ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

VIA EMAIL

June 1, 2016

Mr. Jerry Menikoff
Director, Office for Human Research Protections
Department of Health and Human Services
Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Dear Director Menikoff:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel and empowered the panel to conduct a full and complete investigation regarding the medical practice of abortion providers and the business practices of firms that procure and resell fetal tissue.

During the course of our investigation, we have uncovered documents and received testimony from confidential informants indicating that StemExpress, LLC ("StemExpress"), a for-profit firm which procures fetal tissue from abortion clinics and transfers it to research customers, violated 45 CFR 46 by using the appearance of compliance with the regulations, while fraudulently using invalid consent forms, and misleading customers to believe it had a valid Institutional Review Board ("IRB") approval.

In addition to this letter, I have included as Attachment A another referral to the U.S. Department of Health and Human Services, Centralized Case Management Operations.

Background

StemExpress was founded in 2010 as a for-profit company and continues operations as StemExpress Foundation. Through its corporate existence, StemExpress' activities were obtaining contractual relationships with abortions clinics for the purpose of embedding a StemExpress company employee inside the clinic. The employees had access to confidential patient medical records, which they used to obtain consent and procure fetal tissue. StemExpress then resold that tissue to researchers. StemExpress pays the abortion clinic a per-specimen fee and then marks up the specimen four to six hundred percent for sale to a research institution.

Stem Express' tissue procurement technicians embedded inside the abortion clinics had the following daily **work sequence**:

- A researcher / customer placed an order for human fetal tissue using an online business portal provided by StemExpress. The web portal allowed the customer to request a particular gestational range for the fetal tissue. (See Attachment B, "Researcher Procurement Record.").

- When it first began operations, the abortion clinics from which StemExpress procured fetal tissue faxed the next day's schedule of potential patients directly to the StemExpress tissue procurement technician assigned to the clinic. (See Attachment C, "Fax from The Alameda, San Jose [Planned Parenthood clinics] to StemExpress, Jan. 10, 2013.").

- The day the abortion procedures were scheduled, StemExpress emailed the procurement schedule to its tissue technicians. (See Attachment D, "Updated Task Assignment: Procurement Schedule Wednesday, 3/30/13.").

- Emails produced by StemExpress demonstrate that its employees knew beforehand protected health information, including gestation periods of fetuses. For example: On January 6, 2015, a StemExpress employee emailed a customer that: "There are no patients that qualify for your request today. You will be on the schedule again for tomorrow, but the cases are all low gestation." On January 14, 2015, at 12:40 p.m., a StemExpress employee emailed a researcher: "Unfortunately, there is nothing within your gestational requirements today. There will be some potentials tomorrow, would you like to be on the schedule?" Hours later, the customer emailed: "Yes, please put me on the schedule for tomorrow." On April 14, 2015, a StemExpress employee emailed a researcher: We have a trisomy patient scheduled for this week and could try to procure a brain sample for you . . . ." (See Attachement E, "Emails.").

- As the firm became more computerized, tissue procurement technicians logged into a Website. (See Attachement F, "Navigating The Task Board.").

- The StemExpress procurement technician then sought out particular patients by name and obtained their consent to donate fetal tissue while they were awaiting their procedures. (See Attachment G, "Clinic Procedures and Policies.").

- StemExpress procurement technicians were paid an hourly wage and a per tissue "bonus" for each item they procured from the order page. (See Attachment H, "Procurement Technician Compensation Policy for Tissue and Blood Procurement.").

- StemExpress paid the abortion clinic a per tissue fee and then marked up the tissue four to six hundred percent for sale to the researcher. (See Attachment I, "StemExpress Services Agreement with Planned Parenthood Shasta Pacific," "StemExpress Services Agreement with Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties;" and Attachment J, "Purchase Order No. 60856806," "Purchase Order No. 3000014694," "Purchase Order No. 60836838," "Purchase Order No. 60858758," and "StemExpress Invoice # 1439.").

Documents produced to the Panel prove that StemExpress' tissue procurement technicians knew in advance of the abortion schedules, the clinics assisted them with obtaining consent, and the entire work flow was designed to maximize the firm's profits. For example instructions to the tissue procurement technicians (See Attachment K, "Standard Operating Procedure") states:

> The day before [the abortion] surgery: Check WebOffice [apparently an earlier version of the Task Board] for research requests; Determine your location for the next day; Call the clinic to verify how many surgeries are scheduled . . . .
>
> 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.
>
> . . . On the day of the surgery, the following steps are taken to procure tissue from POC [Products Of Conception; i.e., fetal tissue] . . . Print a copy of the day's Procurement Schedule. Following along the chart flow so you know what gestations to expect.
>
> . . . Keep track of [the] time [of procurement], gestation [age], fetal foot size or sono[gram] report and date.
>
> . . . If you have an excellent sample with no researcher listed on today's schedule, please contact Cate [Dyer, Stem Express' President and CEO] immediately, and

> they will work to call researchers who may be interested even though they are not currently scheduled.

The work sequence, when combined with the supporting documents reveals that StemExpress did not have a medically valid reason to see, and the abortion clinics did not have a reason to provide, patients' protected health information ("PHI"). Instead, the abortion clinics shared patients' PHI with StemExpress in furtherance of contractual agreements that financially benefitted StemExpress and the clinics.

Informed Consent

HHS requires investigators to obtain informed consent from each human being used as a research subject.[1] The "basic elements of informed consent" include the following information:

> (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental; . . . [and]
>
> (3) A description of any benefits to the subject or to others which may reasonably be expected from the research . . .[2]

Documents produced by StemExpress to the Select Panel indicate the firm did not follow those regulations. One of those documents is Attachment L, "A Form for Informed Consent To Participate In A Clinical Research Study, involving the donation of aborted pregnancy tissue for medical research, education, or treatment." It states:

> 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 more. . . .
>
> The benefits of consenting to donation today include furthering medical research in finding cures for disease like diabetes, leukemia, lymphoma, Parkinson's disease and more.

The Panel notes that the StemExpress consent form specifically does not conform to the General requirements for informed consent mandated under 45 CFR 46 §116. Witnesses at a recent Select Panel hearing agreed that forms similar to the one StemExpress used apparently do not conform to the HHS regulations on informed consent.[3]

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[1] 45 CFR 46 §116.

[2] *Id.*

[3] See generally House of Reps., Select Investigative Panel on Infant Lives, *Hearing on Bioethics and Human Tissue*, Mar. 2, 2016.

Coercion or Undue Influence

The requirements for informed consent further state that investigators "shall seek such consent only under circumstances that provide the prospective subject with . . . sufficient opportunity to consider whether or not to participate and that **minimize the possibility of coercion or undue influence**." [emphasis added].[4]

The regulations further state: "When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as . . . pregnant women . . . additional safeguards" are included.[5] Documents produced by StemExpress indicate the firm only obtained fetal tissue from women who had undergone abortions at abortion clinics, and the company's employees were the ones obtaining consent. It is unclear whether such consent occurred before or after the procedures was conducted.

Additional documents produced by StemExpress demonstrate that tissue procurement technicians engaged in real-time email correspondence with researchers while abortions were taking place - presumably before they obtained informed consent to procure fetal tissue - and yet StemExpress employees already were promising to deliver products of conception. (See Attachment M, "Emails regarding PO # 60858758."). The emails reveal that a customer had placed an order for a skull and limbs.

On January 22, 2015, at 12:26 p.m., the customer emailed a StemExpress employee stating: "Just wanted to check in and see if there are any cases within our gestation range for today? Need to book some time on the equipment if so." Within minutes, at 12:30:11 p.m., the StemExpress employee replied: "There is one case currently in the room, I will let you know how the limbs and calvarium [skull] look to see if you are able to take them in about fifteen minutes." Less than two minutes later, the customer wrote: "Great thank you so much." At 1:20:32 p.m., the StemExpress employee informed the customer: "The calvarium is mostly intact, with a tear up the back of the suture line, but all pieces look to be there. The limbs, one upper and one lower, are totally intact, with one upper broken at the humerus, and one lower broken right above the knee. Please let me know if these are acceptable. I have set them aside and will await your reply." Approximately five minutes later, the customer replied: "That sounds great we would like both of them. Please send them our way. Thanks again . . ." The StemExpress employee responded: "Limbs and calvarium will be there between 3:30 and 4:00."

The fact that StemExpress was attempting to interest a customer in fetal body parts **before an abortion had taken place** raises serious concerns that there may have been coercion or undue influence upon the patient to consent to procurement. Both Members and witnesses at our recent hearing raised the same question.[6]

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[4] 45 CFR 46 §110(4) and (7)(b).

[5] *Id.*

[6] See generally House of Reps., Select Investigative Panel on Infant Lives, *Hearing on Bioethics and Human Tissue*, Mar. 2, 2016.

IRB

Documents produced by StemExpress violated 45 CFR 46 by misleading customers into believing it had a valid IRB approval. StemExpress obtained approval for its "study" from BioMed IRB (Seen Attachment N, "Informed Consent To Participate In A Clinical Research Study," and "BioMed IRB Continual Approval Notification.").

In fact, one of StemExpress' marketing materials advertises the firm provides clinics with "IRB Certified Consents," and that "Our IRB approved **protocols** and **consents** protect you as well as donor's privacy in accordance with HIPAA guidelines." (Attachment O, StemExpress marketing brochure.).

At our recent hearing, Dr. G. Kevin Donovan, the senior clinical scholar at the Kennedy Institute of Ethics at Georgetown University, and director of the Pellegrino Center for Clinical Bioethics at Georgetown University, said actions such as those undertaken by StemExpress "would never pass muster for an IRB."[7] Yet StemExpress purportedly had the approval of an IRB.

HHS regulations require IRBs to "prepare and maintain adequate documentation" of its activities, including:

> (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 . . . .[8]

On March 29, 2016, the Panel issued a subpoena to BioMed IRB which required it to produce documents sufficient to show BioMed IRB's ongoing oversight, within the definition of Title 45 Code of Federal Regulations Part 46, of any entity involved with fetal research or transplantation of fetal tissue for which it issued an IRB approval.[9]

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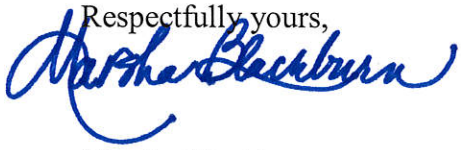
[7] House of Reps., Select Investigative Panel on Infant Lives, *Hearing on Bioethics and Human Tissue*, Mar. 2, 2016, at. P. 91.
[8] 45 CFR § 46.115 (a).
[9] House of Representatives, Select Investigative Panel on Infant Lives, Subpoena to Biomedical Research Institute of America, Mar. 29, 2016.

BioMed IRB's executive director informed the Panel on April 4, 2016 that, in regards to those records, "there are none."[10] This apparently is a direct violation of 45 CFR 46.

While regulation of IRBs does not fall under the auspices of OHRP, it may interest you to know that, in March of 2012, the Food and Drug Administration ("FDA") issued a warning letter to BioMed IRB, citing: A failure to fulfill membership requirements; failure to prepare, maintain, and follow adequate written procedures for conducting the review of research, including initial and continuing review; and keeping minutes that were not sufficient 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. As a result, the FDA ruled it "will withhold approval of all new studies subject to 21 CFR Part 56 and reviewed by the IRB; and [n]o new subjects are to be enrolled in any ongoing studies subject to 21 CFR Part 56 and approved by the IRB."[11] That ban was lifted in January 2013.[12]

Given the facts outlined above, and the supporting documentation, I urge your office to conduct a thorough investigation into whether StemExpress violated 45 CFR 46, and, if OHRP agrees that such violations occurred, to take all appropriate actions.

Respectfully yours,



Marsha Blackburn
Chair, Select Investigative Panel

cc: Rep. Jan Schakowsky
Ranking Member

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[10] Email from Fred Fox, Executive Director, Biomedical Research Institute of America, to Select Panel staff, Apr. 4, 2016.

[11] Letter from Mary A. Malarkey, Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, to Fred Fox, Executive Director, Biomedical Research Institute of America dba BioMed IRB, Mar. 29, 2012.

[12] Letter from Mary A. Malarkey, Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, to Fred Fox, Executive Director, Biomedical Research Institute of America dba BioMed IRB, Jan. 16, 2013.

Attachment A:

Letter to Ms. Jocelyn Samuels,

Director, Centralized Case Management Operations

U.S. Department of Health and Human Services

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VIA EMAIL

June 1, 2016

Ms. Jocelyn Samuels, Director
Centralized Case Management Operations
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Room 509F HHS Bldg.
Washington, D.C. 20201

Dear Director Samuels:

On October 7, 2015, the U. S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the business practices of businesses who procure and resell fetal tissue.

The Panel's investigation uncovered a series of business contracts between StemExpress,[1] a tissue procurement business ("TPB"), and several abortion clinics. These contracts included provisions for the payment of fees by StemExpress to the abortion clinics for fetal tissue and maternal blood. StemExpress then resold the fetal tissue and blood to researchers.

These contracts produced a regime of cooperation between StemExpress and each clinic. In particular: (1) the day before scheduled abortions, StemExpress received a fax from a clinic with information about the abortions scheduled for the next day; (2) StemExpress employees were granted access to the medical files of individual patients; (3) The clinic's medical employees (doctors and nurses) directed the StemExpress employees to particular patients who were "good candidates" for fetal tissue donations; (4) the StemExpress employees had access to the "patient terminal" inside the abortion clinic; and (5) the StemExpress employees were permitted by the abortion clinic to interview the patients about personal information, including their dates of birth.

[1] StemExpress and Stem-Ex are the same company.

In particular, the Panel's investigation has uncovered information indicating that StemExpress and Planned Parenthood Mar Monte ("PPMM"), Planned Parenthood Shasta Pacific ("PPSP") and Family Planning Specialists Medical Group ("FPS") (hereinafter "the abortion clinics") committed systematic violations of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") privacy rule from about 2010 to 2015. **These violations occurred when the abortion clinics disclosed patients' *individually identifiable health information* to StemExpress to facilitate the TPB'S efforts to procure human fetal tissue for resale.** This complaint is against each of these entities, and we request a swift and full investigation by the Office of Civil Rights in the Department of Health and Human Services.

In addition to this letter, we are submitting a referral to the HHS Office for Human Research Protections indicating that StemExpress violated 45 CFR 46 by using invalid consent forms and failing to have valid Institutional Review Board ("IRB") approval.[2]

I. BACKGROUND

The abortion clinics are "covered entities" under HIPAA, while StemExpress is not.[3] StemExpress "procure[s] tissues and isolate[s] cells for researchers' individual needs in its own labs."[4]

From about 2010 to 2015, the abortion clinics permitted StemExpress employees to: enter their clinics and procure human fetal tissue from aborted infants; obtain *individually identifiable health information*, or *protected health information* ("PHI") about their patients; interact with patients; and seek and obtain patient consent for tissue donation.[5] StemExpress embedded tissue procurement technicians inside the abortion clinics whose **work sequence** followed a daily routine:

1. A researcher / customer placed an order for human fetal tissue using an online business portal provided by StemExpress. The web portal allowed the customer to request a particular gestational range for the fetal tissue.[6]

2. The abortion clinics from which StemExpress procured fetal tissue faxed the next day's schedule of potential patients directly to the StemExpress tissue procurement technician assigned to the clinic.[7]

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[2] *See* Attachment A.

[3] *See* 45 CFR Part 160.103 (Covered Entity means: (1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.) *See also* OCR Privacy Brief, Summary of the HIPAA Privacy Rule, *available at* http://www.hhs.gov/sites/default/files/privacysummary.pdf (last visited May 5, 2016) (used as reference throughout this complaint).

[4] Stemexpress, About Us, *available at* http://stemexpress.com/about/ (last visited Apr. 29, 2016).

[5] *See* Attachment B: Clinic Procedures & Policies.

[6] *See* Attachment C: Researcher Procurement Record.

[7] *See* Attachment D: Fax from The Alameda, San Jose [Planned Parenthood clinics] to StemExpress, Jan. 10, 2013.

3. The day the abortion procedures were scheduled, StemExpress posted the order on a website "task board" (order page) to be accessed by their procurement technician or communicated the order to the tissue technician via email.[8]

4. The StemExpress procurement technician informed the clinic what they wished to procure (*i.e.*, the type of tissue and gestational range) based on the order page, and the abortion clinic provided the medical files, including PHI, for the patients with abortions scheduled for that day.[9]

5. The StemExpress procurement technician then sought out particular patients by name and obtained their consent to donate fetal tissue while they were awaiting their procedures. The procurement technician was also permitted to interview patients and obtain their PHI.[10]

6. StemExpress procurement technicians were paid an hourly wage and a per tissue "bonus" for each item they procured from the order page.[11]

7. StemExpress paid the abortion clinic for each fetal tissue and each blood sample and then marked up the tissue four to six hundred percent for sale to the researcher.[12]

The work sequence, when combined with supporting documentation, reveals that StemExpress did not have a medically valid reason to see, and the abortion clinics did not have a reason to provide, patients' PHI. Instead, the abortion clinics shared patients' PHI with StemExpress in furtherance of contractual agreements that financially benefitted StemExpress and the clinics.[13]

II. THE HIPAA PRIVACY RULE

The HIPAA privacy rule ("Privacy Rule") protects all *individually identifiable health information* held or transmitted by a covered entity or its business associate, and calls this information *protected health information* ("PHI").[14] PHI identifies an individual, or can reasonably be believed to be useful in identifying an individual (*e.g.*, name, address, birth date, Social Security Number), and includes demographic data relating to: an individual's past, present, or future physical or mental health condition; the provision of health care to the individual; or the past, present, or future payment for the provision of health care to the individual.[15]

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[8] *See* Attachment E: Updated Task Assignment: Procurement Schedule Wednesday, 3/20/13 and Attachment F: Navigating The Task Board.
[9] *See* Attachment G: StemExpress Emails.
[10] *See* Attachment B, *supra*: Clinic Procedures and Policies and Attachment H: Consenting Patients.
[11] *See* Attachment I: Procurement Technician Compensation Policy for Tissue and Blood Procurement.
[12] See Attachment J: StemExpress Services Agreement with Planned Parenthood Shasta Pacific; StemExpress Services Agreement with Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties; Purchase Order No. 60856806; Purchase Order No. 3000014694; Purchase Order No. 60836838; Purchase Order No. 60858758; and StemExpress Invoice # 1439.
[13] *See* Attachment K: Standard Operating Procedure.
[14] 45 C.F.R. § 160.103.
[15] 45 C.F.R. § 160.103.

A covered entity may not use or disclose an individual's PHI except as the Privacy Rule permits or requires,[16] or as the individual or their representative authorizes in writing (see discussion below). HHS may impose civil money penalties on covered entities that fail to comply with the Privacy Rule. Further, both a covered entity that discloses, and any person who knowingly obtains, PHI in violation of the Privacy Rule can face criminal fines or imprisonment.[17]

III. THE CONTRACTS BETWEEN STEMEXPRESS AND THE ABORTION CLINICS

Particular language, contained within the four corners of the written contracts between StemExpress and the abortion clinics raises serious concerns that the parties violated the Privacy Rule.

The written contracts between StemExpress and the abortion clinics contain the following language:

> [a]ny information obtained from [the abortion clinics] patients' charts shall be privileged, and [Stem-Ex / StemExpress] will treat the information in order to preserve the confidentiality of the patients. [Stem-Ex / StemExpress] will not receive any information concerning identity of donors **except as necessary to obtain patients' consent** for use of POCs and maternal bloods (emphasis added).[18]

This admission, on the face of the contracts, that the abortion clinics granted StemExpress access to patients' PHI raises the question whether any HIPAA provision permits or requires such disclosure without patients' express authorization. This question is compounded by the contracts' admission that StemExpress reviewed PHI **prior to obtaining patients' consent to donate fetal tissue *or* patients' authorization to view their PHI.**

IV. VIOLATIONS OF THE HIPAA PRIVACY RULE BY STEMEXPRESS AND THE ABORTION CLINICS

This complaint argues that the agreements between StemExpress and the abortion clinics, on their face and in practice, are fundamentally flawed. A contractual agreement requiring StemExpress to "treat the information obtained from patients' charts in order to preserve the confidentiality of the patients" **cannot trump a law prohibiting the abortion clinics from permitting these disclosures in the first place.** As discussed below, the abortion clinics—covered entities under HIPAA—were not permitted to disclose or make available to StemExpress any patient's PHI without the patient's express authorization.

The abortion clinics and StemExpress violated the HIPAA privacy rule because: (A) The disclosures of patients' PHI made by the abortion clinics, and received by StemExpress, were

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[16] 45 C.F.R. §164.502(a).
[17] Pub. L. 104-191; 42 U.S.C. §§ 1320d-5 – 1320d-6.
[18] *See* Attachments L, M, and N.

neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye or tissue transplantation or for research; (B) The consents for fetal tissue donation ostensibly obtained by StemExpress from the abortion clinics' patients did not constitute sufficient authorizations for the disclosure of PHI; (C) The disclosures of patients' PHI made by the abortion clinics to StemExpress were not the minimum necessary disclosures to facilitate the procurement of human fetal tissue from aborted infants; and (D) StemExpress is not a *Business Associate* of the abortion clinics under HIPAA.

A. The disclosures of patients' PHI made by the abortion clinics, and received by StemExpress, were neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye or tissue transplantation or for research.

The disclosures of PHI that the abortion clinics made to StemExpress are neither required[19] nor permitted[20] by law. StemExpress was not involved in the treatment of patients, in the payment for treatment, or in clinic operations.[21] **Rather, StemExpress wanted patients' PHI to facilitate the procurement of human tissue from aborted infants for resale to researchers.**

1. Cadaveric organ, eye or tissue transplantation

Importantly, the disclosures to StemExpress do not fall under the provision in law permitting disclosure of PHI to aid organ transplantation. While the contracts reference the "National Organ Transplant Act," 42 U.S.C. 274e(c)(1), the abortion clinics were not facilitating the donation and *transplantation* of cadaveric organs, eyes, and tissue. **Instead, the clinics were facilitating the donation of human fetal tissue from aborted infants for *research,* which is not covered by the cadaveric organ, eye or tissue exception.**[22]

2. Research

Further, the disclosures to StemExpress do not meet the rigorous requirements applicable to PHI disclosures for research purposes. A covered entity is not permitted to disclose an individual's PHI for research purposes without the individual's authorization unless the covered entity (1) obtains verification of approval from an Institutional Review Board ("IRB") for disclosure without authorization; (2) the researcher represents that the use or disclosure of the PHI is solely to prepare research protocol and the PHI will not be removed from the covered entity, and that the PHI is necessary for the research; or (3) the research is on PHI of deceased individuals.[23]

3. Violations Preceding "Consent"

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[19] 45 C.F.R. § 164.502(a)(2) (The only "required" disclosures are to (1) an individual or their personal representative when they request access to, or an accounting of disclosures of, their protected health information; and (2) to HHS when it is undertaking compliance investigation or review or enforcement action).
[20] *See* 45 C.F.R. § 164.502(a)(1).
[21] *See* 45 C.F.R. § 164.506(c).
[22] *See* 45 C.F.R. § 164.512(h).
[23] 45 C.F.R. § 164.512(i).

Because StemExpress employees actually sought consent for tissue donation from patients, the abortion clinics permitted the employees to view patients' charts. Medical charts are filled with HIPAA-protected PHI, including names, addresses, past and present medical treatment, and more. **Each time that an abortion clinic employee shared a medical chart with a StemExpress employee, both violated the HIPAA privacy rule.**

No evidence suggests the abortion clinics' patients provided authorization for StemExpress staff to view their PHI *prior* to seeking their consent to donate tissue. Therefore, regardless of whether a patient *ultimately* consented to tissue donation and authorized disclosure of her PHI to StemExpress, her privacy was violated.

The abortion clinics could have directly consented their patients for tissue donation, and entered an agreement with StemExpress to provide a limited data set[24] regarding the patients they were seeing on a particular day. Instead, they violated the Privacy Rule by permitting StemExpress to view the most intimate information about their patients.

These disclosures made by the abortion clinics to StemExpress were inarguably direct and intentional—not incidental.[25] StemExpress employees did not merely overhear a patient's name while in the clinic—they were handed her medical chart by her healthcare provider in blatant violation of the HIPAA privacy rule.

B. The consent for fetal tissue donation obtained by StemExpress from the abortion clinics' patients did not constitute sufficient authorizations for the disclosure of PHI.

While StemExpress purportedly obtained consents from patients prior to procuring human fetal tissue from their aborted infants, the forms that they used were insufficient to authorize the disclosure of PHI under the HIPAA privacy rule.

The Privacy Rule requires a covered entity to obtain an individual's written authorization for any use or disclosure of PHI that is not permitted or required by law.[26] Such authorization must be in plain language and contain specific information regarding the information to be disclosed or used, the person(s) disclosing and receiving the information, expiration, right to revoke in writing, and other data.[27]

Neither the consent form provided by StemExpress ("SE form") nor the consent form provided by Planned Parenthood ("PP form") to obtain patient consent for the donation of human fetal tissue of aborted infants met these stringent requirements.[28] The statement in the SE form that a patient's "health information will be protected at all times" is ironic given that StemExpress's possession of the patient's PHI already placed the abortion clinics and StemExpress in violation of the HIPAA privacy rule.

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[24] *See* 45 C.F.R. § 164.514(e).
[25] *See* 45 C.F.R. §§ 164.502(a)(1)(iii).
[26] 45 C.F.R. § 164.508.
[27] 45 C.F.R. § 164.508(c).
[28] *See* Attachments O: StemExpress Consent Form and P: Planned Parenthood Consent Form.

The SE form also stated that "[i]n accordance with federal laws (HIPAA), your personal identifying information will be protected . . . health information . . . may be used or disclosed . . . [but] will NOT be connected to your name or any other personal identifier."[29]

Like the privacy provision in the contracts between Stem Express and the abortion clinics, this nod towards HIPAA requirements failed to meet the requirements of the HIPAA privacy rule. The SE form did not describe the specific patient information that will be disclosed or used, but rather provided a generic, nonexclusive list of information that *may* be disclosed. The SE form did not state who will disclose or use the patient's PHI. It also did not state when the patient's authorization will expire, or that the patient can withdraw her authorization for the use of her PHI (it mentioned that the patient cannot withdraw her consent to the tissue donation after she leaves the clinic).

The PP form, purportedly used to obtain patient consent for human fetal tissue donation at PPMM and PPSP,[30] was grossly insufficient. The form did not address privacy at all, with no information regarding: PHI that may be disclosed or used; the person(s) disclosing and receiving the PHI; any expiration on the availability of the patient's PHI to researchers or others; or the patient's right to revoke her authorization in writing.

C. The disclosures of patients' PHI made by the abortion clinics to StemExpress were not the minimum necessary disclosures to facilitate the procurement of human fetal tissue from aborted infants.

The abortion clinics and StemExpress violated a central aspect of the Privacy Rule by disclosing/obtaining more than the "minimum necessary" PHI to facilitate the procurement of human fetal tissue from aborted infants.[31] StemExpress employees did not need to know the names of patients, and they certainly did not need to directly obtain the patients' consent in order to procure fetal tissue. Instead, these deeply private activities could have been performed by the abortion clinics.

As addressed above, the abortion clinics could have established a relationship with StemExpress that did not require or result in the disclosure of any PHI. Instead, the Planned Parenthood affiliates permitted StemExpress to use PHI to directly encourage patients to donate human fetal tissue—tissue that would later be sold by StemExpress to researchers at a huge mark-up.

D. StemExpress is not a *Business Associate* of the abortion clinics under HIPAA.

A *Business Associate* under HIPAA is a person or organization, other than a member of a covered entity's workforce, that performs certain functions or activities on behalf of, or provides certain services to, a covered entity that involve the use or disclosure of individually identifiable health information. *Business Associates* are generally involved in claim processing, data analysis, utilization review, and billing. Their services are limited to legal, actuarial, accounting,

---

[29] Attachment O, *supra*.
[30] Attachment P, *supra*.
[31] 45 C.F.R. §§ 164.502(b) and164.514(d).

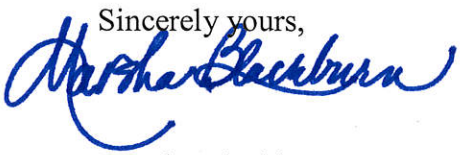
consulting, data aggregation, management, administrative, accreditation, or financial services, where the provision of the services involves the disclosure of PHI.[32]

Clearly, StemExpress did not perform one of these services for the abortion clinics, and is therefore not a *Business Associate* permitted to obtain the PHI of the abortion clinics' patients.

CONCLUSION

We appreciate your swift attention to the serious and systematic violations of the HIPAA privacy rule committed by StemExpress, Planned Parenthood Mar Monte, Planned Parenthood Shasta Pacific, and Family Planning Specialists Medical Group. If you have any questions about this request, please contact Mary Harned, Investigative Counsel at (202) 480-7160, or by email at Mary.Harned@mail.house.gov.

Sincerely yours,



Marsha Blackburn
Chair
Select Investigative Panel

Attachment(s)

cc: The Honorable Jan Schakowsky, Ranking Member
Select Panel on Infant Lives

[32] 45 C.F.R. § 160.103.

Attachment B:

Researcher Procurement Record

RESEARCHER PROCUREMENT RECORD

APPROVALS

All approvals are maintained and controlled in the [redacted] e system.
Please refer to the [redacted] e system for the current controlled revision and approval records.

REVISION HISTORY

AUTHOR	*REVISED SECTION/PARAGRAPH*	*REV*	*RELEASED*
[redacted]	**Initial Release**		01/10/2014

Draft and Archived/Obsolete revisions are not to be used.
Access [redacted] system to verify revision.

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1. PURPOSE

All procurement of tissue and/or blood must have a form of documentation for the client, laboratory, procurement technician, and billing. StemExpress refers to this documentation as an Researcher Procurement Record (RPR). Each RPR is unique to every client and may even be unique to specific researchers under the same client. Identifying information regarding the donor is not included on the RPR and donor anonymity is maintained at all times. This document will cover the correct method for completing an RPR.

2. SCOPE

The *Researcher Procurement Record Standard Operating Procedure* covers the general process for all RPRs. The information used to complete this form is specific to each client's needs and therefore varies from client to client. Subsequent Standard Operating Procedures will cover specific researcher needs.

3. DEFINITIONS

- Gestation- the process of carrying or being carried in the womb between conception and birth. On the RPR, the gestation is listed as the number of weeks the woman has been pregnant.
- RPR- Researcher Procurement Record.
- SOP- Standard Operating Procedure.
- IDS – Infectious Disease Sample

4. RESPONSIBILITIES

- Training Officer – Shall ensure that all personnel are properly trained and oriented to the SOP by providing initial instruction, reviewing the material, and any further instruction or correction at a later time. Shall also maintain training log for the SOP.
- Procurement Technician – Shall follow the SOP to properly perform all aspects of tissue and/or blood procurement.
- Regional Procurement Manager – Shall ensure that the above personnel are correctly performing their job duties.

5. POLICY

5.1 Overview

After the procurement of a specific tissue or blood sample the RPR must be completed for the researcher and for StemExpress records. An IDS sample is usually required for tissue specimens and the information for the IDS test will be included on the RPR. Please refer to *Infectious Disease Screening (IDS) Sample Standard Operating Procedure* for instructions

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on filling out IDS forms and sending IDS samples. Each RPR will include specific tissue and patient/donor information.

5.2 Details

5.2.1 Blood and Tissue RPR Details

5.2.1.1 Select the RPR from the database on the StemExpress WebOffice website (http://stem-ex.webexone.com). More information about the database can be found in *Understanding the Database Standard Operating Procedure.*

5.2.1.2 Start at the top of the document and work down.

5.2.1.3 **DATE:** Using the drop down menu put in the date of the procurement.

5.2.1.4 **SHIP TO**: The name, address, email, and phone contacts will be pre-filled out.

5.2.1.5 **FEDEX ACCOUNT** and **TRACKING #**: The FedEx number will be pre-populated with the client's FedEx account number if the client has requested that their FedEx account be billed. The tracking number is from the FedEx website after the shipping form is prepared. The *FedEx Shipments Standard Operating Procedure* focuses on how to prepare the shipment using the FedEx website.

5.2.1.6 **REF #**: The reference number is usually the Purchase Order # but can also be the Quote #. This information is obtained from the Daily Task Page database under the column heading PO #.

5.2.1.7 **DELIVER BY**: is only used for local delivery. The courier name, or company name should be included here. If FedEx is used to ship the sample, this section is to remain blank.

5.2.1.8 **PROCUREMENT TECH**: the technician ID number who procured the sample.. If more than one technician participated with the procurement of the sample, the second technician ID should be placed in the 'Additional Techs' field. Please see the Training Officer if you do not know or have not been assigned a procurement technician ID number.

5.2.1.9 **LOCATION**: is identified by a number. Each clinic or site has a specific number assigned to it. Please ask the Training Officer for your specific clinic or location ID number.

5.2.1.10 **ID#**: this is a drop down menu and is based on the order the blood/tissue is procured, regardless of the researcher. All ID#s for blood end in the letter 'B'. The numbers without the letter B (01, 02, etc) refer to tissue procurement. The ID# is based on the time the sample is procured, and does not reset for each researcher. One RPR could have ID# 01B, 03B, 04B, and a second RPR for a different researcher would have 02B, 05B, etc. If two blood requests from different clients are filled using a draw from the same patient, the ID number remains the same. For example if 8 tubes are procured on the first draw of the day from one patient, and 4 are going to Researcher A and 4 going to Researcher B, they would both be labeled ID 01B on the separate RPRs.

5.2.1.11 **TIME**: is the time that the blood or tissue specimen is procured. The drop down menu is in 15-minute increments. Round to the nearest time increment when selecting the time of draw..

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5.2.1.12 **PATIENT #**: is automatically generated once the date, procurement tech number, and ID number are entered into the RPR.

5.2.1.13 **SPEC #**: is the specimen number that is either placed on the blood tube or tissue specimen tube, or the label that is already on the blood tube, depending on the researcher. If the tubes are not already labeled, StemExpress labels are to be put on the tubes. StemExpress blood labels end with the letter B, and the tissue specimen labels are numbers only. Please refer to *Labeling Tubes Standard Operating Procedure.*

5.2.1.14 **GEST**: is the gestation of how many weeks pregnant the woman was at the time of the blood draw or tissue collection.

5.2.1.15 **SPECIMEN**: is a drop down menu and is the type of specimen procured.

5.2.1.16 **SEX**: is based on the blood or tissue specimen from whom the blood or tissue was procured. For example: for maternal blood the sex is female, for tissue procurement, the sex would be based on the actual sex of the product of conception (POC). M for male, F for female, or UNK if the sex is not known.

5.2.1.17 **COMMENTS**: this section varies depending on the client/researcher. There are a number of different items that may be referenced here and the items requested will already be generated on the form and must be filled in based on the patient information.

5.2.2 Tissue Sample with IDS

Some tissue samples will require a blood test (IDS) to go with them. From the Daily Task Page under the column heading IDS Testing check to see if the client/researcher has requested any IDS. If so, they will be listed here.

5.2.2.1 Fill out the RPR as described in 5.2.1.

5.2.2.2 Add the IDS test directly underneath the row for the tissue sample.

5.2.2.3 The **ID#** for the blood test is the exact same as the ID# for the tissue. By selecting the same ID# this generates a **patient #** that is the same.

5.2.2.3.1 Although most blood draws have an ID# that ends with the letter 'B', the IDS sample does not.

5.2.2.4 The **Time** is the same time listed for the tissue procurement and must be in military time.

5.2.2.5 The **specimen number** is the number on the label that was affixed on the blood sample tube. This number will be a StemExpress blood label and will end with the letter 'B'.

5.2.2.6 The **gestation** is the same as the tissue gestation.

5.2.2.7 The **specimen** is 'Maternal Blood Test'.

5.2.2.8 The **sex** is always female for IDS testing because it is a maternal blood sample.

5.2.2.9 Under **comments**, the blood tests required are specified. For example HIV, HBSAG, HCV. This information is taken directly from the IDS Testing column from the Daily Task Page.

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5.2.2.10 A second form must be sent with the tissue RPR when there is an IDS sample. More information on how to fill this out can be found in the *Infectious Disease Screening (IDS) Sample Standard Operating Procedure*.

6. APPLICABLE REFERENCES

- See attached RPR

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Attachment C:

Fax from The Alameda, San Jose [Planned Parenthood clinics] to StemExpress, Jan. 10, 2013

CMP19 D19

SUSTAINING QUALITY OF LIFE
THROUGH RESEARCH™

Main Address
2869 Cold Springs Rd
Placerville CA 95667
T 877-900-STEM (7836)
F 530-380-3800
info@stem-ex.com
www.stem-ex.com

Shipping and Receiving
484 Main Street, Suite 1
Diamond Springs, CA 95619

Send To: StemExpress
From / Clinic: THE ALAMEDA SAN JOSE
Recipients Fax Number: [redacted]
From: [redacted]
Date: 01/10/13
Total Pages: (Includes Cover) 14

Fax

Urgent ☐ Reply ASAP ☐ Please Comment ☒ Please Review ☐ For Your Information ☐

Comments:

Next Days Schedule: Potential Patients: US/MAB 20 PT____ ROB____ AB____
Time of First Appt: 0830

Attachment D:

Updated Task Assignment: Procurement Schedule
Wednesday, 3/30/13

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

The following task has been updated on the "StemExpress" 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] Cate Dyer, [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 [redacted] 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] PhD, Research Specialist Melton Group, HHMI/Harvard Dept of Stem Cell and Regenerative Biology, [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 [redacted]
1 SPEC=
Researcher: [redacted]

Brain/14+wks (2cm in width)/Whole brain In-tact or one whole Hemis intact/Dry

Brain/14+wks (2cm in width)/Whole brain in tact or one whole Hemis intact/Dry
Ice on aluminum foil protocol/FedEx Priority Overnight/HIV,HCV,HbC,HBSAG,RPR/Yale
[redacted]
IMPORTANT: Please document PO#SNP5725137 in the reference section. Donor information required: Sex of fetus if identifiable,Age,Ethnicity,Past drug use if known.
3 SPEC=
Researcher: [redacted]

Same Day, Pick Up

PROCURE ON THURSDAY ONLY Fetal kidney (In-tact: Renal vein/artery, ureter, inferior vena cava(descending aorta); without Digoxin applied)/18-20 wks/RPMI/Wet Ice/Same day pick-up/ Ganogen, Inc. [redacted]
1 Spec=
Call [redacted] Personal pick-up on site near clinic location to reduce ishemia time

PROCURE ON THURSDAY ONLY- Brain/17+ gestation/Both Hemis In-tact -or- call for approval of hemis, forebrain, hindbrain, brainstem(semi-intact(70%)approved)/RPMI/Wet Ice/Stanford [redacted]
1 SPEC=
Note: Please call [redacted] with a best guess delivery time window (Ex: eta- 11am to 1pm) Mobile:[redacted]

Brain 8+wks/Inact Calvarium -or- <7wks/Whole Embryo/RPMI(1-2hrs;ASAP)/Wet Ice+barrier/The Rockefeller University[redacted]
1 Spec=
Ships to StemExpress Lab for procedure
IMPORTANT: Please document PO#419428 in the reference section.

Same Day, Local Delivery

To access the task in the web office, click the link below:
<http://stem-ex.webexone.com/r.asp?a=19&id=26397>

Attachment E:

StemExpress Emails

Subject: Re: Procurement update
Date: Wednesday, January 7, 2015 at 10:13:36 AM Pacific Standard Time
From: Redacted
To:

Ok.

Actually, if you have a good sample from any gestational week today, I would like you to please send it.

Best,
Redacted

On Tue, Jan 6, 2015 at 1:53 PM, Redacted wrote:
Hello,

There are no patients that qualify for your request today. You will be on the schedule again for tomorrow, but the cases are all low gestation. Thank you,

Redacted

StemExpress
Redacted
778 Pacific Street
Placerville, CA 95667
Redacted
stemexpress.com

Subject: FW: Procurement update
Date: Wednesday, January 14, 2015 at 8:02:34 PM Pacific Standard Time
From:
To: Redacted

just fyi

From: Redacted
Sent: Wednesday, January 14, 2015 4:03 PM
To: Redacted
Subject: Re: Procurement update

Hi,

Yes, please, put me on the schedule for tomorrow. Can you also change the gestational requirements, to allow any gestational stage (I have changed some things in the protocol, and so need to redo the middle stages).

I am aiming for an even coverage of gestational stages, to get a full view of pancreas development. As I get samples that cover different stages the requirements change.

Best,
Redacted

On Wed, Jan 14, 2015 at 12:40 PM, Redacted wrote:
Hello,

Unfortunately there is nothing within your gestational requirements today. There will be some potentials tomorrow, would you like to be on the schedule?

Thank you,

Redacted

From: Redacted
Sent: Wednesday, January 14, 2015 12:27 PM
To: Redacted
Subject: Re: Procurement update

Hi Redacted

How is the pancreas forecast today - any possible procurements?

Best,
Redacted

Sent from my iPhone

Subject: Re: Trisomy Tissue
Date: Monday, April 13, 2015 at 15:46:28 Pacific Daylight Time
From:
To: Redacted
CC:

Hi Redacted

There is one sample left on PO#60856806 (the trisomy + normal). We have a trisomy patient scheduled this week and could try to procure the brain sample for you, but the PO would have to be edited to reflect the cost of the potential trisomy sample, or we could create a new PO for 1 trisomy sample.

There is also one sample left on PO#60924493.

Thank you,

Redacted

StemExpress
Redacted
778 Pacific Street
Placerville, CA 95667
Redacted
stemexpress.com

On Apr 13, 2015, at 3:19 PM, Redacted wrote:

> Hi Redacted
>
> the trisomy tissue worked very well and we are interested in procuring more of them. i believe there should be one more additional order of calvarium open on the PO for trisomy tissue. initially we did put in 1 normal and 1 trisomy tissue. at this point we will take either for the 2nd tissue on the trisomy order.
>
> i also wanted to put in another order of 4 normal fetal brains distributed as before one each for
> <13 wks
> 13-15 wks
> 15-17 wks
> >17 wks
>
> please send me a quote for the same
>
> Thanks
> Redacted

Attachment F:

Navigating the Task Board

NAVIGATING THE TASK BOARD

APPROVALS

All approvals are maintained and controlled in the X3 ERP system.
Please refer to the EX ERP system for the current controlled revision and approval records.

REVISION HISTORY

AUTHOR	*REVISED SECTION/PARAGRAPH*	*REV*	*RELEASED*
[redacted]	**Initial Release**		11/23/2014

Draft and Archived/Obsolete revisions are not to be used.
Access X3 ERP system to verify revision.

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1. PURPOSE

StemExpress has a wide variety of requests for tissue and blood that change on a daily basis. There are many clinics operating daily. It is necessary for multiple users in remote locations to be able to: access and update information that identifies each researcher or clients specific requests: provides pertinent information and necessary documentation for packaging and shipping of the sample(s): and keeps track of what is being procured by each technician and each clinic daily.

2. SCOPE

Navigating the Task Board Standard Operating Procedure explains how to interpret the information on the Task Board, which can be found at http://[redacted] and will describe all functions and menus within the Task Board. The Task Board is essential for knowing what samples to procure, how to ship the samples, what media is used, along with specific researcher requirements.

3. DEFINITIONS

- Gestation – the process of carrying or being carried in the womb between conception and birth.
- IDS – Infectious Disease Screening
- POC – The product of conception
- Procurement – The act of obtaining a sample
- Researcher Procurement Record – or packing slip. A document that displays the specimen information requested by the researcher. It is shipped with the samples to the client.
- SOP –Standard Operating Procedure
- Task Board - Online system used by StemExpress to share information within the company, as well as remote sites, and obtain information necessary for procurement and billing.

4. RESPONSIBILITIES

- Procurement Technician – Shall follow the SOP to properly perform all aspects of tissue and/or blood procurement.
- Training Officer – Shall ensure that all personnel are properly trained and oriented to the SOP by providing initial instruction, reviewing the material, and any further instruction or correction at a later time. Shall also maintain training log for the SOP.
- Supervisory Personnel – Shall ensure that the above personnel are correctly performing their job duties in a safe and effective manner.

5. POLICY

5.1 Overview

Navigating the Daily Task Page Standard Operating Procedure explains what information is in each section of the Task Board and how the Procurement Technician uses that

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information. The content of the Task Board is updated daily by a supervisor. It also changes in real time as samples are procured in the field and the technician's update what samples have been fulfilled. The specific details for procurement, number of specimen procured by each technician, and the packing slip (Researcher Procurement Record) can all be found on this database.

5.2 Details

5.2.1 Navigating the Task Board

5.2.1.1 From the Internet browser, navigate to http://[redacted]
Enter your ***Username*** and ***Password***, and then click ***Log In.***

5.2.1.2 At the top of the page is a drop down menu labeled *Clinic*. Click on the drop down arrow and choose the clinic that you are assigned to that day.. If the user that is signed in only procures from one clinic, there will not be a drop down menu and the clinic will be automatically listed.

5.2.1.3 Up at the top right hand side of the screen there is a ***Logout*** option that can be clicked on at any time to log out of the open session.

5.2.1.4 On the left side of the screen there are 4 items: ***Dashboard, Procurement, Orders,*** and ***Printing***.

5.2.2 Dashboard

5.2.2.1 The Dashboard is not currently being used by procurement technicians and if clicked will display a blank screen.

5.2.3 Procurement

The Procurement section lists the client orders that are open that the procurement technician can procure against. Instructions on how to use the Procurement page once a sample has been collected is located in **5.2.4 Filling Out a Procurement Form**. There are eight columns on the Procurement screen that are described below.

5.2.3.1 **Order**: The order column shows the order numbers associated with the items requested from the client and are system generated automatically.

5.2.3.2 **Customer**: The customer column reflects the client that requested the samples.

5.2.3.3 **Item**: The item number is the catalog product code for the type of sample being requested.

5.2.3.4 **Description**: brief description of the sample requested by the researcher.

5.2.3.5 **Gest Range**: The gestational range that the client will accept for the specimen procured. If the sample is not maternal or fetal this line will be blank.

5.2.2.7 **Type**: The type of sample requested, such as whole blood or maternal blood.

5.2.2.8 **Progress**: This item shows how many samples have been procured against the total number of samples requested. If 2 samples have been procured towards an order of 100 samples it will be displayed as 2/100. This means there are 98 more samples to be procured within the clinics.

5.2.2.9 **Due Date**: The due date is the date that the samples must be collected by.

5.2.4 Filling Out a Procurement Form

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Click on the ***Procurement*** option on the left hand side of the screen. A list of orders that are open to procure against for the clinic the tech is signed in under will be displayed here. This is where a technician can go to find out what samples can be collected for the day. Once a sample has been procured the steps below need to be taken to create a packing slip (Researcher Procurement Form) to accompany the sample.

5.2.4.1 Click on the order that the sample was collected for and the browser will open to a screen that has the same information that was shown on the Procurement screen, as well as blank boxes that need to be filled in by the technician. All of the blank boxes are information that is required by the researcher and cannot be left blank.

5.2.4.2 ***Order***, ***Customer***, ***Item***, ***Item Type***, ***Description***, and ***Gestational Range*** will be filled in already. Descriptions for each of those items are in **5.2.3**.

5.2.4.3 **Notes**: Any notes from the researcher or management will be located here. This includes, but is not limited to, volume requirements, shipping temperature, special instructions, and client specifications for a particular order.

5.2.4.4 If a red field is displayed with notification that an IDS specimen is required for the sample, the technician must procure the IDS blood sample with the tissue sample. More information on how to procure and label an IDS sample can be found in the *Infectious Disease Screening SOP SEC-FP-0001* of the Training Manual.

5.2.4.5 The technician must fill out all open fields that are located below the Notes section. The fields displayed in the Notes section only include the specific information that was requested by the researcher. These fields will differ for each project and must be filled in by the technician. They may include all or some of the following:

- **Age**: The age of the patient donating
- **Ethnicity: of the donor.**
- **Gestation**: The length of pregnancy measured in weeks and days. This is determined by an ultrasound or estimated from the first day of the woman's last menstrual period. For example, the value would be written as 12.3 weeks for 12 weeks and 3 days.
- **Smoking history**: Should be indicated as smoker or non-smoker.
- **Date of Birth**: Patient's date of birth.
- **Height**: in feet and inches. For example 5' 7".
- **Donor Number**: The number assigned to donors donating in the StemExpress Donation Center.
- **Fetal Abnormality**: Classifies any physical or genetic abnormalities of the fetus.
- **Drug Use**: indicate any drugs the patient is taking.
- **Weight**: in pounds. For example 145 lbs.
- **P.O.C.**- Product of conception. If two specimens were taken from one P.O.C. they would both have the same P.O.C. number. For example if a liver specimen and kidney specimen are taken

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from the first P.O.C. collected by the technician, they would both have a value of 01.

- **Sex of Fetus: Male, Female, Unknown.**
- **Diseases**: Any diseases that the patient is known to have.
- **IDS Specimen Number**: If the sample requires an infectious disease screening (IDS), the specimen number from the StemExpress blood label should be placed in this field. Instructions for procuring an IDS sample are in the *Infectious Disease Screening SOP SEC-FP-0001.*
- **Comments**: Any comments relating to the sample procured can be typed here. This may include, but it not limited to, volumes, abnormalities in a blood draw, or any relevant patient information. This section can also be left blank.

5.2.4.6 Any forms that are necessary for the procurement of the sample are identified in the bottom section of the screen under **File Name**. A brief description of the file will be visible. The technician must review all documents in this section. They will vary depending on the researcher and the order.

5.2.4.7 Once all information is filled in, click the **Submit** button at the bottom right hand corner of the screen. If the sample cannot be shipped or the information is incorrect, click **Cancel** in the bottom left corner.

5.2.4.8 After clicking submit, a new screen will pop up which shows all of the information that the technician entered on the procurement screen. This is the last chance to review the information for errors and make edits. If everything is correct, click **Submit**. Once Submit is clicked on this screen the order cannot be edited. It is extremely important that all information be reviewed for accuracy before clicking **Submit**.

5.2.5 Orders

The Orders section of the Task Board is a place to view all open orders for the clinic the technician is signed in under. This menu is available for technicians to view but will not be used during procurement.

5.2.5.1 Click on **Orders** on the left hand menu. A screen titled Orders will appear with a list of all open orders for the clinic specified in the top menu bar. The list will have the following items:

- **Order**: The number assigned to the order by the system.
- **Customer**: The name of the client.
- **Due Date**: Date that the order was entered into the system.
- **Status**: The status of the order. The order will remain open and visible to the technician until the samples have been billed for.

5.2.5.2 Click on the line of the order of interest.

5.2.5.3 The order number and name of the client will be at the top of the screen. The **Status**, **Assigned to**, and **Order date** will be automatically generated.

5.2.5.4 The first tab listed is **Lines**. The catalog number for the product is in the column **Item**. **Description** is a brief description of the item requested by the client.

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Filled is how many samples in the order have been procured. **Ordered** indicates how many samples were ordered in total. **Delivery Date** is the day that the samples need to be filled by.

5.2.5.5 The second tab is labeled **Attachments.** Any attachments that are relevant to the order will be attached here. They can also be accessed when viewing an order in the ***Procurement*** section of the Task Board.

5.2.6 Packing Lists

Packing lists, or Researcher Procurement Forms, are documents that need to be printed out for each order and included with the samples as well as faxed to the Procurement Manager. The forms contain all relevant information pertaining to the samples and the client including shipping address, type of sample, specimen number, and specific patient information that was entered in the ***Procurement*** section of the Task Board. All information on the form is auto populated.

5.2.6.1 Click ***Packing Lists*** on the left hand side of the screen. There will be a list of orders that have been procured in the clinic selected at the top of the screen within the Clinics drop down menu. The Order, Customer, and Due Date are identified.

5.2.6.2 Click on the order that a packing slip needs to be printed for. Each sample for that order will be listed. The first column is the auto generated **Lot Number**. The lot number is created from the sample procurement number, date, location number, and technician ID number. The **Item** is the catalog number for the samples procured. **Item Description is** the brief description of the sample procured.

5.2.6.3 Check each box to the left of the Lot Number that should be included on the packing list and click **Submit**.

5.2.6.4 Review the packing slip to make sure that all items that are being shipped are on the form and that all information is accurate. Review the client name, address, and all sample information for errors. The client name and address listed on the packing slip are to be used to create a FedEx shipping label to ship the samples. Instructions on how to create the shipping label using FedEx.com can be found in the *FedEx Shipments Standard Operating Procedure* SEC-FP0006.

5.2.6.5 Two copies of the Packing Slip should be printed. One copy will go with the samples and the second should be faxed at the end of the day to the Procurement Manager. More information on how to package samples and the Packing Slip can be found in the *Packaging Blood and Tissue Samples Standard Operating Procedure* SEC-FP-00005.

6. APPLICABLE REFERENCES

- FedEx Shipments SOP
- Infectious Disease Screening (IDS) Sample SOP
- Packaging Blood and Tissue Samples SOP

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Attachment G:

Clinic Procedures and Policies

Clinic Procedures and Policies

As a representative of StemExpress 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 Confidentially for Patient Information

I have read and understand the above Clinic Procedures and Policies

[redacted] [redacted] [redacted]

Print Name Signature Date

778 Pacific Street / Placerville CA 95667
T: 530-626-7000 F: 530-26-7900 / info@stemexpress.com / www.stemexpress.com

Attachment H:

Procurement Technician Compensation Policy for Tissue and Blood Procurement

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 Procurable 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 equality 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.

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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

778 Pacific Street / Placerville CA 95667
T: 530-626-7000 F: 530-26-7900 / info@stemexpress.com / www.stemexpress.com

Procurement Technician Compensation Policy for Mileage and Other Expenses Effective 01/01/2013

Mileage Reimbursement

- Each StemExpress contractor is assigned a worksite location, which generally is the primary assigned clinic. Any mileage driven on behalf of StemExpress exceeding the mileage to and from their resident and their current assigned worksite location will be reimbursed at $.55 per mile based on the Federal Mileage Rate. This rate is subject to change via the federal government and will be changed accordingly.

Expenses

- On occasion, StemExpress Contractor's will need to purchase supplies, i.e. ice for shipping. StemExpress Contractor's will be reimbursed for these necessary items. Receipts are required for reimbursement.

778 Pacific Street / Placerville CA 95667
T: 530-626-7000 F: 530-26-7900 / info@stemexpress.com / www.stemexpress.com

Attachment I:

StemExpress Services Agreement with Planned Parenthood of Santa Barbara, Ventura & San Louis Obispo Counties

Services Agreement

This agreement is made as of 5/15/2012 between StemExpress, LLC, a limited liability company, and Planned Parenthood Shasta Pacific, a professional corporation.

WHEREAS, StemExpress 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 Shasta Pacific provides medical services, education programs, and advocacy initiatives in order to improve people's lives;

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. 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.

2. The term "product of conception" ("POC") means any fetal organ or other fetal or placental material taken from the human uterus during an abortion.

3. The term "maternal bloods" means blood samples taken from a pregnant woman.

4. Planned Parenthood Shasta Pacific will provide, and StemExpress will pay the reasonable costs for, services and facilities at mutually agreed upon health centers (hereinafter collectively referred to as "services") associated with the following: the removal of fetal organs from POCs; the processing, preservation, quality control, and transportation of the fetal organs; appropriate space in which StemExpress representatives and employees may work; disposal services for non-used portions of cadaveric materials; obtaining maternal bloods; seeking consent for donation of fetal organs and maternal bloods from appropriate donors, and; maintaining records of such consents so that verification of consent can be supported.

5. The reasonable costs associated with the services specified in this Agreement shall be fifty-five dollars ($55.00) per POC determined in the clinic to be usable, and ten dollars ($10.00) per maternal blood. Planned Parenthood Shasta Pacific will invoice StemExpress monthly for the number of POC's and number of maternal bloods procured by StemExpress. StemExpress will pay Planned Parenthood Shasta Pacific within thirty days of receipt of the invoice.

6. Any information obtained from Planned Parenthood Shasta Pacific patients' charts shall be privileged, and StemExpress will treat the information in order to preserve the confidentiality of the patients. StemExpress will not receive any information concerning identity of donors except as necessary to obtain patients' consent for use of POCs and maternal bloods.

7. The term of this Agreement shall be for one year, beginning from the date hereof, and terminating one year thereafter. Parties may, at any time, give each other thirty days written notice of the intention to terminate this Agreement, whereupon the Agreement shall terminate thirty days after the receipt of such notice. In the absence of such termination, this Agreement shall continue for further successive terms of one year thereafter.

8. Written notices pursuant to this Agreement shall be sent to the following:

Attn: Medical Director
Planned Parenthood Shasta Pacific
2185 Pacheco St.
Concord, CA 94520

StemExpress
484 Main Street, Ste. 1
Diamond Springs, CA 95619

9. The parties do not know how many patients will consent to donate POCs or maternal bloods for research, and thus do not know how many POCs or maternal bloods will be obtained pursuant to this Agreement. Planned Parenthood Shasta Pacific is not obligated to provide any minimum number of POCs or maternal bloods. StemExpress is not obligated to take any minimum number of POCs or maternal bloods, nor is StemExpress obligated to take all the POCs or maternal bloods made available by Planned Parenthood Shasta Pacific.

10. 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.

11. No modification to this Agreement, nor any waiver of any rights, shall be effective unless agreed to in writing by the party charged with such waiver or modification. Waiver of any breach or default shall not constitute a waiver of any other right hereunder, or any subsequent breach or default.

12. This Agreement constitutes the entire and exclusive agreement between the parties.

13. This Agreement shall be governed by and interpreted under the laws of the State of California, and venue for any dispute arising hereunder shall be in the County of Sacramento.

14. The prevailing party in any action to enforce the terms of the Agreement shall be entitled to reimbursement by the other party for all costs, including the reasonable attorney fees and professional fees, incurred in connection with such proceeding.

15. This Agreement may be executed in counterparts, each of which will be deemed an original, but both of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have executed this agreement by their duly authorized representatives as of the date written above.

Planned Parenthood Shasta Pacific

By: [redacted]

Title: President/CEO

StemExpress, LLC

By: _____

Title: CEO 5/16/12

484 Main Street, Suite 1 / Diamond Springs, CA 95619 / Shipping & Receiving
2869 Cold Springs Rd / Placerville CA 95667
T: 877-900-STEM (7836) F: 530-647-2500 / info@stemexpress.com / www.stemexpress.com

Services Agreement

This agreement is made as of October 23, 2103 between StemExpress, a limited liability company, and Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties, Inc. (PPSBVSLO) a professional corporation.

WHEREAS, StemExpress 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, PPSBVSLO provides medical services, education programs, and advocacy initiatives in order to improve people's lives;

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. 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.

2. The term "product of conception" ("POC") means any fetal organ or other fetal or placental material taken from the human uterus during an abortion.

3. The term "maternal bloods" means blood samples taken from a pregnant woman.

4. PPSBVSLO will provide, and StemExpress will pay the reasonable costs for, services and facilities at mutually agreed upon health centers (hereinafter collectively referred to as "services") associated with the following: the removal of fetal organs from POCs; the processing, preservation, quality control, and transportation of the fetal organs; appropriate space in which StemExpress representatives and employees may work; disposal services for non-used portions of cadaveric materials; obtaining maternal blood; seeking consent for donation of fetal organs and maternal blood from appropriate donors, and; maintaining records of such consents so that verification of consent can be supported.

5. The reasonable costs associated with the services specified in this Agreement shall be fifty dollars ($50.00) per 60cc's of maternal blood, and seventy five dollars ($75.00) for the collection of fetal tissue, if collected solely by PPSBVSLO staff. If StemExpress staff is onsite to physically collect the sample, then there would be a cost adjustment for the collection of the sample. PPSBVSLO will invoice StemExpress monthly for the number of POC's and number of maternal bloods

procured by StemExpress. StemExpress will pay PPSBVSLO within thirty days of receipt of the invoice.

6. Any information obtained from PSBVSLO patients' charts shall be privileged, and StemExpress will treat the information in order to preserve the confidentiality of the patients. StemExpress will not receive any information concerning identity of donors except as necessary to obtain patients' consent for use of POCs and maternal bloods. This will always be done in accordance with HIPAA guidelines.

7. The term of this Agreement shall be for one year, beginning from the date hereof, and can be renegotiated for successive years there after. Parties may, at any time, give each other a ninety days written notice of the intention to terminate this Agreement, whereupon the Agreement shall terminate ninety days after the receipt of such notice. .

8. Written notices pursuant to this Agreement shall be sent to the following:

   Attn: [redacted] Medical Director
   Planned Parenthood of Santa Barbara, Ventura
   & San Luis Obispo Counties, Inc.
   518 Garden Street | Santa Barbara, CA 93101

   Attn: Cate Dyer, CEO
   StemExpress
   778 Pacific Street
   Placerville, CA 95667

9. The parties do not know how many patients will consent to donate POCs or maternal bloods for research, and thus do not know how many POCs or maternal bloods will be obtained pursuant to this Agreement. PPSBVSLO is not obligated to provide any minimum number of POCs or maternal bloods. StemExpress is not obligated to take any minimum number of POCs or maternal bloods, nor is StemExpress obligated to take all the POCs or maternal bloods made available by PPSBVSLO.

10. 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.

11. No modification to this Agreement, nor any waiver of any rights, shall be effective unless agreed to in writing by the party charged with such waiver or modification. Waiver of any breach or default shall not constitute a waiver of any other right hereunder, or any subsequent breach or default.

12. This Agreement constitutes the entire and exclusive agreement between the parties.

13. This Agreement shall be governed by and interpreted under the laws of the State of California, and venue for any dispute arising hereunder shall be in the County of Sacramento.

14. The prevailing party in any action to enforce the terms of the Agreement shall be entitled to reimbursement by the other party for all costs, including the reasonable attorney fees and professional fees, incurred in connection with such proceeding.

15. This Agreement may be executed in counterparts, each of which will be deemed an original, but both of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have executed this agreement by their duly authorized representatives as of the date written above.

StemExpress, LLC

By: _____

Name: **Cate Dyer**

Title: **CEO**

Planned Parenthood Santa Barbara, Ventura & San Luis Obispo Inc.

By: [redacted]

Name: [redacted]

Title: President / CEO

778 Pacific Street / Placerville CA 95667
T: 530-626-7000 F: 530-626-7900 / info@stemexpress.com /
www.stemexpress.com

Attachment J:

Purchase Orders No. 60856806, 3000014694, 60836838, 60858758 & StemExpress Invoice # 1439

Redacted

PURCHASE ORDER

Winter Closure Warning: Redacted will be closed for Winter Break from Monday, December 22, 2014 through January 4, 2015. Redacted 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.
12-DEC-2014	60856806
PAGE NO.	REVISION NO.
Page 1 of 1	0

To: STEMEXPRESS LLC
778 Pacific St
Placerville, CA 95667
United States
ATTN : Redacted

Ship To: Redacted

ORDER PLACED WITH	FOB	FREIGHT	VENDOR: If freight not included in price, prepay and add	DELIVERY DATE	TERMS
	Destination			17-DEC-2014	N30

ITEM NUMBER	DESCRIPTION	QUANTITY	UNIT	UNIT PRICE	EXTENDED PRICE
1	5263 Stemexpress invoice 5263 for trisomy and normal Fetal calvarium	1	EACH	2,130.00	2,130.00

TAXABILITY

Exempt because items are for resale. California Sellers Permit: Redacted

Exempt as purchase on behalf of U.S. Government

Exempt because use is exempted.

Authorized Signature: Redacted
Chief Procurement Officer

Direct questions to: Redacted

ESTIMATED TAX: 186.38

TOTAL: 2,316.38

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.

This Purchase Contract may be accepted only on the terms set forth herein. The complete Terms and Conditions can be found at: Link. Terms in any acceptance by Seller which are in addition hereto or not identical with the terms hereof will not become a part of any Purchase Contract unless Buyer specifically and expressly agrees in writing that such other terms are accepted. By accepting this Purchase Contract or any part hereon, Seller agrees to and accepts all the provisions of the Purchase Contract.

INSTRUCTIONS

Applicable unless otherwise stated

A. **Invoices** - Separate invoices for each purchase order. Show purchase order number on all documents. Mail invoices to Accounts Payable at:

Redacted

If this order involves services and you have not advised Redacted of your tax status, please contact the Financial Support Center at Redacted Failure to provide tax information may result in delayed payment. For more information, email Redacted

B. **Correspondence** - Redacted Redacted

C. **Transportation** - If freight is not included in price, prepay and state separately on invoice. **Do not ship collect.** Include a packing list with each shipment, and attach to outside (not inside) of container. Show purchase order number on outside of each container

D. **Late Shipment** - Advise at once if order will not reach destination on time.

E. **Terms and Conditions** - Link.

Redacted

Purchase Order

3000014694

Purchase Order	Date	Revision	Page
3000014694	2014-10-04		1 of 2
Payment Terms	**Freight Terms**	**Ship Via**	
Due Now	FOB DEST	BEST WAY	
Buyer	**Phone**		**Currency**
Redacted	Redacted		USD

Vendor: Redacted
STEMEXPRESS LLC
778 PACIFIC STREET
PLACERVILLE CA 95667
United States

Ship To:
Redacted

Bill To:
Redacted

Purchase Order Comments

Redacted

Attached are the quote and meditract documents.
PLEASE ATTN: 3000014694
PLEASE CONTACT Redacted FOR QUESTIONS: Redacted OR Redacted
IF SHIPPING CHARGES ARE APPLIED PLEASE USE FED EX COLLECT Redacted (FOR COLD ITEMS PLEASE SHIP USING "STANDARD OVERNIGHT"
FOR NON COLD ITEMS PLEASE SHIP 2ND DAY.
PLEASE SEND CONFIRMATION/ETA/TRACKING INFO TO: Redacted

PLEASE ATTN: 3000014694
PLEASE CONTACT Redacted FOR QUESTIONS: Redacted OR Redacted
IF SHIPPING CHARGES ARE APPLIED PLEASE USE FED EX COLLECT Redacted (FOR COLD ITEMS PLEASE SHIP USING "STANDARD OVERNIGHT"
FOR NON COLD ITEMS PLEASE SHIP 2ND DAY.
PLEASE SEND CONFIRMATION/ETA/TRACKING INFO TO: Redacted

Line-Sch	Item #/Description	Vendor Item ID	Quantity	UOM	Unit Price	Extended Amt	Due Date	Tax Y/N
1 - 1	Human Fetal Tissue-Pancreas; Infectious Disease Screening: HIV, HBsAg, HCV; Packaging-Gel Pack or Wet Ice	1144	1.00	EA	760.00	760.00	10/07/2014	Y
					SUT Code: LA (9%)	68.40		
				Schedule Total		828.40		

Contract ID: Redacted Version: 1 Contract Line: 0 Category Line: 0 Release: 3
For Redacted Reference Only

Authorized Signature
Redacted

Redacted

PURCHASE ORDER

Winter Closure Warning: Redacted will be closed for Winter Break from Monday, December 22, 2014 through January 4, 2015. Redacted 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: STEMEXPRESS LLC
778 Pacific St
Placerville, CA 95667
United States
ATTN : Redacted

Ship To: Redacted

ORDER PLACED WITH	FOB	FREIGHT	VENDOR: If freight not included in price, prepay and add	DELIVERY DATE	TERMS
	Destination			19-NOV-2014	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

Exempt because items are for resale. California Sellers Permit: Redacted ☐

Exempt as purchase on behalf of U.S. Government ☐

Exempt because use is exempted. ☐

Authorized Signature: Redacted

Chief Procurement Officer

Direct questions to: Redacted

ESTIMATED TAX: 292.25

TOTAL: 3,632.25

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.

This Purchase Contract may be accepted only on the terms set forth herein. The complete Terms and Conditions can be found at: Link. Terms in any acceptance by Seller which are in addition hereto or not identical with the terms hereof will not become a part of any Purchase Contract unless Buyer specifically and expressly agrees in writing that such other terms are accepted. By accepting this Purchase Contract or any part hereon, Seller agrees to and accepts all the provisions of the Purchase Contract.

INSTRUCTIONS

Applicable unless otherwise stated

A. **Invoices** - Separate invoices for each purchase order. Show purchase order number on all documents. Mail invoices to Accounts Payable at:

Redacted

If this order involves services and you have not advised Redacted of your tax status, please contact the Financial Support Center at Redacted Failure to provide tax information may result in delayed payment. For more information, email Redacted

B. **Correspondence** - Redacted Redacted

C. **Transportation** - If freight is not included in price, prepay and state separately on invoice. **Do not ship collect.** Include a packing list with each shipment, and attach to outside (not inside) of container. Show purchase order number on outside of each container

D. **Late Shipment** - Advise at once if order will not reach destination on time.

E. **Terms and Conditions** - Link.

Redacted

PURCHASE ORDER

Winter Closure Warning: Redacted will be closed for Winter Break from Monday, December 22, 2014 through January 4, 2015. Redacted 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.
16-DEC-2014	60858758
PAGE NO.	REVISION NO.
Page 1 of 1	0

To: STEMEXPRESS LLC
778 Pacific St
Placerville, CA 95667
United States
ATTN : Redacted

Ship To: Redacted

ORDER PLACED WITH	FOB	FREIGHT	VENDOR: If freight not included in price, prepay and add	DELIVERY DATE	TERMS
	Destination			17-DEC-2014	N30

ITEM NUMBER	DESCRIPTION	QUANTITY	UNIT	UNIT PRICE	EXTENDED PRICE
1	FT0101F Human Fetal Tissue (Estimate 5251) - Gestation requirements: 17-18 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

Exempt because items are for resale. California Sellers Permit: Redacted

Exempt as purchase on behalf of U.S. Government

Exempt because use is exempted.

Authorized Signature: Redacted

Chief Procurement Officer

Direct questions to: Redacted

ESTIMATED TAX: 129.95

TOTAL: 1,614.95

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.

This Purchase Contract may be accepted only on the terms set forth herein. The complete Terms and Conditions can be found at: Link. Terms in any acceptance by Seller which are in addition hereto or not identical with the terms hereof will not become a part of any Purchase Contract unless Buyer specifically and expressly agrees in writing that such other terms are accepted. By accepting this Purchase Contract or any part hereon, Seller agrees to and accepts all the provisions of the Purchase Contract.

INSTRUCTIONS

Applicable unless otherwise stated

A. **Invoices** - Separate invoices for each purchase order. Show purchase order number on all documents. Mail invoices to Accounts Payable at:

Redacted

If this order involves services and you have not advised Redacted of your tax status, please contact the Financial Support Center at Redacted Failure to provide tax information may result in delayed payment. For more information, email Redacted

B. **Correspondence** - Redacted Redacted

C. **Transportation** - If freight is not included in price, prepay and state separately on invoice. **Do not ship collect.** Include a packing list with each shipment, and attach to outside (not inside) of container. Show purchase order number on outside of each container

D. **Late Shipment** - Advise at once if order will not reach destination on time.

E. **Terms and Conditions** - Link.

Okay to Pay Invoice 1047732.00.0061AM.833695.733001

IMG74120201-EML001_0031

stem express

STEMEXPRESS, LLC
2869 Cold Springs Road
Placerville, CA
95667
877.900.7836
stemexpress.com

Initiator = [redacted]

Invoice

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

Bill To
Yale University School of Medicine, Neurobiology [redacted] New Haven, CT 06510 USA

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

Ship Via	Researcher	Shipping
FedEx	[redacted]	StemExpress Acct

Description	Qty	Price	Amount Due
01/14/2012			
• 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
Subtotal: 01/14/2012 = $2,945.00			
01/17/2012			
• 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
Subtotal: 01/17/2012 = $2,230.00			
01/19/2012			
• 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
Subtotal: 01/19/2012 = $ -2,945.00			
		Total	$2,230.00

Thank you for your business. If you have any questions, contact [redacted] at [redacted] or by email at [redacted]@stemexpress.com.

[redacted]

X [redacted]

[redacted] Administrator [redacted] 01/27/2012

Attachment K:

Standard Operating Procedure

January 3, 2011

Protocol Number: 101-01

Protocol Date: January 24, 2011

Study Title: Tissue Procurement for Non-therapeutic Research

Sponsor: StemExpress, LLC.

Primary Investigator: Redacted
StemExpress, LLC
778 Pacific Street
Placerville, CA 95667
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

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 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.

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 StemExpress.

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 StemExpress immediately if there are printer problems.

If you have an excellent sample with no researcher listed on today's schedule, please contact Cate 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

Attachment L:
A Form for Informed Consent To Participate
In A Clinical Research Study

INFORMED CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Study Title: Tissue Procurement for Non-therapeutic Research

Sponsor: Stem Express, LLC

Protocol Number: 101-01

Protocol Date: January 24, 2011

Principal Investigator: Cate Dyer

24-Hour Phone Number: 877-900-7836

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.

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.

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 StemExpress at 877-900-7836.

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

Signature:_____ Date:_____

Witness:_____ Date:_____

FOR CALIFORNIA RESIDENTS ONLY
EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or other procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of a signed and dated written consent form when one is required.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

Printed Name of Subject	Signature of Subject	Date
Printed Name of Witness	Signature of Witness	Date

Attachment M: Emails Involving P0 #60858758

Subject: Re: PO# 60858758
Date: Thursday, February 5, 2015 at 1:58:50 PM Pacific Standard Time
From:
To: Redacted
CC:

Hi Redacted

I procured a 17.5 limbs and calvarium for you. The limbs are intact, the calvarium is somewhat crushed but looks to be all there. Please confirm if you would like one or both as soon as possible, as I will be contacting my courier shortly.

Thank you,

Redacted

From: Redacted
Sent: Monday, February 02, 2015 4:18 PM
To:
Cc: Redacted
Subject: Re: PO# 60858758

Hi Redacted

I would be happy to put you on the schedule for this week. Please send over a new PO if you have not already.

Thank you,

Redacted

From: Redacted
Sent: Monday, February 02, 2015 11:14 AM
To: Redacted
Subject: Re: PO# 60858758

Hi Redacted

The sample we received the other week was perfect thanks for all your help with procurement. We are ready for the next one. Can you please put us on the list for Tues Wed and Thurs of this week for the same order.

Thanks again,

Redacted

----- Original Message -----
From: Redacted
To: Redacted
Sent: Thursday, January 22, 2015 1:57:00 PM

Subject: RE: PO# 60858758

Redacted

Limbs and Calvarium will be there between 3:30 and 4:00.

Thank you,

Redacted

From: Redacted
Sent: Thursday, January 22, 2015 1:07 PM
To: Redacted
Subject: Re: PO# 60858758

Redacted

That sounds great we would like both of them.

Please send them our way,

Thanks again,

Redacted

----- Original Message -----
From: Redacted
To:
Cc: Redacted
Sent: Thursday, January 22, 2015 1:02:32 PM
Subject: RE: PO# 60858758

Redacted

The Calvarium is mostly intact, with a tear up the back suture line, but all pieces look to be there.

The limbs, one upper and one lower are totally intact, with one upper broken at the humerus, and one lower broken right above the knee. Please let me know if these are acceptable. I have set them aside and will await your reply.

Thank you,

Redacted

From: Redacted
Sent: Thursday, January 22, 2015 12:33 PM
To: Redacted
Subject: Re: PO# 60858758

Great thank you so much.

----- Original Message -----
From: Redacted
To: Redacted
Cc: Redacted

Sent: Thursday, January 22, 2015 12:30:11 PM
Subject: RE: PO# 60858758

Hello,

There is one case currently in the room, I will let you know how the limbs and calvarium look to see if you are able to take them in about fifteen minutes.

Thank you,

Redacted

From: Redacted
Sent: Thursday, January 22, 2015 12:26 PM
To:
Cc: Redacted
Subject: Re: PO# 60858758

Hi Redacted

Just wanted to check in and see if there were any cases within our gestation range for today? Need to book some time on the equipment if so.

Thanks,

Redacted

----- Original Message -----
From: Redacted
To:
Cc: Redacted
Sent: Wednesday, January 21, 2015 3:23:30 PM
Subject: RE: PO# 60858758

Redacted

I will be happy to do that.

Thank you,

Redacted

From: Redacted
Sent: Wednesday, January 21, 2015 3:19 PM
To:
Cc: Redacted
Subject: Re: PO# 60858758

Redacted

Thank you for letting me know. We are now ready to include the skull so if you could please include that in our order for tomorrow that would be great. Just to clarify we are happy to receive one or the other depending on damage/integrity. If there is a case tomorrow could you please have someone contact me with the condition of both the long bones and the calvarium and I will be happy to let you know if we would like one or both.

Attachment N: Informed Consent to Participate In A Clinical Research Study

&

BioMed IRB Continued Approval Notification

INFORMED CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Study Title: Tissue Procurement for Non-therapeutic Research

Sponsor: Stem Express, LLC

Protocol Number: 101-01

Protocol Date: January 24, 2011

Principal Investigator: Cate Dyer

24-Hour Phone Number: 877-900-7836

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.

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.

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 StemExpress at 877-900-7836.

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

Signature:_____ Date:_____

Witness:_____ Date:_____

FOR CALIFORNIA RESIDENTS ONLY
EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or other procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of a signed and dated written consent form when one is required.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

Printed Name of Subject	Signature of Subject	Date
Printed Name of Witness	Signature of Witness	Date

BioMed•IRB

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: Stem Express, LLC

Protocol Number: 101-01

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

Principal Investigator: Cate Dyer

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

than thirty (30) days from the date of discovery.

- Any changes in the research activity (i.e. changes in study staff, facility etc.) should be reported promptly. In addition, the investigator will not make any changes in the research without the IRB's approval, except when necessary to eliminate apparent immediate hazards to study subjects.
- Any other unanticipated problems involving risks to study subjects.

BioMed IRB is comprised of a diverse group of individuals in accordance with the Federal Regulations and the International Conference on Harmonization, Global Harmonization or other appropriate guidance for Good Clinical Practice. BioMed IRB follows written procedures for performing review, documenting meeting minutes, disclosure of member conflict of interest prior to deliberation or voting, as well as the retention of all records containing research materials as required by the Code of Federal Regulations (21CFR parts 50 and 56; and 45 CFR part 46).

On behalf of the BioMed IRB, I certify that the information contained in this letter is true and correct as verified by the minutes and records of the BioMed IRB.

Please keep a copy of the continual review material, as well as a copy of this letter, in your files for future reference. Should you have questions or concerns, please do not hesitate to contact this office.

Sincerely,

[redacted]

Authorized Signature

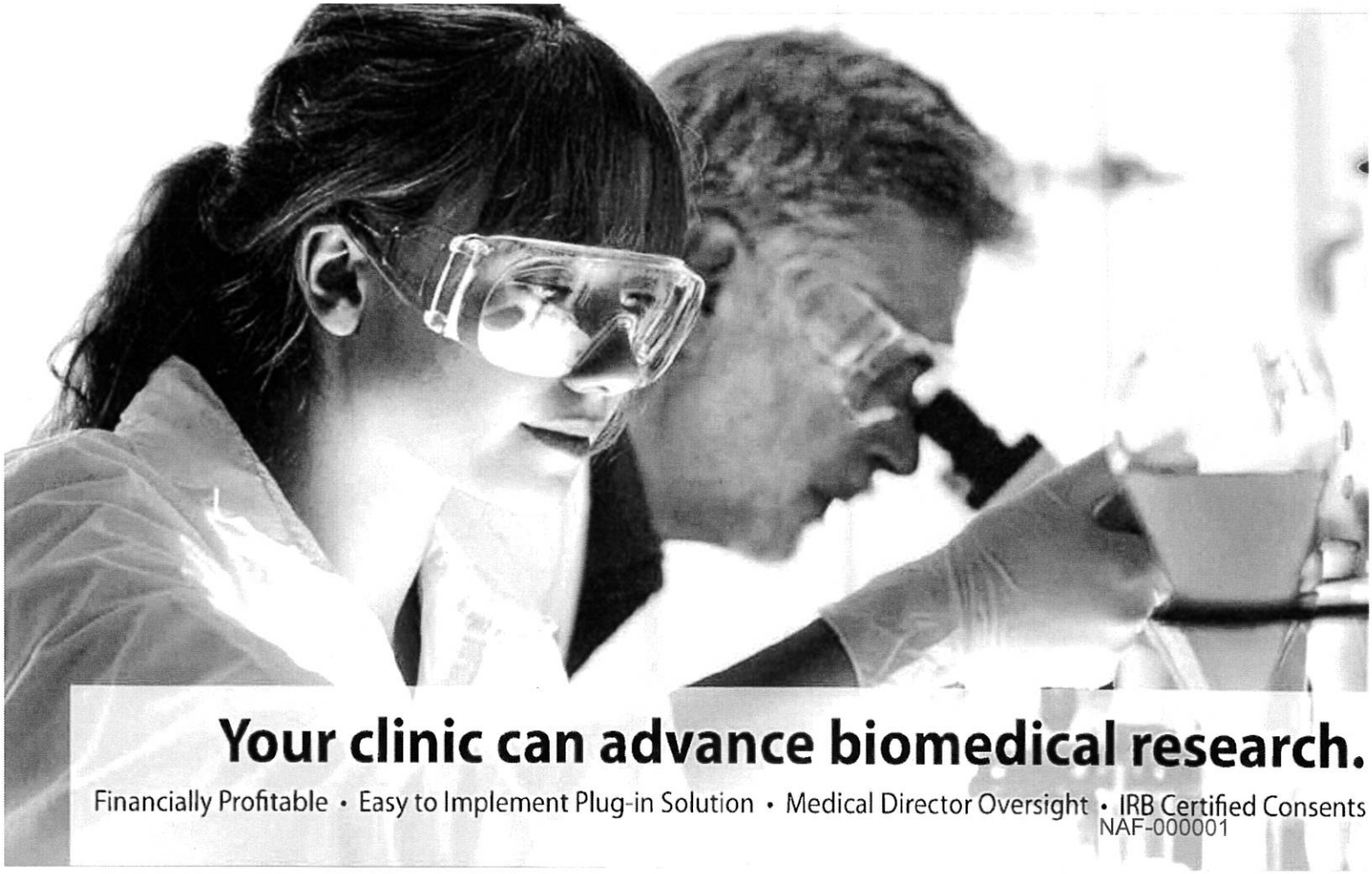
Chairman Emeritus
Title

Fred Fox
Printed Name

February 3, 2015
Date

Attachment O:

StemExpress Marketing Brochure


Your clinic can advance biomedical research.
Financially Profitable • Easy to Implement Plug-in Solution • Medical Director Oversight • IRB Certified Consents
NAF-000001

stem express

[redacted]
778 Pacific St. Placerville, CA 95667
[redacted] stemexpress.com

About StemExpress

StemExpress is a California-based biomedical company that provides qualified research laboratories with human cells, fluids, blood and tissue products for the pursuit of disease detection and cure. We procure, preserve, isolate and deliver cell lines exclusively to research facilities across the world. StemExpress products are not available for patient care. Stem Express is accredited by an independent biomedical Institutional Review Board.

"Our partnership with StemExpress is beneficial in a number of ways. First, it allows us to contribute to life-saving research that is advancing diagnostic and medical care. Second, StemExpress has a Plug-in Solution that allows us to add additional clinics quickly. Lastly, I feel confident that our patient's anonymity is secure through their strict protocols and practices."

– Dr. Dorothy Furgerson, Planned Parenthood-Mar Monte

Advancing BioMedical Research Together

Join the StemExpress 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. StemExpress 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

StemExpress promotes global biomedical research while also providing a financial benefit to your clinic. By partnering with StemExpress, 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 StemExpress to research laboratories with complete professionalism and source anonymity.