



Message

From: Robert Sarkis [bob@biomaxps.com]
Sent: 6/30/2015 8:30:24 PM
To: Farrell, Melissa [melissa.farrell@ppgulfcoast.org]
CC: Susan Tennenbaum [susan@biomaxps.com]; Rebecca Wagner [rebecca@biomaxps.com]; Nguyen, Tram [tram.nguyen@ppgulfcoast.org]
Subject: Liver/Thymus Procurement
Attachments: BioMax_FLagreement.pdf

Hi Missy,

I hope you are enjoying the start of summer as much as possible! We just heard the good news about the Supreme Court and the TRAP law, but imagine it must still be tense in Texas.

We had some admin changes recently but I wanted to be sure to get back in touch with you about starting procurement at the Houston facility. As we discussed previously, this is a great opportunity for your patients, your affiliate, and our clients.

We want to make sure that our specimens are being procured and handled according to our client specifications. We are excited about the opportunity although we do not have a technician available to station in Houston right now.

In discussing more with Susan we think that a good solution right now would be to start a trial period of fetal liver/thymus procurement and we can get to know your and Tram's process better. I've drafted a re-tooled agreement for procurement and compensation—see Exhibit A in attached agreement. Please look it over with Tram; we are hoping this can be a good foundation but of course expect to customize it to accommodate your needs.

Thanks for your passion and dedication! Talk to you soon,

-Robert

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Robert Daoud Sarkis
Procurement Manager/VP Operations
BioMax Procurement Services, LLC
562.281.5041 (o)
408.645.0293 (c)



United States District Court
Northern District of California

DEFENDANTS' EXHIBIT
1823

Case No. 3:16-cv-00236-WHO
Date Entered _____
By _____
Deputy Clerk

CM01434

1823-0001

BIOSPECIMEN MATERIALS PROCUREMENT AGREEMENT



This Clinic Biospecimen Material Procurement Agreement (the "Agreement") is made effective _____, 2015 (the "Effective Date") by and between *BioMax Procurement Services LLC*, located at 6444 E. Spring Street, Ste. 725, Long Beach, CA 90815 ("BioMax"), and *Planned Parenthood Gulf Coast, Inc.* located at 4600 Gulf Freeway, Houston, TX 77023, ("Planned Parenthood"), individually and collectively referred to as "party" and "parties," respectively.

WHEREAS, BioMax is a company devoted to providing services related to the procurement of human organs, tissues, and blood for medical research in order to facilitate medical research utilizing those tissues; and

WHEREAS, Planned Parenthood is a company devoted to providing services related to medical and comprehensive reproductive health care, including termination of pregnancy;

NOW, THEREFORE, in consideration of the premises and mutual covenants contained in this Agreement, and in order to further their mutual goals, the parties agree as follows:

1. DEFINITIONS

- 1.1. The term "Biospecimen Material" means, individually and collectively, Fetal Organ(s), Product of Conception and Maternal Blood, as defined herein.
- 1.2. The term "Fetal Organ" has the same meaning as the term defined in the National Organ Transplant Act (42 U.S.C.A. 274e(c)(1)) and means the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ or any subpart thereof, as from a fetus.
- 1.3. The term "Product of Conception" ("POC") means any fetal organ or other fetal or placental material taken from the human uterus during an abortion.
- 1.4. The term "Maternal Blood" means blood samples taken from a pregnant woman.

2. SERVICES

- 2.1. Planned Parenthood will provide, and BioMax will pay the reasonable fees for, services associated with the following: the removal of Fetal Organs from POCs; the processing, preservation, quality control, and transportation of the Fetal Organs; obtaining maternal blood; seeking consent for donation of Biospecimen Material from appropriate donors, and; maintaining records of such consents so that verification of consent can be supported. The fees for each Biospecimen Material shall be as listed in Exhibit A, hereto.
- 2.2. Biospecimen Materials provided by Planned Parenthood:

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- 2.2.1. will not be derived from any donor with positive results from an infectious disease screen; and,
- 2.2.2. liver-Fetal Organs will be of a minimum volume as provided in Exhibit A and of a quality to be determined through mutual dialogue between the parties during the first four (4) months following the Effective Date. BioMax will give timely and specific feedback to Planned Parenthood regarding the quality of liver-Fetal Organs and Planned Parenthood will procure for BioMax only those fetal-Liver Organs that comply with the mutually developed criteria; thereafter, BioMax will not be obligated to compensate Planned Parenthood for liver-Fetal Organs that are not compliant with the criteria.
- 2.3. The parties acknowledge they do not know how many donors will consent to donate POCs for research, and thus do not know how many POCs will be obtained pursuant to this Agreement. Planned Parenthood is not obligated to provide any minimum number of POCs and BioMax is not obligated to take any minimum number of POCs nor is BioMax obligated to take all the POCs made available by Planned Parenthood.
- 2.4. Notwithstanding Section 2.2, Planned Parenthood will provide to BioMax all liver-Fetal Organs Biospecimen Materials procured by Planned Parenthood that meet the criteria in Exhibit A and BioMax agrees to acquire from Planned Parenthood all such liver-Fetal Organs under the terms and provisions set forth herein.
- 2.5. Any Biospecimen Material delivered pursuant to this Agreement is human blood or tissue and may have hazardous properties. Planned Parenthood and BioMax respectively shall be solely responsible for training their respective staff in handling and disposal of Biospecimen Material.
- 2.6. BioMax agrees to use and dispose of the Biospecimen Material in compliance with all applicable statutes and regulations, including but not limited to, those relating to research involving the use of human subjects, CDC Universal Precautions, and biohazard waste disposal.
- 2.7. Planned Parenthood will secure each donor's informed written consent using the Planned Parenthood Federation of America Medical Standards and Guidelines form.
- 2.8. With exception of Section 8.9, Planned Parenthood makes no representations and extends no warranties of any kind, either expressed or implied. Further, Planned Parenthood makes no express or implied warranties of merchantability or fitness for a particular purpose, or that the use of the Biospecimen Material will not infringe any patent, copyright, trademark, or other proprietary rights.
- 2.9. BioMax will not share or otherwise disclose donor or patient individually identifiable information with its customers or other parties, unless: (1) such disclosure is specified in the service section and with an IRB-approved written donor informed consent or HIPAA authorization, and/ or (2) is allowable or required by law or regulation.

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- 2.10. In the event that Planned Parenthood obtains donor information that impacts the safety of individuals in the chain of custody of that donor's Biospecimen Material, Planned Parenthood shall immediately notify BioMax using an anonymized donor identifier. As an example, such immediate notification shall be appropriate when Planned Parenthood receives or otherwise learns of any donor information indicating an associated Biospecimen Material having any positive test result associated with that Biospecimen Material was accidentally shipped to BioMax.
- 2.11. Planned Parenthood represents it has proper accreditation and licensure from Federal, State and local regulatory agencies to procure, store and convey blood and blood products, as applicable. BioMax may request, and Planned Parenthood shall provide within a timely manner, evidence of such licensure or accreditation. Planned Parenthood agrees to maintain its accreditation throughout the term of this agreement. If Planned Parenthood's licensure or accreditation is suspended or terminates during the term of this contract, Planned Parenthood shall notify BioMax immediately.
- 2.12. Both parties shall provide timely notification to the other with information it receives from a regulatory or accrediting agency of significant findings such as, but not limited to: FDA 483 Observations; FDA Warning Letters; CLIA/CMS, State or accrediting agency inspection findings; or any significant findings that relate to the quality of services performed or product provided under this Agreement. Additionally, responses by the party to the above observations or findings shall be provided. Timely notification of the following shall occur within two (2) weeks of receipt: FDA Warning Letters; any notice of intent to revoke licensure, or notice of a more serious regulatory or accreditation agency enforcement action.
- 2.13. Any information on donor chart that is obtained from Planned Parenthood shall be privileged and confidential, and BioMax will treat the information as such in order to preserve the confidentiality of the donors. BioMax will not receive any information concerning identity of donors except as necessary to obtain donors' consent for use of POCs and maternal bloods. This handling of donor information will always be undertaken in accordance with HIPAA guidelines.

3. TERM AND TERMINATION

- 3.1. The term of this Agreement shall be for two (2) year(s) commencing with the Effective Date of this Agreement.
- 3.2. Absent prior notice to the non-terminating party as provided for in this Section, this Agreement shall automatically renew for successive one (1) year periods commencing on the second anniversary of the Effective Date.
- 3.3. Either party may terminate this Agreement without cause upon thirty (30) days written notice.
- 3.4. This Agreement may be terminated by either party immediately for cause upon the occurrence of any one of the following:
 - 3.4.1. An act of fraud or other violation of federal or state law.
 - 3.4.2. Breach of standards and/or procedures resulting in injury to or death of donor.
 - 3.4.3. Loss of licensure/accreditation of either party.

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- 3.4.4. Failure of either party to employ qualified personnel as ascertained by BioMax and/or to properly train such qualified persons.
- 3.4.5. Dissolution or transfer of ownership of either party.
- 3.4.6. Bankruptcy or insolvency of either party.
- 3.5. This Agreement may be terminated by either party upon ten (10) days' written notice of a breach of the general terms and conditions of the Agreement. If the breaching party fails to cure the breach within the 10-day period, this Agreement shall terminate on the eleventh (11th) day.
- 3.6. Termination of this Agreement or termination of Services shall not affect the provisions under Sections 5, and 6 hereof, which shall survive any termination.

4. PAYMENT & PRICING

- 4.1. Planned Parenthood will invoice BioMax each month for the quantity of compliant Biospecimen Materials sent to BioMax multiplied by the associated fee in Exhibit A.
- 4.2. Planned Parenthood will further invoice BioMax each month for the costs of Biospecimen Materials shipping to BioMax research clients, with documentation of receipts.
- 4.3. BioMax will pay each invoice within thirty (30) days of invoice receipt. Invoices that are not paid within forty-five (45) days are subject to a service charge of 1% per month (12% per annum) on the outstanding balance.

5. CONFIDENTIALITY

- 5.1. The Parties recognize and acknowledge that each Party possesses certain confidential information that constitutes a valuable, special, and unique asset. As used herein, the term "Confidential Information" includes all information and materials belonging to, used by, or in the possession of a Party relating to its products, processes, services, technology, inventions, patents, ideas, contracts, financial information, developments, business strategies, pricing, current and prospective clients and customers, marketing plans, and trade secrets of every kind and character, but shall not include:
 - 5.1.1. Information that was already within the public domain at the time the information is acquired by the receiving Party,
 - 5.1.2. Information that subsequently becomes public through no act or omission of the receiving Party,
 - 5.1.3. Information that is disclosed to the Receiving Party without restriction after the effective date of this Agreement by a third party having a right to make such disclosure, or
 - 5.1.4. Information that is independently developed by either Party, as evidenced by that Party's written records.
- 5.2. Except as otherwise provided in this Agreement, each Party shall maintain the confidentiality of all provisions of this Agreement, including without limitation, the

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preamble and attachments and the existence of this Agreement between the parties. To assist the parties in identifying and managing Confidential Information, the parties will endeavor to (1) first disclose Confidential Information in tangible form that is conspicuously marked "Confidential," "Proprietary" or the like or (2) first disclose nontangible Confidential Information by orally identifying such as confidential at the time of disclosure and summarizing in tangible form and conspicuously marked as "Confidential" within thirty (30) days of the original disclosure.

- 5.3. Planned Parenthood and BioMax agree that all of the Confidential Information is and shall continue to be the exclusive property of originating Party, whether or not prepared in whole or in part by receiving Party and whether or not disclosed to or entrusted to receiving Party's custody. The Parties agree that they shall not, at any time following the execution of this Agreement, use or disclose in any manner any Confidential Information of the other Party.

6. INDEMNITY

- 6.1. Subject to Section 2.9, the parties mutually agree to defend, protect, and hold harmless each other's officers, directors, agents, employees, and consultants from and against any and all expenses, liabilities, demands or claims for loss or damage to property, or for personal injury or death suffered as a result of any actions by the parties in the performance of the Agreement and attributable to the fault or negligence of the parties or their respective officers, directors, agents, employees, or consultants.

7. RELATIONSHIP OF PARTIES

- 7.1. Each party's status under this Agreement is an independent entity and neither party nor their employees have authority to bind or act on behalf of the other except as otherwise expressly stated herein.

8. MISCELLANEOUS

- 8.1. Inventions. Any invention(s) conceived, reduced to practice, made or developed by BioMax as a result of using the Biospecimen Material ("Inventions") shall be the sole and exclusive property of BioMax, and Planned Parenthood shall have no proprietary or other ownership rights therein. To the extent that all or a portion of any Invention is owned or deemed to be owned by Planned Parenthood, Planned Parenthood hereby transfers, grants and assigns any such Invention to BioMax, and agrees not to challenge the ownership of any such Invention by BioMax, and the payment being made by BioMax to Planned Parenthood contemplates and provides consideration for such complete transfer, grant and assignment.
- 8.2. Dispute Resolution. If the parties cannot resolve a dispute between them relating to this Agreement or the relationship between the parties after using good faith efforts to resolve the dispute formally, the parties shall submit the dispute to binding arbitration in accordance with the then prevailing Commercial Arbitration Rules of JAMS. The parties

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shall bear the arbitrator's fees and expenses equally. Judgment upon the award may be entered and enforced in the appropriate state and federal courts.

- 8.3. Attorneys' Fees. Should either party hereto, or any heir, personal representative, successor or assign of either party hereto, resort to legal proceedings in connection with this Agreement or the relationship between the parties, the party prevailing in such legal proceedings may be entitled, in addition to such other relief as may be granted, to recover its or their reasonable attorneys' fees and costs in such legal proceedings from the non-prevailing party or parties.
- 8.4. Governing Law. This Agreement shall be governed by and interpreted under the laws of the State of California.
- 8.5. Force Majeure. No party shall be liable for any failure to perform its obligations in connection with any action described in this Agreement, if such failure results from any act of God, riot, war, civil unrest, flood, earthquake, or other cause beyond such party's reasonable control (including any mechanical, electronic, or communications failure, but excluding failure caused by a party's financial condition or negligence).
- 8.6. Ambiguities. Each party has participated fully in the review and revision of this Agreement. Any rule of construction to the effect that ambiguities are to be resolved against the drafting party shall not apply in interpreting this Agreement. The language in this Agreement shall be interpreted as to its fair meaning and not strictly for or against any party.
- 8.7. Assignment. This Agreement shall not be assigned by either Party in whole or in part, and no Party shall delegate or subcontract any or part of its responsibilities under this Agreement without the prior written consent of the other Party; provided, however, either party may assign this Agreement without such consent pursuant to a merger or acquisition of a controlling interest in the assigning party. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve any party of responsibility for the performance of any accrued obligation, which such party then has hereunder.
- 8.8. Insurance. BioMax and Planned Parenthood agree to maintain and keep in full force and effect during the entire term of this Agreement, at their own expense and cost, professional liability insurance and comprehensive general liability insurance, or an equivalent program of self-insurance, covering the activities contemplated under this Agreement, in the minimum amount of one million dollars (\$1,000,000) per incident and at least three million dollars (\$3,000,000) aggregate.
- 8.9. Warranty. Planned Parenthood warrants that it has the legal right to provide the Biospecimen Material to BioMax. Each party warrants and represents that the terms of this Agreement are not inconsistent with other contractual and/or legal obligations it may have.
- 8.10. Publicity. Neither party shall disclose the terms of this Agreement or use the name of the other party in any publicity, advertising or information disseminated to the general public without the prior written approval of the other party.
- 8.11. Amendment. This Agreement may be amended only by a writing signed by a duly authorized representative of both parties.

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- 8.12. Severability. If any term, provision, covenant or condition of this Agreement, or the application thereof to any person, place or circumstance, shall be held to be invalid, unenforceable or void, the remainder of this Agreement and such term, provision, covenant or condition as applied to other persons, places and circumstances shall remain in full force and effect.
- 8.13. Construction. The headings and captions of this Agreement are provided for convenience only and are intended to have no effect in construing or interpreting this Agreement. The language in all parts of this Agreement shall be in all cases construed according to its fair meaning and not strictly for or against either party.
- 8.14. Rights Cumulative. The rights and remedies provided by this Agreement are cumulative, and the exercise of any right or remedy by either party hereto (or by its successor), whether pursuant to this Agreement, to any other agreement, or to law, may not preclude or waive its right to exercise any or all other rights and remedies.
- 8.15. Non-waiver. No failure or neglect of either party hereto in any instance to exercise any right, power or privilege hereunder or under law shall constitute a waiver of any other right, power or privilege or of the same right, power or privilege in any other instance. All waivers by either party hereto must be contained in a written instrument signed by the party to be charged and, in the case of BioMax, by an officer of BioMax or other person duly authorized by BioMax.
- 8.16. Remedy for Breach. The parties hereto agree that, in the event of breach or threatened breach of any covenants, the damage or imminent damage to the value and the goodwill of the aggrieved party may be inestimable, and that therefore any remedy at law or in damages may be inadequate. Accordingly, the parties hereto agree that the aggrieved party may be entitled to injunctive relief in the event of any breach or threatened breach of any of such provisions by the breaching party, in addition to any other relief (including damages) available to the aggrieved party under this Agreement or under law.
- 8.17. Notices. Any notice, request, consent or approval required or permitted to be given under this Agreement or pursuant to law shall be sufficient if in writing, and if and when sent by certified or registered mail, with postage prepaid, or by facsimile or electronic mail with confirmed answer-back, to appropriate party's principal office, as noted below).

If to Planned Parenthood:

Planned Parenthood Gulf Coast, Inc.
4600 Gulf Freeway
Houston, TX 77023
Attn: Melissa Farrell
Email: melissa.farrell@ppgulfcoast.org

If to BioMax:

BioMax Procurement Services, LLC
6444 E. Spring Street, Ste. 725
Long Beach, CA 90815
Attn: Robert Sarkis
Email: bob@biomaxps.com

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- 8.18. Assistance. Planned Parenthood shall, during and after termination of services rendered, upon reasonable notice, furnish such information and proper assistance to BioMax as may reasonably be required in connection with service provided to BioMax.
- 8.19. Entire Agreement. This Agreement contains the entire agreement and understanding between the parties hereto and supersedes any prior or contemporaneous written or oral agreements, representations and warranties between them respecting the subject matter hereof.

9. EXECUTION

9.1. THIS AGREEMENT is made effective as of the Effective Date by the signed authority of the appropriate representatives of BioMax and Planned Parenthood, as evidenced by the following:

BioMax Procurement Services, LLC
6444 E. Spring St., Ste. 725
Long Beach, CA 90815

Planned Parenthood Gulf Coast, Inc.

Susan Tennenbaum, CEO

Date: _____

Date: _____

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Exhibit A

BIOSPECIMEN MATERIALS, FEES & PROCUREMENT GUIDELINES

Planned Parenthood will provide to BioMax Biospecimen Materials as provided in that certain Clinic Biospecimen Materials Procurement Agreement, to which this Exhibit is incorporated in its entirety.

1. BIOSPECIMEN MATERIALS & FEES

Biospecimen Material	Description	Fee (USD)
Fetal Liver	Collection of 5cc or more of fetal liver tissue	\$750.00
Fetal Liver + Thymus	Collection of fetal liver (5cc) <i>and</i> thymus from the same POC	\$1,600.00
Other Biospecimen Materials *	Collection of other fetal tissues as requested by BioMax	TBD per Donor Request

* Availability and supply of such other tissues to be agreed upon in advance by BioMax and Planned Parenthood.

** BioMax will provide Planned Parenthood with POC collection kits, at no cost to Planned Parenthood, or reimburse Planned Parenthood's assembly of such kits, which will include:

- a. Conical tubes and media for tissue storage
- b. Blood collection kit and tubes
- c. Researcher Procurement Form
- d. Packaging materials
- e. Detailed written instructions
- f. BioMax pre-printed label with courier account information