

# Hearing on the Pricing of Fetal Tissue

## *Annotated Index of Documents*

### **Issue**

Does the acquisition of fetal tissue by a middleman procurement business (PB) from abortion clinics (ACs) for resale to customers (C) violate the prohibition against profiting from the sale?

#### **I.     *Exhibit A – Rule of Law* *Tab A***

Title 42 USC §289 g-2(a) – Requires that no profit be made on acquisition or transfer of fetal tissue.

#### **II.    *Exhibit A-1 – Graphic of Statute: Profit and non Profit* *Tab A***

Show the simplicity of nonprofit and profit model.

#### **III.   *Exhibits B1- 6 -- Business Model of the Middleman Procurement Business* *Tab B***

The Documents in Exhibit B show the business model of the Procurement Business, its own marketing statements about the product it offers to Abortion Clinics, its marketing trajectory, and its growth since its inception. These document show that the PB constantly sought additional abortion clinics as a source of fetal tissue.

Exhibit B 1   *This is the business model the hearing will discuss*

Exhibit B 2 *This is the company Brochure used to market the PB to Abortion Clinics*

Exhibit B 3 *PB website promoting partnership agreements with Abortion Clinics.*

Exhibit B 4 *Chart showing growth of the PB in number of Abortion Clinics*

Exhibit B 5 *Chart showing growth of PB revenue*

Exhibit B 6 *This is the Contact between the PB and a national abortion organization to acquire an additional 400 clinics.*

**IV. Exhibit C1-14 The Turnkey Business Product the PB placed inside of Abortion Clinics Tab C**

The “C” documents show, in great detail, that all possible management guidance, tasks, and responsibilities are undertaken by the PB procurement tech employee and that that no tasks are performed by the abortion clinic. Thus, that costs of tissue acquisition are entirely born by entities other than the abortion clinic.

Exhibit C 1 *This is the daily work flow of the PB procurement tech procuring fetal tissue inside Abortion Clinics*

Exhibit C 2 *This is a list of the tasks performed by the PB procurement Tech inside the Abortion Clinics*

Exhibit C 3 *Web site screen grab of how to order any fetal tissue you want*

Exhibit C 4 *Website and phone orders sent to procurement tech via email inside abortion clinics*

Exhibit C 5 *Form the procurement tech uses to check gestation periods so that patients can be matched with orders.*

Exhibit C 6 *Work instructions on procurement given to the procurement tech by the PB for work performed inside the abortion clinic.*

Exhibit C 7 *Procurement Kit provided by the PB*

Exhibit C 8 *PB guidance on obtaining patient consent by procurement tech*

Exhibit C 9 *PB directs it tissue tech to tell the abortion clinic manager what is being procured that day.*

Exhibit C 10 *PB Guidance to the procurement tech on keeping track of tissues procured*

Exhibit C 11 *PB Guidance on procurement tech responsibility to obtain disease screening.*

Exhibit C 12 *PB Guidance to procurement tech regarding supplies for shipping to customers*

Exhibit C 13 *Supplies inventory that the PB provides for the procurement tech*

Exhibit C 14 *The compensation plan for the procurement tech*

Exhibit C 15 *Copy of the IRB document provided by the PB for the benefit of the customer*

Exhibit C 16 *Food and Drug Administration regulations on IRBs*

Exhibit C 17 *List of tasks performed by procurement tech*

V. **Exhibit D1-3 Payments from the PB to Abortion Clinics for Fetal Tissue**

Exhibits D 1-3 *These documents show the monthly payments from the PB to several abortion clinics*

**VI. Exhibit E 1-4 Payments from customers to the PB**

Exhibits E 1-4 *These document show payments from customers to the PB*

**VII. Exhibit F Payments from a customer to the PB**

Exhibit F *This document shows annual payments from a single customer to the PB*

**VIII. Exhibit G Reasonable Costs Associated with fetal tissue procurement**

Exhibit G *This graphic shows who bears the reasonable costs associated with fetal tissue procurement.*

**IX. Exhibit H Rep. Waxman quote**

Exhibit H *This graphic is a quote from Rep. Waxman during the floor debate over H.R. 4.*



## Exhibit A1

### Understanding 42 USC § 289g-2

To profit under Title 42 USC § 289g-2, the transfer of any fetal tissue for valuable consideration must exceed the reasonable costs associated with the procurement.

The statute reads in part:

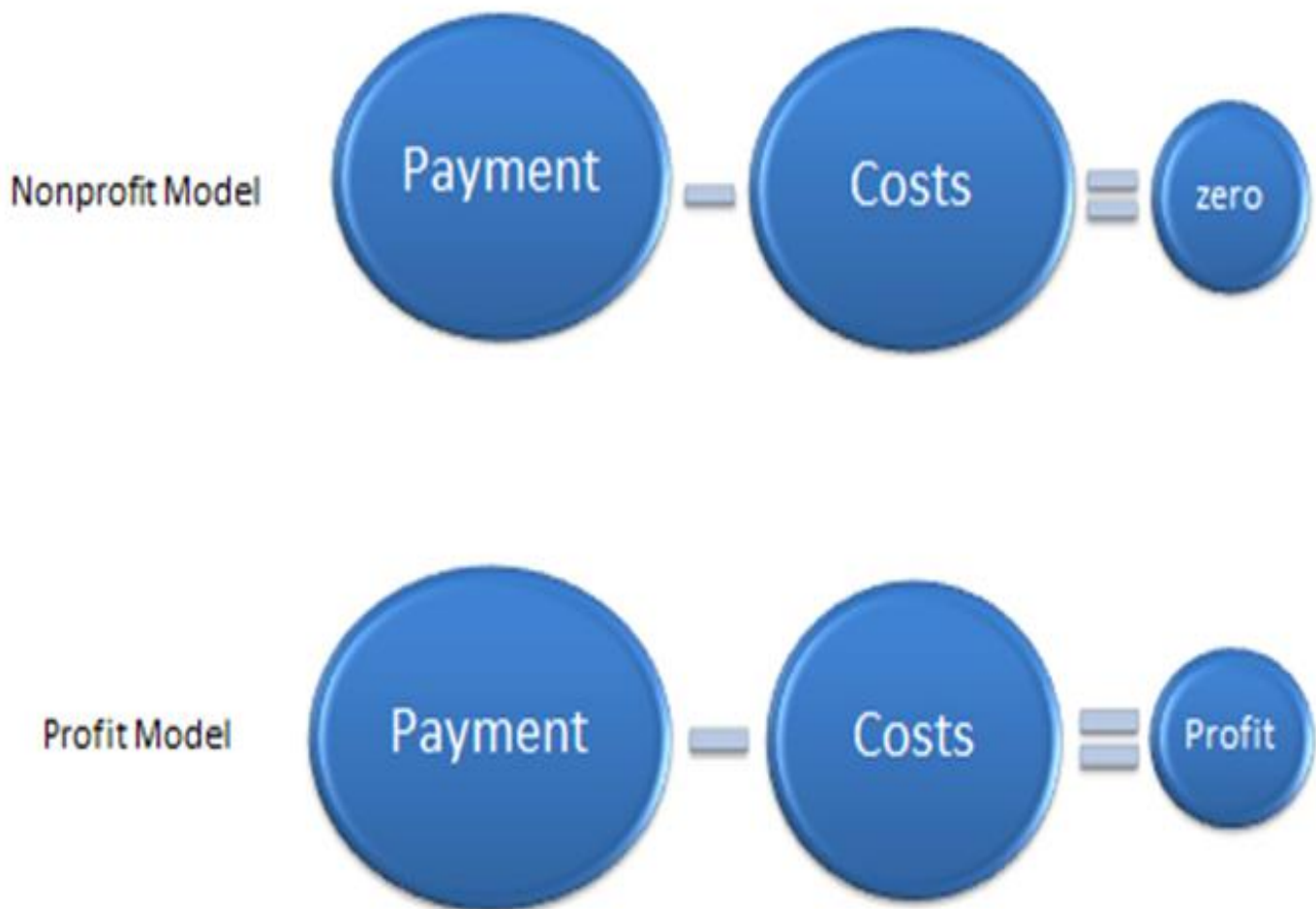
§ 289g-2(a): It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any fetal tissue for **valuable consideration** if the transfer affects interstate commerce.

§ 289g-2(e)(3): The term **“valuable consideration”** does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.

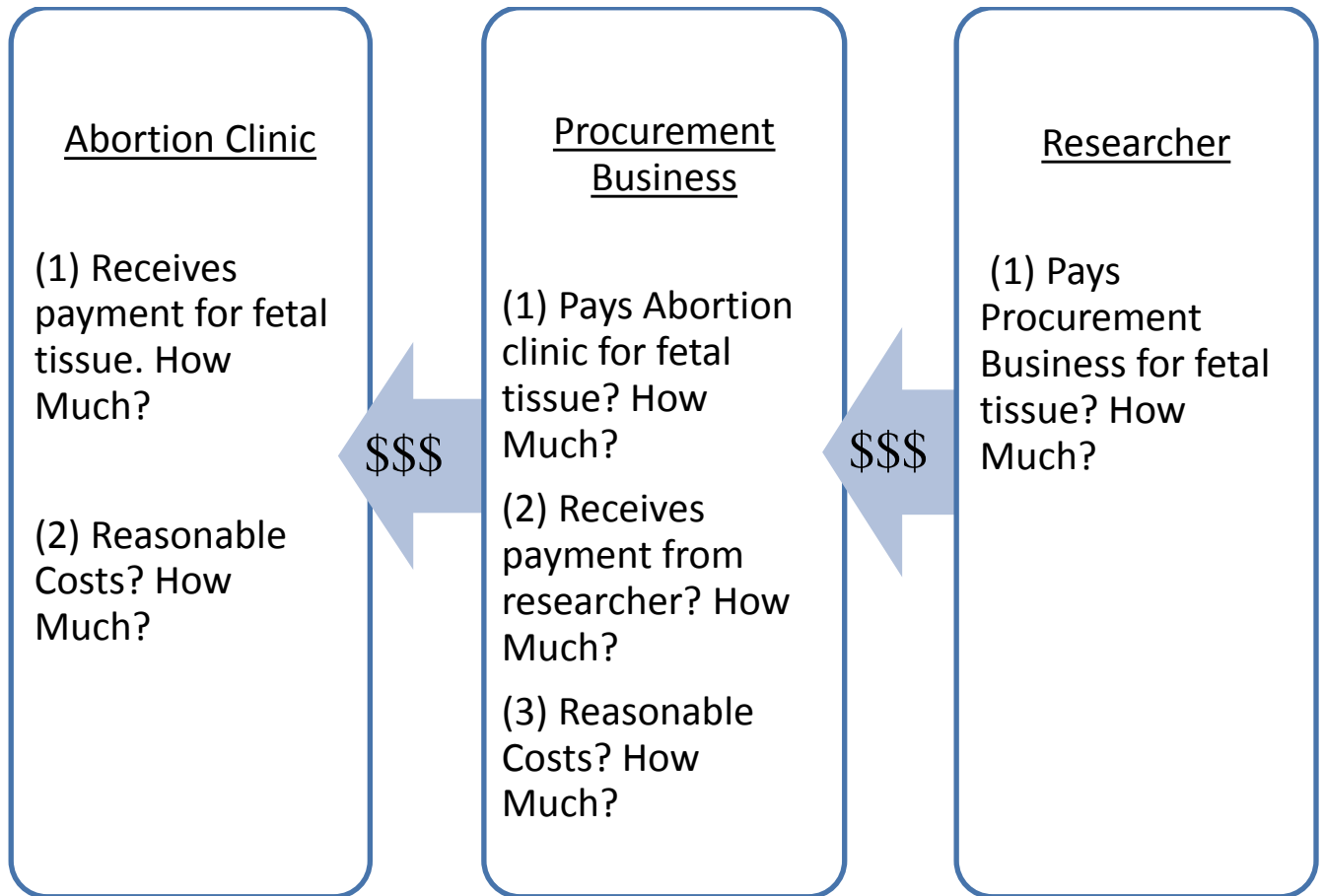
## Exhibit A2

Title 42 USC § 289g-2 requires that the transfer of fetal tissue not result in a profit.

### Two Models



## Exhibit B1



## Exhibit B2



**Your clinic can advance biomedical research.**

Financially Profitable • Easy to Implement Plug-in Solution • Medical Director Oversight • IRB Certified Consents

### Advancing BioMedical Research Together

Join the [REDACTED] partner program that fiscally rewards clinics for contributing to the advancement of life-saving research — with a solution that is easy to incorporate into your clinic practices. [REDACTED] is a California-based biomedical company that provides human tissue products ranging from fetal to adult tissues and healthy to diseased samples to many of the leading research institutions in the world. Our IRB approved protocols and consents protect you as well as donor's privacy in accordance with HIPAA guidelines.

### Partnering with Obstetrical-Care Clinics

Cell-free fetal DNA circulates in maternal blood throughout pregnancy. Noninvasive, stem cell free methods to obtain fetal DNA are being used for earlier detection of genetic diseases as well as reproductive decision-making. Research pioneers who develop noninvasive diagnostic technologies rely on the blood samples that are collected from hospitals and clinics throughout the United States.


### Easy to Implement Program + Financial Profits


[REDACTED] promotes global biomedical research while also providing a financial benefit to your clinic. By partnering with [REDACTED], not only are you offering a way for your clients to participate in the unique opportunity to facilitate life-saving research, but you will also be contributing to the fiscal growth of your own clinic. The stem cell rich blood and raw materials that are usually discarded during obstetrical procedures can, instead, be expedited through [REDACTED] to research laboratories with complete professionalism and source anonymity.







## Exhibit B3

Sign In Register My Account Create Wishlist Order  0 Items - \$0

Select Language 




Enter Product or Catalog Number 

home products & bioservices about 

become a provider get involved news contact

## Partnerships

### Easy to Implement Program + Financial Profits

 promotes global biomedical research while also providing a financial benefit to your clinic. By partnering with , not only are you offering a way for your clients to participate in the unique opportunity to facilitate life-saving research, but you will also be contributing to the fiscal growth of your own clinic. The stem cell rich blood and raw materials that are usually discarded during procedures can, instead, be expedited through  to research laboratories with complete professionalism and source anonymity.

### Your Clinic can Advance Biomedical Research



- Financially Profitable
- Easy to Implement Plug-in Solutions
- Medical Director Oversight
- IRB Certified Consents

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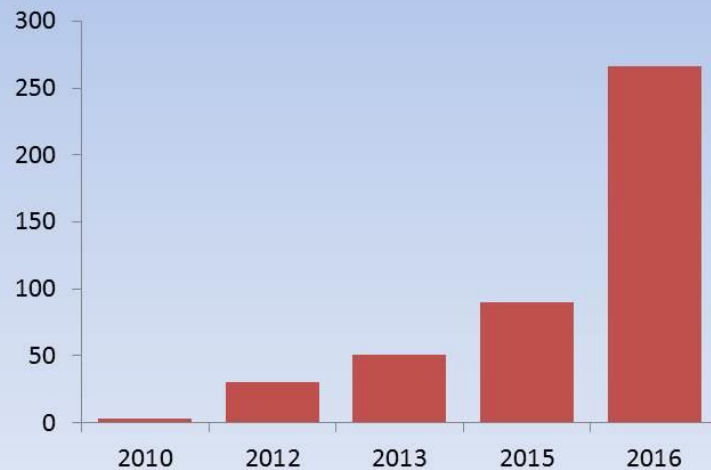
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Join the  partner program that fiscally rewards clinics for contributing to the advancement of life-saving research – with a solution that is easy to incorporate into your clinic practices.  is a California-based biomedical company that provides human tissue products ranging from fetal to adult tissues and healthy to diseased samples to many of the leading research institutions in the world. Our IRB approved protocols and consents protect you as well as donor's privacy in accordance with HIPAA guidelines.

**Exhibit B4**

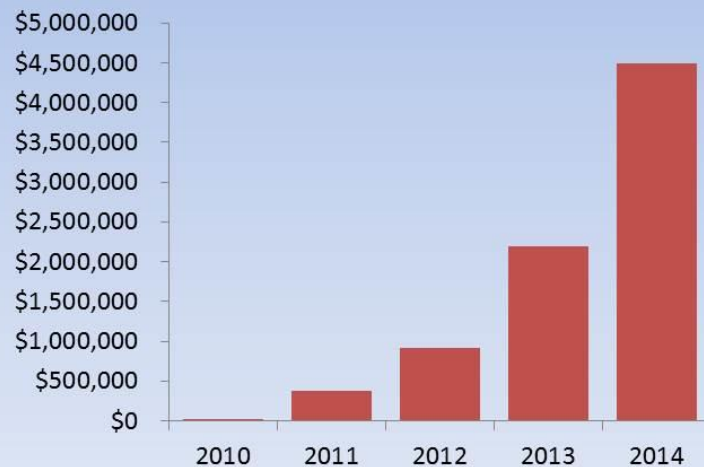
## **PROCUREMENT BUSINESS' CLINIC GROWTH STRATEGY**

Number of partnerships with abortion clinics



**Exhibit B5**

## **PROCUREMENT BUSINESS' REVENUE GROWTH**



## Exhibit B6

[Excerpt of a draft contract between the PB and the abortion trade association.]

### PARTNERSHIP AGREEMENT

This Partnership Agreement (this "Agreement") is entered into as of March 25, 2015 ("Effective Date"). between [PB] . . . and the [abortion trade association] . . .

[The PB] agrees to make a donation to the [abortion trade association] in the amount of US \$10,000 and undertake the activities listed in Appendix B . . .

#### [Abortion trade association's] Commitment

For the aforementioned sum mentioned in the section marked "Payment for Services," [the trade association] commits to performing the following for one year to assist [the PB] in presenting its collection program to [association] members:

- Create and disseminate to [association] members correspondence from [the association's] Group Purchasing Manager about [the PB] and the collection program twice yearly at the request of [the PB].
- Create a content section on [the association's] members-only website dedicated to [the PB], including a link to a [PB] email address for contacts and collection program information.
- Disseminate to [association] members the name and contact information of [the PB's] collection program representative who is available to answer questions about the [PB] collection program and participation on an ongoing basis.
- Provide a cover letter for [the association's] President and CEO pertaining to the [PB] collection program which [the PB] can use to accompany marketing materials for [association] members.
- Include a [PB] marketing brochure regarding [the PB's] collection program in each [association] membership welcome packet.
- Invite select [association] members to join [association] on a conference call paid for by the [PB] to discuss [the PB's] collection program and the benefits of member participation at least once a year.
- Provide mailing list for [PB] to send out marketing materials to [association] members regarding the background of [the PB], its collection program, and benefits of member participation in the program.
- Provide assistance to [the PB] in gathering testimonials from existing program participants from among [association] members.
- Provide one complimentary exhibit space at [association's] Annual Meeting in the spring for [the PB] with up to 3 complimentary exhibitor registrations and up to 4 invitations to the member luncheons. In addition, the opportunity to create a bag insert that will be given to every attendee at registration.
- Supply [the PB] with a quarterly updated list of members.

## Exhibit B6

### APPENDIX B

#### [PB's] Commitment

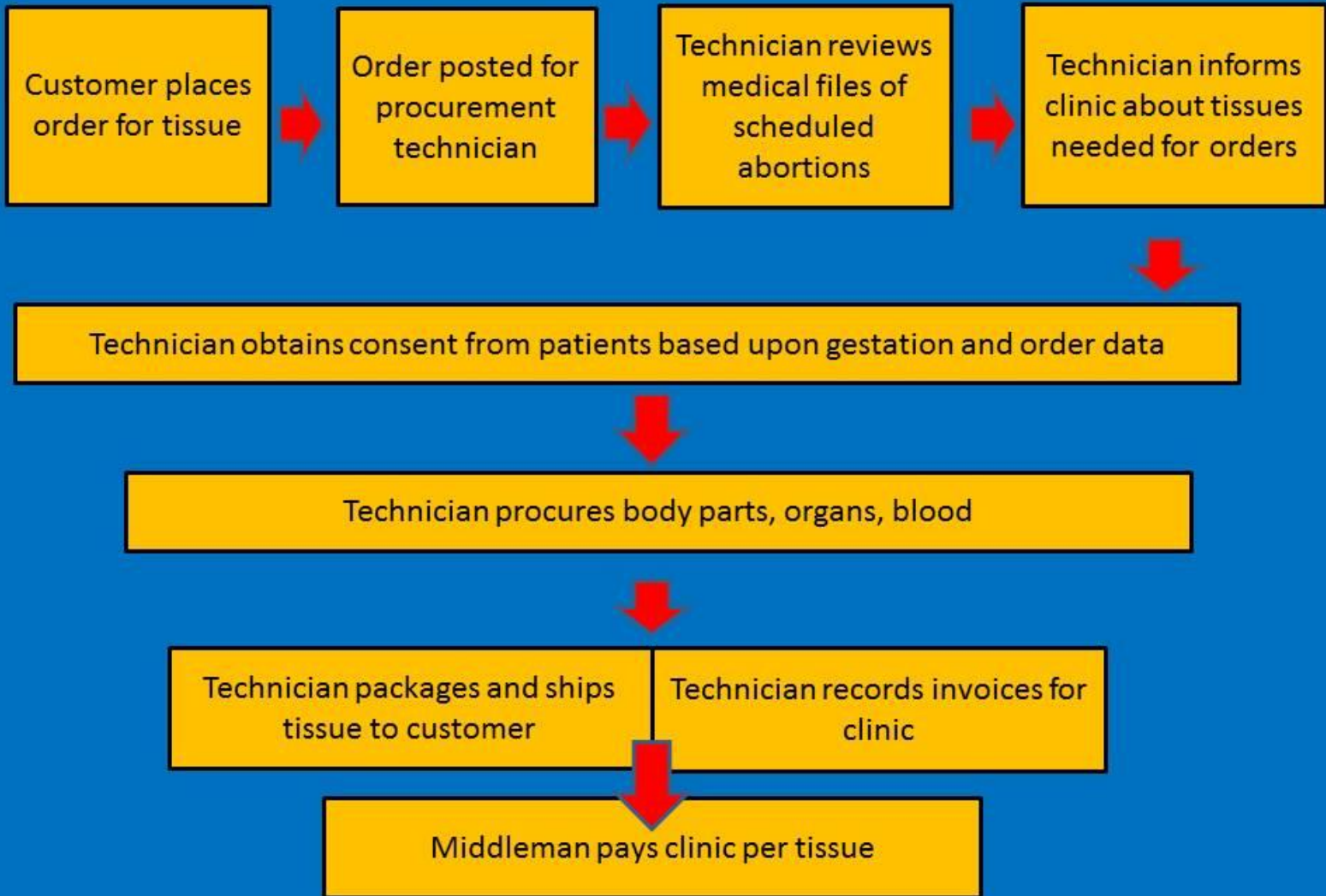
[The PB] commits to performing the following for one year to market its collection services to [association] members:

- Conduct a webinar for [association] members with a question and answer forum discussing member participation in the [PB] collection program at the launch and yearly thereafter.
- Create and produce a marketing brochure detailing [the PB's] collection service program. This brochure shall include [PB] contact information. [The PB] will supply a copy of the brochure to [the association] to include in their membership welcome packets.
- Create and produce marketing "slicks" on the background of [the PB], its capabilities, and highlight participation benefits.
- Provide, at no charge to [the association], informative sessions or meetings that present the collection program.
- Develop client success stories on how [the PB] brought a value added service to participating members. This will help to inform members about [the PB's] offerings.
- Commit to attending [the association's] Annual Meeting in April of each year.
- Pursue all leads from [the association], introducing [the PB] and what [the PB's] capabilities are.



Exhibit C1

# Middleman Turnkey Business Flow



## **Exhibit C2**

# **WORKFLOW OF THE PROCUREMENT BUSINESS**

- 1) Customer orders fetal tissue on-line. Exhibit C3.
- 2) Procurement business obtains Institutional Review Board approval. Exhibit C15.
- 3) Tissue technicians review the current researcher order list. Exhibit C4.
- 4) Tissue technicians discuss with the clinic the type of tissue being sought. Exhibit C9.
- 5) Review the schedule of abortions to match orders to gestational information and patient information. Exhibits C5, C7.
- 6) Tissue technicians obtain consent from women awaiting their procedure. Exhibit C8.
- 7) Procure blood and perform any tests on patients. Exhibits C6, C7, C10, C11.
- 8) Procurement business provides materials to tissue technicians. Exhibit C13.
- 9) Tissue technicians package and ship tissue to researcher using portable packaging materials. Exhibit C12.
- 10) Tissue technicians compensated per-tissue sample obtained. Exhibit C14.

## Exhibit C3

File Edit View History Bookmarks Dev

https://[redacted]products/tissue-order

Theme Options Template Builder

What type of tissue would you like to order? \*

Number of Specimens \*

Gestational Range Start \*

Gestational Range End \*

Add another tissue type?

Shipping Options \*

Transport Method \*

Media \*

Additional Notes

--- Organs and Tissues ---

- Brain
- Heart
- Heart (Veins & Arteries Attached)
- Lungs
- Liver
- Liver and Thymus
- Thymus
- Thyroid w/parathyroid
- Spleen
- Large Intestine
- Small Intestine
- Gallbladder
- Pancreas
- Bladder
- Testis
- Female Reproductive System and Ovaries
- Kidneys
- Esophagus
- Stomach
- Rectum/Anus
- Ureter/Urethra Skin
- Appendix
- Spinal Cord
- Eyes
- Ears
- Nose
- Diaphragm
- Tongue
- Aorta
- Umbilical Cord
- Placenta
- Chorionic villi
- Bone Marrow
- Lymph nodes
- Sternum
- Meninges
- Costal cartilage
- Scalp
- Adipose tissue
- Adrenal glands
- Blood ---
- Whole Blood
- Diseased Blood
- Fetal Blood & Fluids ---
- Maternal

Adv... Tissue Order Form | [redacted] Howdy, dr

Delivered \*Available in select locations only

your location roughly around 8 a.m. the day after

location roughly around 10:30 a.m. the day after

-by-case basis

## Exhibit C4

From: [REDACTED]  
Subject: Updated Task Assignment: Procurement Schedule Wednesday 3/20/13  
Date: March 20, 2013 at 9:00 AM  
To: [REDACTED]

---

The following task has been updated on the [REDACTED] web office site.

TASK NAME: Procurement Schedule Wednesday 3/20/13

ASSIGNED BY: [REDACTED]

PROJECT: Procurement Schedule

CATEGORY: Procurement Schedule

PRIORITY: 2-Normal

STATUS: 1-Not Started

ASSIGNED TO: [REDACTED]

VISIBLE TO: Everyone

### DETAILS:

Liver & Thymus (same donor)/16-20wks/RPMI/Wet Ice/HIV,HBSAG,HCV,CMV/FedEx  
Priority Overnight/Mass General Hospital ([REDACTED])

1 SPEC=

\*IMPORTANT: Please document PO#0005446200 in the reference section\*

Liver & Thymus (Same donor)/16-20wks/RPMI /Wet Ice/ HIV,HBSAG,HCV/FedEx Priority  
Overnight/UMASS ([REDACTED])

1 SPEC=

\*IMPORTANT: Please document PO#0006147108 in the reference section.\*

Liver/18-22wks/RPMI/Wet Ice/FedEx Priority Overnight/ UCLA ([REDACTED])

\*IMPORTANT: Please document PO#1559NQA55800 in the reference section.\*

2 SPEC=

\*\*This used to be researcher- UCLA: [REDACTED]\*\*

Liver, Thymus & Skin (Same donor)/16-20wks/RPMI /Wet Ice/ HIV,HBSAG,HCV/FedEx  
Priority Overnight/HARVARD ([REDACTED])

1 SPEC=

\*\*IMPORTANT: Use FedEx account #431793989. Note: THE LIVER AND THYMUS SHIP  
TO [REDACTED] AT UMASS AND THE SKIN SHIPS TO [REDACTED] AT HARVARD. SHIP  
ALL TISSUE UNDER HARVARD'S FEDEX NUMBER.\*\*

\*\*[REDACTED] Research Specialist Melton Group, HHMI/Harvard Dept  
of Stem Cell and Regenerative Biology, 7 Divinity Avenue-Fairchild 360, Cambridge,  
MA 02138, email-[REDACTED] Phone: [REDACTED]

\*\*PROCURE ON WEDNESDAY ONLY\*\*- Pancreas/14wks/HEPES with antibiotic/Gel Pack/HIV,  
HBSAG, HCV/FedEx Priority Overnight/UMASS ([REDACTED])

2 SPEC=

\*IMPORTANT: Use gel packs that are NOT frozen but just chilled.\*

\*IMPORTANT: Please document PO#0006147108 in the reference section.\*

Brain /16-18wks/Complete but can be in piecest/Use Client Supplied Media/Wet  
Ice/HIV,HBSAG,HCV/Use Clients FedEx Priority Overnight/Temple Univ ([REDACTED])

1 SPEC=

\*\*Note: Media contains anti-fungal/anti-mycotic and antibiotics\*\*

Researcher: [REDACTED]

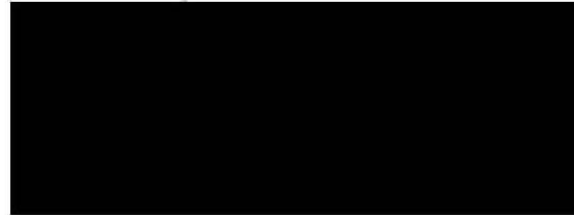
Mid Brain/10+wks/RPMI/Wet Ice//HIV, HBSAG/FedEx Priority Overnight/University  
of Illinois at Chicago (Qu-Yang)

1 SPEC=

Researcher: [REDACTED] or [REDACTED]

Brain/14+wks /2cm in width\Whole brain In-tact or one whole Hemis intact/Drw

## Exhibit C5






### Gestation Tracking Log


Name	Date			Location		
Number of Appointments Scheduled	<11.6wks	12-13.6wks	14-15.6wks	16-17.6wks	18-19.6wks	Total
Number of Appointments Kept	<11.6wks	12-13.6wks	14-15.6wks	16-17.6wks	18-19.6wks	Total
Number of Consents Signed	Blood			Tissue		
Number of Consent with Non Procurable Tissues – No Identifiable Organs*						
Number of Consents with Procurable Tissues but no Researcher*						

\* High request organs such as Liver, Thymus, Pancreas, Heart



## Exhibit C6

	<b>Work Instruction</b>	Page 5 of 7
	 <b>Procurement Kit 1</b>	VERSION #: 1.0
Document Control Number 		Effective Date: 12 May 2015

### **Maternal Blood Collection**

There are 3 tubes in the  Procurement Kit 1: two 10ml EDTA and one 5ml Z serum sep. clot activator blood collection tube. All 3 tubes must be filled with maternal blood.

After the liver has been procured, use the items in the venipuncture collection kit, which will be either a leu-lok to collect from an existing IV or a needle and hub to collect the blood sample.

- Follow the clinic protocol for sterile blood collection.
  - Fill the red 5ml Z serum sep. clot activator blood collection tube first and follow with the two 10ml EDTA tubes
  - Once the blood is procured, all 3 tubes can go into the second biohazard bag.
  - Seal the biohazard bag.
- If a failed blood draw occurs,  can accept the liver tissue with a minimum of 2ml of maternal blood collected into the 5ml Z serum sep. clot activator blood collection tube. If the clinic is unable to procure any maternal blood for the tissue sample,  is unable to accept the tissue.

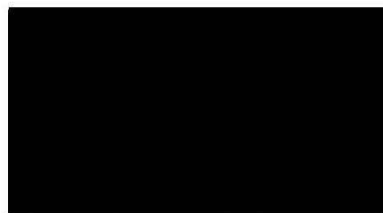
### **Filling out the Procurement Form**

The sections of the Procurement Form that need to be filled out by the clinic are highlighted. The clinic is responsible for providing the following information:

- Date- date of procurement
- Time- time of procurement in military time
- Gest- gestation in weeks and days. For example: *18.3wks*
- Sex- sex of the fetus. *F* for female, *M* for male or *Unk* for unknown
- Donor age- age of the patient who consented to donate tissue and blood
- Height- in feet and inches. For example *5'3"*
- Weight- in pounds. For example *145 lbs*
- Ethnicity- ethnicity of the patient
- Smoker?- answer *yes* or *no*

## Exhibit C7

<div style="background-color: black; width: 100%; height: 100%;"></div>	<h1>Work Instruction</h1> <h2>Procurement Kit 1</h2>	Page 6 of 7
		VERSION #: 1.0
Document Control Number <div style="background-color: black; width: 150px; height: 1.2em; display: inline-block;"></div>		Effective Date: 12 May 2015



## Researcher Procurement Form

DATE

5/1/15

## Delivery Instructions:

☐ Billed/Recipient☐ Billed/

## Ship To:

Name

Email:

C/O

Email 2:

Address

Email 3:

Address 2

Phone #

City

Cell Phone

Country

Alt. Phone #

FedEx Account

Tracking #

Ref#

Local Delivery: ☐ AM ☐ PM

Deliver By

Procurement Tech

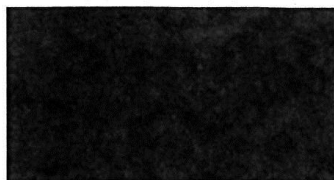
Additional Techs

Location CFP-70

ID#	TIME	PATIENT#	SPEC#	GEST	SPECIMEN	SEX	COMMENTS
	14:00		6306	18.3wks	Liver	M	Donor age: 23 Height: 5'3" Weight: 145lbs Ethnicity: Hispanic Smoker? No
	14:15		31187B		Maternal Blood	F	2EDTA, 1 Z Serum Sep



## Exhibit C8



### Consenting Patients

It's important to connect with the patient, be compassionate as well as offering them an opportunity to make a difference in our future.

#### Blood and Tissue

I work with a company that assists researchers in finding cures for many debilitating diseases like cancer, diabetes and many other. The law in the state of California requires that the tissue from your procedure be incinerated. Would you be willing to give your consent to donate blood and the tissue from your procedure to research? Participation is completely anonymous.

#### Blood Only

I work with a company that assists researchers in finding cures for many debilitating diseases like cancer, diabetes and many other. Would you be willing to give your consent to donate a blood sample to research? Participation is completely anonymous.



## Exhibit C8

### INFORMED CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

**Study Title:** Tissue Procurement for Non-therapeutic Research

**Sponsor:** [REDACTED]

**Protocol Number:** 101-01

**Protocol Date:** January 24, 2011

**Principal Investigator:** [REDACTED]

**24-Hour Phone Number:** [REDACTED]

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Client Information for Informed Consent  
**DONATION OF ABORTED PREGNANCY TISSUE FOR MEDICAL RESEARCH,  
EDUCATION, OR TREATMENT**

Research using donated tissue and blood is currently underway to uncover the causes of and ultimately find cures for things like: Heart Disease, Diabetes, Parkinson's Disease, Sickle Cell Anemia, Leukemia, Lymphoma, Cancer, Spinal Cord Disease, and many more. Tissue can be obtained as a result of donation of pregnancy tissue after an abortion. Before you give your consent to donate pregnancy tissue and/or a blood sample, read each of the following statements. If there is any statement you do not understand, or if you have any questions, someone will discuss them with you. Your participation is entirely voluntary.

Before this consent was ever offered to me, I had previously decided to have an abortion and signed an informed consent document.

I agree to donate the tissue from the abortion and/or miscarriage, and a blood sample if needed, as a bodily gift to be used for the advancement of medical science. 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. The benefits of consenting to donation today include furthering medical research in finding cures for diseases like diabetes, leukemia, lymphoma, Parkinson's disease and more. The risks to this donation are minimal in that your abortion procedure will not change in any way; your health information will be protected at all times; and most blood donors have only minor discomfort from the needle stick, although some people may have a light-headed feeling, an upset stomach, bruising, or pain where the needle stick was. The alternative to this donation is to refuse consent.

**Protocol Number:** 101-01

**Subject Initials** \_\_\_\_\_

*BioMed IRB Approved*

**Consent Date:** March 19, 2013

Page 1 of 4

## Exhibit C8

I understand the donation is made without any restriction regarding who might receive the donated tissue or for what research purpose it might be used. I have not been informed of the identity of any individual who will receive the tissue that I am donating, and I understand that cells derived from the donation may be stored for years.

If you choose to participate, you will have your blood drawn by a trained phlebotomist or nurse. The amount is small, usually 10-60ml which is about 1-3 tablespoons. You will have no responsibilities once you leave the clinic.

In accordance with federal laws (HIPAA), your personal identifying information will be protected and not connected with your donation once the procedure is completed. Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, your age, ethnicity, medical history, and number of previous pregnancies or abortions. All of this information will NOT be connected to your name or any other personal identifier.

Protocol Number: 101-01

Consent Date: March 19, 2013

*BioMed IRB Approved*

Subject Initials \_\_\_\_\_

Page 2 of 4

## Exhibit C8

### CONSENT

You have the right to withdraw your donation at any time while in the clinic. Since your donation is completely ANONYMOUS, you cannot withdraw your donation once you leave the clinic as it will no longer be possible to know which donation was yours.

I understand there will be no payment to me for the donated tissue or for any product, process or service that may result from this donation.

I understand the method, timing or procedure of abortion cannot and will not be substantively altered for the purpose of obtaining the tissue. I understand that I may refuse to donate pregnancy tissue, and this will not affect my current medical care or my ability to get any future medical services at this clinic.

I understand that, if I have any questions about my donation, I can contact [REDACTED]

By signing below, I agree to donate tissue and/or blood as described above.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Witness: \_\_\_\_\_ Date: \_\_\_\_\_

Protocol Number: 101-01

Consent Date: March 19, 2013

*BioMed IRB Approved*

Subject Initials \_\_\_\_\_

## Exhibit C9

# Clinic Procedures and Policies

As a representative of [REDACTED] you are required to act in a professional manner and follow all clinic policies. Please take note the following procedures and policies are **extremely important** regarding our presence in the clinics:

1. **Communication with the Assistant Manager and HSS's** – Upon arrival, inform the staff clearly what you are procuring for the day. Just as important, you must inform the Assistant Manager and HSS's when you have completed your work. This will insure they do not continue to consent and draw unnecessary blood samples. In addition, please **notify the Assistant Manager upon departure** of the clinic and remember to thank them for their assistance.
2. **Cell Phone Use** – It is essential we follow clinic rules with respect to cell phone use. **Please DO NOT pull your cell phones out in the hallways for ANY reason.** While we realize our cell phones are critical to our internal communication, we need to follow the etiquette set by the clinic. If you receive a text or call, step to an appropriate private area or into the nearest unoccupied room to read the text or answer your phone. Phones should always be on vibrate while in the clinics.
3. **Perfume Free Policy** – All clinics have a Perfume Free Policy, Please refrain from applying perfume or any fragrance prior to or when you are in the clinic.
4. **General Clinic Etiquette:**
  - ◆ Calm demeanor
  - ◆ Sensitive to Patients' Privacy and Situation
  - ◆ Professional at all Times
  - ◆ Respectful to Patients and Clinic Staff
  - ◆ Maintain Confidentiality for Patient Information





## Exhibit C10



# Daily ID Numbering System

The Daily ID Numbering System allows us to track the number of bloods draws or tissue collections from a clinic. This is [REDACTED] Internal Tracking System, therefore it's important to number them properly and sequentially.

### Blood Collection –

- ID Numbering for Blood Collections are always identified with a B on the end of the sequential number, i.e. 01B, 02B, 03B, etc.
- Start at 01B each day and sequentially number additional blood collections throughout the day, i.e. 01B, 02B, 03B, etc.
- IMPORTANT NOTE: We collect blood for multiple researchers. The ID# relates to the number of blood collections at the clinic NOT the researcher. For instance, let's say you draw the first 5 bloods for one researcher and then start getting bloods for another researcher, the first 5 bloods are 01B to 05B, then you would start numbering the second researcher at 06B. You would NOT start from 01B again. In addition, if you were alternating draws for different researchers, one may have 01B and 03B, and the other would be 02B and 04B.

## **Exhibit C11**



### **Tissue Collection and Infectious Disease Screening (HIV, HBSAG, HCV, etc.) –**

#### **Tissue Collection:**

- ID Numbering for Tissue Collections are identified as a sequential number, i.e. 01, 02, 03, etc. This relates to each case. For instance, if you procure multiple organs from a single case, they would all be identified as the same POC number.
- Start at 01 each day and sequentially number additional tissue collections throughout the day, i.e. 01, 02, 03, etc. Number only the cases you collect tissue.

#### **Infectious Disease Screening (HIV, HBSAG, HCV, etc.):**

- ID Numbering for Infectious Disease Screening are identified as the same ID # in conjunction with the tissue it relates to. For instance, if you procure a tissue sample identified as ID #01 and the researcher requests Infectious Disease Screening on this patient, the blood test is the same ID #.
- **IMPORTANT:** Infectious Disease Screening relates to tissue collection only, therefore they are NOT identified with a B at the end of the ID number.

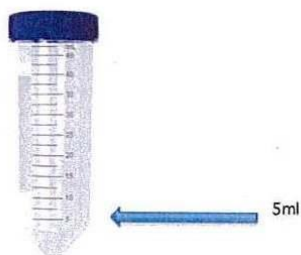
## Exhibit C12

	<b>Work Instruction</b> [REDACTED] Procurement Kit 1	Page 4 of 7
		VERSION #: 1.0
Document Control Number [REDACTED]	Effective Date: 12 May 2015	

### Packaging Tissue

After the liver is identified and separated from other tissue, place it in the 50ml conical tube provided in the kit.

- Separate the liver from the other fetal tissue. It can be in pieces or damaged but the combined volume must equal more than 5ml. The 5ml mark is clearly identifiable and visible on the conical tube.



- Remove and dispose of the parafilm from around the opening of the 50ml conical tube with the RPMI media.
- Place the liver tissue into the conical tube with the RPMI media and screw the top on tightly.
- Wrap the conical tube with parafilm to prevent any leakage.
  - Remove the paper backing from the parafilm.
  - Hold the parafilm down against the lid and with the other hand stretch the parafilm.
  - Stretch the parafilm around the lid of the conical tube in a clockwise direction.
  - Push the end of the parafilm into the conical tube to create a seal.
- Place the conical tube into a biohazard bag and seal the bag.

	<b>Work Instruction</b> [REDACTED] Procurement Kit 1	Page 7 of 7
		VERSION #: 1.0
Document Control Number [REDACTED]	Effective Date: 12 May 2015	

### Assembling the kit for shipment

The items of the kit should be reassembled in the same placement as they were when the kit was received.

- Place the specimens inside of the plastic bag liner
  - One sealed biohazard bag with the 50ml conical tube (containing RPMI and the liver specimen)
  - One sealed biohazard bag with 3 tubes of maternal blood (two 10ml EDTA and one 5ml Z serum sep. clot activator blood collection tube)
  - 2 chilled gel packs
- Seal the plastic bag liner by tying it in a knot
- Place the tied plastic bag inside of the Styrofoam box
- Place the Styrofoam lid on the Styrofoam box
- Adhere a biohazard sticker on opposite sides of the Styrofoam box so they seal the top of the box to the bottom.
- Place Styrofoam box inside the cardboard box
- Place completed Procurement Form on top of the Styrofoam box
- Tape the cardboard box shut
- Adhere the FedEx shipping label to the top of the cardboard box

Once the package is ready for shipment call FedEx (1 800 GoFedEx or 1 800 463 3339) to schedule a pick up or drop the package off at the nearest FedEx location by 16:30 on the day of procurement.



## Exhibit C13

Supply Inventory- North Clinic: by Supply Inventory

### Supply Inventory- North Clinic: by Supply Inventory (44 items)

Product	Volume Shipped	Quantity on Hand	Activity Type	Date Modified	Activity Notes	Modified By
<b>Blood Tube (4 items)</b>						
5ml Red Top Vacuettes for Marshall	50 per Flat	45	Supplies Received	Friday, January 11, 2013 2:40 PM PST	Received	
ACD-A Tubes	100 per flat	100	Supplies Received	Friday, January 11, 2013 2:40 PM PST	ACD tubes received	
EDTA Tubes	100 per flat	0	Supplies Received	Friday, January 11, 2013 2:41 PM PST	EDTA tubes received	
Streck Tubes	100 per flat	39	Supplies Shipped	Wednesday, January 23, 2013 10:40 AM PST	sent 1 flat	
<b>Phlebotomy Misc. (14 items)</b>						
20 Gauge Needles	Box of 100	200	Supplies Received	Friday, January 11, 2013 2:42 PM PST	Needles received	
21 Gauge Needles	Box of 100	100	Supplies Received	Friday, January 11, 2013 2:43 PM PST	Needles received	
Alcohol Prep Pads	1 box	30	Supplies Received	Friday, January 18, 2013 8:22 AM PST	1 box received	
Band Aids	Box of 25	75	Supplies Received	Friday, January 11, 2013 2:43 PM PST	Band-aids received	
Bio Hazard Labels Rolls	Roll of 50	80	Supplies Received	Friday, January 11, 2013 2:47 PM PST	Supplies received	
Bio Hazard Ziploc Bags	Bag of 25	60 bags	Supplies Shipped	Monday, January 21, 2013 2:07 PM PST	sent 1 bag	
Blood Tube Packing Sleeves	Shipped as requested	22	Supplies Received	Friday, January 11, 2013 2:48 PM PST	Bags received	
Cotton Balls	Bag of 100	100	Supplies Shipped	Monday, October 01, 2012 11:13 AM PST	Sent 1 ziploc bag of cotton balls	
Gel Ice Packs	Shipped as requested	9	Supplies Shipped	Tuesday, May 22, 2012 3:06 PM PST	sent via courier	
Needle Hubs w/ Safeties	Bag of 50	100	Supplies Received	Friday, January 18, 2013 8:22 AM PST	Received	
Labels (Blood)	Roll of 200	120 labels	Supplies Shipped	Tuesday, April 24, 2012 9:58 AM PST	shipped via courier	
Surgical Tape(Micropore)	1 roll	2 roll	Supplies Shipped	Monday, January 21, 2013 2:07 PM PST	sent 1 roll	



## Exhibit C13

Supply Inventory- North Clinic: by Supply Inventory

Product	Volume Shipped	Quantity on Hand	Activity Type	Date Modified	Activity Notes	Modified By
Tourniquet	Shipped as requested	5				
Ziploc Bags (Regular)	Box of 54	50	Supplies Shipped	Tuesday, October 16, 2012 12:18 PM PST	sent 1 box ziploc	
<b>Shipping (11 items)</b>						
Box Liners	Roll of 100	180	Supplies Shipped	Tuesday, April 24, 2012 9:59 AM PST	shipped via courier	
Bubble Wrap	Small roll	7 pouches	Supplies Requested	Thursday, January 24, 2013 9:22 AM PST	1 roll please	
Cardboard Only (Large)	Shipped as requested	8	Supplies Requested	Thursday, January 24, 2013 9:21 AM PST	3 please	
Cardboard Only (Small)	Shipped as requested	6	Supplies Requested	Thursday, January 24, 2013 9:21 AM PST	4 please	
FedEx Pouches	Bag of 25	18	Supplies Shipped	Tuesday, June 05, 2012 2:31 PM PST	shipped via courier	
Shipping Kit (Large)	Shipped as requested	0	Supplies Shipped	Tuesday, October 25, 2011 11:58 AM PST	10 large shipping kits sent via courier on 10/20/11	
Shipping Kit (Small)	Shipped as requested	0	Supplies Shipped	Tuesday, October 25, 2011 11:58 AM PST	10 small boxes sent via courier on 10/20/11.	
Shipping Labels	Roll of 100	0	Supplies Shipped	Wednesday, February 15, 2012 12:09 PM PST	Supplies shipped via courier 2-15-12	
Shipping Tape	0	0.5	Supplies Requested	Thursday, January 24, 2013 9:19 AM PST	1 roll please	
Styrofoam Only (Large)	Shipped as requested	9	Supplies Requested	Thursday, January 24, 2013 9:20 AM PST	3 large styrofoams please	
Styrofoam Only (Small)	Shipped as requested	6	Supplies Requested	Thursday, January 24, 2013 9:20 AM PST	4 small styrofoams	
<b>Special Projects - Researcher Provided Supplies (5 items)</b>						
Ariosa Collection Kits	10	1				
Ariosa Preprinted Labels	20	10	Supplies Received	Friday, September 14, 2012 9:37 PM PST	1 set of 20 Ariosa pre-printed labels.	
Ariosa Shipping Kits	10	2				
Natera Collection Kits	10 kits	5 Kits	Supplies Received	Thursday, August 09, 2012 9:20 AM PST	39 Natera kits	
Sequenom Labels	Bag of 100	50	Supplies Received	Friday, January 18, 2013 8:27 AM PST	Labels received	
<b>Tissue Procurement (10 items)</b>						

## Exhibit C14



# Procurement Technician Compensation Policy for Tissue and Blood Procurement Effective 01/01/2013

### Procurement Fees

- Procurement Technicians are compensated at a rate of \$10.00 per hour plus a per tissue or blood bonus as outlined in the table below:

Tissue Bonus Structure			
# Specimens	Category A*	Category B*	Category C
1-10 Specimens	\$35/Tissue	\$15/Tissue	\$10/Blood
11-20 Specimens	\$45/Tissue	\$20/Tissue	\$15/Blood
21-30 Specimens	\$55/Tissue	\$25/Tissue	\$20/Blood
31-40 Specimens	\$65/Tissue	\$30/Tissue	\$25/Blood
41-50 Specimens	\$75/Tissue	\$35/Tissue	\$30/Blood

\*Blood Samples may be obtained with these specimens in which case Category C bonus does not apply.

Please refer to the Procurement Specimens by Category dated 01/01/2013 for a detailed listing of Tissues.

### Two or More Procurement Technicians working in Unison

- Procurement Technicians often work in unison so procurements are split equally between the technicians.

For example, if two technicians are working together at the same clinic, and two maternal bloods are procured, each technician would receive \$5 for the Blood Procurement.

## Exhibit C14



# Procurable Specimens by Category Effective 01/01/2013

### Category A\*

Brain  
Heart  
Lungs  
Liver  
Thymus  
Thyroid w/parathyroid  
Liver  
Spleen  
Large Intestine  
Small Intestine  
Gallbladder  
Pancreas  
Bladder  
Testis  
Ovaries  
Esophagus  
Stomach  
Rectum/Anus  
Ureter/Urethra  
Appendix  
Spinal Cord  
Spinal Column  
Eyes  
Diaphragm  
Lymph nodes  
Sternum  
Adipose tissue  
Lymph nodes  
All Muscle tissue  
All Bone structures

### Category B\*

Kidneys  
Adrenal glands  
Ear  
Decidua  
Chorionic Villi  
Umbilical Cord  
Placenta  
Amniotic Fluid  
Large Intestine  
Small Intestine  
Skin  
Nose  
Tongue  
Scalp

### Category C

Maternal Blood  
Post Surgery Blood  
Umbilical Cord Blood  
Trisomy Blood

\*Note: Blood Samples may be obtained with these specimens in which case Category C bonus does not apply



## Exhibit C15



**IRB Meeting Date:** February 3, 2015

**Expiration Date:** February 5, 2016

### BIOMED IRB CONTINUAL APPROVAL NOTIFICATION

**Study Title:** Tissue Procurement for Non-therapeutic Research

**Sponsor:**

**Protocol Number:** 101-01

**Protocol Dates:** January 24, 2011  
Amendment # 1 dated January 24, 2011

**Principal Investigator:**  
**Approved Facilities:**

BioMed IRB has approved the above referenced study as having satisfied the criteria for continuing research at the February 3, 2015 meeting. This approval is effective from February 5, 2015.

The IRB committee has determined that the risk assessment for this study is Minimal. The IRB has determined that continuing review of this study will occur annually.

Approximately thirty days before February 5, 2016, you will be required to complete a Continuing Review Report Form. Continual review is the responsibility of the Principal Investigator. If you do not receive this form, please contact the IRB office immediately. The Continual Review Report Form must be received by the due date to allow ample time for ongoing review before the study's expiration date.

IRB approval is granted conditional on your adherence to the following requirements:

- The information submitted to the IRB is true and correct.
- Research will be conducted in accordance with the approved protocol.
- All materials used to recruit study subjects must be pre-approved by the IRB.
- Additional safeguards will be followed when vulnerable subjects, such as children or minors, are participants in the study.

The investigator agrees to report the following information to the IRB:

- Serious Adverse Events occurring at your site should be reported within ten (10) calendar days from the date of discovery by the investigator.
- Serious Adverse Events (IND Safety Reports) occurring at other sites should be reported no later



## Exhibit C16

### TITLE 21--FOOD AND DRUGS CHAPTER I--FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBCHAPTER A--GENERAL PART 56 INSTITUTIONAL REVIEW BOARDS

Subpart D--Records and Reports  
Sec. 56.115 IRB records.

(a) An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

- (1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
  - (2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
  - (3) Records of continuing review activities.
  - (4) Copies of all correspondence between the IRB and the investigators.
  - (5) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.
  - (6) Written procedures for the IRB as required by 56.108 (a) and (b).
  - (7) Statements of significant new findings provided to subjects, as required by 50.25.
- (b) The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Food and Drug Administration at reasonable times and in a reasonable manner.
- (c) The Food and Drug Administration may refuse to consider a clinical investigation in support of an application for a research or marketing permit if the institution or the IRB that reviewed the investigation refuses to allow an inspection under this section.

## Exhibit C17

January 3, 2011

Protocol Number: [REDACTED]

Protocol Date: January 24, 2011

Study Title: Tissue Procurement for Non-therapeutic Research

Sponsor: [REDACTED]

Primary Investigator: [REDACTED]

---

### Standard Operating Procedure

#### 1. Purpose

This SOP covers Tissue Procurement for Non-therapeutic Research.

This protocol describes the set up, equipment and procedures for procuring cadaverous tissue to use in non-therapeutic research.

#### 2. Scope

This applies to all procurements for non-therapeutic research.

#### 3. Prerequisites

The day before surgery:

Check WebOffice for researcher requests;

Determine your location for the next day;

Call the clinic to verify how many surgeries are scheduled.

#### 4. Responsibilities

It is the procurement technician's responsibility to bring the general and medical supplies listed in this SOP to each clinic. The clinic staff will identify donors. It is the procurement technician's responsibility to retrieve the tissue and package it appropriately for the given researcher. It is also the procurement technician's responsibility to update WebOffice so everyone is aware what tissue has been obtained and for whom.

#### 5. Equipment

General supplies:

Current blank RPR (Researcher Procurement Record)

logs Pre-printed FedEx forms

## Exhibit C17

### General supplies:

Current blank RPR (Researcher Procurement Record) logs  
Pre-printed FedEx forms

### Medical supplies:

Scrubs  
RPMI  
Hepes Solution with antibiotic added  
Petri dishes  
Shipping boxes  
Personal instruments to procure  
Conical tubes  
Mini urine specimen cups  
Cold packs

### 6. Procedure

On the day of surgery, the following steps are taken to procure tissue from POC: Arrive at the clinic and change into scrubs.

Inform the consenting staff of which gestations to consent. Place chucks down.

Set up the light box, instruments, RPMI, Hepes, petri dishes and tubes or cups. Set up enough blood draw bags for the day.

Get out the sequential numbering labels.

Print a copy of the day's Procurement Schedule.

Follow along with the chart flow so you know what gestations to expect.

If required, initiate blood draw from clinic staff. We do NOT want a patient label on the blood tube. Give the clinic staff the blood bags and correct blood tubes for the given researcher. If these are blood samples to accompany the tissue sample, number them in order as soon as complete. See the SOP "Maternal Blood Samples for Infectious Disease Testing" for specific guidance on those blood samples.

Once a consenting donor has undergone surgery, procure the specimen(s) on the petri dish and light box.

With minimal manipulation after isolating the specimen(s), move the petri dish to the packaging room and carefully transfer the specimen(s) to the appropriate container (conical tube or mini urine specimen cup). Add the researchers media of choice and seal with parafilm.

Keep track of time, gestation, fetal foot size or sono report and date.

Package the specimens and blood tubing for shipment once all specimens have a number. Be sure to place them on ice or cold packs.

Note the specimen numbers on the RPR log. For delivery:

If the specimen is local courier, be sure to call the courier once you know you have obtained an appropriate specimen.

If the specimen is going by FedEx, be sure to know the local cut-off times for your closest FedEx office. Each FedEx location is listed under "contacts" in WebOffice. Always know which FedEx you will be dropping off at and consider traffic. Log on to [www.fedex.com](http://www.fedex.com) with your assigned log on and password. Print shipping label and affix to box.

All instruments must be sterilized once you are done for the day.

Clean the area(s) thoroughly and discard all unused POC in the appropriate receptacle. Gather your supplies to leave and change out of your scrubs.

## Exhibit C17

### 7. Cautions

#### Health and Safety Warnings

All blood and tissue should be handled with standard Biohazard care. Gloves and other personal protective equipment should be worn at all times when handling blood or tissue. Meticulous care should be taken while using sharp dissecting instruments. Immediately report any injury to [REDACTED]

#### Interferences

Care should be taken to preserve the longevity of the equipment. This includes dissecting tools, light boxes, packaging supplies and media. Gentle handling of specimens is essential to quality control. Do not move or manipulate the tissue any more than is absolutely necessary. Ensure proper printer functioning first thing in the day, and contact [REDACTED] immediately if there are printer problems.

If you have an excellent sample with no researcher listed on today's schedule, please contact [REDACTED] immediately, and they will work to call researchers who may be interested even though they are not currently scheduled.

### 8. References

Researcher Procurement Record  
MSDS for RPMI  
MSDS for Hepes  
MSDS for Antibiotic  
SOP "Blood Samples for Infectious Disease"  
HIPAA  
Biohazard  
Presentation

I agree to conduct this clinical study in accordance with the design and specific provisions of this protocol; deviations from the protocol are acceptable only with a mutually agreed upon protocol amendment with the IRB approval. I also agree to report all information or data in accordance with the protocol, and in particular I agree to report serious adverse experiences as defined in this protocol.

[REDACTED]

3/17/2011

\_\_\_\_\_  
Signature of Principal Investigator

\_\_\_\_\_  
Date

[REDACTED]

\_\_\_\_\_  
Printed Name of Principal  
Investigator



## Exhibit D1

9/5/12

Invoice Number: [REDACTED]

Please include the invoice number on all payments to [REDACTED]

For August 2012 sample collections.

Fresno (FL)

38 POCs x \$55.00 = \$2090.00 ✓

49 Bloods x \$10.00 = \$490.00 ✓

Sacramento, "B" Street (BC)

68 POCs x \$55.00 = \$3740.00 ✓

80 Blood x \$10.00 = \$800.00 ✓

Fruitridge (FR)

0 POCs x \$55.00 = 0

0 Bloods x \$10.00 = 0

San Jose (SJ)

65 POCs x \$55.00 = \$3575.00 ✓

63 Bloods x \$10.00 = \$630.00 ✓

Mountain View (MV)

0 POCs x \$55.00 = 0

0 Bloods x \$10.00 = 0

Seaside (SS)

0 POCs x \$55.00 = 0

0 Bloods x \$10.00 = 0

N. Highlands (NH)

0 POCs x \$55.00 = 0

0 Bloods x \$10.00 = 0

Stockton (NC)

0 POCs x \$55.00 = 0

0 Bloods x \$10.00 = 0

Eastland Plaza (EP)

0 POCs x \$55.00 = 0

4 Bloods x \$10.00 = \$40.00

Total = \$11,365.00

Please remit payment to:

ENTERED  
9/11/12

## Exhibit D2

March 14, 2011

Invoice Number: [REDACTED]

Please include the invoice number on all payments to [REDACTED]

For January and February 2011 sample collections.

Stockton (NC)

1 POC's x \$55.00 = \$55.00

121 Bloods x \$10.00 = \$1210.00

Sacramento, "B" Street (BC)

27 POC's x \$55.00 = \$1485.00

327 Blood's x \$10.00 = \$3270.00

Fresno (FL)

12 POC's x \$55.00 = \$660.00

238 Bloods x \$10.00 = \$2380.00

Total = \$9060.00

Please remit payment to:

### Exhibit D3

February 17, 2014

Invoice Number: [REDACTED]

Please include the invoice number on all payments to [REDACTED]  
Payments are due and payable within 30 days.

For January 2014 sample collections.

✓ Fresno (FL)

1 POCs x \$55.00 = \$55

5 POC's x \$35.00 = \$175

68 Bloods x \$10.00 = \$680

Fruitridge (FR)

0 POCs x \$55.00 = \$0

0 Bloods x \$10.00 = \$0

✓ Mountain View (MV)

2 POCs x \$55.00 = \$110

0 Bloods x \$10.00 = \$0

N. Highlands (NH)

0 POCs x \$55.00 = \$0

0 Bloods x \$10.00 = \$0

Eastland Plaza (EP)

0 POCs x \$55.00 = \$0

0 Bloods x \$10.00 = \$0

✓ Sacramento, "B" Street (BC)

18 POCs x \$55.00 = \$990

0 POCs x \$35.00 = \$0

40 Bloods x \$10.00 = \$400

✓ San Jose (SJ)

25 POCs x \$55.00 = \$1375

0 POCs x \$35.00 = \$0

74 Bloods x \$10.00 = \$740

✓ Seaside (SS)

7 POCs x \$55.00 = \$385

0 POC x \$35.00 = \$0

8 Bloods x \$10.00 = \$80

✓ Stockton (NC)

13 POCs x \$55.00 = \$715

1 POC x \$35.00 = \$35

27 Bloods x \$10.00 = \$270

Total = \$6010.00

# Exhibit E1

**Redacted**

## PURCHASE ORDER

Winter Closure Warning: [Redacted] will be closed for winter break from Monday, December 15, 2014 through January 4, 2015. [Redacted] will reopen on Monday, January 5, 2015. No staff will be here to receive deliveries during this closure unless they have made special arrangements with you to be here to receive this shipment. If you cannot deliver by Friday, December 19, 2014 please schedule your shipment to arrive as soon as possible on or after, Monday January 5, 2015.

DATE	PURCHASE ORDER NO.
14-NOV-2014	60836838
PAGE NO.	REVISION NO.
Page 1 of 1	0

To:

United States  
ATTN: [Redacted]

Ship To:

**Redacted**

ORDER PLACED WITH	POB Destination	FREIGHT	VENDOR: If freight not included in price, prepay and add	DELIVERY DATE 19-NOV-2014	TERMS N30
ITEM NUMBER	DESCRIPTION	QUANTITY	UNIT	UNIT PRICE	EXTENDED PRICE
1	5231 4 Human Fetal Brains As described in Invoice # 5231	1	EACH	3,340.00	3,340.00
TAXABILITY				ESTIMATED TAX:	292.25
Exempt because items are for resale: California Sellers Permit: [Redacted] Exempt as purchase on behalf of U.S. Government: [Redacted] Exempt because use is exempted: [Redacted]				TOTAL:	3,632.25
Authorized Signature: [Redacted]				Direct questions to: [Redacted]	
Chief Procurement Officer					

Unless specifically stated otherwise, [Redacted] is subject to Sales Tax. Suppliers should invoice for taxable items. If a Supplier does not have the authority to collect California Sales Tax, [Redacted] will advise the tax and remit to the State Board of Equalization in the form of Use Tax.

California Revenue and Taxation Code, Section 11662, require withholding for payments made to nonresidents of California for income earned in California related to independent contractor services, rent, and royalty distributions. For more information on this requirement reference <http://www.ftb.ca.gov/publications/2011/1011.pdf>.

# Exhibit E2

Redacted

## PURCHASE ORDER

DATE	PURCHASE ORDER NO.
25-SEP-2014	60762875
PAGE NO.	REVISION NO.
Page 1 of 1	0

To: /

Ship To:

United States

ATTN : Redacted

Redacted

ORDER PLACED WITH	FOB Destination	FREIGHT	VENDOR: If freight not included in price, prepay and add	DELIVERY DATE 27-SEP-2014	TERMS N30
ITEM NUMBER	DESCRIPTION	QUANTITY	UNIT	UNIT PRICE	EXTENDED PRICE
1	#FT0101F Human Fetal Tissue: Gestation requirements: 12-20 weeks	10	EACH	595.00	5,950.00
2	#PKG0100 Packaging- Gel Pack or Wet Ice	10	EACH	15.00	150.00
3	#SD00103 Local Delivery Flat Rate - 101 to 150 miles	10	EACH	225.00	2,250.00

TAXABILITY	Authorized Signature	Direct questions to	ESTIMATED TAX:
Exempt because items are for resale. California Sellers Permit: <input type="checkbox"/> Redacted	Exempt as purchase on behalf of U.S. Government <input type="checkbox"/>	Exempt because use is exempted. <input type="checkbox"/>	730.64
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>			TOTAL: 9,080.64
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>			

Redacted

Redacted

Chief Procurement Officer

Unless specifically stated otherwise, Redacted is subject to Sales Tax. Suppliers should invoice for taxable items. If a Supplier does not have the authority to collect California Sales Tax, Redacted will accrue the tax and remit to the State Board of Equalization in the form of Use Tax.

California Revenue and Taxation Code, Section 18662, require withholding for payments made to nonresidents of California for income earned in California related to independent contractor services, rent, and royalty distributions. For more information on this requirement reference <https://www.ftb.ca.gov/forms/2012/12,1017.pdf>.

# Exhibit E3

**Redacted**

## PURCHASE ORDER

DATE	PURCHASE ORDER NO.
09-FEB-2015	60891260
PAGE NO.	REVISION NO.
Page 1 of 1	0

To:

Ship To:

United States

ATTN : **Redacted**

**Redacted**

ORDER PLACED WITH	FOB Destination	FREIGHT	VENDOR: If freight not included in price, prepay and add	DELIVERY DATE 09-FEB-2015	TERMS N30
ITEM NUMBER	DESCRIPTION	QUANTITY	UNIT	UNIT PRICE	EXTENDED PRICE
1	FT0101F Human Fetal Tissue (Estimate 5251) - Gestation requirements: 18-19 weeks - - upper and lower limbs with hands and feet	1	EACH	890.00	890.00
2	FT0101F Human Fetal Tissue (Estimate 5251) - Calvarium - Matched to upper and lower limbs	1	EACH	595.00	595.00
TAXABILITY			Authorized Signature	Direct questions to	ESTIMATED TAX: 129.95
Exempt because items are for resale, California Sellers Permit:	Exempt as purchase on behalf of U.S. Government	Exempt because use is exempted.	<b>Redacted</b>	<b>Redacted</b>	TOTAL: 1,614.95
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Chief Procurement Officer		

Unless specifically stated otherwise, **Redacted** is subject to Sales Tax. Suppliers should invoice for taxable items. If a Supplier does not have the authority to collect California Sales Tax, **Redacted** will accrue the tax and remit to the State Board of Equalization in the form of Use Tax.

California Revenue and Taxation Code, Section 18662, require withholding for payments made to nonresidents of California for income earned in California related to independent contractor services, rent, and royalty distributions. For more information on this requirement reference [https://www.ftb.ca.gov/forms/2012/12\\_1017.pdf](https://www.ftb.ca.gov/forms/2012/12_1017.pdf).



# Exhibit E4

Okay to Pay Invoice

Initiator =

## Invoice

Date	Invoice #
01/19/2012	1439
Terms	Due Date
Due on receipt	01/19/2012

Bill To

Purpose: the tissues are used for RNA extraction  
to perform genome-wide gene expression  
of brains exposed to environmental stressors

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Description	Ship Via	Researcher	Shipping
	FedEx		
Description	Qty	Price	Amount Due
<b>01/14/2012</b>			
• Fetal Brain Procurement Project: 5-24 wks - exposed to environmental factors, e.g. seizure, infection, hypoxia, alcohol, smoking, drug abuse. HIV Testing, Snap Freezing, Shipped on Dry Ice. Sample to be provided intact or in 4 parts/tube (anterior, middle, posterior cortex, and brain stem) POC #01, 02, 04, 05	4:00	715.00	2,860.00
• Fedex Priority Overnight	1:00	85.00	85.00
<b>Subtotal: 01/14/2012 = \$2,945.00</b>			
<b>01/17/2012</b>			
• Fedex Priority Overnight	1:00	85.00	85.00
• Fetal Brain Procurement Project: 5-24 wks - exposed to environmental factors, e.g. seizure, infection, hypoxia, alcohol, smoking, drug abuse. HIV Testing, Snap Freezing, Shipped on Dry Ice. Sample to be provided intact or in 4 parts/tube (anterior, middle, posterior cortex, and brain stem) POC #01, 02, 03	3:00	715.00	2,145.00
<b>Subtotal: 01/17/2012 = \$2,230.00</b>			
<b>01/19/2012</b>			
• Credit for 1/14/12 Samples - Fetal Brain Procurement Project: 5-24 wks - exposed to environmental factors, e.g. seizure, infection, hypoxia, alcohol, smoking, drug abuse. HIV Testing, Snap Freezing, Shipped on Dry Ice. Sample to be provided intact or in 4 parts/tube (anterior, middle, posterior cortex, and brain stem) POC #01, 02, 04, 05	-4	715.00	-2,860.00
• Credit for 1/14/12 - Fedex Priority Overnight	-1	85.00	-85.00
<b>Subtotal: 01/19/2012 = \$ -2,945.00</b>			
	<b>Total</b>		<b>\$2,230.00</b>

X

Administrator

01/27/2012

## Exhibit F

### Fetal Tissue Sales by Client Detail

January - December 2014

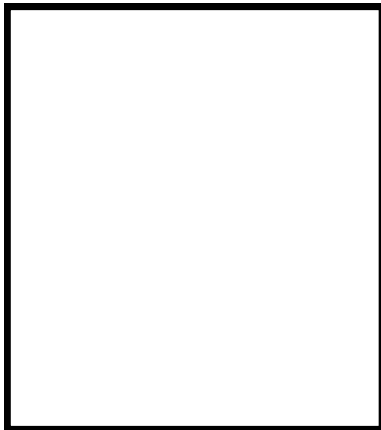
[illegible]

	06/10/2014	Invoice	4323	FT0101F	Item #FT0101F: Human Fetal Tissue - Liver	1.00	595.00	595.00
	06/17/2014	Invoice	4369	FT0101F	Item #FT0101F: Human Fetal Tissue - Heart	1.00	595.00	595.00
	06/19/2014	Invoice	4438	FT0101F	Item #FT0101F: Human Fetal Tissue - Heart	1.00	595.00	595.00
	07/02/2014	Invoice	4449	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	07/10/2014	Invoice	4529	FT0101F	Item #FT0101F: Human Fetal Tissue - Heart	1.00	595.00	595.00
	07/10/2014	Invoice	4529	FT0101F	Item #FT0101F: Human Fetal Tissue - Liver	1.00	595.00	595.00
	07/17/2014	Invoice	4544	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	07/22/2014	Invoice	4583	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	07/22/2014	Invoice	4584	FT0101F	Item #FT0101F: Human Fetal Tissue - Heart	1.00	595.00	595.00
	07/31/2014	Invoice	4658	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	2.00	595.00	1,190.00
	07/31/2014	Invoice	4639	FT0101F	Item #FT0101F: Human Fetal Tissue - Heart	1.00	595.00	595.00
	08/05/2014	Invoice	4681	FT0101F	Item #FT0101F: Human Fetal Tissue - Liver	1.00	595.00	595.00
	08/05/2014	Invoice	4681	FT0101F	Item #FT0101F: Human Fetal Tissue - Heart	1.00	595.00	595.00
	08/13/2014	Invoice	4753	FT0101F	Item #FT0101F: Human Fetal Tissue - Heart	1.00	595.00	595.00
	08/13/2014	Invoice	4752	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	08/13/2014	Invoice	4728	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	08/14/2014	Invoice	4763	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	08/14/2014	Invoice	4761	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	08/19/2014	Invoice	4799	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	08/19/2014	Invoice	4802	FT0101F	Item #FT0101F: Human Fetal Tissue - Heart	1.00	595.00	595.00
	08/27/2014	Invoice	4844	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	09/02/2014	Invoice	4882	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	09/11/2014	Invoice	4934	FT0101F	Item #FT0101F: Human Fetal Tissue - Heart	1.00	595.00	595.00
	09/16/2014	Invoice	4960	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	09/16/2014	Invoice	4962	FT0101F	Item #FT0101F: Human Fetal Tissue - Heart	1.00	595.00	595.00
	09/16/2014	Invoice	4963	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	09/16/2014	Invoice	4964	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	09/23/2014	Invoice	5013	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	09/23/2014	Invoice	5012	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	09/30/2014	Invoice	5037	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	10/01/2014	Invoice	5055	FT0101F	Item #FT0101F: Human Fetal Tissue - Liver	1.00	595.00	595.00
	10/09/2014	Invoice	5104	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	10/15/2014	Invoice	5111	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	10/21/2014	Invoice	5137	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	10/21/2014	Invoice	5136	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	11/12/2014	Invoice	5278	FT0101F	Item #FT0101F: Human Fetal Tissue - Liver	1.00	595.00	595.00
	11/12/2014	Invoice	5279	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	11/18/2014	Invoice	5321	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	11/20/2014	Invoice	5345	FT0101F	Item #FT0101F: Human Fetal Tissue - Fetal Upper/Lower Limbs	1.00	890.00	890.00
	12/02/2014	Invoice	5392	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	12/03/2014	Invoice	5398	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	12/10/2014	Invoice	5431	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
Total for 30 days								\$ 42,535.00

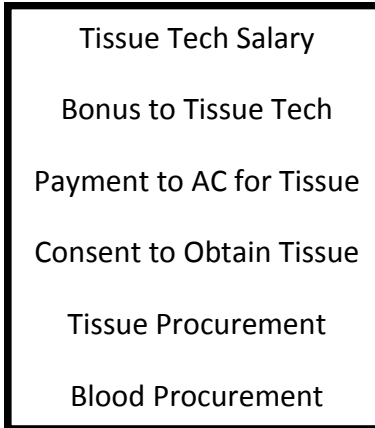
## Exhibit G

### Who Bears the Reasonable Cost of Tissue Procurement?

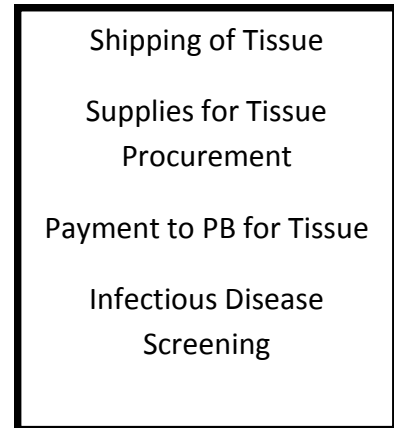
#### Abortion Clinic



#### Procurement Business



#### Customer



Explanation: The AC has **no costs** so the payments from the PB to the AC are pure profit. All costs are born by the PB or the Customer. The payments from the Customer to the PB exceed its cost by a factor of 300 to 400 percent.

# **REP. HENRY WAXMAN**

## **ON THE SALE OF FETAL TISSUE**

“This amendment that I am offering as a substitute would enact the most important safeguards, and those are the safeguards to prevent any sale of fetal tissue for any purpose, just not for the purpose of research. It would be abhorrent to allow for a sale of fetal tissue and a market to be created for that sale.”

-139 Cong. Rec. H1131 (Mar. 10, 1993)