

<h1 style="margin: 0;">REQUISITION</h1>				PROCUREMENT REQUEST NO. 1108971	
1. NAME, PHONE NUMBER, AND ROUTING SYMBOL OF PERSON TO CONTACT (b) (6)				REQUISITION DATE 07/27/2012	
3. ORIGINATING OFFICE DATA (b) (6) FDA				2. TYPE OF REQUEST (Check one) A. <input checked="" type="checkbox"/> NEW REQUEST B. <input type="checkbox"/> CHANGE TO PENDING PR NO. _____ C. <input type="checkbox"/> MODIFICATION TO CONTRACT OR ORDER NO. _____	
4. ADDITIONAL INFORMATION (Suggested supply sources, security data, etc.)				6. CONSIGNEE AND DESTINATION WHITE OAK CAMPUS, BUILDING 64 The US Food and Drug Administration 10903 New Hampshire Avenue Building 64 Silver Spring MD 20993	
5. APPROVALS					
APPROVING OFFICIALS (A)	ROUTING SYMBOL (B)	DATE (C)	INTERNAL ROUTING		
INITIALS (D)	ROUTING SYMBOL (E)				
(1) AUTHORIZED REQUISITIONER (b) (6)	BUSINESS G	07/27/2012			
(2) (b) (6)	BUSINESS G	07/27/2012			
(3) (b) (6)	BUSINESS G	07/27/2012			
(4)					
7. DATE(S) REQUIRED 08/15/2012					
8. GOVERNMENT FURNISHED PROPERTY <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO (If "yes," see par. 8 of instructions on next page.)					
9. DESCRIPTION OF ITEMS OR SERVICES					
ITEM NO. (A)	ITEM OR SERVICE (Include Specifications and Special Instructions) (B)	QUANTITY (C)	UNIT (D)	ESTIMATED COST	
				UNIT (E)	AMOUNT (F)
1	Tissue procurement for Humanized Mice Appr. Yr.: 2012 CAN: 6993354 Object Class: 2522 CenterTag: D48095AA274NNBD FOB: Destination Tissue procurement for Humanized Mice	1	EA	12,000.00	12,000.00
				TOTAL ESTIMATED COST \$12,000.00	
10. ACCOUNTING DATA Accounting Info : 2012.6993354.2522					

Staff Manual Guide 2610.7, Section 5.

Effective Date: 06/01/2009

5.A. – Requisition Package Part I: SMG 2610.7 Requisition Package Cover Sheet**U.S. FOOD AND DRUG ADMINISTRATION
OFFICE OF ACQUISITIONS & GRANTS SERVICES (OAGS)****SMG 2610.7 Requisition Package Cover Sheet
(To be used ONLY for Proposed Contract Actions Less Than or Equal to
the Simplified Acquisition Threshold)****1a. Project Title/Description:** Tissue procurement for Humanized Mice**1b. iProcurement Requisition No. (if known):****1c. Date Award Required:** 17 September 2012**1d. Date of Request:** 25 July 2012**2. Suggested Type of Action:****2.a. New:**

- ☐ Competitive Award
- ☒ Non-Competitive Award:
- ☐ GSA / GWAC
- ☐ Delivery/Task Order Number: # of Contract Number: #

2b. Modification to:

- ☐ Contract Number:
- ☐ Delivery/Task Order Number: # of Contract Number: #

3a. Estimated Amount of this Action: \$60,000**3b. Amount of Funds Provided at this Time:** \$12,000**4a. Period of Performance of Basic Contract or modification:**

	Years		Months		From:	9/17/12	To:	9/16/13
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4b. Indicate Number of Option Periods (if any) and Performance Period of Each:

	Period of Performance Start Date	Period of Performance End Date
Option 1	9/16/13	9/15/14
Option 2	9/16/14	9/15/15
Option 3	9/16/15	9/15/16
Option 4	9/16/16	9/15/17

**5. Contact Information of Proposed Project Officer and Contracting Officer's
Technical Representative, if applicable:**

	Project Officer	COTR
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Effective Date: 06/01/2009

Name:		(b) (6)
Center:		CDER
Office:		OTR
Telephone:		(b) (6)

6. Notes / Special Requests transmitted to the Contracting Officer / Contract Specialist:

Suggest that this be set up as an IDIQ. Timing of need for tissues affected by a variety of factors that cannot be specified in advance.

7. List of Attachments, as Required:

	Statement of Work (SOW) / Performance Work Statement (PWS) / Requested Changes to the SOW / PWS
	Independent Government Cost Estimate (IGCE)
	iProcurement Requisition Document
	Clearance / Approval Checklist
	Technical Evaluation Criteria, if applicable
	Justification for Other Than Full and Open Competition (JOFOC), if applicable
	Limited Source Justification (LSJ) for GSA FSS Orders, if applicable
	Market Research / Suggested Source List
	Project Officer Certification or Equivalent, if applicable
	Contracting Officer's Technical Representative FAC-COTR Certification, if applicable
	Shipping Instructions
	Special Provisions and/or Instructions
	Other (specify):

Form Approved by: (b) (6) - OAGS

Last Updated: March 20, 2009

5.B. – Requisition Package Part II: Project Information

“Source Selection Information – see FAR 2.101 and 3.104”

1. Statement of Need

The Division of Drug Safety Research (DDSR) OTR/OPS/CDER is developing a research program to evaluate the usefulness of humanized mice (HM) for regulatory purposes. The HM are created by surgical implantation of human tissue into mice that have multiple genetic mutations that block the development of the mouse immune system at a very early stage. The absence of the mouse immune system allows the human tissues to grow and develop into functional human tissues. As part of this process DDSR needs to repeatedly acquire the proper type of tissues. In order for the humanization to proceed correctly we need to obtain fetal tissue with a specific set of specialized characteristics.

2. Statement of Work (SOW)/Performance Work Statement (PWS)

The supplier will provide human fetal tissue with the following characteristics:

- Age range 16-24 weeks
- Liver and thymus tissue from the same donor unless liver only is requested.
- Tissue must be fresh and never frozen.
- No tissues where the mother is known to be positive for HIV or for Hepatitis A, B, or C viruses.
- No known chromosomal abnormalities.

The supplier will be notified of the need for tissue by email or phone and will notify the investigator by email as to the availability of tissues. Tissue will be requested approximately two to three times per month.

3. Period of Performance/Basis

One year from the date of award of the contract plus four option years.

4. Sources

Advanced Bioscience Resources Inc
1516 Oak St, Suite 303
Alameda, CA 94501
Phone: 510-865-5872
Fax: 510-865-4090

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Contact: Ms. Perrin Larton CTBS
Procurement Manager
pvlarton@abr-inc.com

5. Competition

a. Justification for Other than Full and Open Competition (JOFOC) / Limited Source Justification (LSJ)

Scientists within FDA and in the larger field of humanized mouse research have searched extensively over the past several years and ABR is the only company in the U. S. capable of supplying tissues suitable for HM research. No other company or organization is capable of fulfilling the need.

b. Brand Name Justification (BNJ)

Not applicable.

6. Source Selection Procedures/Criteria

Company must be capable of supplying tissues with required characteristics.

7. Government Furnished Property (GFP)

Not applicable.

5.C. – Requisition Package Part III: SMG 2610.7 Clearance/Approval Checklist

- ☐ **1. Advisory and Assistance Services for Evaluation of Proposals.**
Not applicable.
- ☐ **2. Animal Welfare.**
Not applicable.
- ☐ **3. Contracts with Federal Employees.**
Not applicable.
- ☐ **4. Foreign Research Contracts.**
Not applicable.
- ☒ **5. Human Subjects.**

The application for IRB exemption is in process. A similar IRB exemption has been previously approved for tissue procurement from the same supplier to support a humanized mouse project in another part of the FDA. Tissues will not be ordered until approval has been received.

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- ☐ **6. Public Affairs Services.**
Not applicable.
- ☐ **7. EIT.**
Not applicable.
- ☐ **8. Other Clearance(s)/Approval(s).**
Not applicable.

5.D. – Requisition Package Part IV: Independent Government Cost Estimate

Costs are estimated at \$230 per tissue x two tissues per shipment = \$460 plus \$95 shipping = \$555 per shipment. A total of 21 shipments = \$11,655.00.

5.E. – Requisition Package Part V: Attachments

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