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,

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

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
- > 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

```
>
>
>> 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
>
```

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#
2/7/2018	(b)(6)	1034601
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	DESCRIPT	ION	RESEARCHER	FEE
2/7/2018 2/7/2018	670703 670703	2233 2234	18 18	Thymus, 2nd Trimester Liver, 2nd Trimester		HASENKRUG HASENKRUG	(b)(4)
				02/16/18 PAID via VISA Request by Kim Hasenkrug.	(b)(6)		
l	mal GG	18:22 17:377 17:801					
18972 15 18972	e Entry Nethod: Manual GSBD: DIO	17:18:22 (App. Code: 697377 Batchi: 947801	04853	r Capri Ramsaction			
STE 383 A.AMICA. IA 9484 (528) USS 5877 (II: 6811) ID: 6811	Sale	(8 899908 (Anline	NS Code: JJP MRICH Z XVZ Code: NATCH N Recovered Ref. W. Bissubbiss	CAFTUMES FOR			
Bark Di Perchant Term Di	VIS Total:	62/16/18 Inv #: 86			Total	\$680.	.00

SEQ: 1889656

| PO#: (b)(6) | Requester: Messer, Ronald

CAN: 8335424 FY: 18 Owner: (b)(6)

Order Total: 680.00 Project: 107833

Date Needed: 02/07/2018 Emergency: No Order Type: Purchase Card

Requestor Phone: +1 406 363 9276 Order Status: Archive

Vendor Advanced Bioscience Resources, 1516 Oak Street, Suite 303, Alameda, CA 94501

Phone: 510-865-5872 SmlBs: No FSS: EIN: BPA: GSA:

Site: Clerk:

E-mail:

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

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

### **QUOTES**

### **JUSTIFICATION**

These tissues, liver and thymus, are required by Ron Messer for ongoing studies of HIV in the Hasenkrug Lab, LPVD. 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 beginning or equivalent. Please contact the vendor at 510-865-5872 ext beginning or equivalent. 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.

Alternate Sources:

No No No Yes

AGENT

Purchase Order #:<sup>(b)(6)</sup> Estimated Ship Date:

Custodial Code: 30102

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

Date Entered into NBS: 02/06/2018

Expected Delivery Date: 02/09/2018

FSS: Select Agents: No

NBS Ref Order #: 4870397 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	02/07/2018		
Submitted to NBS	02/06/2018		
NBS Confirmation	02/07/2018		
Award Created	02/07/2018		
Award Received	02/06/2018		
Estimated Ship Date			
Received	02/12/2018		
Canceled			

### **Routing History**

Name Messer, Ronald		Role	Date In	STATUS IN	ACTION
		Requester	01/12/2018	New order	Approved
(b)(6)	(recalled by Messer, Ronald)	Administrative Officer	01/12/2018	Released	Recall
Messer, R	tonald	Requester	01/12/2018	New order	Approved
(b)(6)		Administrative Officer	02/05/2018	Released	Approved
		Purchasing Agent	02/05/2018	Approved	Approved
NBS, NB	S	NBS	02/06/2018	Sent to NBS	Approved
Messer, R	tonald <sup>(b)(6)</sup>	Requester for receiving	02/06/2018	Pending receiving	Take
(b)(6)		Requester for receiving	02/12/2018	Pending receiving	Approved
		Archive	02/12/2018	Archive	(N/A)

### **Receiving Report**

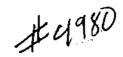
# Description	Total Qty Ordered	Total Qty Received	Date Received
Tissue, 2nd Trimester (1 each of liver and thymus)	2	2	02/12/2018
2 shipping estimate	1	1	02/12/2018

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

FAX	•			Exe	mpt: #:	4980
To:	Hasenkrug, Kim					
	NIAID					1
	RML - Rocky Mou	ıntain Laboratorie	s. 3/218			
Fron	n: Office of Human S	Subjects Research	n (OHSR)			
Re tiss pro ner all	sue develop a human in pject proposal is to crea utralizing antibodies in	ionstrated that imr mmune system ar ate such humanize vaccine protection same human cells	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 develop	ease. The good basets and want of a co	goal of this virus- ohort of mice
	ponsible NIH Research		Kim Hasenkrug, NIAII	n		
		<del> </del>	ov 19, 2009 has determine	•		
_						The OUID
	determination of Not I Involving Coded Priva on Engagement of Ins AMENDMENT OF AN The activity is designa OF ANY SIGNIFICAN ACTIVITY.	Human Subjects I ate Information or stitutions in Huma NY CHANGES TH ated EXEMPT, ar NT CHANGES TH	of human subjects do not Research is based on the Biological Specimens" (on Subjects Research (CHAT MAY ALTER THIS FORTH MAY ALTER THE EAT MAY ALTER THE	e interpretation of OHRP, Revised Oletober 16, 2008). RESEARCH ACTIVATE OHSR database XEMPT STATUS	45 CFR 46, 2 ctober 16, 2 NOTIFY OF /ITY. e. <u>PLEASE</u> OF THIS RI	under "Research 2008) and Guidance HSR VIA AN E-MAIL ENOTIFY OHSR ESEARCH
			mation in order to deterr	,		-   '
	Confidentiality Agreer	ment				
	Reliance					
	Amendment			-		
	Other					!
Not	<b>e</b> : 0)(6)		Office P	erson LB	Admin Assi	ist. CB
		CIP	)			
<sub>∨</sub> _Cե	arlotte Holden, JD		Acting Director, OHSR		12/14/20	09
Sig	nature	•	Title		Date	·
Don	nestic/International:	•				
Dor	mestic			OHOR III		
Hun	nan Subjects Data: Ye	es		OHSR Use Only		1c 🗆 c
	ogic Material: Ye			∐1 ∐2 <u>∐</u> 3	4 🗆	15 🗆 6

11/10/2000

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.

Dr. 11/19/2009
To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146
From: Kim J Jasen Kung
(Signature)
(b)(6)
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_
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 mm<sup>3</sup> 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 ap	plicable, list your non-NIH Collab	oorating Investigator(s).  Address Tel. # FAX #
		<u></u>
_	d start date of your researchApd completion date _April, 2013	· ——
4. Will you	bethese samples or dat	ta?
	ng Yes/No 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 biomedie NIH guie NOTA g		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	s project? (Check all that apply)
Analyze	samples/data only.	•
Consult	ant/advisor to collaborator(s) listed	above.
	of the protocol that is being implem question #2).	ented by your collaborating investigator
Co-suth	orship 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 pan Institutional Review Board (IRB) elsew	
<del></del>	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. 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,ZIP: ACCOUNTING	Hamilton, MT 59840
	06-363-9286	P.O. # (if requir	red by your company):
DELIVERY		Credit Card #:	quired to submit application
Maxio	Day: Commercial carrier, hand delivered mizes cell viability (geographical limits) Day: Pickup, delivery Mon-Sat daytime	Name on CC: Expiration Date	·VJSA/MC
Всопо	omical for fresh, frozen specimens	SHIP TO:	Kim J Hasenkrug
Applicant wi	ll be charged for delivery fees.		_Rocky Mountain Labs
Applicant may	y designate preferred carrier:		903 S. 4th St
Carrier Name: Account #:	PEDEX (b)(4)		
	e how you heard about ABR: (b)(6)		
II. HUM	IAN FETAL TISSUE		, ,
Tissue specim	iens requested:thymus, liver, cord bloc	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 our control of the following tests to be performed by the control of the cont	f test results varies f by ABR:	from 24 hours to 7 days after procurement.
_x_	No testing required HI HB 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		
<b>v</b> .	— 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.

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)(6)			

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

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.

#### 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
- > 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)
\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
>
```

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 #
3/1/2018	(b)(6)	1034691
	TERMS	CUSTOMER#
B	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	DESC	RIPTION	RESEARCHER	FEE
3/1/2018 3/1/2018	310101 310101	5113 5114	17 17	Thymus, 2nd Trimester Liver, 2nd Trimester		HASENKRUG HASENKRUG	(b)(4)
				 B/16/18 PAID via VISA equest by Kim Hasenkrug. 	(b)(6)		
	[B]	8 558					
7. 91. 384 1. 385 1. 3872 185-5872	<del>=</del>	5869.00 18:17:18 Appr Code: 064614 Batchii: 073091	Hlbd3	- Cepy AMGACTION			
1010 LWA C. 15 15 384 1010 LWA C. 15 364 1010 LWA C. 1567 1010	Sale	Otal: \$  6/16/18  w #: \$68067  Pstruck: Unline	WS Code: ZIP MICH Z SVZ Code: MiCH M Herreval Net.11: Sullenous	Chatomal Cepy	_		
Bank 10: Berchand Term 10:	55	10tal 62/16/18 Inv #: 96 forror: 0	38.0 68.2 68.2 88.2 88.2 88.2 88.2 88.2 88.2		Total	\$680.	00

SEQ: 1896051 PO#: (b)(6) Requester: Messer, Ronald

CAN: 8335424

Requestor Phone: +1 406 363 9276

FY: 18

Owner: (b)(6)

Order Total: 680.00

/29/2019 Emar

Project: 107833

Date Needed: 02/28/2018

Emergency: No

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 estimate	8335424		2613	6509	1 each at \$0	.00
О	rder Total: 680.00						

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

### **QUOTES**

Vendor	Price	Good Until	Available
There are no quotes in t	he order		

### JUSTIFICATION

These tissues, liver and thymus, are required by Ron Messer for ongoing studies of HIV in the Hasenkrug Lab, LPVD. Our mice will be ready for reconstitution in early March. 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.

No

Alternate Sources:

NIH Surplus: No

UNICOR:

GSA Stock Catalog:

No

GSA Self Service:

Federal Supply:

No

Open Market:

Yes

AGENT

Purchase Order #: (b)(6)
Custodial Code: 30102

Estimated Ship Date:

-1

Date Entered into NBS: 02/22/2018 Expected Delivery Date: 03/08/2018

Order Reference: em'd order FSS:

Select Agents: No

NBS Ref Order #: 4888471

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	02/28/2018	
Submitted to NBS	02/22/2018	
NBS Confirmation	02/23/2018	
Award Created	02/23/2018	
Award Received	02/22/2018	
Estimated Ship Date		
Received	03/23/2018	
Canceled	1   1	

#### **Routing History**

Nam	Role	Date In	STATUS IN	ACTION
Messer, Ronald	Requester	02/22/2018	New order	Approved
b)(6)	Administrative Officer	02/22/2018	Released	Approved
	Purchasing Agent	02/22/2018	Approved	Approved
NBS, NBS	NBS	02/22/2018	Sent to NBS	Approved
Messer, Ronald (b)(6)	Requester for receiving	02/22/2018	Pending receiving	Take
b)(6)	Requester for receiving	03/23/2018	Pending receiving	Approved
	Archive	03/23/2018	Archive	(N/A)

#### **Receiving Report**

# Description	<b>Total Qty Ordered</b>	Total Qty Received	Date Received
Tissue, 2nd Trimester (1 each of liver and thymus)	2	2	03/23/2018
2 shipping estimate	1	1	03/23/2018

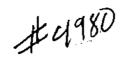
### OHSR RESPONSE TO REQU**ESTIFOR REVIEW OF RESEARCH** ACTIVITY INVOLVING HUMAN SUBJECTS

FAX		Exempt: #:	4980
To:	Hasenkrug, Kim		
	NIAID		1
	RML - Rocky Mountain Laboratories, 3/218		
From	Office of Human Subjects Research (OHSR)		
Re tiss pro nei	re of Research Activity: cent reports have demonstrated that immunodeficient mice reconstitute develop a human immune system and are susceptible to HIV infect proposal is to create such humanized mice to study the role of intralizing antibodies in vaccine protection. The experiments will entain reconstituted with the same human cells so as to be histocompatible.	ction and disease. The nmune cell subsets and I the 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 to	hat:	
⊠	Federal regulations for the protection of human subjects do not appl determination of Not Human Subjects Research is based on the intellinvolving Coded Private Information or Biological Specimens" (OHR on Engagement of Institutions in Human Subjects Research (October AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESE	erpretation of 45 CFR 46 P, Revised October 16, er 16, 2008). NOTIFY O	under "Research 2008) and Guidance
	The activity is designated <b>EXEMPT</b> , and has been entered in the OI OF ANY <b>SIGNIFICANT</b> CHANGES THAT MAY ALTER THE EXEMINACTIVITY.	HSR database. <u>PLEAS</u> <u>PT STATUS OF THIS R</u>	<u>ESEARCH</u>
	<b>NOT EXEMPT.</b> OHSR recommends IRB review. Please forward you may ask you to provide additional information in order to determine appropriate.	•	- 1 '
	Confidentiality Agreement		
	Reliance		
	Amendment		
	Other		!
	Office Person	LB Admin Ass	<sub>ist.</sub> CB
Note	); )(6)		
6,	CIP		
<sub>Ն</sub> cha	rlotte Holden, JD Acting Director, OHSR	12/14/20	009
Sig	nature Title	Date	<del></del>
Don	estic/International:		
Dor	nestic		
Hun	an Subjects Data: Yes	SR Use Only	_
	egic Material: Yes	1 🗆 2 🔲 3 🗀 4 🗀	J5 □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)
(b)(6)
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_
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 mm<sup>3</sup> 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 ap	plicable, list your non-NIH Collab	oorating Investigator(s).  Address Tel. # FAX #
		<u></u>
_	d start date of your researchApd completion date _April, 2013	· ——
4. Will you	bethese samples or dat	ta?
	ng Yes/No 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 biomedie NIH guie NOTA g		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	s project? (Check all that apply)
Analyze	samples/data only.	•
Consult	ant/advisor to collaborator(s) listed	above.
	of the protocol that is being implem question #2).	ented by your collaborating investigator
Co-suth	orship 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	
<del></del> _ :	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. APP	LICANT INFORMATION			
NAMB:	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 #: _ ALT. #:	: _Hamilton, MT 59840 406-363-9310	CITY,ST,ZIP: ACCOUNTING	Hamilton, MT 59840  DEPT. PHONE #:406-363-9438	
	06-363-9286	P.O. # (if requi	red by your company):	
EMAIL: khasenkrug@nih.gov DELIVERY OPTIONS:		Credit Card #:	required 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: Account #:	(b)(4)		_Hamilton, MT 59840	
Account #.	(0)(4)			
Please 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): 17-19 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 ( ABR:	from 24 hours to 7 days after procurement	
_x_	No testing required HIV HB: CM	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		
<b>v</b> .	— 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,

)(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
- > 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:
- Disciallici.
- > 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) (b) (c) 
>> Reply-To: (b) (6) 
>> Pate: Mon. 2 Nov. 200
```

```
>> From: Pertin Larton (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

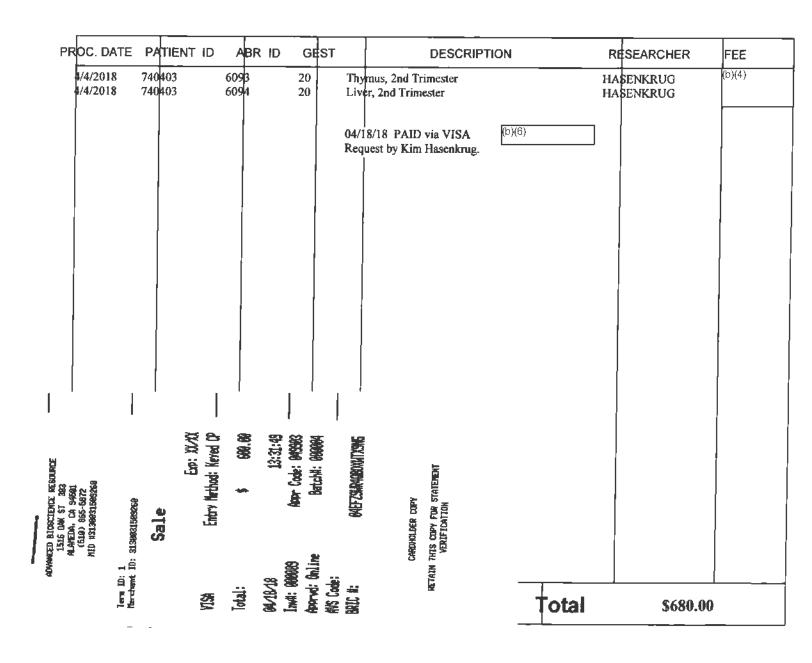


### TISSUE ACQUISITION INVOICE

DATE	P.O. #	II	IVOICE #
4/4/2018	(b)(6)		1034799
	TERMS	CU	STOMER#
	Due Upon Receipt		0522

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DILL IV	
· ·	
	<del></del>

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



SEQ: 1901469

Obtained via FOIA by Judicial Watch, Inc.

Requester: Messer, Ronald

Owner: (b)(6)

CAN: 8335424 FY: 18

Order Total: 680.00 Project: 107833

Date Needed: 03/23/2018 Emergency: No Order Type: Purchase Card

Requestor Phone: +1 406 363 9276 Order Status: Archive

Vendor Advanced Bioscience Resources, 1516 Oak Street, Suite 303, Alameda, CA 94501

Phone: 510-865-5872 SmlBs: No FSS: EIN: BPA: GSA:

Site: Clerk:

E-mail:

#	Description	CAN	Catalog	OC Code	Category	Qty at Price	Total
	Tissue, 2nd Trimester (1 each of liver and thymus)	8335424	none	2613	6509	(b)(4)	680.00
2	shipping estimate	8335424		2613	6509	1 each at \$0	.00
H	order Total: 680.00	0000121	)	2015	0000	1 cach at \$0	.00

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

#### **QUOTES**

#### **JUSTIFICATION**

These tissues, liver and thymus, are required by Ron Messer for ongoing studies of HIV in the Hasenkrug Lab, LPVD. 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 60/60—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.

Alternate Sources:

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

AGENT

Purchase Order #: (b)(6)

Estimated Ship Date:

Custodial Code: 30102

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

Date Entered into NBS: 03/22/2018

Expected Delivery Date: 03/29/2018

FSS: Select Agents: No NBS Ref Order #: 4918808 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	03/23/2018	
Submitted to NBS	03/22/2018	
NBS Confirmation	03/23/2018	
Award Created	03/22/2018	
Award Received	03/22/2018	
Estimated Ship Date		
Received	04/10/2018	
Canceled		

#### **Routing History**

Name	Role	Date In	STATUS IN	ACTION Approved	
Messer, Ronald	Requester	03/22/2018	New order		
(b)(6)	Administrative Officer	03/22/2018	Released	Approved	
	Purchasing Agent	03/22/2018	Approved	Approved	
NBS, NBS	NBS	03/22/2018	Sent to NBS	Approved	
Messer, Ronald (b)(6)	Requester for receiving	03/22/2018	Pending receiving	Take	
(b)(6)	Requester for receiving	111/2// 111// / 111/ 8	Pending receiving	Approved	
	Archive	04/10/2018	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	04/10/2018
2 shipping estimate	1	1	04/10/2018

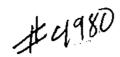
### OHSR RESPONSE TO REQU**ESTIFOR REVIEW OF RESEARCH** ACTIVITY INVOLVING HUMAN SUBJECTS

FAX				Exe	mpt: #:	4980
To:	Hasenkrug, Kin	n				
	NIAID					:
	RML - Rocky M	lountain Laboratorie	s, 3/218			
From	n: Office of Humar	n Subjects Research	n (OHSR)			
Re tiss pro net	sue develop a humai oject proposal is to ci utralizing antibodies	emonstrated that iming in immune system are reate such humanize in vaccine protection	munodeficient mice recond are susceptible to HIV ed mice to study the role n. The experiments will as 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- ohort of mice
Origi	nal Request Receive	ed in OHSR on:	11/19/2009			·
Resp	onsible NIH Resear	ch Investigator(s):	Kim Hasenkrug, NIAI			
OHS	SR review of your re	quest dated Thu, No	ov 19, 2009 has determin	ned that:		
	determination of No Involving Coded Pr on Engagement of AMENDMENT OF The activity is design	ot Human Subjects I ivate Information or Institutions in Huma ANY CHANGES TH gnated <b>EXEMPT</b> , ar	of human subjects do not Research is based on the Biological Specimens" (on Biological Specimens" (on Biological Speciment Biological Specimentered in the speciments of the second second second in the second seco	e interpretation of A OHRP, Revised O ctober 16, 2008). I RESEARCH ACTIV ne OHSR database	45 CFR 46 ctober 16, 2 NOTIFY OF /ITY. e. <u>PLEASE</u>	under "Research 2008) and Guidance HSR VIA AN E-MAIL E NOTIFY OHSR
		ANT CHANGES TH	<u>IAT MAY ALTER THE E</u>	<u>XEMPT STATUS (</u>	<u>DF THIS RI</u>	<u>ESEARCH</u>
			RB review. Please forwa mation in order to detern	,		- 1 '
	Confidentiality Agre	ement				
	Reliance					
	Amendment			-		
	Other					!
Note	e:		Office Pe	erson LB	Admin Assi	ist. CB
(b)	)(6)	CIF	)			
√ <u>Cha</u>	arlotte Holden, JD		Acting Director, OHSR		12/14/20	09
Sig	nature	<del></del>	Title		Date	<del></del> -
Don	nestic/International:	•				
Dor	nestic					
Hum	nan Subjects Data:	Yes		OHSR Use Only		, _
	-	Yes		□1 □2 □3	<b>∐4</b> □	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: (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. 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 mm<sup>3</sup> 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 #		
		······································		
	oposed start date of your researchApril, 2010_ oposed completion date _April, 2013			
4. Wil	ll you bethese samples or data?			
Re	ollecting Yes/No ecciving Yes/No ending Yes/No			
	the samples or data:  Already exist? Yes x No			
	Or are they being collected for the express purpose "yes," please describe:	of this study? _XYesNo		
Re bio NI NO	-19 week fetal cells and tissue will be obtained from sources, Inc., a non-profit foundation established uncomedical researchers access to human tissues in comp H guidelines. Consent to donate is obtained in accop OTA guidelines. Related documents including the coached.	der California law to provide pliance with state, federal, and rdance with UAGA and		
(c)	Or a combination of (a) and (b)?Yes	No		
6.	What role will you have in this research project?	(Check all that apply)		
A	nalyze samples/data only.			
C	onsultant/advisor to collaborator(s) listed above.			
	uthor of the protocol that is being implemented by you	our collaborating investigator		
C	o-suthorship on publication(s)/manuscript(s) pertaini	ng 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 <u>that you are p</u> an Institutional Review Board (IRB) elsewl	
<del></del>	s been reviewed by the following IRB (s)
(Please provide the following information for	encu (KD):
N	lame of institution that provided the review
A	ddress of reviewing institution
N	lame of PI for the IRB approved protocol
Ti	tle 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 regusubjects. For a list of domestic and internation <a href="http://ohrp.cit.nih.gov/search/asearch.asp#ASI">http://ohrp.cit.nih.gov/search/asearch.asp#ASI</a>	to conduct clinical research that the latter lations for the protection of human lal 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.	ical Director about this matter before
***The January 5, 2005 NIH Guide to Preven research conducted at NIH, <a href="http://ohsr.od.nih.">http://ohsr.od.nih.</a>	

# 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. A	PPLICANT INFORMATION			
NAME:	Kim J Hasenkrug		BILLING INFORMATION:	
TITLB:	_Senior Investigator		Kim J Hasenkrug	
COMPAN	Y:NIAID, NIH		Rocky Mountain Labs	
ADDRESS			903 S. 4th St	
ADDRESS	8: _903 S. 4th St	ADDRESS:		
CITY,ST, PHONE #. ALT. #:	ZIP: _Hamilton, MT 59840 :406-363-9310	CITY,ST,ZIP: ACCOUNTING	Hamilton, MT 59840	
FAX#:	406-363-9286	P.O. # (if required by your company):		
EMAIL: khasenkrug@nih.gov  DELIVERY OPTIONS:x Same Day: Commercial carrier, hand delivered		Credit Card #:	equired to submit application	
		Name on CC: Expiration Date	:VJSA/MC	
Бо	conomical 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 Na Account #			_Hamilton, MT 59840	
Picase ind	leate how you heard about ABR: (b)(6)			
II. H	UMAN FETAL TISSUE			
Tissue spe	cimens requested:thymus, liver, cord blood	d	·	
Pr Pr	eferred gestational age (6-24 weeks):17-19 oposed starting date:May, 2010	wks		
CONTAGI Applicant	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 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		
<b>v</b> .	— 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.

Seaking 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.
- Representations and Warranties. ABR hereby represents and warrants to researcher that (I) ABR will make no payments to anyone for any tissue transferred in connection with this agreement, and (ii) ABR will verify for each tissue delivery that appropriate consent was obtained for use of such tissue and any associated serum samples, and that adequate records of such consent are 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 set not 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, sec. 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. Paymonia. 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. Shloment 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 flable under any section of this agreement or under any contract, negligence, strict liability or other logal 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. Indemnification. Researcher shall indemnify, defend and hold ABR harmless from and against all claims, causes of actions, suits, demages and coats 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) adjusts 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)			

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

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
- , 12111
- > 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
>
```

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

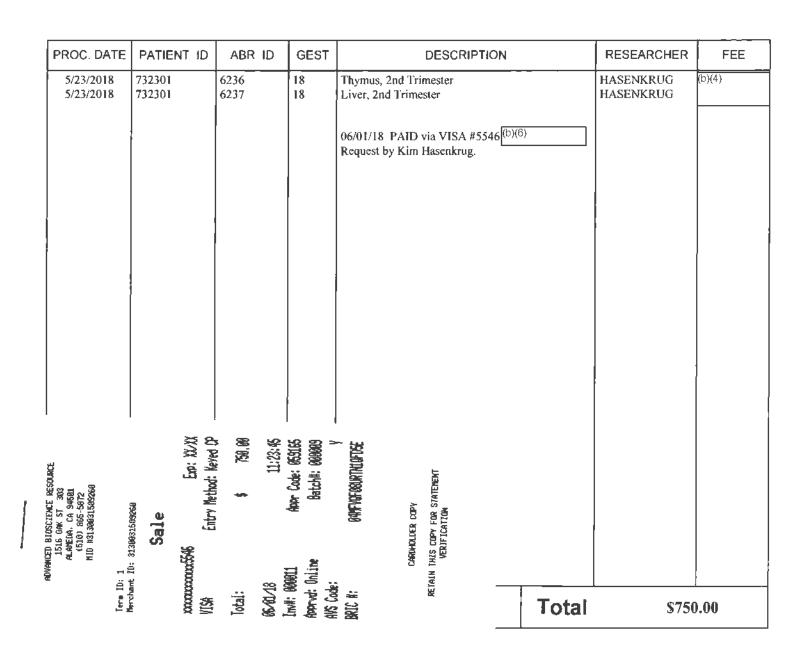


# TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE#
5/23/2018	(b)(6)	1034930
	TERMS	CUSTOMER#
	Due Upon Reccipt	0522

**BILL TO** 

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



ia FOIA by Judicial Watch, Inc PO#: (b)(6) SEQ: 1909000 Requester: Messer, Ronald Owner: (b)(6) CAN: 8335424 FY: 18 Order Total: 750.00 Project: 107833 Order Type: Purchase Card Date Needed: 05/10/2018 Emergency: No Order Status: Archive Requestor Phone: +1 406 363 9276 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 750.00 2613 thymus) 2 shipping estimate 8335424 2613 6509 1 each at \$0 .00Order Total: 750.00 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, LPVD. 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<sup>(b)(6)</sup> 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. Alternate Sources: GSA Stock Catalog: GSA Self Service: Federal Supply: UNICOR: Open Market: NIH Surplus: No No No No Yes AGENT Purchase Order #: (b)(6) Estimated Ship Date: Custodial Code: 30102 Date Entered into NBS: 05/09/2018

Expected Delivery Date: 05/11/2018

Select Agents: No

Clearance Requested: No

Order Reference: (b)(6)

NBS Ref Order #: 4969099

FSS:

## 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	4		
Releaser2			
NBS			
Receiving Official			

## Dates

Description	Date
Needed By	05/10/2018
Submitted to NBS	05/09/2018
NBS Confirmation	05/10/2018
Award Created	05/09/2018
Award Received	05/09/2018
Estimated Ship Date	
Received	05/29/2018
Canceled	

# **Routing History**

Name	Role	Date In	STATUS IN	ACTION	
Messer, Ronald	Requester	05/08/2018	New order	Approved	
(b)(6)	Administrative Officer	05/08/2018	Released	Approved	
	Purchasing Agent	05/08/2018	Approved	Take	
	Purchasing Agent	05/08/2018	Approved	Approved	
NBS, NBS	NBS	05/09/2018	Sent to NBS	Approved	
Messer, Ronald (b)(6)	Requester for receiving	05/09/2018	Pending receiving	Take	
(b)(6)	Requester for receiving	05/29/2018	Pending receiving	Approved	
	Archive	05/29/2018	Archive	(N/A)	

# **Receiving Report**

# Description	<b>Total Qty Ordered</b>	Total Qty Received	Date Received
Tissue, 2nd Trimester (1 each of liver and thymus)	2	2	05/29/2018
2 shipping estimate	1	1	05/29/2018

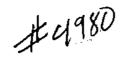
# OHSR RESPONSE TO REQU**ESTIFOR REVIEW OF RESEARCH** ACTIVITY INVOLVING HUMAN SUBJECTS

FAX	•			Exer	npt: #:	4980
To:	Hasenkrug, Kim	ı				
	NIAID					1
	RML - Rocky Mo	ountain Laboratorie	s, 3/218			
From	n: Office of Human	Subjects Research	n (OHSR)			·
Re tiss pro nei all	sue develop a human oject proposal is to cre utralizing antibodies i	monstrated that important immune system and eate such humanized in vaccine protections ame human cells	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 disea of immune cell sub entail the developm	ase. The gosets and votent of a co	goal of this virus- phort of mice
_	oonsible NIH Researd		Kim Hasenkrug, NIAII	<b>1</b>		
			ov 19, 2009 has determine	•		
	Federal regulations determination of No Involving Coded Pri on Engagement of I AMENDMENT OF A	for the protection of the Human Subjects I ivate Information or Institutions in Huma ANY CHANGES TH	of human subjects do not Research is based on th Biological Specimens" ( an Subjects Research (O HAT MAY ALTER THIS F and has been entered in t	apply to above nar e interpretation of 4 OHRP, Revised Oc october 16, 2008). N RESEARCH ACTIVI	5 CFR 46 tober 16, 2 IOTIFY OF	under "Research 2008) and Guidance HSR VIA AN E-MAIL
	ACTIVITY. NOT EXEMPT. OH	ISR recommends II	HAT MAY ALTER THE E RB review. Please forwa mation in order to detern	ard your request to	the Chair o	of your IRB, who
	Confidentiality Agree	ement				
	Reliance					
	Amendment			-		
	Other					
<b>Not</b>	e: (6)		Office Pe	erson LB A	Admin Assi	st. CB
		CIF	)			
ν <u>ch</u>	ariotte Holden, JU		Acting Director, OHSR		12/14/20	09
Sig	nature		Title		Date	
Don	nestic/International:	-				
Dor	nestic			01105		
Hun	nan Subjects Data: N	Yes		OHSR Use Only		le De
	-	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: Hasen knig
(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. 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 mm<sup>3</sup> 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 #					
		<u></u>			
_	d start date of your researchApd completion date _April, 2013	· ——			
4. Will you	bethese samples or dat	ta?			
	ng Yes/No 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 biomedie NIH guie NOTA g		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	s project? (Check all that apply)			
Analyze	samples/data only.	•			
Consult	ant/advisor to collaborator(s) listed	above.			
	of the protocol that is being implem question #2).	ented by your collaborating investigator			
Co-suth	orship 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	
<del></del> _ :	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		
NAME:	Kim J Hasenkrug		BILLING INFORMATION:
TITLE:	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 #: ALT. #:	_Hamilton, MT 59840 406-363-9310	CITY,ST,ZIP: ACCOUNTING	Hamilton, MT 59840
FAX#: 400	5-363-9286	P.O. # (if requi	red by your company):
DELIVERY O		Credit Card #:	equired to submit application
Mexim	Day: Commercial carrier, hand delivered izes cell viability (geographical limits) ay: Pickup, delivery Mon-Sat daytime		:VJSA/MC
Всопол	nical 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: Account #:	PEDEX		
Account #.	(b)(4)		
Piesse indicate	how you heard about ABR: (b)(6)		
II. HUM	an fetal tissue		
Tissue specime	ns requested:thymus, liver, cord blo	ood	
Preferçe Propos	ed gestational age (6-24 weeks): 17- ed starting date:May, 2010	19 wks	
CONTAGIOUS Applicant requi	DISEASE SCREENING: Availability res the following tests to be performed	of test results varies to by ABR:	from 24 hours to 7 days after procurement.
_x_	н	IV BSAG 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		
<b>v</b> .	— 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.

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)			

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

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
- 17III
- > 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
>
```

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 #
5/31/2018	(b)(6)	1034960
	TERMS	CUSTOMER#
	Due Upon Receipt	0522

**BILL TO** 

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

PROC. DAT	E P	ATIENT ID	АВІ	R ID	GEST		DESCRIPTI	ION	RESEARCHER	FEE
5/31/2018 5/31/2018		3101 3101	6262 6263		19 19	Thymus, Liver, 2n	2nd Trimester d Trimester		HASENKRUG HASENKRUG	(b)(4)
							PAID via VISA by Kim Hasenkrug.	(b)(6)		
	!									
								ı		
									,	
155.6 CAM ST 383 ALAPED (AM ST 383 (\$1.9) B65-5877 NIO #31.30631589266	23154922648	Sate Ene XXX	\$ 78,85	15:10:32 Ann Cala 02004	Batchii: 668612	OPPOLICATE LICENAL PPLO	CARDALLOER COPY Retain this copy for statement Verification			
1516 ALME: (516 (100 #3 Term 10: 1	Northark 10: 9138631682268	o VSIń	Total:	65/25/18 Trut: 300304	Approved: Online AMS Code:	<b>::</b> #:	CANTAIN THIS CI VERTI	Total	\$750	.00

SEQ: 1912038 PO#: Requester: Messer, Ronald Owner: (b)(6) CAN: 8335424 FY: 18 Order Total: 750.00 Project: 107833 Order Type: Purchase Card Date Needed: 05/29/2018 Emergency: No Order Status: Archive Requestor Phone: +1 406 363 9276 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)	750.00
2	shipping estimate	8335424		2613	6509	1 each at \$0	.00
0	order Total: 750 00						

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

## QUOTES

Vendor	Price	Good Until	Available
There are no quotes in t	ne order		

### JUSTIFICATION

These tissues, liver and thymus, are required by Ron Messer for ongoing studies of HIV in the Hasenkrug Lab, LPVD. 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.

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

Purchase Order #: (b)(6)

Estimated Ship Date: Date Entered into NBS: 05/25/2018

Custodial Code: 30102 Order Reference: em'd(b)(6)

Expected Delivery Date: 06/01/2018

FSS:

Select Agents: No

NBS Ref Order #: 4988220

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	05/29/2018
Submitted to NBS	05/25/2018
NBS Confirmation	05/26/2018
Award Created	05/25/2018
Award Received	05/25/2018
Estimated Ship Date	
Received	06/12/2018
Canceled	

### **Routing History**

Name	Role	Date In	STATUS IN	ACTION
Messer, Ronald	Requester	05/25/2018	New order	Approved
(b)(6)	Administrative Officer	05/25/2018	Released	Approved
	Purchasing Agent	05/25/2018	Approved	Approved
NBS, NBS	NBS	05/25/2018	Sent to NBS	Approved
Messer, Ronald (b)(6)	Requester for receiving	05/25/2018	Pending receiving	Take
(b)(6)	Requester for receiving	06/12/2018	Pending receiving	Approved
	Archive	06/12/2018	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	06/12/2018
2 shipping estimate	1	1	06/12/2018

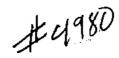
### OHSR RESPONSE TO REQU**ESTIFOR REVIEW OF RESEARCH** ACTIVITY INVOLVING HUMAN SUBJECTS

FAX				1	Exempt: #:	4980
To:	Hasenkrug, Kir	η				
	NIAID					i
	RML - Rocky M	flountain Laboratories	s, 3/218			
From	n: Office of Huma	n Subjects Research	(OHSR)			
Retiss	sue develop a huma eject proposal is to c utralizing antibodies	emonstrated that imn in immune system an create such humanize in vaccine protection	munodeficient mice red nd are susceptible to he ed mice to study the ro n. The experiments w also as to be histocomi	IIV infection and ble of immune cel iil entail the deve	disease. The of the office of	goal of this virus- ohort of mice
Origi	nal Request Receiv	ed in OHSR on:	11/19/2009			
Resp	onsible NIH Resea	rch Investigator(s):	Kim Hasenkrug, NiA	AID .		
OHS	SR review of your re	quest dated Thu, No	v 19, 2009 has detern	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 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 design	gnated <u>EXEMPT,</u> an	nd has been entered in AT MAY ALTER THE	the OHSR datat	oase. <u>PLEASE</u>	
			RB review. Please for mation in order to dete	•		- 1 '
	Confidentiality Agre	eement				
	Reliance					
	Amendment			-		
	Other					!
			Office	Person LB	Admin Ass	ist. CB
Note	<b>∋</b> : )(6)					
	,,,,	CIP	1			
<sub>∨</sub> Cha	arlotte Holden, JD	,	Acting Director, OHSR	<b>!</b>	12/14/20	09
Sig	nature		 Title		Date	<del>-</del>
Don	nestic/International:					
Dor	nestic					
Hum	nan Subjects Data:	Yes		OHSR Use O	-	
	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.

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146
From: Kim J Hasen knig
(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 mm<sup>3</sup> 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 # 3. Proposed start date of your research \_\_April, 2010\_\_\_\_ Proposed completion date April, 2013 4. Will you be \_\_\_ these samples or data? Collecting Yes/Qo Receiving Yes/No Sending Yes/No 5. Do the samples or data: (a) Already exist? Yes x No (b) Or are they being collected for the express purpose of this study? X Yes No If "yes," please describe:\_ 17-19 week fetal cells and tissue will be obtained from Advanced Bioscience Resources, Inc., a non-profit foundation established under California law to provide biomedical researchers access to human tissues in compliance with state, federal, and NIH guidelines. Consent to donate is obtained in accordance with UAGA and NOTA guidelines. Related documents including the consent form are (c) Or a combination of (a) and (b)? Yes 6. What role will you have in this research project? (Check all that apply) \_\_\_\_ Analyze samples/data only. Consultant/advisor to collaborator(s) listed above. Author of the protocol that is being implemented by your collaborating investigator (identified in question #2).

\_\_\_ Co-suthorship 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	
<del></del> _ :	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. APF	PLICANT INFORMATION		
NAME:	Kim J Hasenkrug		BILLING INFORMATION:
TITLB:	_Sentor Investigator	BILL TO:	Kim J Hasenkrug
COMPANY:	NIAID, NIH	_ COMPANY:	Rocky Mountain Labs
ADDRESS:	_Rocky Mountain Lab		903 S. 4th St
ADDRESS:	_903 S. 4th St	ADDRESS:	
	P: _Hamilton, MT 59840 406-363-9310	CITY,ST,ZIP: ACCOUNTING	Hamilton, MT 59840
	06-363-9286	P.O. # (if requi	red by your company):
DELIVERY		Credit Card #:	equired to submit application
Mexi	Day: Commercial carrier, hand delivered mizes cell viability (geographical limits)  Day: Pickup, delivery Mon-Sat daytime	Name on CC: Expiration Date	:VJSA/MC
Всоп	omical for fresh, frozen specimens	SHIP TO:	Kim J Hasenkrug
Applicant wi	ill be charged for delivery fees.		_Rocky Mountain Labs
Applicant ma	y designate preferred carrier:		903 S. 4th St
Carrier Name Account #:	:		_Hamilton, MT 59840
Piesse indica	te how you heard about ABR: (b)(6)		
II. HUD	MAN FETAL TISSUE		•
Tissue specin	nens requested:thymus, liver, cord bloo	d	·
Profe Propo	rred gestational age (6-24 weeks):17-19  osed starting date;May, 2010	9 wks	
CONTAGIOU Applicant req	JS DISEASE SCREENING: Availability of juices 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	DAS	HSV RPR HCV OTHER

#### III. **PRESERVATION**

	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		
<b>v</b> .	— 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,

(6)(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:
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> 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
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```
> This action is based on guidance issued on Aug. 10, 2004 by the HHS
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> OHSR - National Institutes of Health
> Bldg 10, Suite 2C146
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> 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]

Cc: (b)(6)

Subject: Re: HFT Application

#### Hi Kim,

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

#### Perrin

- > Dear Perrin, the Office of Human Subjects Research is asking me for a
- > letter
- > from you stating that personally identifiable information regarding the
- > fetal tissue will be revealed to me. Would you kindly send me a letter
- > stating such so that I can forward it to them? It would be greatly
- > appreciated and let us begin our experiments. I attached a copy your
- > 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#
6/27/2018	(b)(6)	1035043
	TERMS	CUSTOMER#
	Due Upon Receipt	0522

_		
		1 ( )

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

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION		RESEARCHER	
6/27/2018 6/27/2018	672704 672704	2433 2434	21 21	Thymus, 2nd Trimester Liver, 2nd Trimester	nymus, 2nd Trimester ver, 2nd Trimester HASENKRUG HASENKRUG		(b)(4)
		i.		07/06/18 PAID via VISA . (b) Request by Kim Hasenkrug.	0(6)		
	-						
			I		Total	\$750	0.00

SEQ: 1916109

Obtained via FOIA by Judicial Watch, Inc.

Requester: Messer, Ronald

CAN: 8335424 FY: 18 Owner: (b)(6)

Order Total: 750.00 Project: 107833

Date Needed: 06/22/2018 Emergency: No Order Type: Purchase Card

Requestor Phone: +1 406 363 9276 Order Status: Archive

Vendor Advanced Bioscience Resources, 1516 Oak Street, Suite 303, Alameda, CA 94501

Phone: 510-865-5872 SmlBs: No FSS: EIN: BPA: GSA:

Site: Clerk:

E-mail:

Description	CAN	Catalog	OC Code	Category	Qty at Price	Total
Tissue, 2nd Trimester (1 each of liver and thymus)	8335424	none	2613	6509	(b)(4)	750.00
shipping estimate	8335424		2613	6509	1 each at \$0	.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, LPVD. 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 ext60/60—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.

Alternate Sources:

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

AGENT

Purchase Order #: (b)(6) Estimated Ship Date:

Custodial Code: 30102

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

Date Entered into NBS: 06/22/2018

Expected Delivery Date: 06/29/2018

FSS: Select Agents: No
NBS Ref Order #: 5018824 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	06/22/2018		
Submitted to NBS	06/22/2018		
NBS Confirmation	06/22/2018		
Award Created	06/22/2018		
Award Received	06/22/2018		
Estimated Ship Date			
Received	07/10/2018		
Canceled			

### **Routing History**

Name	Role	Date In	STATUS IN	ACTION Approved
Messer, Ronald	Requester	06/20/2018	New order	
(b)(6)	Administrative Officer	06/20/2018	Released	Approved
	Purchasing Agent	06/20/2018	Approved	Approved
NBS, NBS	NBS	06/22/2018	Sent to NBS	Approved
Messer, Ronald (b)(6) JASON)	Requester for receiving	06/22/2018	Pending receiving	Take
(b)(6)	Requester for receiving	07/10/2018	Pending receiving	Approved
	Archive	07/10/2018	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	07/10/2018
2 shipping estimate	1	1	07/10/2018

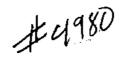
## OHSR RESPONSE TO REQU**ESTIFOR REVIEW OF RESEARCH** ACTIVITY INVOLVING HUMAN SUBJECTS

FAX	· •			Exempt: #:	4980
To:	Hasenkrug, Kim				
	NIAID				-
	RML - Rocky Mounta	n Laboratories, 3/218			
Fron	n: Office of Human Subj	ects Research (OHSR)			
Re tiss pro ner all	sue develop a human imm oject proposal is to create utralizing antibodies in vac	trated that immunodeficient miceune system and are susceptible such humanized mice to study the cine protection. The experiment e human cells so as to be histored the contract of the the contra	to HIV infection and ne role of immune ce ts will entail the deve	I disease. The ell subsets and elopment of a c	goal of this virus- ohort of mice
	oonsible NIH Research Inv		NIAID		
		dated Thu, Nov 19, 2009 has de	<del>_</del> -		<del></del>
	Federal regulations for the determination of Not Hur Involving Coded Private on Engagement of Institute AMENDMENT OF ANY The activity is designated OF ANY SIGNIFICANT OF ACTIVITY.	e protection of human subjects of nan Subjects Research is based information or Biological Specimitions in Human Subjects Resea CHANGES THAT MAY ALTER T EXEMPT, and has been entered CHANGES THAT MAY ALTER T	do not apply to above on the interpretation on the interpretation ens." (OHRP, Revise rch (October 16, 2007) THIS RESEARCH And in the OHSR data THE EXEMPT STAT	n of 45 CFR 46 ed October 16, 08). NOTIFY OI CTIVITY. abase. <u>PLEASI</u> US OF THIS R	under "Research 2008) and Guidance HSR VIA AN E-MAIL E NOTIFY OHSR ESEARCH
		dditional information in order to	,		- I '
	Confidentiality Agreemer	t			
	Reliance				
	Amendment		-		
	Other				!
Not	e: (6)	Of CIP	fice Person LB	Admin Ass	ist. CB
_ [ ∵Chi	arlotte Holden, JD	 Acting Director, Ol	HSR	12/14/20	ing :
	nature	Title		Date	<u>.</u>
Don	nestic/International:				
	mestic				
Hun	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.

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146
From: Kim J Jasen Kura
(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_
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 mm<sup>3</sup> 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

	iviral activity of the immune cells. The fimmunity against HIV.	e goal of these experiments is to establish			
2. If ap	2. If applicable, list your non-NIH Collaborating Investigator(s).				
Name	Institution	Address Tel. # FAX #			
	ed start date of your researchAped completion date _April, 2013				
4. Will you	bethese samples or dat	a?			
Collecti Receivi Sending	ing Yes/No ng Yes/No Yes/No				
	samples or data: eady exist?Yes _xNo				
	are they being collected for the expre "please describe:_	ss purpose of this study? _XYesNo			
Resourc biomedi NIH gui	ical researchers access to human tissuidelines. Consent to donate is obtain guidelines. Related documents include	plished under California law to provide les in compliance with state, federal, and ed in accordance with UAGA and			
(c) Or a	a combination of (a) and (b)?	_YesNo			
6. What	t role will you have in this research	project? (Check all that apply)			
Analyz	e samples/data only.				
Consul	tant/advisor to collaborator(s) listed a	bove.			
	of the protocol that is being implement a question #2).	nted by your collaborating investigator			
Co-auth	norship 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 <u>that you are p</u> an Institutional Review Board (IRB) elsewl	
<del></del>	s been reviewed by the following IRB (s)
(Please provide the following information for	encu (KD):
N	lame of institution that provided the review
A	ddress of reviewing institution
N	lame of PI for the IRB approved protocol
Ti	tle 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 regusubjects. For a list of domestic and internation <a href="http://ohrp.cit.nih.gov/search/asearch.asp#ASI">http://ohrp.cit.nih.gov/search/asearch.asp#ASI</a>	to conduct clinical research that the latter lations for the protection of human lal 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.	ical Director about this matter before
***The January 5, 2005 NIH Guide to Preven research conducted at NIH, <a href="http://ohsr.od.nih.">http://ohsr.od.nih.</a>	

# 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. APF	PLICANT INFORMATION		
NAME:	Kim J Hasenkrug		BILLING INFORMATION:
TITLB:	_Sentor 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,ZH PHONE #: _ ALT. #:	P: _Hamilton, MT 59840 406-363-9310	CITY,ST,ZJP: ACCOUNTING	Hamilton, MT 59840 DEPT. PHONE #:406-363-9438
	06-363-9286	P.O. # (if requi	red by your company):
EMAIL: khasenkrug@nih.gov DELIVERY OPTIONS:		Credit Card #:	equired to submit application
Mexi	e Day: Commercial carrier, hand delivered mizes cell viability (geographical limits) Day: Pickup, delivery Mon-Sat daytime	I limits) Expiration Date	:VJSA/MC
Всоп	omical for fresh, frozen specimens	SHIP TO:	Kim J Hasenkrug
Applicant wi	lll be charged for delivery fees.		_Rocky Mountain Labs
Applicant ma	y designate preferred carrier:		903 S. 4th St
Carrier Name:PEDEX			_Hamilton, MT 59840
Account #:	(b)(4)		
Piesse indica	te how you heard about ABR: (b)(6)		
II. HUM	MAN FETAL TISSUE		
Tissue specin	nens requested:thymus, liver, cord blood	d	
Prefe Prope	rred gestational age (6-24 weeks):17-19 osed starting date;May, 2010	) wks	
CONTAGIOU Applicant req	JS DISEASE SCREENING: Availability of juires 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	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		
<b>v</b> .	— 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.

Seaking 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.
- Representations and Warranties. ABR hereby represents and warrants to researcher that (I) ABR will make no payments to anyone for any tissue transferred in connection with this agreement, and (ii) ABR will verify for each tissue delivery that appropriate consent was obtained for use of such tissue and any associated serum samples, and that adequate records of such consent are 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 set not 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, sec. 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. Paymonia. 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. Shloment 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 flable under any section of this agreement or under any contract, negligence, strict liability or other logal 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. Indemnification. Researcher shall indemnify, defend and hold ABR harmless from and against all claims, causes of actions, suits, demages and coats 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) adjusts 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)			

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

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
>
```

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#
8/15/2018	(b)(6)	1035180
	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	PATI	ENT ID	ABI	R ID	GEST		DESCRIPTION		RESEARCHER	FEE
8/15/2018 8/15/2018	67150: 67150:		2519 2520		20 20		s, 2nd Trimester 2nd Trimester		HASENKRUG HASENKRUG	(b)(4)
						08/23/1 Reques	8 PAID via VISA #7382(b)(6) t by Kim Hasenkrug.			
			l							
		·								
		Es: XXX	750 188	88:16:57	Patchii: 600021 V	Z'8912 <sub>4</sub> )	t-			
ALMEDA, CA 94561 (510) 655-1677 AID #3130631589256 (5:1)	Sale	Exp: XX/XX Entry Nethod: Keyed OP	-48-	08:16:57	Patchi	ORNOSTUNYT X421BBLZ	CARCHOLDER COPY AETAIN THIS CAPY FOR STATEMENT VERIFICATION			
ALAFEDA, CA 94 (510) 855-59 (510) 855-59 MID #313083150 Term ID: 1	S	roncener/1982 VISA		Account	Approd: Online AVS Code:		CARDHOL TAIN THIS CC			
Ters I		20000 VISA	Total;	18/23/18 1 m/#: 00000m	Approd: D	361C #:	· E	Γotal	\$750	.00

SEQ: 1926966 PO#: (b)(6) Requester: Messer, Ronald

CAN: 8335424 FY: 18 Owner: (b)(6)

Order Total: 750.00 Project: 107833

Date Needed: 08/13/2018 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:

Total	Qty at Price	Category	OC Code	Catalog	CAN	Description
750.00	(b)(4)	6509	2613	none	8335424	Tissue, 2nd Trimester (1 each of liver and thymus)
.00	1 each at \$0	6509	2613		8335424	shipping estimate
=	1 each at \$0	6509	2613		8335424	shipping estimate order Total: 750.00

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, LPVD. 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 60-60 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.

Alternate Sources:

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

No No No Yes

AGENT

Purchase Order #:[0)(6) Estimated Ship Date:

Custodial Code: 30102

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

Date Entered into NBS: 08/10/2018

Expected Delivery Date: 08/13/2018

FSS: Select Agents: No
NBS Ref Order #: 5081081 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	08/13/2018		
Submitted to NBS	08/10/2018		
NBS Confirmation	08/10/2018		
Award Created	08/10/2018		
Award Received	08/10/2018		
Estimated Ship Date			
Received	08/16/2018		
Canceled			

### **Routing History**

Name	Role	Date In	STATUS IN	ACTION
Messer, Ronald	Requester	08/09/2018	New order	Approved
(b)(6)	Administrative Officer	08/09/2018	Released	Approved
	Purchasing Agent	08/09/2018	Approved	Approved
NBS, NBS	NBS	08/10/2018	Sent to NBS	Approved
Messer, Ronald (b)(6)	Requester for receiving	08/10/2018	Pending receiving	Take
(b)(6)	Requester for receiving	IIII X/ LO/ /LLLX	Pending receiving	Approved
	Archive	08/16/2018	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	08/16/2018
2 shipping estimate	1	1	08/16/2018

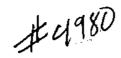
# OHSR RESPONSE TO REQU**ESTIFOR REVIEW OF RESEARCH** ACTIVITY INVOLVING HUMAN SUBJECTS

FAX				E	Exempt: #:	4980
To:	Hasenkrug, Ki	jim				
	NIAID					1
	RML - Rocky I	Mountain Laboratorie	s, 3/218			
From	n: Office of Huma	an Subjects Research	ı (OHSR)			
Re tiss pro net	sue develop a huma eject proposal is to utralizing antibodie:	demonstrated that imrean immune system are create such humanizes in vaccine protection	munodeficient mice red nd are susceptible to H ed mice to study the ro n. The experiments wi s so as to be histocome	IIV infection and only of immune cell if entail the devel	disease. The of subsets and of a co	goal of this virus- ohort of mice
Origi	nal Request Recei	ived in OHSR on:	11/19/2009			
Resp	onsible NIH Resea	arch Investigator(s):	Kim Hasenkrug, NIA	MD		
OHS	SR review of your re	equest dated Thu, No	ov 19, 2009 has determ	nined that:		
$\boxtimes$	determination of N Involving Coded F on Engagement of	Not Human Subjects f Private Information or of Institutions in Huma	if human subjects do n Research is based on t Biological Specimens" In Subjects Research ( IAT 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 <b>EXEMPT</b> , an	nd has been entered in IAT MAY ALTER THE	the OHSR datab	ase. <u>PLEASE</u>	
			RB review. Please for mation in order to dete	,		- 1 '
	Confidentiality Ag	reement				
	Reliance					
	Amendment			-		
	Other					!
Note	e:		Office	Person LB	Admin Assi	ist. CB
(b	) <del>(</del> 6)	CIP	)			
√ <u>Ch</u>	arlotte Holden, JD	,	Acting Director, OHSR	<u>:                                    </u>	12/14/20	09
Sig	nature	•	Title		Date	<del>.</del>
Don	nestic/International	· -				
Dor	nestic			OHOD II -	_1	
Hun	nan Subjects Data:	Yes		OHSR Use Or	-	le 🗆 c
	ogic Material:	Yes		∐1 ∐2 L	]3 □4 □	15 116

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.

<del></del>
To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146
From: Hasen knig
(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_
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 mm<sup>3</sup> 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 #				
	ed start date of your researchAped completion date _April, 2013					
4. Will you	bethese samples or dat	a?				
Collecti Receivi Sending	ing Yes/No ng Yes/No Yes/No					
	samples or data: eady exist?Yes _xNo					
	are they being collected for the expre "please describe:_	ss purpose of this study? _XYesNo				
Resourc biomedi NIH gui	ical researchers access to human tissuidelines. Consent to donate is obtain guidelines. Related documents include	plished under California law to provide les in compliance with state, federal, and ed in accordance with UAGA and				
(c) Or a	a combination of (a) and (b)?	_YesNo				
6. What	t role will you have in this research	project? (Check all that apply)				
Analyz	e samples/data only.					
Consul	tant/advisor to collaborator(s) listed a	bove.				
	of the protocol that is being implement a question #2).	nted by your collaborating investigator				
Co-auth	norship 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	
<del></del> _ :	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. APP	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,ZIF PHONE #: _ ALT. #:	2: _Hamilton, MT 59840 406-363-9310	CITY,ST,ZJP: ACCOUNTING	Hamilton, MT 59840
FAX #: 4	06-363-9286	P.O. # (if requi	red by your company):
DELIVERY		Credit Card #:	equired to submit application
Mexi	Day: Commercial carrier, hand delivered mizes cell viability (geographical limits) Day: Pickup, delivery Mon-Sat daytime	Name on CC: Expiration Date	:VJSA/MC
Boon	omical for fresh, frozen specimens	SHIP TO:	Kim J Hasenkrug
Applicant wi	ll be charged for delivery fees.		_Rocky Mountain Labs
Applicant ma	y designate preferred carrier:		903 S. 4th St
Carrier Name			_Hamilton, MT 59840
Account #:	(b)(4)		
Piesse indica	te how you heard about ABR: (b)(6)		
II. HUM	MAN FETAL TISSUE		
Tissue specin	nens requested:thymus, liver, cord bloo	d	
Prefe Propo	rred gestational age (6-24 weeks):17-19 osed starting date:May, 2010	9 wks	
CONTAGIOU Applicant req	IS DISEASE SCREENING: Availability of uires 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	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		
<b>v</b> .	— 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.

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,

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

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.
- >
- > 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: 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
>> respond to your query.
>>
>> Perrin Larton CTBS
>> Procurement Manager
>> Advanced Bioscience Resources
>
```

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

PO#: (b)(6) SEQ: 1926967 Requester: Messer, Ronald Owner: (b)(6) CAN: 8335424 FY: 18 Order Total: 750.00 Project: 107833 Order Type: Purchase Card Date Needed: 08/24/2018 Emergency: No Order Status: Archive Requestor Phone: +1 406 363 9276 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)	750.00
shipping estimate	8335424		2613	6509	1 each at \$0	.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

Sources:

NIH Surplus: No 

UNICOR: GSA Stock Catalog: GSA Self Service: Federal Supply: Open Market: Yes

#### AGENT

FSS:

Alternate

Purchase Order #:[b)(6)

Custodial Code: 30102

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

NBS Ref Order #: 5081916

Estimated Ship Date: Date Entered into NBS: 08/10/2018

Expected Delivery Date: 08/24/2018

Clearance Requested: No

Select Agents: 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	08/24/2018
Submitted to NBS	08/10/2018
NBS Confirmation	08/10/2018
Award Created	08/10/2018
Award Received	08/10/2018
Estimated Ship Date	
Received	09/10/2018
Canceled	

### **Routing History**

Name	Role	Date In	STATUS IN	ACTION
Messer, Ronald	Requester	08/09/2018	New order	Approved
(b)(6)	Administrative Officer	08/09/2018	Released	Approved
	Purchasing Agent	08/09/2018	Approved	Approved
NBS, NBS	NBS	08/10/2018	Sent to NBS	Approved
Messer, Ronald (b)(6)	Requester for receiving	08/10/2018	Pending receiving	Take
(b)(6)	Requester for receiving	09/10/2018	Pending receiving	Approved
	Archive	09/10/2018	Archive	(N/A)

### **Receiving Report**

# Description	Total Qty Ordered	<b>Total Qty Received</b>	Date Received
Tissue, 2nd Trimester (1 each of liver and thymus)	2	2	09/10/2018
2 shipping estimate	1	1	09/10/2018

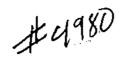
# OHSR RESPONSE TO REQU**ESTIFOR REVIEW OF RESEARCH** ACTIVITY INVOLVING HUMAN SUBJECTS

FAX	:		Exempt: #:	4980
To:	Hasenkrug, Kim			
	NIAID			ì
	RML - Rocky Mountain Labo	ratories, 3/218		
From	n: Office of Human Subjects Ro	esearch (OHSR)		
Re tiss pro nei	ire of Research Activity: cent reports have demonstrated sue develop a human immune sy pject proposal is to create such hi utralizing antibodies in vaccine pri reconstituted with the same hum	stem and are susceptible to HIV umanized mice to study the role otection. The experiments will e	infection and disease. The of immune cell subsets and entail the development of a c	goal of this virus- cohort of mice
Origi	inal Request Received in OHSR	on: 11/19/2009		•
Resp	ponsible NIH Research Investigat	or(s): Kim Hasenkrug, NIAID		
OHS	SR review of your request dated 1	lhu, Nov 19, 2009 has determin	ed that:	
⊠	Federal regulations for the prote determination of Not Human Su Involving Coded Private Informa on Engagement of Institutions in AMENDMENT OF ANY CHANC	bjects Research is based on the ation or Biological Specimens" (C a Human Subjects Research (Oc	e interpretation of 45 CFR 46 DHRP, Revised October 16, ctober 16, 2008). NOTIFY C	under "Research 2008) and Guidance
	The activity is designated <b>EXEM</b> OF ANY <b>SIGNIFICANT</b> CHANG ACTIVITY.	MPT, and has been entered in th SES THAT MAY ALTER THE EX	ie OHSR database. <u>PLEAS</u> ( <u>EMPT STATUS OF THIS F</u>	RESEARCH
	NOT EXEMPT. OHSR recomm may ask you to provide addition appropriate.		•	- 1 '
	Confidentiality Agreement			
	Reliance			
	Amendment		-	
	Other			!
		Office Pe	erson LB Admin As	sist CB
Note	e: )(6)			
	· · ·	CIP		
<sub>Ն</sub> Cha	arlotte Holden, JD	Acting Director, OHSR	12/14/2	009
Sig	nature	Title	 Date	<del></del>
Don	nestic/International:			
Dor	nestic			
Hun	nan Subjects Data: Yes		OHSR Use Only	
	ogic Material: Yes			<b>⊥5</b> □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 S tasen knig
(Signature)
Through: (ecfing)
(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 mm<sup>3</sup> 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 applic	Institution	Address Tel. # FAX #
	art date of your researchApt mpletion date _April, 2013	
4. Will you be	these samples or data	a?
Collecting Receiving Sending	Yes/No Yes/No Yes/No	
5. Do the samp (a) Already	oles or data: exist?Yes _xNo	
	hey being collected for the expressase describe:	ss purpose of this study? _XYesNo
Resources, l biomedical : NIH guideli	researchers access to human tissunes. Consent to donate is obtain elines. Related documents include	olished under California law to provide es in compliance with state, federal, and ed in accordance with UAGA and
(c) Or a cor	mbination of (a) and (b)?	_YesNo
6. What rol	c will you have in this research	project? (Check all that apply)
Analyze saı	mples/data only.	
Consultant/	advisor to collaborator(s) listed a	bove.
Author of the control of the con		nted by your collaborating investigator
Co-authors	hip 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	
<del></del> _ :	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. A	PPLICANT INFORMATION		
NAMB:	Kim J Hasenkrug		BILLING INFORMATION:
TITLB:	_Senior Investigator		Kim J Hasenkrug
COMPAN	Y:NIAID, NIH		Rocky Mountain Labs
ADDRESS			903 S. 4th St
ADDRESS	3: _903 S. 4th St	ADDRESS:	
CITY,ST,? PHONE #: ALT. #:	ZIP: _Hamilton, MT 59840 :406-363-9310	CITY,ST,ZJP: ACCOUNTING	Hamilton, MT 59840 DEPT. PHONE #:406-363-9438
FAX#:	406-363-9286	P.O. # (if requi	red by your company):
DELIVER	khasenkrug@nih.gov	Credit Card #:	equired to submit application
M	me 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	may designate preferred carrier:		903 S. 4th St
Carrier Nat Account #:			_Hamilton, MT 59840
	icate how you heard about ABR: (b)(6)  UMAN FETAL TISSUE		
Tissue spe	cimens requested:thymus, liver, cord blood	d	·
Pro Pro	eferred gestational age (6-24 weeks):17-19 oposed starting date:May, 2010	wks	
CONTAGI Applicant	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 HBS CM	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		
<b>v</b> .	— 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 it 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 flable 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.

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

```
> 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
- < 17111
- > 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 #
9/6/2018	(b)(6)	1035240
	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	PATIE	ENT ID	ABR	l ID	GEST		DESCRIPT	ION	RESEARCHER	FEE
9/6/2018 9/6/2018	310601 310601		5338 5340		21 21	Thymus Liver, 2	, 2nd Trimester nd Trimester		HASENKRUG HASENKRUG	(b)(4)
							PAID via VISA by Kim Hasenkrug.	(b)(6)		
										,
ALALD UNF CA 9881 (610) 865-6872 MID #3138631695260	30150260 Sale	Eso: XX/XX Entry Method: Keyed OP	\$ 120.00 \$	<b>3.4</b> .3	Betch#: 686823	OFF GROSETING ZACKER!?	CARCHOLDER CORY Retain This Cory For Statement Verletcation			
ALANED ALANED (519 AID #3	Archant ID: 3136631569266	<i>5</i>	Total:	85/14/18	inva: coccor Approd: Online AVS Code:	BRIC #:	CARCHIO Retain this c Vert	Tota	s750	-

SEQ: 1926969

| PO#: (b)(6) | Requester: Messer, Ronald

CAN: 8335424 FY: 18 Owner: Messer, Ronald

Order Total: 750.00 Project: 107833

Date Needed: 09/07/2018 Emergency: No Order Type: Purchase Card

Requestor Phone: +1 406 363 9276 Order Status: Pending receiving

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)	750.00
2	shipping estimate	8335424		2613	6509	1 each at \$0	.00
	der Total: 750.00	0000121	)	2010	0005	1 4441 44 40	100

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

#### **QUOTES**

#### **JUSTIFICATION**

These tissues, liver and thymus, are required by Ron Messer for ongoing studies of HIV in the Hasenkrug Lab, LPVD. 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 place 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.

Alternate Sources:

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

AGENT

Purchase Order #: (b)(6)

Custodial Code: 30102 Order Reference: em'd (b)(6)

FSS: NBS Ref Order #: 5081917 Estimated Ship Date:

Date Entered into NBS: 08/10/2018 Expected Delivery Date: 09/07/2018

Select Agents: No

Clearance Requested: No

### SF-37 Code:

#### Notes

There are no notes in the order

#### IT Clearance

Never seen by IT officer

#### **ROUTE HISTORY**

## Role Summary

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

#### Dates

Description	Date
Needed By	09/07/2018
Submitted to NBS	08/10/2018
NBS Confirmation	08/10/2018
Award Created	08/10/2018
Award Received	08/10/2018
Estimated Ship Date	
Received	
Canceled	

## **Routing History**

Name	Role	Date In	STATUS IN	ACTION	
Messer, Ronald	Requester	08/09/2018	New order	Approved	
(b)(6)	Administrative Officer	08/09/2018	Released	Approved	
	Purchasing Agent	08/09/2018	Approved	Approved	
NBS, NBS	NBS	08/10/2018	Sent to NBS	Approved	
Messer, Ronald Requester for receiving		08/10/2018	Pending receiving	(N/A)	

## **Receiving Report**

# Description	<b>Total Qty Ordered</b>	Total Qty Received	Date Received

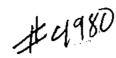
# OHSR RESPONSE TO REQU**ESTIFOR REVIEW OF RESEARCH** ACTIVITY INVOLVING HUMAN SUBJECTS

FAX	:		Exempt: #: 4980
To:	Hasenkrug, Kim		
	NIAID		
	RML - Rocky Mountain La	aboratories, 3/218	
From	n: Office of Human Subjects	Research (OHSR)	
Re tiss pro net	sue develop a human immune oject proposal is to create such utralizing antibodies in vaccine	ed that immunodeficient mice reconstitute system and are susceptible to HIV infection humanized mice to study the role of immeter protection. The experiments will entail the tuman cells so as to be histocompatible.	on and disease. The goal of this nune cell subsets and virus- ne development of a cohort of mice
Origi	nal Request Received in OHS	SR on: 11/19/2009	•
Resp	oonsible NIH Research Investi	gator(s): Kim Hasenkrug, NIAID	
OHS	SR review of your request date	ed Thu, Nov 19, 2009 has determined tha	t:
	determination of Not Human Involving Coded Private Infor on Engagement of Institution: AMENDMENT OF ANY CHA The activity is designated <b>EX</b>	rotection of human subjects do not apply to Subjects Research is based on the interpretation or Biological Specimens" (OHRP, is in Human Subjects Research (October NGES THAT MAY ALTER THIS RESEAL (EMPT, and has been entered in the OHS) NGES THAT MAY ALTER THE EXEMPT	retation of 45 CFR 46 under "Research Revised October 16, 2008) and Guidano 16, 2008). NOTIFY OHSR VIA AN E-MAI RCH ACTIVITY. SR database. <u>PLEASE NOTIFY OHSR</u>
	ACTIVITY.		
		mmends IRB review. Please forward you ional information in order to determine wh	· · · · · · · · · · · · · · · · · · ·
	Confidentiality Agreement		
	Reliance		
	Amendment	-	
	Other		
N <u>ot</u> e		Office Person	LB Admin Assist, CB
(b)	(6)	CIP	
⊬ <mark>Ch</mark> a	arlotte Holden, JD	Acting Director, OHSR	12/14/2009
Sig	nature	Title	Date
Don	nestic/International:		
Dor	nestic		
Hun	nan Subjects Data: Yes	_	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.

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146					
1 . 1 1					
From: KIM & tasen know					
(Signature)					
(b)(6)					
Through: acting					
(Signature of appropriate Official for IC, e.g., Lab/Branch Chief)					
Protocol Title:Study of HIV infection and vaccine protection in mice reconstituted					
with a human immune system					
Name of NIH Principal Investigator(s):Kim J Hasenkrug, Senior Investigator_					
TO ATTATO THE ADDITION OF THE					
ICNIAID_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 mm<sup>3</sup> 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 # 3. Proposed start date of your research \_\_April, 2010\_\_\_\_ Proposed completion date April, 2013 4. Will you be \_\_\_ these samples or data? Collecting Yes/Qo Receiving (Yes/No Sending Yes/No. 5. Do the samples or data: (a) Already exist? Yes x No (b) Or are they being collected for the express purpose of this study? X Yes No If "yes," please describe:\_ 17-19 week fetal cells and tissue will be obtained from Advanced Bioscience Resources, Inc., a non-profit foundation established under California law to provide biomedical researchers access to human tissues in compliance with state, federal, and NIH guidelines. Consent to donate is obtained in accordance with UAGA and NOTA guidelines. Related documents including the consent form are Yes (c) Or a combination of (a) and (b)? 6. What role will you have in this research project? (Check all that apply) \_\_\_\_ Analyze samples/data only. Consultant/advisor to collaborator(s) listed above. Author of the protocol that is being implemented by your collaborating investigator (identified in question #2).

\_\_\_\_ Co-suthorship 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	
<del></del> _ :	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. AF	PPLICANT INFORMATION				
NAME:	Kim J Hasenkrug		BILLING INFORMATION:		
TITLE:	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		
Me	ne Day: Commercial carrier, hand delivered ximizes cell viability (geographical limits) at Day: Pickup, delivery Mon-Sat daytime	Name on CC: Expiration Date	:VJSA/MC		
Бсо	pnomical for fresh, frozen specimens	SHIP TO:	Kim J Hasenkrug		
Applicant	will be charged for delivery fees.		_Rocky Mountein Labs		
Applicant n	nay designate preferred carrier:		903 S. 4th St		
Carrier Name: PEDEX Account #: (b)(4)			_Hamilton, MT 59840		
	cate how you heard about ABR: (b)(6)  JMAN FETAL TISSUE				
Tissue spec	imens requested:thymus, liver, cord blood	I	· · ·		
Pre Pro	ferred gestational age (6-24 weeks): 17-19 posed starting date: May, 2010	wks			
CONTAGIO Applicant r	OUS DISEASE SCREENING: Availability of equires the following tests to be performed by	test results varies (	from 24 hours to 7 days after procurement.		
_>	C No testing required         HIV           CM^*	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		
<b>v</b> .	— 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 if on 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 flable 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)(G)

(D)(O)			

### 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
- > 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: 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
>> 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.



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