH guidance***, have conflicts of been resolved? XYesNo no conflicts of inte	
If your answer is no, please see your Clipproceeding with this research.	nical Director about this matter before
***The January 5, 2005 NIH Guide to Prever research conducted at NIH, http://ohsr.od.nih	

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.

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 theraples 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

Obtained via FOIA by Judicial Watch, Inc.

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	BILLING INFORMATION:
TITLE: _Senior Investigator	BILL TO:Kim J Hasenkrug
COMPANY:NIAID, NIH	
ADDRESS: _Rocky Mountain Lab	
ADDRESS: _903 S. 4th St	ADDRESS:
CITY,ST,ZIP: _Hamilton, MT 59840 PHONE #:406-363-9310 ALT. #:	CITY,ST,ZIP:Hamilton, MT 59840ACCOUNTING DEPT. PHONE #:406-363-9438
FAX #: 406-363-9286	P.O. # (if required by your company):
EMAIL: khasenkrug@nih.gov DELIVERY OPTIONS;	P.O. # is not required to submit application Credit Card #:
x Same Day: Commercial carrier, hand delive Maximizes cell viability (geographical line)	
Next Day: Pickup, delivery Mon-Sat dayti	me '
Economical for fresh, frozen specimens	SHIP TO:Kim J Hasenkrug
Applicant will be charged for delivery fees.	_Rocky Mountain Labs
Applicant may designate preferred carrier:	903 S. 4th St
Carrier Name:PEDEX	Hamilton, MT 59840
Account #: (b)(4)	<u> </u>
Piesse indicate how you heard about ABR: (b)(6)	
II. HUMAN FETAL TISSUE	·
	•
Tissue specimens requested:thymus, liver, core	l blood
Preferred gestational age (6-24 weeks): Proposed starting date:May, 2010	_17-19 wks
CONTAGIOUS DISEASE SCREENING: Availabil Applicant requires the following tests to be perform	ity of test results varies from 24 hours to 7 days after procurement ned by ABR:
X No testing required	HIV HSV
<u> </u>	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	y ice	_ Media provided by applicant _ Media provided by ABR (RPMI)
IV.	DONOR INFORMATION		
	SENT VERIFICATION: Consent for tissue donation is obtain nely confidential in nature and shall not be communicated to t		cimen procurement. The consent is
	CIFIC DONOR INFORMATION: Charts are routinely examing information sought and indicate contraindications to specin		
	HIV+ status contraindicates procurement		
v .	— RESEARCH DATA		
TITLE protecti	E OF RESEARCH PROJECT: The role of virus-specition against HIV-1 in humanized mice	fic CD4+T o	zells, CD8+ T cells and antibody in vaccine
research tissue s Updates as pron patents ABR o	will provide tissue to researchers who provide information of intent. (Please attach a brief synopsis of the research personal solely for research purposes and to acknowledge ABR in any less on research progress will be requested at six-month interval omptly after the completion of the research as is reasonably as or copyrights necessary to protect its ownership or control of the name of the publication and the date of the issue in we rement to make the results available to the general public through	project named publications resist. Researchers possible without the results of the results of the results.	above.) Researchers must agree to use the ulting from the use of ABR provided tissue. agree to publish the results of the research at jeopardizing the sponsor's right to secure the research. Researchers agree to inform a will be published. It is the intent of this
VI.	SOURCE OF FUNDING		
	e identify the primary source of funding for this project. X Other Federal or State Grants Foundation Gra	nis Oti	ner (specify)
other co condition express	s application is approved by ABR, ABR shall provide servi conditions on the reverse side, and the signature of the aptions by applicant. The entire agreement between ABR and any set forth herein, and any modification of or addition then don behalf of ABR by a duly authorized representative.	plicant shall c d applicant rel	onstitute acceptance of all such terms and ating to the services provided by ABR is
	IGNING BELOW, THE APPLICANT ACKNOWLEDGES HE FOLLOWING PAGE AND AGREES TO SUCH TER		
	kin D Hasenling		,
_Senio SIONA	or Investigator	DATE 11/2/2	009
CONI	Please return to: DITIONS OF SERVICES	1516 OAK ST ALAMBDA, (Telephone: 51 Fax: 51	BIOSCIENCE RESOURCES, INC. TREET, SUITE 303 CALIFORNIA 94501 0-865-5872 0-865-4090 r@abr-inc.coinTERMS AND

Services_

During the term of this agreement, and pursuant to the terms and conditions hereinofter set forth. ABR will use its bost offorts 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 engoing 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 tissuc.

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 zerum, 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 acction 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 itssue 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 self nor transfer for valuable consideration any lissue 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. Tarms. 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 heret 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 aforesald 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. <u>Paymenta.</u> 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 noither 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 itssues. 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 Hability. ABR shall not be responsible or Habie 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 setually received by ABR from researcher on account of this agreement.
- 7. No warrantles. It is understood that human tissue is by nature noither 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. <u>Indemnification</u>. Researcher shall indemnify, defend and hold ABR harmless from and against all claims, causes of actions, suits, demages 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. Qeneral. This agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of faw. 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 (NIĤ/DDIR)

Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up Flag Status: Green

Attachments: IRB Letter with letterhead nonidentity.doc

> From: "OHSR (NIH/DDIR)" <ohsr nih ddir@od.nih.gov>

> Date: Tue, 24 Nov 2009 10:27:55 -0500



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

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

```
> 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

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: Flag Status:

Follow up 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.

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

Kim J Hasenkrug, Ph.D.

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: "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
```

Re: HFT Application

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.

Рептіп

- > 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: Pertin Larton (b)(6)
\Rightarrow 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
>> 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

Re: HFT Application

>> respond to your query.

>> Advanced Bioscience Resources

>> Perrin Larton CTBS >> Procurement Manager

>>

>

12/8/2009

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 Projections, 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



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 2/8/2017	670802 670802	6483 6484	21 21	Thymus, 2nd Trimester Liver, 2nd Trimester		HASENKRUG HASENKRUG	(b)(4)
			,	02/15/17 PAID via VISA Request by Kim Hasenkrug.	(6)		-
							341,000 3413,000
1, 163 1, 155, 5872 1, 155, 5872 1, 151, 151	le Entry Method: Manual 680.00	Appar B	ट्रज्ञातान्त्र <u>।</u>	tretonce Coer			 قار چ
STR (80) All Amiles On Years US (8) USS SATZ SAUX III. BUTL For Chaine III. LUMALE IDEN	Sale NS Total: \$	62-15-17 Inv N: 668086 Approd: Online and Code. 719 MSTON	MY Cole; MACH II	4.1 PK-14.1 1	Total	\$680	.00

PO#: (b)(6) SEQ: 1833955 Requester: Messer, Ronald Owner: (b)(6) CAN: 8335424 FY: 17 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: OC # Description CAN Category Oty at Price Total Catalog Code (b)(4) Tissue, 2nd Trimester (1 each of liver and 6509 8335424 none 2613 680.00 thymus) 2 shipping 8335424 2613 6509 1 each at \$0 .00Order 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) give her the PO number and credit card information. Alternate Sources: GSA Stock Catalog: GSA Self Service: Federal Supply: Open Market: UNICOR: NIH Surplus: No No No No Yes AGENT

Purchase Order #: (tb)(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

Clearance Requested: No

Select Agents: 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
Tissue, 2nd Trimester (1 each of liver and thymus)	2	2	03/29/2017
2 shipping	1	1	03/29/2017

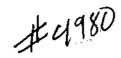
OHSR RESPONSE TO REQU**ESTIFOR REVIEW OF RESEARCH** ACTIVITY INVOLVING HUMAN SUBJECTS

FAX			Exempt: #:	4980
To:	Hasenkrug, Kim			
	NIAID			:
	RML - Rocky Mountain Laborator	ries, 3/218		
From	n: Office of Human Subjects Resear	rch (OHSR)		
Re tiss pro net	re of Research Activity: cent reports have demonstrated that i sue develop a human immune system pject proposal is to create such human utralizing antibodies in vaccine protect reconstituted with the same human ce	and are susceptible to HIV infections and are susceptible to HIV infections. The experiments will entail	ction and disease. The imune cell subsets and the development of a c	goal of this virus- ohort of mice
Origi	nal Request Received in OHSR on:	11/19/2009		·
Resp	oonsible NIH Research Investigator(s)	Kim Hasenkrug, NIAID		
OHS	SR review of your request dated Thu,	Nov 19, 2009 has determined th	at:	
	Federal regulations for the protection determination of Not Human Subject Involving Coded Private Information on Engagement of Institutions in Human AMENDMENT OF ANY CHANGES The activity is designated EXEMPT .	s Research is based on the inter or Biological Specimens" (OHRF man Subjects Research (Octobe THAT MAY ALTER THIS RESE and has been entered in the OH	rpretation of 45 CFR 46 P, Revised October 16, Ir 16, 2008). NOTIFY OI ARCH ACTIVITY. ISR database. <u>PLEAS</u>	under "Research 2008) and Guidance HSR VIA AN E-MAIL E NOTIFY OHSR
	OF ANY SIGNIFICANT CHANGES	<u> THAT MAY ALTER THE EXEMP</u>	<u>PT STATUS OF THIS R</u>	<u>ESEARCH</u>
	NOT EXEMPT. OHSR recommends may ask you to provide additional infappropriate.	•	•	- I '
	Confidentiality Agreement			
	Reliance			
	Amendment	-		
	Other			!
Note	e:	Office Person	LB Admin Ass	ist. CB
(b)	C/ ₁	p		
_√ Chi	arlotte Holden, JD	Acting Director, OHSR	12/14/20	009
Sig	nature	Title	Date	
Don	nestic/International:			
Dor	nestic			
Hun	nan Subjects Data: Yes	_	SR Use Only	
	ogic Material: Yes	□1	□2 □3 □4 □	15 □6

Date

11/19/2009

Obtained via FOIA by Judicial Watch, Inc.



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.

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146
From: KIM J Hasen Kura
(Signature)
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_
ICNIAID_Laboratory/Branch LPVD_Building & Room NoRML 3218_
Tel. No. 406-363-9310 FAX No. 406-363-9286
Is the Principal investigator an NIH employee?x_YesNo
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 mm³ 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 naive 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.

If applicable, list your non-NIH Collaborating Investigator(s).		
Name	Institution	Address Tel, # FAX #
	osed start date of your research osed completion date _April, 201	
4. Will <u>y</u>	ou bethese samples o	r data?
	ecting Yes/No iving Yes/No ing Yes/No	
	ne samples or data: Already exist?Yes _xNo	
	Or are they being collected for the es," please describe:	express purpose of this study? _X_YesNo
Reso bion NIH	urces, Inc., a non-profit foundation edical researchers access to human guidelines. Consent to donate is a guidelines. Related documents	e obtained from Advanced Bioscience n established under California law to provide n tissues in compliance with state, federal, and obtained in accordance with UAGA and including the consent form are
(c) (Or a combination of (a) and (b)?	YesNo
6. W	hat role will you have in this reso	earch project? (Check all that apply)
Ana	lyze samples/data only.	•
Con	sultant/advisor to collaborator(s) li	sted above.
	nor of the protocol that is being imped in question #2).	plemented by your collaborating investigator
Co-	uthorship on publication(s)/manus	cript(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		

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) RepositoryYes No
(b) Pathological waste YesNo
(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? YesNo

13. Has the research activity that you are an Institutional Review Board (IRB) elsew	
Yes, the NIH research activity hat (Please provide the following information for	as been reviewed by the following IRB (s)
(x tease provide the following information for	i enell (ICO).
1	Name of institution that provided the review
	Address of reviewing institution
1	Name of PI for the IRB approved protocol
т	Citle of IRB approved protocol and protocol #
	Federal Wide Assurance (FWA) number**
(**An FWA is a contract between the U.S. I (DHHS) and an entity receiving DHHS funds will follow ethical guidelines and federal reg subjects. For a list of domestic and internatio http://ohrp.cit.nih.gov/search/asearch.asp#AS	s to conduct clinical research that the latter ulations for the protection of human nal institutions go to
14. Per NIH guidance***, have conflicts of been resolved? XYesNo no conflicts of inte	
If your answer is no, please see your Cli proceeding with this research.	nical Director about this matter before
***The January 5, 2005 NIH Guide to Prever research conducted at NIH, http://ohsr.od.nih	

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.

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 theraples 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

Obtained via FOIA by Judicial Watch, Inc.

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. AP	PLICANT INFORMATION		
NAME:	Kim J Hasenkrug		BILLING INFORMATION:
TITLB:	Senior Investigator	BILL TO:	Kim J Hasenkrug
COMPANY	':NIAID, NIH	_ COMPANY:	Rocky Mountain Labs
ADDRESS:			903 S. 4th St
ADDRESS:	_903 S. 4th St	ADDRESS:	
CITY,ST,Z PHONE #: ALT. #:	IP: _Hamilton, MT 59840 406-363-9310	CITY,ST,ZIP: ACCOUNTING	Hamilton, MT 59840
	406-363-9286	P.O. # (if requi	red by your company):
DELIVERY	hasenkrug@nih.gov Y OPTIONS;	Credit Card #:	equired to submit application
Mex	ne Day: Commercial carrier, hand delivered kimizes cell viability (geographical limits) at Day: Pickup, delivery Mon-Sat daytime	Name on CC: Expiration Date	:VJSA/MC
Bco.	nomical for fresh, frozen specimens	SHIP TO:	Kim J Hasenkrug
Applicant v	vill be charged for delivery fees.		_Rocky Mountain Labs
Applicant m	ay designate preferred carrier:		903 S. 4th St
Carrier Nam Account #:	re:		_Hamilton, MT 59840
Piesse indic	rate how you heard about ABR: (b)(6)		
II. HU	MAN FETAL TISSUE		•
Tissue speci	imens requested:thymus, liver, cord blood	i	
Pret Proj	ferred gestational age (6-24 weeks): 17-19 posed starting date:May, 2010	wks	
CONTAGIO Applicant re	OUS DISEASE SCREENING: Availability of equires the following tests to be performed by	test results varies : ABR:	from 24 hours to 7 days after procurement
_x	No testing required HIV HBS CM	DAG	HSV RPR 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	y ice	_ Media provided by applicant _ Media provided by ABR (RPMI)
IV.	DONOR INFORMATION		
	SENT VERIFICATION: Consent for tissue donation is obtain nely confidential in nature and shall not be communicated to t		cimen procurement. The consent is
	CIFIC DONOR INFORMATION: Charts are routinely examing information sought and indicate contraindications to specin		
	HIV+ status contraindicates procurement		
v .	— RESEARCH DATA		
TITLE protecti	E OF RESEARCH PROJECT: The role of virus-specition against HIV-1 in humanized mice	fic CD4+T o	zells, CD8+ T cells and antibody in vaccine
research tissue s Updates as pron patents ABR o	will provide tissue to researchers who provide information of intent. (Please attach a brief synopsis of the research personal solely for research purposes and to acknowledge ABR in any less on research progress will be requested at six-month interval omptly after the completion of the research as is reasonably as or copyrights necessary to protect its ownership or control of the name of the publication and the date of the issue in we rement to make the results available to the general public through	project named publications resist. Researchers possible without the results of the results of the results.	above.) Researchers must agree to use the ulting from the use of ABR provided tissue. agree to publish the results of the research at jeopardizing the sponsor's right to secure the research. Researchers agree to inform a will be published. It is the intent of this
VI.	SOURCE OF FUNDING		
	e identify the primary source of funding for this project. X Other Federal or State Grants Foundation Gra	nis Oti	ner (specify)
other co condition express	s application is approved by ABR, ABR shall provide servi conditions on the reverse side, and the signature of the aptions by applicant. The entire agreement between ABR and any sect forth herein, and any modification of or addition then don behalf of ABR by a duly authorized representative.	plicant shall c d applicant rel	onstitute acceptance of all such terms and ating to the services provided by ABR is
	IGNING BELOW, THE APPLICANT ACKNOWLEDGES HE FOLLOWING PAGE AND AGREES TO SUCH TER		
	kin D Hasenling		,
_Senio SIONA	or Investigator	DATE 11/2/2	009
CONI	Please return to: DITIONS OF SERVICES	1516 OAK ST ALAMBDA, (Telephone: 51 Fax: 51	BIOSCIENCE RESOURCES, INC. TREET, SUITE 303 CALIFORNIA 94501 0-865-5872 0-865-4090 r@abr-inc.coinTERMS AND

Services_

During the term of this agreement, and pursuant to the terms and conditions hereinofter set forth. ABR will use its bost offorts 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 engoing 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 tissuc.

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 zerum, 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 acction 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 itssue 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 self nor transfer for valuable consideration any lissue 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. Tarms. 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 heret 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 aforesald 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. <u>Paymenta.</u> 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 noither 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 itssues. 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 Hability. ABR shall not be responsible or Habie 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 setually received by ABR from researcher on account of this agreement.
- 7. No warrantles. It is understood that human tissue is by nature noither 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. <u>Indemnification</u>. Researcher shall indemnify, defend and hold ABR harmless from and against all claims, causes of actions, suits, demages 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. Qeneral. This agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of faw. 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 (NIĤ/DDIR)

Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up Flag Status: Green

Attachments: IRB Letter with letterhead nonidentity.doc

> From: "OHSR (NIH/DDIR)" <ohsr nih ddir@od.nih.gov>

> Date: Tue, 24 Nov 2009 10:27:55 -0500



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

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

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> 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

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: Flag Status:

Follow up 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.

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

Kim J Hasenkrug, Ph.D.

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

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> 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.
```

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> 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
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Re: HFT Application

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.

Рептіп

- > 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
- < 1711
- > 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

Re: HFT Application

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>
>
>> From: Pertin 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
>> 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 Projections, 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



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	DE\$CR!PTI	ON	RESEARCHER	FEE
3/9/2017 3/9/2017	730901 730901	5162 5163	19 19	Thymus, 2nd Trimester Liver, 2nd Trimester		HASENKRUG HASENKRUG	(b)(4)
				03/24/17 PAID via VISA Request by Kim Hasenkrug.	(b)(6)		
511 348. Sec. 20.	e Entry Nethou's fanual GRAD DA	13:13:28 Name Code: 183677 Batchis: 183881	r9n	- 445A(. 11014			· · · · · · · · · · · · · · · · · · ·
15.16 Gate at ST 383 R 641 Gat at 385 15.104 085 5872 Early 16 Construction 15.104 0813 Resident 16 Construction 15.00	NS EM		ANS Code: JIP MAICH Z CNV2 Code: MAICH M Religious metals and common	100 100	Total	\$680	.00

PO#: (b)(6) SEQ: 1838455 Requester: Messer, Ronald Owner: (b)(6) CAN: 8335424 FY: 17 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: OC # Description CAN Category Oty at Price Total Catalog Code (b)(4)Tissue, 2nd Trimester (1 each of liver and 6509 8335424 none 2613 680.00 thymus) 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: GSA Stock Catalog: GSA Self Service: Federal Supply: Open Market: UNICOR: NIH Surplus: No No No No Yes AGENT Purchase Order #: (b)(6) Estimated Ship Date: Custodial Code: 30102 Date Entered into NBS: 02/28/2017 Order Reference: em'd Expected Delivery Date: 03/03/2017

Select Agents: No

Clearance Requested: No

FSS:

NBS Ref Order #: 4506062

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
Tissue, 2nd Trimester (1 each of liver and thymus)	2	2	03/23/2017
2 shipping	1	1	03/23/2017

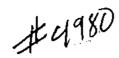
OHSR RESPONSE TO REQU**ESTIFOR REVIEW OF RESEARCH** ACTIVITY INVOLVING HUMAN SUBJECTS

FAX		Exempt: #:	4980
To:	Hasenkrug, Kim		
	NIAID		}
	RML - Rocky Mountain Laboratories, 3/218		
From	Office of Human Subjects Research (OHSR)		
Re tiss pro nei	e of Research Activity: cent reports have demonstrated that immunodeficient mice reconstituted ue develop a human immune system and are susceptible to HIV infectio ect proposal is to create such humanized mice to study the role of immi tralizing antibodies in vaccine protection. The experiments will entail th econstituted with the same human cells so as to be histocompatible. The	on and disease. The une cell subsets and e development of a c	goal of this virus- ohort of mice
Origi	nal Request Received in OHSR on: 11/19/2009		·
Resp	onsible NIH Research Investigator(s): Kim Hasenkrug, NIAID		
OHS	R review of your request dated Thu, Nov 19, 2009 has determined that:		
	Federal regulations for the protection of human subjects do not apply to determination of Not Human Subjects Research is based on the interpretation of Coded Private Information or Biological Specimens" (OHRP, I on Engagement of Institutions in Human Subjects Research (October 1 AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESEAR	etation of 45 CFR 46 Revised October 16, 6, 2008). NOTIFY OI	under "Research 2008) and Guidance
	The activity is designated EXEMPT , and has been entered in the OHSI OF ANY SIGNIFICANT CHANGES THAT MAY ALTER THE EXEMPT ACTIVITY.	R database. <u>PLEAS</u> STATUS OF THIS R	<u>ESEARCH</u>
	NOT EXEMPT. OHSR recommends IRB review. Please forward your may ask you to provide additional information in order to determine who appropriate.	•	- 1 '
	Confidentiality Agreement		
	Reliance		
	Amendment		
	Other		!
Note	Office Person L	B Admin Ass	ist. CB
(b)			
	CIP		
<u>√ Ch</u>	rlotte Holden, JD Acting Director, OHSR	12/14/20	09
Sig	nature Title	Date	
Don	estic/International:		
Dor	nestic		
Hun	an Subjects Data: Ves	Use Only	1
	gic Material: Yes	□2 □3 □4 □	15 ∐6

Date:

11/19/2009

Obtained via FOIA by Judicial Watch, Inc.



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.

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146
From: KIM J tasen know
(Signature)
Through:
(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. No406-363-9310_FAX No. 406-363-9286
Is the Principal investigator an NIH employee?x_YesNo
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 mm³ 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 naive 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.

If applicable, list your non-NIH Collaborating Investigator(s).				
Name	Institution	Address Tel. # FAX #		
	osed start date of your research osed completion date _April, 2013			
4. Will <u>y</u>	you bethese samples or	r data?		
	ecting Yes/No living Yes/No ling Yes/No			
	ne samples or data: Already exist?Yes _xNo			
	Or are they being collected for the ees," please describe:	express purpose of this study? _X_YesNo		
Reso bion NIH NOT	urces, Inc., a non-profit foundation ledical researchers access to human	e obtained from Advanced Bioscience a established under California law to provide a tissues in compliance with state, federal, and obtained in accordance with UAGA and including the consent form are		
(c) (Or a combination of (a) and (b)?	YesNo		
6. W	hat role will you have in this rese	earch project? (Check all that apply)		
Ana	lyze samples/data only.	•		
Con	sultant/advisor to collaborator(s) lis	sted above.		
	nor of the protocol that is being imped in question #2).	plemented by your collaborating investigator		
Co-	authorship on publication(s)/manus	cript(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

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) RepositoryYes No
(b) Pathological waste YesNo
(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? YesNo

13. Has the research activity that you are pan Institutional Review Board (IRB) elsew	
	s been reviewed by the following IRB (s)
(Please provide the following information for	eact (KB):
	Name of institution that provided the review
	Address of reviewing institution
	Name of PI for the IRB approved protocol
Т	itle of IRB approved protocol and protocol #
F	ederal Wide Assurance (FWA) number**
(**An FWA is a contract between the U.S. D (DHHS) and an entity receiving DHHS funds will follow ethical guidelines and federal regu subjects. For a list of domestic and internation http://ohrp.cit.nih.gov/search/asearch.asp#AS	to conduct clinical research that the latter allations for the protection of human nal institutions go to
14. Per NIH guidance***, have conflicts of been resolved? XYesNo no conflicts of inter	
If your answer is no, please see your Clin proceeding with this research.	nical Director about this matter before
***The January 5, 2005 NIH Guide to Prever research conducted at NIH, http://ohsr.od.nih.	

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.

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 theraples 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. AP	PLICANT INFORMATION				
NAME:	Kim J Hasenkrug		BILLING INFORMATION:		
TITLB:	Senior Investigator		Kim J Hasenkrug		
COMPANY	':NIAID, NIH		Rocky Mountain Labs		
ADDRESS:			903 S. 4th St		
ADDRESS:	_903 S. 4th St	ADDRESS:			
CITY,ST,ZIP: _Hamilton, MT 59840 PHONE #:406-363-9310 ALT. #:		CITY,ST,ZIP:Hamilton, MT 59840_ ACCOUNTING DEPT. PHONE #:406-363-9438			
FAX#:	406-363-9286	P.O. # (if required by your company):			
EMAIL: khasenkrug@nih.gov DELIVERY OPTIONS:		Credit Card #:	equired to submit application		
Max	ne Day: Commercial carrier, hand delivered kimizes cell viability (geographical limits) at Day: Pickup, delivery Mon-Sat daytime	Name on CC: Expiration Date	:VJSA/MC		
Bco	nomical for fresh, frozen specimens	SHIP TO:	Kim J Hasenkrug		
Applicant v	vill be charged for delivery fees.		_Rocky Mountain Labs		
Applicant m	ay designate preferred carrier:		903 S. 4th St		
Carrier Nam Account #:	re: FEDEX		_Hamilton, MT 59840		
Piesse indic	rate how you heard about ABR: (b)(6)				
II. HU	IMAN FETAL TISSUE		•		
Tissue speci	imens requested:thymus, liver, cord blood	i	·		
Pret Proj	ferred gestational age (6-24 weeks): 17-19 posed starting date:May, 2010	wks			
CONTAGIO Applicant re	OUS DISEASE SCREENING: Availability of equires the following tests to be performed by	test results varies (ABR:	from 24 hours to 7 days after procurement.		
_x	No testing required HIV HBS CM	DAG	HSV RPR 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	y ice	_ Media provided by applicant _ Media provided by ABR (RPMI)
IV.	DONOR INFORMATION		
	SENT VERIFICATION: Consent for tissue donation is obtain nely confidential in nature and shall not be communicated to t		cimen procurement. The consent is
	CIFIC DONOR INFORMATION: Charts are routinely examing information sought and indicate contraindications to specin		
	HIV+ status contraindicates procurement		
v .	— RESEARCH DATA		
TITLE protecti	E OF RESEARCH PROJECT:The role of virus-spection against HIV-1 in humanized mice	fic CD4+T o	ells, CD8+ T cells and antibody in vaccine
research tissue s Updates as pron patents ABR o	will provide tissue to researchers who provide information of intent. (Please attach a brief synopsis of the research personal solely for research purposes and to acknowledge ABR in any less on research progress will be requested at six-month interval omptly after the completion of the research as is reasonably as or copyrights necessary to protect its ownership or control of the name of the publication and the date of the issue in we rement to make the results available to the general public through	project named publications resist. Researchers possible without the results of the results of the results.	above.) Researchers must agree to use the ulting from the use of ABR provided tissue, agree to publish the results of the research at jeopardizing the sponsor's right to secure the research. Researchers agree to inform a will be published. It is the intent of this
VI.	SOURCE OF FUNDING		
	e identify the primary source of funding for this project. X Other Federal or State Grants Foundation Gra	nis Oti	ner (specify)
other co condition express	s application is approved by ABR, ABR shall provide servi conditions on the reverse side, and the signature of the ap tions by applicant. The entire agreement between ABR ar- astly set forth herein, and any modification of or addition then tion behalf of ABR by a duly authorized representative.	plicant shall c d applicant rel	onstitute acceptance of all such terms and ating to the services provided by ABR is
	IGNING BELOW, THE APPLICANT ACKNOWLEDGES HE FOLLOWING PAGE AND AGREES TO SUCH TER		
	kin D Hasenling		,
_Senio SIONA	or Investigator ATURE and TITLE of APPLICANT	DATE 11/2/2	009
CONI	Please return to: IDITIONS OF SERVICES	1516 OAK ST ALAMBDA, C Telephone: 51 Fax: 51	BIOSCIENCE RESOURCES, INC. TREET, SUITE 303 CALIFORNIA 94501 0-865-5872 0-865-4090 r@abr-inc.coinTERMS AND

Services_

During the term of this agreement, and pursuant to the terms and conditions hereinofter set forth. ABR will use its bost offorts 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 engoing 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 tissuc.

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 zerum, 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 acction 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 itssue 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 self nor transfer for valuable consideration any lissue 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. Tarms. 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 heret 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 aforesald 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. <u>Paymenta.</u> 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 noither 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 itssues. 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 Hability. ABR shall not be responsible or Habie 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 setually received by ABR from researcher on account of this agreement.
- 7. No warrantles. It is understood that human tissue is by nature noither 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. <u>Indemnification</u>. Researcher shall indemnify, defend and hold ABR harmless from and against all claims, causes of actions, suits, demages 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. Qeneral. This agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of faw. 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,

(0)(0)			

OHSR (NIH/DDIR)

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

Sent: Wednesday, December 09, 2009 5:41 PM

To: OHSR (NIĤ/DDIR)

Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up Flag Status: Green

Attachments: IRB Letter with letterhead nonidentity.doc

> From: "OHSR (NIH/DDIR)" <ohsr nih ddir@od.nih.gov>

> Date: Tue, 24 Nov 2009 10:27:55 -0500



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

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

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> 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

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: Flag Status:

Follow up 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.

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

Kim J Hasenkrug, Ph.D.

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: "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
```

Re: HFT Application

OHSR (NIH/DDIR)

Perrin Larton (b)(6) From:

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

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

(b)(6)Cc:

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
- > 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
- > 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

Re: HFT Application

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>
>
>> 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
>> 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 Projections, 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



TISSUE ACQUISITION INVOICE

	DATE	P.O. #	INVOICE #
. 934	3/30/2017	(b)(6)	1033450
41		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
3/30/2017 3/30/2017	643003 643003	8600 8601	17 17	Thymus, 2nd Tri-N/C Delivery Delay Liver, 2nd Tri-N/C Delivery Delay	•	HASENKRUG HASENKRUG	0,00 0,00
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					. :		
					·		
_							
					Total	\$0.0)0

SEQ: 1841763 PO#: Requester: Messer, Ronald Owner: (b)(6) CAN: 8335424 FY: 17 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: OC # Description CAN Catalog Category Oty at Price Total Code (b)(4)Tissue, 2nd Trimester (1 each of liver and 6509 8335424 none 2613 680.00 thymus) 2 shipping 8335424 2613 6509 1 each at \$0 .00Order 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: GSA Stock Catalog: GSA Self Service: Federal Supply: Open Market: UNICOR: NIH Surplus: No No No No Yes AGENT

Purchase Order #: (b)(6)

Custodial Code: 30102

Order Reference: em'd (b)(6)

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

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
Tissue, 2nd Trimester (1 each of liver and thymus)	2	2	04/19/2017
2 shipping	1	1	04/19/2017

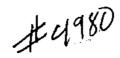
OHSR RESPONSE TO REQU**ESTIFOR REVIEW OF RESEARCH** ACTIVITY INVOLVING HUMAN SUBJECTS

FAX	:			Exempt: #:	4980	
To:	Hasenkrug, Kim					
	NIAID				1	
	RML - Rocky Mountain La	boratories, 3/218				
From	n: Office of Human Subjects	Research (OHSR)				
Re tiss pro nei	re of Research Activity: cent reports have demonstrate sue develop a human immune s sject proposal is to create such utralizing antibodies in vaccine reconstituted with the same hu	system and are susceptible the humanized mice to study the protection. The experiments	to HIV infection and e role of immune ce s will entail the deve	disease. The ell subsets and ellopment of a c	goal of this virus- ohort of mice	
Origi	nal Request Received in OHSF	R on: 11/19/2009				
Resp	ponsible NIH Research Investig	gator(s): Kim Hasenkrug,	NIAID			
OHS	SR review of your request dated	d Thu, Nov 19, 2009 has det	ermined 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.					
	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				!	
		Off	ice Person LB	Admin Ass	ist. CB	
Note	9; (/6)	٦				
	``	CIP				
{Ն} Cha	arlotte Holden, JD	」 Acting Director, OH	ISR	12/14/20	009	
Sig	nature	Title		Date		
Don	nestic/International:					
Dor	nestic					
Hum	nan Subjects Data: Yes		OHSR Use C	-	_	
	ogic Material: Yes		∐1 ∐2	□3 □4 □	15 □6	

Date

11/19/2009

Obtained via FOIA by Judicial Watch, Inc.



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.

<u></u>
To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146
From: Kim & tasen knig
(Signafure)
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_
ICNIAIDLaboratory/Branch LPVD_Building & Room NoRML 3218_
Tel. No. 406-363-9310 FAX No. 406-363-9286
Is the Principal investigator an NIH employee?x_YesNo
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 mm³ 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 #		
	ed start date of your researchApri ed completion date _April, 2013			
4. Will yo	u bethese samples or data	?		
Collec Receiv Sendin	ing Yes/No			
	samples or data: ready exist?Yes _xNo			
	are they being collected for the express," please describe:	s purpose of this study? _X_YesNo		
Resour biomed NIH gr	uidelines. Consent to donate is obtaine guidelines. Related documents includi	ished under California law to provide is in compliance with state, federal, and in accordance with UAGA and		
(c) Or	a combination of (a) and (b)?	YesNo		
6. Wh	at role will you have in this research	project? (Check all that apply)		
Analy	ze samples/data only.	•		
Consu	Itant/advisor to collaborator(s) listed ab	oove.		
	r of the protocol that is being implement in question #2).	ited by your collaborating investigator		
Со-ви	thorship 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

Last revised 8/4/09

3

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) RepositoryYes No
(b) Pathological waste YesNo
(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? YesNo

13. Has the research activity that you are an Institutional Review Board (IRB) elsew	
 _ :	as been reviewed by the following IRB (s)
(Please provide the following information for	r each IRB):
·	Name of institution that provided the review
	Address of reviewing institution
	Name of PI for the IRB approved protocol
Т	Citle of IRB approved protocol and protocol #
	Federal Wide Assurance (FWA) number**
(**An FWA is a contract between the U.S. I (DHHS) and an entity receiving DHHS funds will follow ethical guidelines and federal reg subjects. For a list of domestic and internation http://ohrp.cit.nih.gov/search/asearch.asp#AS	s to conduct clinical research that the latter ulations for the protection of human nal institutions go to
14. Per NIH guidance***, have conflicts of been resolved? XYesNo no conflicts of inte	
If your answer is no, please see your Clipproceeding with this research.	nical Director about this matter before
***The January 5, 2005 NIH Guide to Prever research conducted at NIH, http://ohsr.od.nih	

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.

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 theraples 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

Obtained via FOIA by Judicial Watch, Inc.

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. A	PPLICANT INFORMATION		
NAME:	Kim J Hasenkrug		BILLING INFORMATION:
TITLB:	Senior Investigator	BILL TO:	Kim J Hasenkrug
COMPAN	Y:NIAID, NIH	_ COMPANY:	Rocky Mountain Labs
ADDRESS			903 S. 4th St
ADDRESS	3: _903 S. 4th St	ADDRESS:	
CITY,ST,2 PHONE #: ALT. #:	ZIP: _Hamilton, MT 59840 :406-363-9310	CITY,ST,ZIP: ACCOUNTING	Hamilton, MT 59840
FAX#:	406-363-9286	P.O. # (if requi	red by your company):
DELIVER	khasenkrug@nih.gov KY OPTIONS:	Credit Card #:	equired to submit application
M	ane Day: Commercial carrier, hand delivered aximizes cell viability (geographical limits) ext Day: Pickup, delivery Mon-Sat daytime	Name on CC: Expiration Date	:VJSA/MC
Вс	onomical for fresh, frozen specimens	SHIP TO:	Kim J Hasenkrug
Applicant	will be charged for delivery fees.		_Rocky Mountain Labs
Applicant i	may designate preferred carrier:		903 S. 4th St
Carrier Nar Account #:			_Hamilton, MT 59840
Piesse indi	leate how you heard about ABR: (b)(6)		
п. н	UMAN FETAL TISSUE		•
Tissue spec	cimens requested:thymus, liver, cord bloo	d	·
Pro Pro	eferred gestational age (6-24 weeks):17-19 oposed starting date:May, 2010	wks	
CONTAGI Applicant i	OUS DISEASE SCREENING: Availability of requires the following tests to be performed by	test results varies : ABR:	from 24 hours to 7 days after procurement
_:	X No testing required HIV HB8	DAS	HSV RPR 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	y ice	_ Media provided by applicant _ Media provided by ABR (RPMI)
IV.	DONOR INFORMATION		
	SENT VERIFICATION: Consent for tissue donation is obtain nely confidential in nature and shall not be communicated to t		cimen procurement. The consent is
	CIFIC DONOR INFORMATION: Charts are routinely examing information sought and indicate contraindications to specin		
	HIV+ status contraindicates procurement		
v .	— RESEARCH DATA		
TITLE protecti	E OF RESBARCH PROJECT: The role of virus-specition against HIV-1 in humanized mice	fic CD4+T o	zells, CD8+ T cells and antibody in vaccine
research tissue s Updates as pron patents ABR o	will provide tissue to researchers who provide information of intent. (Please attach a brief synopsis of the research personal solely for research purposes and to acknowledge ABR in any less on research progress will be requested at six-month interval omptly after the completion of the research as is reasonably as or copyrights necessary to protect its ownership or control of the name of the publication and the date of the issue in we rement to make the results available to the general public through	project named publications resist. Researchers possible without the results of the results of the results.	above.) Researchers must agree to use the ulting from the use of ABR provided tissue. agree to publish the results of the research at jeopardizing the sponsor's right to secure the research. Researchers agree to inform a will be published. It is the intent of this
VI.	SOURCE OF FUNDING		
	e identify the primary source of funding for this project. X Other Federal or State Grants Foundation Gra	nis Oti	ner (specify)
other co condition express	s application is approved by ABR, ABR shall provide servi conditions on the reverse side, and the signature of the aptions by applicant. The entire agreement between ABR and any set forth herein, and any modification of or addition then don behalf of ABR by a duly authorized representative.	plicant shall c d applicant rel	onstitute acceptance of all such terms and ating to the services provided by ABR is
	IGNING BELOW, THE APPLICANT ACKNOWLEDGES HE FOLLOWING PAGE AND AGREES TO SUCH TER		
	kin D Hasenling		,
_Senio SIONA	or Investigator	DATE 11/2/2	009
CONI	Please return to: DITIONS OF SERVICES	1516 OAK ST ALAMBDA, (Telephone: 51 Fax: 51	BIOSCIENCE RESOURCES, INC. TREET, SUITE 303 CALIFORNIA 94501 0-865-5872 0-865-4090 r@abr-inc.coinTERMS AND

Services_

During the term of this agreement, and pursuant to the terms and conditions hereinofter set forth. ABR will use its bost offorts 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 engoing 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 tissuc.

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 zerum, 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 acction 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 itssue 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 self nor transfer for valuable consideration any lissue 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. Tarms. 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 heret 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 aforesald 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. <u>Paymenta.</u> 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 noither 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 itssues. 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 Hability. ABR shall not be responsible or Habie 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 setually received by ABR from researcher on account of this agreement.
- 7. No warrantles. It is understood that human tissue is by nature noither 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. <u>Indemnification</u>. Researcher shall indemnify, defend and hold ABR harmless from and against all claims, causes of actions, suits, demages 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. Qeneral. This agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of faw. 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,

(0)(0)			

OHSR (NIH/DDIR)

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

Sent: Wednesday, December 09, 2009 5:41 PM

To: OHSR (NIĤ/DDIR)

Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up Flag Status: Green

Attachments: IRB Letter with letterhead nonidentity.doc

> From: "OHSR (NIH/DDIR)" <ohsr nih ddir@od.nih.gov>

> Date: Tue, 24 Nov 2009 10:27:55 -0500



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

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

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> 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

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: Flag Status:

Follow up 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.

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

Kim J Hasenkrug, Ph.D.

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: "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.
```

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> 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
```

Re: HFT Application

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.

Рептіп

- > 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.
- >
- > **K**im
- > 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

Re: HFT Application

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>
>
>> 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
>> 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 Projections, 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



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 4/20/2017	642002 642002	8627 8628 17	Thymus, 2nd Trimester Liver, 2nd Trimester 05/03/17 PAID via VISA Request by Kim Hasenkrug.	KIM	(b)(4)
				The state of the s	Fifth 1
1515, USB 7517 (11 HB3 218 - 318 318 - 318 318 - 318 (32 HB3) (42 HB3) (42 HB3) (42 HB3) (42 HB3) (43 HB3) (Sale VISH Entry Nethod: Navel	Appropriate Report Repo	increase it as a linear state of the state o		

PO#: (b)(6) SEQ: 1844479 Requester: Messer, Ronald Owner: (b)(6) CAN: 8335424 FY: 17 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
	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
0	rder Total: 680.00		,		.,	,	

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

QUOTES

Vendor	Price	Good Until	Available
There are no quotes in the	ne 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 give her the PO number and credit card information.

Alternate Sources:

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

AGENT

Purchase Order #: (b)(6)

Estimated Ship Date: Custodial Code: 30102 Date Entered into NBS: 03/31/2017 Order Reference: em'd Expected Delivery Date: 04/07/2017

FSS: Select Agents: No

NBS Ref Order #: 4543155 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	1
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 Messer, Ronald		Role	Date In	STATUS IN	ACTION
		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, Ronal	ld (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
Tissue, 2nd Trimester (1 each of liver and thymus)	2	2	04/19/2017
2 shipping	1	1	04/19/2017

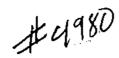
OHSR RESPONSE TO REQU**ESTIFOR REVIEW OF RESEARCH** ACTIVITY INVOLVING HUMAN SUBJECTS

FAX				Exe	mpt: #:	4980
To:	Hasenkrug, Kim					
	NIAID					;
	RML - Rocky Mo	ountain Laboratorie	s. 3/218			
Fron	n: Office of Human	Subjects Research	n (OHSR)			
Re tiss pro ner	sue develop a human oject proposal is to cre utralizing antibodies ir	monstrated that imit immune system at eate such humanizen vaccine protection	munodeficient mice recond are susceptible to HIV ed mice to study the role n. The experiments will a so as to be histocompa	/ infection and dise of immune cell su entail the developr	ease. The good bsets and went of a co	goal of this virus- phort of mice
Origi	inal Request Received	d in OHSR on:	11/19/2009			
Resp	oonsible NIH Researc	h Investigator(s):	Kim Hasenkrug, NIAII			
OH	SR review of your req	uest dated Thu, No	ov 19, 2009 has determin	ned that:		
	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 SIGNIFICA ACTIVITY.	INT CHANGES TH	<u>IAT MAY ALTER THE E</u>	XEMPT STATUS (<u> DE THIS RI</u>	<u>ESEARCH</u>
	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 Agree	ement				
	Reliance					
	Amendment			-		
	Other					!
Not	e:		Office Pe	erson LB ,	Admin Assi	st. CB
0	b)(6)	CIF)			
_∨ Ch:	arlotte Holden, JD		Acting Director, OHSR		12/14/20	09
Sig	nature		Title		Date	
Don	nestic/International:	-				
Dor	nestic					
Hun	nan Subjects Data: Y	'es		OHSR Use Only		
	-	′es		□1 □2 □3	□4 □	15 ∐6

Date

11/19/2009

Obtained via FOIA by Judicial Watch, Inc.



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.

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146					
From: Kim J Jasen Kung					
(Signature)					
Through: (acfing)					
(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_					
ICNIAIDLaboratory/Branch LPVD_Building & Room NoRML 3218_					
Tel. No406-363-9310_FAX No. 406-363-9286					
Is the Principal investigator an NIH employee?x_YesNo					
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 mm³ 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 naive 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.

If applicable, list your non-NIH Collaborating Investigator(s).						
Name	Institution	Address Tel, # FAX #				
	osed start date of your research osed completion date _April, 201					
4. Will <u>y</u>	ou bethese samples o	r data?				
	ecting Yes/No iving Yes/No ing Yes/No					
	ne samples or data: Already exist?Yes _xNo					
	Or are they being collected for the es," please describe:	express purpose of this study? _X_YesNo				
Reso bion NIH	urces, Inc., a non-profit foundation edical researchers access to human guidelines. Consent to donate is a guidelines. Related documents	e obtained from Advanced Bioscience n established under California law to provide n tissues in compliance with state, federal, and obtained in accordance with UAGA and including the consent form are				
(c) (Or a combination of (a) and (b)?	YesNo				
6. W	hat role will you have in this reso	earch project? (Check all that apply)				
Ana	lyze samples/data only.	•				
Con	sultant/advisor to collaborator(s) li	sted above.				
	nor of the protocol that is being imped in question #2).	plemented by your collaborating investigator				
Co-	uthorship on publication(s)/manus	cript(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				

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) RepositoryYes No					
(b) Pathological waste YesNo					
(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? YesNo					

13. Has the research activity that you are an Institutional Review Board (IRB) elsew	
Yes, the NIH research activity hat (Please provide the following information for	as been reviewed by the following IRB (s)
(x tease provide the following information for	i enell (ICO).
1	Name of institution that provided the review
	Address of reviewing institution
1	Name of PI for the IRB approved protocol
т	Citle of IRB approved protocol and protocol #
	Federal Wide Assurance (FWA) number**
(**An FWA is a contract between the U.S. I (DHHS) and an entity receiving DHHS funds will follow ethical guidelines and federal reg subjects. For a list of domestic and internatio http://ohrp.cit.nih.gov/search/asearch.asp#AS	s to conduct clinical research that the latter ulations for the protection of human nal institutions go to
14. Per NIH guidance***, have conflicts of been resolved? XYesNo no conflicts of inte	
If your answer is no, please see your Cli proceeding with this research.	nical Director about this matter before
***The January 5, 2005 NIH Guide to Prever research conducted at NIH, http://ohsr.od.nih	

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.

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 theraples 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

Obtained via FOIA by Judicial Watch, Inc.

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. APP	LICANT INFORMATION		
NAME:	Kim J Hasenkrug		BILLING INFORMATION:
TITLE:		BILL TO:	Kinn J Hasenkrug
COMPANY:	NIAID, NIH	COMPANY:	Rocky Mountain Labs
ADDRESS:	Rocky Mountain Lab		903 S. 4th St
ADDRESS:	_903 S. 4th St	ADDRESS:	
	: _Hamilton, MT 59840 406-363-9310	CITY,ST,ZIP: ACCOUNTING	Hamilton, MT 59840
FAX #: 40	06-363-9286	P.O. # (if requi	red by your company):
DELIVERY		P.O. # is not re Credit Card #: Name on CC:	equired to submit application
x Same Day: Commercial carrier, hand delivered Maximizes cell viability (geographical limits) Next Day: Pickup, delivery Mon-Sat daytime		Expiration Date	:VISA/MC
Всопо	omical for fresh, frozen specimens	SHIP TO:	Kim J Hasenkrug
Applicant wit	il be charged for delivery fees.		_Rocky Mountain Labs
Applicant may	designate preferred carrier:		903 S. 4th St
Carrier Name: Account #:	PEDEX		_Hamilton, MT 59840
Piesse indicat	e how you heard about ABR: (b)(6)		
II. HUM	IAN FETAL TISSUE		•
Tissue specim	ens requested:thymus, liver, cord bloo	od	
Prefer Propo	red gestational age (6-24 weeks): 17-1 sed starting date: May, 2010	9 wks	
CONTAGIOU Applicant requ	S DISEASE SCREENING: Availability of uires the following tests to be performed by	f test results varies : by ABR:	from 24 hours to 7 days after procurement.
x	No testing required HC HE CM	DASI	HSV RPR 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	y ice	_ Media provided by applicant _ Media provided by ABR (RPMI)
IV.	DONOR INFORMATION		
	SENT VERIFICATION: Consent for tissue donation is obtain nely confidential in nature and shall not be communicated to t		cimen procurement. The consent is
	CIFIC DONOR INFORMATION: Charts are routinely examing information sought and indicate contraindications to specin		
	HIV+ status contraindicates procurement		
v .	— RESEARCH DATA		
TITLE protecti	E OF RESBARCH PROJECT:The role of virus-specition against HIV-1 in humanized mice	fic CD4+T o	zells, CD8+ T cells and antibody in vaccine
research tissue s Updates as pron patents ABR o	will provide tissue to researchers who provide information of intent. (Please attach a brief synopsis of the research personal solely for research purposes and to acknowledge ABR in any less on research progress will be requested at six-month interval omptly after the completion of the research as is reasonably as or copyrights necessary to protect its ownership or control of the name of the publication and the date of the issue in we rement to make the results available to the general public through	project named publications resist. Researchers possible without the results of the results of the results.	above.) Researchers must agree to use the ulting from the use of ABR provided tissue. agree to publish the results of the research at jeopardizing the sponsor's right to secure the research. Researchers agree to inform a will be published. It is the intent of this
VI.	SOURCE OF FUNDING		
	e identify the primary source of funding for this project. X Other Federal or State Grants Foundation Gra	nis Oti	ner (specify)
other co condition express	s application is approved by ABR, ABR shall provide servi conditions on the reverse side, and the signature of the aptions by applicant. The entire agreement between ABR and any sect forth herein, and any modification of or addition then don behalf of ABR by a duly authorized representative.	plicant shall c d applicant rel	onstitute acceptance of all such terms and ating to the services provided by ABR is
	IGNING BELOW, THE APPLICANT ACKNOWLEDGES HE FOLLOWING PAGE AND AGREES TO SUCH TER		
	kin D Hasenling		,
_Senio SIONA	or Investigator	DATE 11/2/2	009
CONI	Please return to: DITIONS OF SERVICES	1516 OAK ST ALAMBDA, (Telephone: 51 Fax: 51	BIOSCIENCE RESOURCES, INC. TREET, SUITE 303 CALIFORNIA 94501 0-865-5872 0-865-4090 r@abr-inc.coinTERMS AND

Services_

During the term of this agreement, and pursuant to the terms and conditions hereinofter set forth. ABR will use its bost offorts 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 engoing 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 tissuc.

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 zerum, 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 acction 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 itssue 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 self nor transfer for valuable consideration any lissue 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. Tarms. 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 heret 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 aforesald 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. <u>Paymenta.</u> 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 noither 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 itssues. 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 Hability. ABR shall not be responsible or Habie under any section of this agreement or under any contract, negligence, strict limbility 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 setually received by ABR from researcher on account of this agreement.
- 7. No warrantles. It is understood that human tissue is by nature noither 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. <u>Indemnification</u>. Researcher shall indemnify, defend and hold ABR harmless from and against all claims, causes of actions, suits, demages 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. Qeneral. This agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of faw. This agreement may not be assigned by either party without the prior written consent of the other.

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 (NIĤ/DDIR)

Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up Flag Status: Green

Attachments: IRB Letter with letterhead nonidentity.doc

> From: "OHSR (NIH/DDIR)" <ohsr nih ddir@od.nih.gov>

> Date: Tue, 24 Nov 2009 10:27:55 -0500



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

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

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> 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.
```

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> 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
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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

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: Flag Status:

Follow up 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.

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

Kim J Hasenkrug, Ph.D.

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

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> 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
```

Re: HFT Application

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.

Рептіп

- > 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
- 151111
- > 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

Re: HFT Application

```
>
>
>> From: Perrin Larton (b)(6)
\Rightarrow 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
>> 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 Projections, 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



TISSUE ACQUISITION INVOICE

DATE P.O.#		INVOICE #
5/17/2017	(b)(6)	1033628
	TERMS	CUSTOMER#
	Duc 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 5/17/2017	311702 311702	6559 6560	21 21		0)(6)	HASENKRUG HASENKRUG	(b)(4)
				Request by Kim Hasenkrug.			
Sil and Market Sil and All and	Sale (ISA Entry Method: Manual Total: \$ 689.00	ا الاحماد	ANS CORE: 219 PATCH 1. CARZ Code: MATCH II.	tanton control	Total	\$680	

SEQ: 1846665 PO#: Requester: Messer, Ronald Owner: (b)(6) CAN: 8335424 FY: 17 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: OC # Description CAN Catalog Category Oty at Price Total Code (b)(4) Tissue, 2nd Trimester (1 each of liver and 8335424 none 6509 2613 680.00 thymus) 2 shipping 8335424 2613 6509 1 each at \$0 .00Order 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: GSA Stock Catalog: GSA Self Service: Federal Supply: Open Market: UNICOR: NIH Surplus: No No No No 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

Clearance Requested: No

NBS Ref Order #: 4563860

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
Tissue, 2nd Trimester (1 each of liver and thymus)	2	2	05/15/2017
2 shipping	1	1	05/15/2017

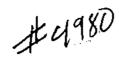
OHSR RESPONSE TO REQU**ESTIFOR REVIEW OF RESEARCH** ACTIVITY INVOLVING HUMAN SUBJECTS

FAX:				Exer	npt: #:	4980
To:	Hasenkrug, Kim	1				
	NIAID					;
	RML - Rocky Mo	ountain Laboratorie:	s. 3/218			
From	n: Office of Human	n Subjects Research	ı (OHSR)			
Rei tiss pro net	sue develop a human nject proposal is to cr autralizing antibodies i	emonstrated that imre n immune system ar reate such humanize in vaccine protection	munodeficient mice recoind are susceptible to HIV ed mice to study the role n. The experiments will as so as to be histocompa	/ infection and disea of immune cell sub entail the developm	ase. The gosets and votent of a co	goal of this virus- phort of mice
Origi	nal Request Receive	ed in OHSR on:	11/19/2009			
Resp	onsible NIH Researc	ch Investigator(s):	Kim Hasenkrug, NIAIE			
OHS	SR review of your req	quest dated Thu, No	ov 19, 2009 has determin	ned that:		
	determination of No Involving Coded Pri on Engagement of I AMENDMENT OF A The activity is desig	ot Human Subjects F ivate Information or Institutions in Huma ANY CHANGES TH gnated EXEMPT , an	of human subjects do not Research is based on the Biological Specimens" (G In Subjects Research (O HAT MAY ALTER THIS R and has been entered in the HAT MAY ALTER THE EX	e interpretation of 4 OHRP, Revised Oc ctober 16, 2008). N ESEARCH ACTIVI ne OHSR database	5 CFR 46 tober 16, 2 IOTIFY OH TY. <u>PLEASE</u>	under "Research 2008) and Guidance HSR VIA AN E-MAIL E NOTIFY OHSR
	ACTIVITY.	ANT CHANGES IN	IAT WAT ALTER THE EA	KEMPI SIA 103 C	r mon	=SEAICH
	NOT EXEMPT. OH		RB review. Please forwa mation in order to determ	•		- '
	Confidentiality Agre	ement				
	Reliance					
	Amendment			-		
	Other					!
Mate			Office Pe	erson LB A	dmin Assi	st. CB
Note	: (a)(6)					•
	, , , , , , , , , , , , , , , , , , ,	CIP)			
Cha	arlotte Holden, JD		Acting Director, OHSR		12/14/20	09
	nature		Title		Date	 -
Don	nestic/International:	-				
Dor	nestic					
Hum	nan Subjects Data: N	Yes		OHSR Use Only		
	-	Yes		□1 □2 □3	□4 □	₁5 □€
	-			□1 □2 □3	□4 □	5 □6

Date

11/19/2009

Obtained via FOIA by Judicial Watch, Inc.



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.

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146
From: Kim & tasen knig
(Signature)
Through: (b)(6)
(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 NoRML 3218_
Tel. No406-363-9310_FAX No. 406-363-9286
Is the Principal investigator an NIH employee?x_YesNo
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 mm³ 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 a	pplicable, list your non-NIH Collabo	rating Investigator(s).
Name	Institution	Address Tel, # FAX #
	ed start date of your researchApri ed completion date _April, 2013	
4. Will yo	u bethese samples or data	?
Collec Receiv Sendin	ing Yes/No	
	samples or data: ready exist?Yes _xNo	
	are they being collected for the express," please describe:	s purpose of this study? _X_YesNo
Resour biomed NIH gr	uidelines. Consent to donate is obtaine guidelines. Related documents includi	ished under California law to provide is in compliance with state, federal, and in accordance with UAGA and
(c) Or	a combination of (a) and (b)?	YesNo
6. Wh	at role will you have in this research	project? (Check all that apply)
Analy	ze samples/data only.	•
Consu	Itant/advisor to collaborator(s) listed ab	oove.
	r of the protocol that is being implement in question #2).	ited by your collaborating investigator
Со-ви	thorship 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

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) RepositoryYes No				
(b) Pathological waste YesNo				
(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? YesNo				

13. Has the research activity that you are an Institutional Review Board (IRB) elsew	
 _ :	as been reviewed by the following IRB (s)
(Please provide the following information for	r each IRB):
·	Name of institution that provided the review
	Address of reviewing institution
	Name of PI for the IRB approved protocol
Т	Citle of IRB approved protocol and protocol #
	Federal Wide Assurance (FWA) number**
(**An FWA is a contract between the U.S. I (DHHS) and an entity receiving DHHS funds will follow ethical guidelines and federal reg subjects. For a list of domestic and internation http://ohrp.cit.nih.gov/search/asearch.asp#AS	s to conduct clinical research that the latter ulations for the protection of human nal institutions go to
14. Per NIH guidance***, have conflicts of been resolved? XYesNo no conflicts of inte	
If your answer is no, please see your Clipproceeding with this research.	nical Director about this matter before
***The January 5, 2005 NIH Guide to Prever research conducted at NIH, http://ohsr.od.nih	

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.

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 theraples 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. APPI	LICANT INFORMATION		
NAME:	Kim J Hasenkrug		BILLING INFORMATION:
TITLB:	Senior Investigator		Kim J Hasenkrug
COMPANY:	NIAID, NIH		Rocky Mountain Labs
ADDRESS:	Rocky Mountain Lab		903 S. 4th St
ADDRESS:	_903 S. 4th St	ADDRESS:	
CITY,ST,ZIP: PHONE #:	_Hamilton, MT 59840 406-363-9310	CITY,ST,ZIP: ACCOUNTING	Hamilton, MT 59840
	6-363-9286	P.O. # (if requi	red by your company):
DELIVERY O		Credit Card #:	equired to submit application
Mexim	Day: Commercial carrier, hand delivered hizes cell viability (geographical limits) Day: Pickup, delivery Mon-Sat daytime	Name on CC: Expiration Date	:VJSA/MC
Всопо	mical for fresh, frozen specimens	SHIP TO:	Kim J Hasenkrug
Applicant will	be charged for delivery fees.		_Rocky Mountain Labs
Applicant may	designate preferred carrier:		903 S. 4th St
Carrier Name:	PEDEX		_Hamilton, MT 59840
Account #:	(b)(4)		
Piesse indicate	how you heard about ABR: (b)(6)		
II. HUM	AN FETAL TISSUE		•
Tissue specime	ens requested:thymus, liver, cord blo	od	
Preferr Propos	ed gestational age (6-24 weeks): 17- ed starting date:May, 2010	19 wks	
CONTAGIOUS Applicant requ	DISEASE SCREENING: Availability of ires the following tests to be performed in	of test results varies ; by ABR:	from 24 hours to 7 days after procurement.
x		V B886 MV	HSV RPR 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	y ice	_ Media provided by applicant _ Media provided by ABR (RPMI)
IV.	DONOR INFORMATION		
	SENT VERIFICATION: Consent for tissue donation is obtain nely confidential in nature and shall not be communicated to t		cimen procurement. The consent is
	CIFIC DONOR INFORMATION: Charts are routinely examing information sought and indicate contraindications to specin		
	HIV+ status contraindicates procurement		
v .	— RESEARCH DATA		
TITLE protecti	E OF RESEARCH PROJECT: The role of virus-specition against HIV-1 in humanized mice	fic CD4+T o	zells, CD8+ T cells and antibody in vaccine
research tissue s Updates as pron patents ABR o	will provide tissue to researchers who provide information of intent. (Please attach a brief synopsis of the research personal solely for research purposes and to acknowledge ABR in any less on research progress will be requested at six-month interval omptly after the completion of the research as is reasonably as or copyrights necessary to protect its ownership or control of the name of the publication and the date of the issue in we rement to make the results available to the general public through	project named publications resist. Researchers possible without the results of the results of the results.	above.) Researchers must agree to use the ulting from the use of ABR provided tissue. agree to publish the results of the research at jeopardizing the sponsor's right to secure the research. Researchers agree to inform a will be published. It is the intent of this
VI.	SOURCE OF FUNDING		
	e identify the primary source of funding for this project. X Other Federal or State Grants Foundation Gra	nis Oti	ner (specify)
other co condition express	s application is approved by ABR, ABR shall provide servi conditions on the reverse side, and the signature of the aptions by applicant. The entire agreement between ABR and any sect forth herein, and any modification of or addition then don behalf of ABR by a duly authorized representative.	plicant shall c d applicant rel	onstitute acceptance of all such terms and ating to the services provided by ABR is
	IGNING BELOW, THE APPLICANT ACKNOWLEDGES HE FOLLOWING PAGE AND AGREES TO SUCH TER		
	kin D Hasenling		,
_Senio SIONA	or Investigator	DATE 11/2/2	009
CONI	Please return to: DITIONS OF SERVICES	1516 OAK ST ALAMBDA, (Telephone: 51 Fax: 51	BIOSCIENCE RESOURCES, INC. TREET, SUITE 303 CALIFORNIA 94501 0-865-5872 0-865-4090 r@abr-inc.coinTERMS AND

Services_

During the term of this agreement, and pursuant to the terms and conditions hereinofter set forth. ABR will use its bost offorts 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 engoing 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 tissuc.

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 zerum, 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 acction 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 itssue 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 self nor transfer for valuable consideration any lissue 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. Tarms. 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 heret 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 aforesald 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. <u>Paymenta.</u> 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 noither 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 itssues. 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 Hability. ABR shall not be responsible or Habie under any section of this agreement or under any contract, negligence, strict limbility 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 setually received by ABR from researcher on account of this agreement.
- 7. No warrantles. It is understood that human tissue is by nature noither 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. <u>Indemnification</u>. Researcher shall indemnify, defend and hold ABR harmless from and against all claims, causes of actions, suits, demages 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. Qeneral. This agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of faw. 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,

OHSR (NIH/DDIR)

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

Sent: Wednesday, December 09, 2009 5:41 PM

To: OHSR (NIĤ/DDIR)

Subject: Re: HasenkrugK_NIAID_4980_CY2009

Follow Up Flag: Follow up Flag Status: Green

Attachments: IRB Letter with letterhead nonidentity.doc

> From: "OHSR (NIH/DDIR)" <ohsr nih ddir@od.nih.gov>

> Date: Tue, 24 Nov 2009 10:27:55 -0500



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

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

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> 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

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: Flag Status:

Follow up 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.

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

Kim J Hasenkrug, Ph.D.

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

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> 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
```

Re: HFT Application

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.

Рептіп

- > 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
- _ 1711
- > 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

Re: HFT Application

```
>
>
>> 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
>> 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 Projections, 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



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 6/28/2017	672804 672804	6783 6784	22 22	Thymus, 2nd Trimester Liver, 2nd Trimester		Kim Kim	(b)(4)
						· i	
					·	-	·
P 1	1				Apprint of the second		
							kolumbu [‡] si shabbawa dar, wa
					Total	\$680	.00

PO#: (b)(6) SEQ: 1851291 Requester: Messer, Ronald Owner: (b)(6) CAN: 8335424 FY: 17 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: OC # Description CAN Category Oty at Price Total Catalog Code (b)(4) Tissue, 2nd Trimester (1 each of liver and 8335424 none 6509 2613 680.00 thymus) 2 shipping 8335424 2613 6509 1 each at \$0 .00Order 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 give her the PO number and credit card information. Alternate Sources: GSA Stock Catalog: GSA Self Service: Federal Supply: Open Market: UNICOR: NIH Surplus: No No No No Yes AGENT Purchase Order #: (b)(6) Estimated Ship Date: Custodial Code: 30102 Date Entered into NBS: 05/12/2017 Order Reference: (b)(6) Expected Delivery Date: 05/18/2017 FSS: Select Agents: No

Clearance Requested: No

NBS Ref Order #: 4589328

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

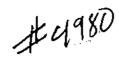
OHSR RESPONSE TO REQU**ESTIFOR REVIEW OF RESEARCH** ACTIVITY INVOLVING HUMAN SUBJECTS

FAX			Exempt: #:	4980
To:	Hasenkrug, Kim			
	NIAID			1
	RML - Rocky Mountain I	_aboratories, 3/218		
From	n: Office of Human Subject	s Research (OHSR)		
Retiss	sue develop a human immuno ject proposal is to create suc utralizing antibodies in vaccin	ted that immunodeficient mice reconstile system and are susceptible to HIV into the humanized mice to study the role of the protection. The experiments will entain man cells so as to be histocompatible	fection and disease. The immune cell subsets and ail the development of a c	goal of this virus- cohort of mice
Origi	nal Request Received in OH	SR on: 11/19/2009		·
Resp	oonsible NIH Research Inves	tigator(s): Kim Hasenkrug, NIAID		
OHS	SR review of your request da	ted Thu, Nov 19, 2009 has determined	that:	
	determination of Not Human Involving Coded Private Info on Engagement of Institutio	protection of human subjects do not apply a Subjects Research is based on the intermetion or Biological Specimens" (OH ins in Human Subjects Research (Octol ANGES THAT MAY ALTER THIS RES	terpretation of 45 CFR 46 RP, Revised October 16, ber 16, 2008). NOTIFY O	under "Research 2008) and Guidance
		XEMPT, and has been entered in the C ANGES THAT MAY ALTER THE EXEM		i i
		ommends IRB review. Please forward to itional information in order to determine	•	- '
	Confidentiality Agreement			
	Reliance			
	Amendment	-		
	Other			!
Note	a·	Office Perso	on LB Admin Ass	sist. CB
)(6)	コー		
		CIP		
∵ Cha	arlotte Holdjen, JD	Acting Director, OHSR	12/14/20	009
Sig	nature	Title		
Don	nestic/International:			
Dor	nestic			
Hum	nan Subjects Data: Yes	_	HSR Use Only	·
	ogic Material: Yes	Ц	l1 □2 □3 □4 □	」5 □ 6

Date

11/19/2009

Obtained via FOIA by Judicial Watch, Inc.



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.

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146
From: KIM J tasen know
(Signature)
10/0/
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 NoRML 3218_
Tel. No. 406-363-9310 FAX No. 406-363-9286
Is the Principal investigator an NIH employee?x_YesNo
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 mm³ 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 naive 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. Ií	applicable, list your non-NIH C	ollaborating Investigator(s).
Name	Institution	Address Tel, # FAX #
	osed start date of your research osed completion date _April, 201	
4. Will <u>y</u>	ou bethese samples o	r data?
	ecting Yes/No iving Yes/No ing Yes/No	
	ne samples or data: Already exist?Yes _xNo	
	Or are they being collected for the es," please describe:	express purpose of this study? _X_YesNo
Reso bion NIH	urces, Inc., a non-profit foundation edical researchers access to human guidelines. Consent to donate is a guidelines. Related documents	e obtained from Advanced Bioscience n established under California law to provide n tissues in compliance with state, federal, and obtained in accordance with UAGA and including the consent form are
(c) (Or a combination of (a) and (b)?	YesNo
6. W	hat role will you have in this reso	earch project? (Check all that apply)
Ana	lyze samples/data only.	•
Con	sultant/advisor to collaborator(s) li	sted above.
	nor of the protocol that is being imped in question #2).	plemented by your collaborating investigator
Co-	uthorship on publication(s)/manus	cript(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