DX-68

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

December 1, 2016

VIA EMAIL

The Honorable Ken Paxton
Attorney General
State of Texas
300 W. 15th Street
Austin, TX 78701

Dear Attorney General Paxton:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the practices of entities that procure and transfer fetal tissue.

Over the course of our investigation, we have uncovered documents and received testimony that indicates that Planned Parenthood Gulf Coast ("PPGC"), an abortion facility that procured fetal tissue and transferred it to researchers,[1] allegedly violated state law, including but not limited to the Tex. Penal Code § 48.02, and Tex. Penal Code Title 8 § 37.08.

[1] *See* Select Investigative Panel of the H. Comm. on Energy and Commerce, Interim Update to the U.S. House of Representatives, Jul. 14, 2016, https://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/114/analysis/20160714Interim_Update.pdf.

202.225.2.9022

Background on Planned Parenthood Gulf Coast

PPGC has a research department[2] that conducted studies for pharmaceutical companies,[3] the medical device industry,[4] and academic institutions, mostly in Texas.[5] PPGC procured fetal tissue for the University of Texas Medical Branch, Galveston.[6] PPGC bought its headquarters in 2010 largely because it met the needs of the research department.[7]

PPGC conducts in-house fetal tissue extraction, processing, storage, and shipping.[8] PPGC also ships tissue, but it requires the study sponsors to set up a FedEx account. PPGC prints the air bill, puts the air bill on the container, places the shipment on dry ice, and either has FedEx pick up the shipments or a PPGC staffer will drop it off.[9] PPGC bills customers for any sterile supplies needed for tissue procurement.[10]

Despite those costs incurred by PPGC, there are indications that PPGC made money from its sales of fetal tissue. Melissa Farrell, PPGC's director of research, stated "this research department generates more revenue than the entire OB GYN research program at Baylor [College of] Medicine. . . .multiple, multiple times more revenue."[11]

PPGC Interactions with University of Texas Medical Branch

From 2010 through 2011, PPGC procured fetal tissue for the University of Texas Medical Branch, Galveston ("UTMB").[12] While PPGC personnel generally obtained consent from patients to donate fetal tissue, and procured the tissue, emails produced by UTMB indicate that its personnel also obtained consent from patients and procured the fetal tissue.

October 20, 2010 email from Dr. Regan N. Theiler to Ms. Farrell

In an October 10, 2010 email to Dr. Regan N. Theiler at UTMB, Ms. Farrell wrote:

> We need to renegotiate the budget for both studies based on feedback from [PPGC staff] . . . . here is their proposal:
>
> $50 enrollment/consent process (consent per PPGC SOP, physician statements)[.]

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[2] *See* Center for Medical Progress, "Transcript, Meeting with Melissa Farrell, Director of Research, Planned Parenthood Gulf Coast; Tran Nguyen, Ambulatory Surgery Director, Planned Parenthood Gulf Coast; Dr. Anitra Beasley, Physician, Planned Parenthood Gulf Coast; Medical Assistant, Planned Parenthood Gulf Coats; [and] Two Actors posing as fetal tissue procurement company," Apr. 9, 2015, attachment 1. [hereinafter CMP].
[3] *Id.* at 5.
[4] *Id.* at 6.
[5] *Id.* at 35.
[6] Documents produced by University of Texas Medical Branch.
[7] CMP at 96.
[8] *Id.* at 9, 14, 19-20, 29; 31, 40.
[9] *Id.* at 19-20.
[10] *Id.* at 90.
[11] *Id.*
[12] *Id.* at 7.

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> $100 room set up/collection (strip machines, sterile equipment, rinse hosing with sterile water, biological sample collection) [.]
>
> $50 enrollment/consenting fee if tech leaves without tissue (staff performed the work and tech didn't/couldn't stay to collect sample).
>
> $2000 annual admin fee (new or retraining staff . . . and Research Mgmt oversight, consent storage, supply storage).
>
> It would also be preferable if we amended the contracts to provision $Xamount/yr for a spend-down grant. PPGC is paid in advance for a set number of samples/yr, and then you collect at will . . .. [13]

UTMB invoices and proposed amended contract

UTMB produced invoices to the Panel from PPGC that show PPGC billed UTMB a total of $21,424.98 in annual administrative fees, consent payments, staff training, and supplies.[14]

An unexecuted amended contract between PPGC and UTMB would have provided for the college to pay PPGC $150 for each executed informed consents of patients (up to 500 patients), plus $2,000 in annual administrative fees, and $1,500 for training UTMB staff.[15] Had the contract been executed as drafted, PPGC would have received $75,000 solely for consent forms signed by patients.

April 2011 Planned Parenthood Federation of America memo on fetal tissue donations

On April 4, 2011, Planned Parenthood Federation of America ("PPFA")'s senior director for public policy litigation and law sent a memorandum to affiliate chief executives, affiliate medical directors, and patient service directors, on federal regulations for participation in fetal tissue donation programs.[16] The memorandum notes that applicable federal laws "forbid the payment or receipt of valuable consideration for fetal tissue. However, they permit 'reasonable payments associated with the transportation, implantation, processing, perseveration, quality control, or storage' of fetal tissue."[17]

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[13] Email from Melissa Farrell to Regan N. Theiler, Re: Study, Oct. 1, 2010, attachment 2. [UTMB 321-322].
[14] Invoice from Planned Parenthood Gulf Coast to University of Texas Medical Branch, Nov. 11, 2010 [UTMB 328]; Invoice from Planned Parenthood Gulf Coast to University of Texas Medical Branch, Nov. 11, 2010 [UTMB 329]; Invoice from Planned Parenthood Gulf Coast to University of Texas Medical Branch, Jun. 11, 2011 [UTMB 344]; Invoice from Planned Parenthood Gulf Coast to University of Texas Medical Branch, Sep. 29, 2011 [UTMB 252], attachment 3.
[15] Tissue Supply and Biological Specimen Agreement, Amended No. 2, between Planned Parenthood Gulf Coast, Inc. and Dr. Yallamalli of University of Texas Medical Branch, Jul. 26, 2011, attachment 4. [UTMB 299-301].
[16] Memorandum from Roger Evans, Senior Director, Public Policy Litigation and Law, Planned Parenthood Federation of America; Kate Thomsen, Acting Vice President for Medical Affairs, Planned Parenthood Federation of America; and Sullen Craig, Vice President for Medical Services, Planned Parenthood Federation of America; to Affiliate Chief Executives, Affiliate Medical Directors, [and] Patient Service Directors, Re: Federal regulations for aborted pregnancy tissue donation programs, Apr. 4, 2001, attachment 5. [PPFA-HOU_E&C-000148 – 000150] [hereinafter Evans memo].
[17] Evans memo [PPFA-HOU_E&C-000149].

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The memorandum states that PPFA affiliates "can chose one of two methods to comply with these laws."[18] The methods outlined in the memorandum are:

> One method would be to recover no costs associated with any aspect of participation in a fetal tissue donation program. This would mean that all staff time, clinic space, supplies, etc., would be donated by the affiliate, and the affiliate would receive no payments or in-kind services from the entity to whom the tissue is being donated.
>
> . . . The second method would be to employ an independent auditor to conduct a credible and good-faith analysis of the actual costs incurred by the affiliate in the transportation, implantation, processing, preservation, quality control, or storage of the fetal tissue and, if the research is supported by federal funds, for the removal of the fetal tissue. Under this method, affiliates must maintain careful records of actual tissue donations and of payments received from the researcher or the tissue-gathering entity. Affiliates must be able to demonstrate that the payments do not exceed the actual costs of the actual tissue donations.
>
> Sometimes tissue-gathering entities offer to pay rent for space occupied by one of their employees who would be on-site at a clinic on a regular basis. If an affiliate determines to enter into such an arrangement, then the independent auditor would also conduct a credible and good-faith computation of the actual cost of the space occupied by the tissue-gathering entity employee, in order to determine the amount of rent to be paid by that entity.[19]

The memorandum goes on to "remind affiliates that, in addition to the federal laws outlined above, there are laws in many states governing fetal tissue donation programs. Affiliates must take great care to assure compliance with those laws as well."[20]

January 2011 redistribution of PPFA memo on fetal tissue donation

The April 2001 memorandum was redistributed to PPFA affiliates in January 2011 under the signature of Dr. Deborah Nucatola, then then senior PPFA director for clinical services.[21] The memorandum from Dr. Nucatola sought

> . . . to remind affiliates about the federal law relating to payment for participation in such programs. The attached memo was sent almost exactly 10 years ago (yikes!).

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[18] Evans memo [PPFA-HOU_E&C-000150].
[19] *Id.*
[20] *Id.*
[21] Memorandum from Deborah Nucatola, Senior Director, Clinical Services, Planned Parenthood Federation of America; [and] Karen Shay, Director, Clinical Services, Planned Parenthood Federation of America; to Affiliate Medical Directors, [and] Patient Services Directors, Re: Aborted pregnancy tissue donation programs, Jan. 26. 2011, attachment 6 [PPFA-HOU_E&C-000146].

 202.622.9025

> Given the time that has elapsed and that there has likely been staff turnover, we thought it would be helpful to resend it to assure continuing compliance with the statutes."[22]

PPFA affiliates, including PPGC, were, thus, twice put on notice about the steps they would have to undertake in order to participate in a fetal tissue donation program, and ensure that any reimbursable costs they received did not constitute valuable consideration under the applicable federal and state laws.

Despite that knowledge, the Panel has learned that the costs included in PPGC's contract and proposed contract with UTMB were based not on an independent auditor's credible and good-faith analysis of the actual costs it incurred to procure fetal tissue for UTMB. Rather it was based on back-of-the-envelope calculations by a single PPGC official. The fact that PPGC ignored the long-standing advice of PPFA's legal director when it drafted the UTMB contract and proposed amendment goes directly to PPGC's knowledge of the duty to comply with the applicable law and its willful decision to ignore the legal advice of its organization.

PPGC Interactions with Baylor College of Medicine

Documents produced by the Baylor College of Medicine ("BCM") show that for more than two years, from November 1, 2014 through November 4, 2015, PPGC entered into negotiations to procure fetal tissue for BCM.[23] Those documents show that PPGC assisted BCM with proposals that would be acceptable to the Institutional Review Board ("IRB") at BCM.

November 1, 2014 email from Ann Schutt-Aine of PPGC to Dr. Silke Paust BCM, a copy of which was sent to Dr. Paul Fine, PPGC's medical director, and Ms. Farrell.

The email states Ms. Schutt-Aine was "putting" Dr. Paust "in touch with our Medical Director (Paul Fine) who oversees all research, as well as our Research Director (Melissa Farrell) who will be your primary contact person during the IRB approval/coordination phase."[24]

March 24, 2014 email from Dr. Paust to Ms. Farrell

Dr. Paust wrote: "Thank you for speaking with me today, and for your help with the IRB. Attached, please find my original [IRB] submission, the [PPFA] consent form draft, and the response from the IRB. . . .Please feel free to contact me any time with any questions you may have."[25] Later that same day, Ms. Farrell replied, "Yes, we can do that."[26] Dr. Paust asked, "Would you have time to speak to me on Friday to discuss the IRB comments?"[27] Ms. Farrell stated, "I can be available Monday."[28]

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[22] *Id.*
[23] Documents produced by Baylor College of Medicine.
[24] Email from Ann Schutt-Aine to Silke Paust, cc: Paul Fine, Melissa Farrell, RE: IRB Pediatrics BCM, Nov. 1, 2013, attachment 7.
[25] Email from Silke Paust to Melissa Farrell, Subject RE: IRB pediatrics BCM, Mar. 2014, attachment 8.
[26] Email from Melissa Farrell to Silke Paust, May 20, 2014, 4:51 PM, attachment 8.
[27] Email from Silke Paust to Melissa Farrell, Subject: Re: IRB pediatrics BCM, Jun. 3, 2014, 6:38 PM, attachment 8.
[28] Email from Melissa Farrell to Silke Paust, Jun. 6, 2014, 3:07 PM, attachment 8.

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May 20, 2014 email from Dr. Paust to Ms. Farrell

Dr. Paust sent an email to Ms. Farrell on May 20, 2014 that stated, "I have received the following response to my IRB submission from BCM, and am wondering if you could comment on the bolded sections."[29]

October 20, 2014 email from Supriya Parikh to Ms. Farrell

In an October 20, 2014 email exchange, Supriya Parikh, an assistant to Dr. Paust emailed Ms. Farrell in which she stated, "I want to follow up once more to see if it would be possible to set [up] a time to touch base over the phone sometime this week. I have spoken to our local IRB and need your approval/guidance before I proceed."[30]

October 20, 2014 email from Ms. Farrell to Ms. Parikh

Ms. Farrell replied: "Yes, that would be fine. I have some this afternoon at 2pm. Would that work for you?"[31]

October 20, 2014 email from Ms. Parikh to Ms. Farrell regarding assigned tasks to assist IRB

On October 20, 2014, Ms. Parikh again emailed Ms.:

> Dear Ms. Farrell:
>
> Thank you so much for the productive phone call. I spoke with Dr [sic] Paust after our phone call ended and she was really excited to know we had made so much progress. I have outlined some of her comments/feedback below in red:
>
> Key Discussion Items (Assigned party):
>
> • Check with PPFA if we can use the generic tissue procurement consent or do we need a site-specific IRB approved consent form **(Ms. Farrell)** [sic] – Generic Information/Release/Acknowledgement form is acceptable. Please move forward with submission of the attached form to the IRS for approval. [sic]
>
> • Develop a budget/contract describing the scope of work and approximate time/effort it will take to execute the study. Ms. Farrell will send us a sample contract she executed with UT Galveston. **(Ms. Farrell/Dr** [sic]**Paust)** [sic] – I can't provide this yet as the details of the project that need to be referenced in the contract are still being negotiated. We will need to make specific reference to the fact no remuneration for specimens will occur. Administrative costs only will be included in a budget. [sic]

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[29] Email from Silke Paust to Melissa Farrell, Subject: Re: IRB pediatrics BCM, May 20, 2014, 11:12 AM, attachment 9.
[30] Email from Supriya Parikh to Melissa Farrell, cc: Silke Paust, Subject: Pediatrics research proposal – Dr [sic] Paust/Baylor College of Medicine, Oct. 20, 2014, 8:34 AM, attachment 10.
[31] Email from Melissa Farrell to Supriya Parikh, cc: Silke Paust, Subject: RE: Pediatrics research proposal – Dr [sic] Paust/Baylor College of Medicine, Oct. 20, 2014, 8:42 AM, attachment 10.

• Dr [sic] Paust needs to provide a description of how the tissue should be collected, processed, stored, and transported.

1. RESPONSE [sic]: Dr [sic] Paust would like the fetal cadaveric tissue transported on ice to our site. However, she would like to know if Planned Parenthood would be willing to separate out and send the brain, thymus, spleen and liver and how much would this process cost us? PPGC is unable to dissect the tissue per request. It is also important to understand PPGC performs D&E's so that there's disarticulation versus a whole fetus. [sic]

• Discuss the new gestational age calculation per TX state regulations with Dr [sic] Paust. Ms. Farrell will provide us with the new gestation age calculation formula. (Ms. Farrell/Dr [sic]Paust) The new state limit is 20 weeks post fertilization so 21.6wks LMP, which is how we calculate and our ultrasound machines are calibrated. Therefore, we could collect samples between 20-21.6wks [sic]
• Ms. Farrell would like to have Dr [sic] Paust and her team over for a meeting before the study is ready to get started. RESPONSE: Dr [sic] Paust agrees with the idea. [sic][32]

Draft contract between PPGC and BCM

BCM produced copies of a draft contract with PPGC for the procurement of fetal tissue that were never executed to the Panel. Under the proposed terms, BCM would have been required to pay PPGC $5,700 for 25 executed informed consents, plus "$50 staff time expense involved in obtaining consent and relevant study documentation. This includes consents for which no sample is obtained. Planned Parenthood [Gulf Coast] will consent up to 500 patients,"[33]reimbursement of $100 per-informed consent for sterile procedure room set-up and sample collection, and annual administrative fees of $2,000 for "Surgical Services and Research Management oversight, consent storage, and supply storage. This list is not all inclusive."[34] Had the contract been executed, BCM would have paid PPGC up to $25,000 for 500 consents.

November 17, 2014 email from Ms. Parikh to Ms. Farrell

On November 17, 2014, Ms. Parikh sent Ms. Farrell an email, the subject of which was to "Pediatrics Research Proposal – Dr [sic] Paust/Baylor College of Medicine – IRB Approval Obtained," that stated: "First, I would like to thank you for your support through our IRB review process . . .. Our IRB proposal for your outlining the study procedures/objectives is also attached for your reference. Lastly, I submitted the clinical consent you provided for tissue donation (attached) to BCM IRB and it was deemed acceptable for use."[35]

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[32] Email from Supriya Parikh to Silke Paust; Melissa Farrell, Subject: RE: Pediatrics research proposal – Dr [sic] Paust/Baylor College of Medicine, Oct. 20, 2014, 3:10 PM, attachment 11. (emphasis and red highlights in original).
[33] Tissue Supply and Biological Specimen Agreement between Planned Parenthood Gulf Coast, Inc. and Baylor College of Medicine, attachment 12.
[34] *Id.*
[35] Email from Supriya Parikh to Melissa Farrell, Subject: RE: Pediatrics research proposal – Dr [sic] Paust/Baylor College of Medicine – IRB approval obtained, Nov. 17, 2014, 10:31 AM, attachment 13.

713.582.9028

November 17, 2014 email from Ms. Farrell to Ms. Parikh

Ms. Farrell replied "Thank you!"[36]

Emails demonstrating PPGC knew that BCM IRB approved the fetal tissue research proposal

Multiple email exchanges between Ms. Farrell and persons at BCM show that PPGC knew the BCM IRB had approved the proposal. For example: On July 7, 2015, Ms. Farrell sent an unknown document to Dr. Paust;[37] Dr. Paust replied, "Just to clarify, you would like me to insert specifics on the experiments we plan to perform and replace the highlighted text with that corrected version of our experimental plans?"[38] Ms. Farrell stated, "Yes, please insert any language that is pertinent to the project – this was meant to be a reference only."[39]

Center for Medical Progress videotapes

On July 14, 2015, the Center for Medical Progress ("CMP") began its release of videotapes obtained during the course of its 30-month long investigation into the sale of fetal tissue by PPFA affiliates to tissue procurement companies.[40] The release of the videos prompted several congressional investigations, and led to the Panel's creation by the U.S. House of Representatives.[41] The timing behind the start of CMP's release of its videotapes is relevant in light of how PPGC ended its negotiations with BCM.

October 13, 2015 email from Dr. Paust to Ms. Farrell

On October 13, 2015, Dr. Paust sent Ms. Farrell an email in which she stated:

> Hello Melissa, I hope that you are well and had a great weekend.
>
> In light of recent events, do we need to make a change to our contract?
>
> I still very much believe in the value of my NIH funded studies, and would very much like to proceed it this is possible.[42]

November 4, 2015 email from Ms. Farrell to Dr. Paust

Ms. Farrell did not reply until November 4, 2015, when she stated:

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[36] Email from Melissa Farrell to Supriya Parikh, Nov. 17, 2014, 12:01 PM, attachment 13.
[37] Email from Melissa Farrell to Silke Paust, Jul. 7, 2015, 4:32 PM, attachment 14.
[38] Email from Silke Paust to Melissa Farrell, Subject: RE: Pediatrics research proposal – Dr [sic] Paust/Baylor College of Medicine – IRB approval obtained, Jul. 7, 2015, 4:40 PM, attachment 15.
[39] Email from Melissa Farrell, Jul. 7, 2015, 4:43 PM, attachment 15.
[40] *See* Center for Medical Progress website, http://www.centerformedicalprogress.org/human-capital/ (last visited Nov. 2, 2016).
[41] *Supra* note 1.
[42] Email from Silke Paust to Melissa Farrell, Subject: RE: Pediatrics research proposal – Dr [sic] Paust/Baylor College of Medicine – IRB approval obtained, Oct. 13, 2015, 2:59 PM, attachment 16.

> Silke,
>
> To clarify: we do not have a valid contract, and I did not offer you a contract. I previously provided some exemplar language that should have been included in any contract regarding feta l tissue with the expectation that BCM Grants and Contracts or a BCM attorney would draft a complete contract for both parties to review.
>
> PPGC will not commit to engage in any fetal tissue research endeavors at this time.
>
> I encourage all academic researchers to escalate their need for donated fetal tissue to their department chair, IRB chairs, chancellors, etc. Academic institutions in Texas cannot remain publically silent regarding their need for donated feta l tissue in research, yet have expectations that research collaboration with Planned Parenthood will remain intact.[43]

October 22, 2015 visit by Texas law enforcement to PPGC

On October 22, 2015, nearly a year after PPGC learned that BCM's IRB had given its approval[44] and Ms. Farrell sent her email to Dr. Paust in which she stated that PPGC would not commit to engage in any fetal tissue research endeavors at this time,[45] representatives of the Texas Department of Public Safety Texas Ranger Division, the House Police Department homicide division, and the Harris County district attorney's office visited PPGC headquarters to investigate allegations that PPGC may have violated Tex. Penal Code 48.02[46] The report refers to PPGC as GCPP.

During the course of this visit, PPGC's attorney introduced the law enforcement representatives to Ms. Farrell, who the attorney described as being a "Long time Baylor employee" who "had been instrumental in building the current research program."[47] The Texas Department of Public Safety Texas Ranger Division report stated that:

> [PPGC's attorney] advised that the last collected fetal tissue specimen collected by GCPP for a scientific study was on 07-26-2011, for the University of Texas Medical Branch. GCPP was recently approached by the Baylor College of Medicine and Rice University for fetal tissue studies. **The Institutional Review Board had not yet given approval for the Baylor or Rice studies.**[48]

The emails cited above demonstrate that Ms. Farrell and potentially other PPGC officials knew that BCM's IRB had approved the research project, despite representations of PPGC's attorney to Texas law enforcement officials that no IRB approval had been obtained by BCM. In addition,

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[43] Email from Melissa Farrell to Silk Paust, Subject: RE: Pediatrics research proposal – Dr [sic] Paust/Baylor College of Medicine – IRB approval obtained, Nov. 4, 2015, 2:59 PM, attachment 17.
[44] Attachments 14, 15, 16, 17.
[45] Attachment 17.
[46] *See* Tex. Dept. of Pub. Safety Tex. Ranger Div., Report of Investigation, attachment 18.
[47] *Id.* at 2, paragraph 3.5.
[48] *Id.* at 4, paragraph 3.17. (emphasis added).

 202.842.9030

the Panel has learned that the release of the CMP videotapes was the reason that Ms. Farrell cancelled the negotiations with BCM, and sent her November 4, 2015 email.

Potential Violations of Texas Law

Prohibition of the Purchase and Sale of Human Organs

The Texas Penal Code makes it a misdemeanor if anyone "**knowingly or intentionally offers to buy, offers to sell, acquires, receives, sells, or otherwise transfers** any human organ for valuable consideration."[49] Under the statute, "valuable consideration" does not include "a fee paid to a physician or to other medical personnel for services rendered in the usual course of medical practice or a fee paid for hospital or other clinical services," "reimbursement of legal or medical expenses incurred for the benefit of the ultimate receiver of the organ;" or "reimbursement of expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ."[50]

The statute defines a human organ as "the human kidney, liver, heart, lung, pancreas, eye, bone, skin, **fetal tissue**, or any other human organ or tissue, but does not include hair or blood, blood components (including plasma), blood derivatives, or blood reagents."[51]

False Report to Peace Officer, Federal Special Investigator, or Law Enforcement Employee

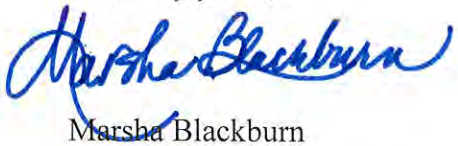
The Texas Penal Code likewise makes it a misdemeanor for a person to lie to a law enforcement officer. The law states:

> A person commits an offense if, with intent to deceive, he knowingly makes a false statement that is material to a criminal investigation and makes the statement to: . . . a peace officer or federal special investigator conducting the investigation; or . . . any employee of a law enforcement agency that is authorized by the agency to conduct the investigation and that the actor knows is conducting the investigation.[52]

[49] Tex. Penal Code § 48.02(b). (emphasis added).
[50] Tex. Penal Code § 48.02(c).
[51] Tex. Penal Code § 48.02(a). (emphasis added).
[52] Tex. Penal Code Title 8, § 37.08.

Based on the facts outlined above and the supporting documentation, I urge your office to conduct a thorough investigation into whether PPGC violated these statutes, and, if you agree that such violations occurred, to take all appropriate action. If you have any questions about this request, please contact T. March Bell at (202) 226-9027, March.Bell@mail.house.gov.

Sincerely yours,



Marsha Blackburn
Chairman
Select Investigative Panel

Attachment

cc: The Honorable Jan Schakowsky
Ranking Member
Select Investigative Panel

CONFIDENTIAL D_0001644 07-31-2015.9032

DX-70

Planned Parenthood
Gulf Coast, Inc.
4600 Gulf Freeway
Houston, Texas 77023
713.522.6240
www.ppgulfcoast.org

75th Anniversary
1936-2011

Date of Invoice: November 11, 2010

Remit to:
Planned Parenthood Gulf Coast, Inc.
4600 Gulf Freeway, Attn: Fiscal R0104
Houston, TX 77023
Invoice Number: UTMB002

Bill to:
Uinversity of Texas Medical Branch
301 University Boulevard
Galveston, TX 77555
Attn: Regan Theiler, MD

Billing Period: February-August 2010

Services	#	Amount	Total
2010-2011 Annual Admin Fee	1	$2.000.00	$2,000.00
2010-2011 Consent Payment	25	$150.00	$3,750.00
Total Due:			$5,750.00

11/11/10

A plan you can love with.

CONFIDENTIAL D_0001647
713.522.9034

Planned Parenthood
Gulf Coast, Inc.
4600 Gulf Freeway
Houston, Texas 77023
713.522.6240
www.ppgulfcoast.org

75th Anniversary
1936-2011

Date of Invoice: November 11, 2010

Remit to:
Planned Parenthood Gulf Coast, Inc.
4600 Gulf Freeway, Attn: Fiscal R0104
Houston, TX 77023
Invoice Number: UTMB001

Bill to:
Uinversity of Texas Medical Branch
301 University Boulevard
Galveston, TX 77555
Attn: Regan Theiler, MD

Billing Period: February-August 2010

Services	#	Amount	Total
CITI Staff Training - 2010	7	$1,500.00	$1,500.00
2010 Consents obtained	32	$25.00	$800.00
Total Due:			$2,300.00

MTaull 11/8/10

A plan you can love with.

CONFIDENTIAL

07-51648.9035

Planned Parenthood
Gulf Coast, Inc.
4600 Gulf Freeway
Houston, Texas 77023
713.522.6240
www.ppgulfcoast.org

75th Anniversary
1936-2011

Date of Invoice: June 21, 2011

Remit to:
Planned Parenthood Gulf Coast, Inc.
4600 Gulf Freeway, Attn: Fiscal R0104
Houston, TX 77023
Invoice Number: UTMB003

Bill to:
University of Texas Medical Branch
301 University Boulevard
Galveston, TX 77555
Attn: Regan Theiler, MD

Billing Period: January 2011-June 2011

Services	#	Amount	Total
Reimbursement for study supplies			$574.98
Consent Payment	12	$150.00	$1,800.00
Total Due:			$2,374.98

MTaseff PW 6/21/11

A plan you can love with.

UTMB 344

Planned Parenthood
Gulf Coast, Inc.
4600 Gulf Freeway
Houston, Texas 77023
713.522.6240
www.ppgulfcoast.org

75th Anniversary
1936-2011

Date of Invoice: September 29, 2011

Remit to:
Planned Parenthood Gulf Coast, Inc.
4600 Gulf Freeway, Attn: Fiscal R0104
Houston, TX 77023
Invoice Number: UTMB-9-2011

Bill to:
University of Texas Medical Branch
301 University Boulevard
Galveston, TX 77555
Attn: Elizabeth Powell or Dr. Yamampalli

Billing Period: Advance payment for up to 50 consent forms for 2011-2012 and associated site fees per contract

Services	#	Amount	Total
Advance Payment for 50 consents	50	$150.00	$7,500.00
CITI Training of new staff		$1,500.00	$1,500.00
Annual Admininstration Fee		$2,000.00	$2,000.00
Total Due:			$11,000.00

9/29/11

A plan you can love with.

DX-72

From: **Schutt-Aine, Ann** AnnSchutt-Aine@pgalliance.org
Subject: RE: IRB Pediatrics BCM
Date: November 1, 2013 at 9:31 AM
To: Paust, Silke Silke.Paust@bcm.edu
Cc: Fine, Paul PaulFine@pgalliance.org, Farrell, Melissa MelissaFarrell@pgalliance.org

Hi Silke:
I'm hopeful that this will work out.

By way of this e-mail, I'm putting you in touch with our Medical Director (Paul Fine) who oversees all research, as well as our Research Director (Melissa Farrell), who will be your primary contact person during the IRB approval/coordination phase. Once everything is approved and we're ready to move forward with specimen collection, you'll likely be coordinating with our surgical center manager to coordinate the details of you (or your designee) actually coming to get the tissue.

Paul and Melissa – Dr. Paust is a BCM PhD working in the department of pediatrics in regenerative medicine. He is hoping to collect immune tissue from second trimester D&E samples. I'll let him share the details of his exciting work.

Take care.

Ann

From: Paust, Silke [mailto:Silke.Paust@bcm.edu]
Sent: Thursday, October 31, 2013 4:07 PM
To: Schutt-Aine, Ann
Subject: IRB Pediatrics BCM

Hello Ann,

Thank you for your help with this matter. I am working on the IRB, and may have a draft to share by next week. Please feel free to contact me with any questions or suggestions you may have.

Best,

Silke

Silke Paust Ph.D.
Assistant Professor

Center for Human Immunobiology
Department of Pediatrics
Section of Allergy, Immunology, & Rheumatology
Baylor College of Medicine
Texas Children's Hospital
Feigin Center FC 330.02
1102 Bates, Houston TX 77030

Phone: 832-824-2588

DX-73

From: **Paust, Silke** Silke.Paust@bcm.edu
Subject: Re: IRB Pediatrics BCM
Date: March 24, 2014 at 1:55 PM
To: Farrell, Melissa Melissa.Farrell@ppgulfcoast.org

Thank you Melissa!

Best wishes,

Silke

Silke Paust Ph.D.
Assistant Professor
Baylor College of Medicine
Center for Human Immunobiology
Department of Pediatrics
Texas Children's Hospital
Feigin Center FC 330.02
1102 Bates, Houston TX 77030

Phone: 832-824-2588
Fax: 832-825-1260
email: silke.paust@bcm.edu

On Mar 24, 2014, at 1:42 PM, "Farrell, Melissa" <Melissa.Farrell@ppgulfcoast.org> wrote:

> Hi Silke,
>
> Here is the reg
>
> http://www.hhs.gov/ohrp/policy/publiclaw103-43.htm.html
>
> I've attached our policy.
>
> Please let me know if I can be of additional assistance.
>
> Kind regards,
> Missy
>
> Melissa Farrell, RN, BSN, CCRC
> Research Director
> Planned Parenthood
> 4600 Gulf Freeway
> Houston, TX 77023
> PH: 713-831-6561
>
> This message contains information which may be confidential and privileged. Unless you are the addressee (or authorized to receive for the addressee), you many not use, copy or disclose to anyone the message or any information contained in the message. If you have received the message in error, please advise the sender by replying and delete the message
>
> -----Original Message-----
> From: Paust, Silke [mailto Silke.Paust@bcm.edu]
> Sent: Monday, March 24, 2014 10:07 AM
> To: Farrell, Melissa
> Subject: RE: IRB Pediatrics BCM
>
> Hi Melissa,
>
> Thank you for speaking with me today, and for your help with the IRB. Attached, please find my original submission, the consent form draft, and the response from the IRB. I left one of my responses (not yet submitted) regarding the specifics of the sequencing in the response letter. Please feel free to contact me any time with any questions you may have. My cell doesn't have very good reception in my office, but if you leave a message, I will call you right back, or you can also reach me at 832-824-2588 (office), or via email.
>
> Best wishes,
>
> Silke

DX-74

From: **Farrell, Melissa** Melissa.Farrell@ppgulfcoast.org
Subject: RE: IRB Pediatrics BCM
Date: May 20, 2014 at 4:51 PM
To: **Paust, Silke** Silke.Paust@bcm.edu

Hi Silke,

Yes, I can do that. I will be out of the office until Tue next week. I will get back to you then.

Missy

Planned Parenthood
Care. No matter what.
Melissa Farrell, RN, BSN, CCRC
Research Director
Planned Parenthood
4600 Gulf Freeway
Houston, TX 77023
PH: 713-831-6561

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From: Paust, Silke [mailto:Silke.Paust@bcm.edu]
Sent: Tuesday, May 20, 2014 11:12 AM
To: Farrell, Melissa
Subject: Re: IRB Pediatrics BCM

Hello Melissa,

I hope this email finds you well and you had a wonderful weekend.

I received the following response to my IRB submission from BCM, and am wondering if you could comment on the bolded sections. Would these changes be agreeable? I am also happy to discuss by phone. I attached a copy of my IRB and consent form draft below.

Thank you!

Silke
Note to PI:
For any research activity to be considered human subjects research, the investigator (whether professional or student) obtains information about an individual that is either (1) Data through intervention or interaction with the individual, or (2) Identifiable private information obtained from a living individual. In this protocol, the fetal cadavers are not human subjects because they are not living individuals, and therefore, not subject to the research regulations under 45 CFR 46. The IRB suggests that this might not qualify as human subjects research if the PI is is not interacting with pregnant women but is only obtaining fetal tissue after termination of pregnancy.
1. The IRB understands that you plan to obtain tissue from aborted fetuses to use to make humanized mouse models to study vaccines. The informed consent document that was submitted it is not directed to the pregnant women as the subject [terminated fetus cannot be a subject as they will be deceased and therefore

From: **Paust, Silke** Silke.Paust@bcm.edu
Subject: Re: IRB Pediatrics BCM
Date: May 20, 2014 at 11:12 AM
To: Farrell, Melissa Melissa.Farrell@ppaudicoast.org

Hello Melissa,

I hope this email finds you well and you had a wonderful weekend.

I received the following response to my IRB submission from BCM, and am wondering if you could comment on the bolded sections. Would these changes be agreeable? I am also happy to discuss by phone. I attached a copy of my IRB and consent form draft below.

Thank you!

Silke

Note to PI:

For any research activity to be considered human subjects research, the investigator (whether professional or student) obtains information about an individual that is either (1) Data through intervention or interaction with the individual, or (2) Identifiable private information obtained from a living individual. In this protocol, the fetal cadavers are not human subjects because they are not living individuals, and therefore, not subject to the research regulations under 45 CFR 46. The IRB suggests that this might not qualify as human subjects research if the PI is is not interacting with pregnant women but is only obtaining fetal tissue after termination of pregnancy.

1. The IRB understands that you plan to obtain tissue from aborted fetuses to use to make humanized mouse models to study vaccines. The informed consent document that was submitted it is not directed to the pregnant women as the subject [terminated fetus cannot be a subject as they will be deceased and therefore not meeting the definition of "human subject" HHS federal regulation 45CFR46.102(f)]. **Please revise the consent form to reflect the pregnant woman as the subject.**

Please clarify who will obtain informed consent for research and what constitutes their training and experience with research informed consent.

2. Per protocol, your research population includes fetal cadavers procured after an abortion at Planned Parenthood to generate humanized mice. We believe that you are telling the IRB that Planned Parenthood requires a research consent form to consent patients before obtaining the research specimen. Please clarify in the protocol summary this requirement, as it seems that this research study does not constitute human subject research and does not fall under the IRB's purview according to federal regulations and the Common Rule. Perhaps a separate clinical (non-research) consent form would be acceptable to Planned Parenthood. This clinical (not research) consent form could be attached to section S of the protocol summary (along with the removal of the research consent in section Q) to complete the protocol file.

IRB draft Paust.pdf

IRB Consent From draft.pdf

Best wishes,

Silke

Silke Paust Ph.D.
Assistant Professor
Baylor College of Medicine

DX-75

From: **Farrell, Melissa** [redacted]
Subject: RE: IRB Pediatrics BCM
Date: June 6, 2014 at 3:07 PM
To: Paust, Silke [redacted]

Hi Silke,

I've been intermittently in the office this week. I can be available Monday.

Missy

Planned Parenthood
Care. No matter what.
Melissa Farrell, RN, BSN, CCRC
Research Director
Planned Parenthood
4600 Gulf Freeway
Houston, TX 77023
PH: 713-831-6561

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From: Paust, Silke [mailto:Silke.Paust@bcm.edu]
Sent: Tuesday, June 03, 2014 6:38 PM
To: Farrell, Melissa
Subject: Re: IRB Pediatrics BCM

Hi Missy,

I hope you had a nice time off.

Would you have time to speak to me on Friday to discuss the IRB comments?

Best wishes,

Silke

Silke Paust Ph.D.
Assistant Professor
Baylor College of Medicine
Center for Human Immunobiology
Department of Pediatrics
Texas Children's Hospital
Feigin Center FC 330.02
1102 Bates, Houston TX 77030

DX-76

I'm back at my desk—sorry about that—had a meeting held over.

[cid:image001.jpg@01CFEC6E.B328FFC0]
Melissa Farrell, RN, BSN, CCRC
Research Director
Planned Parenthood
4600 Gulf Freeway
Houston, TX 77023
PH: 713-831-6561
This message contains information which may be confidential and privileged. Unless you are the addressee (or authorized to receive for the addressee), you many not use, copy or disclose to anyone the message or any information contained in the message. If you have received the message in error, please advise the sender by replying and delete the message

From: Parikh, Supriya [mailto:Supriya.Parikh@bcm.edu]
Sent: Monday, October 20, 2014 8:43 AM
To: Farrell, Melissa
Cc: Paust, Silke
Subject: RE: Pediatrics Research Proposal- Dr Paust/Baylor College of Medicine

Sure- that works perfectly.

I will send out a calendar invite.

Supriya

From: Farrell, Melissa [mailto:Melissa.Farrell@ppgulfcoast.org]
Sent: Monday, October 20, 2014 8:42 AM
To: Parikh, Supriya
Cc: Paust, Silke
Subject: RE: Pediatrics Research Proposal- Dr Paust/Baylor College of Medicine

Dear Supriya,

Yes, that would be fine. I have some time this afternoon at 2pm. Would that work for you?

Missy

[cid:image001.jpg@01CFEC6E.B328FFC0]
Melissa Farrell, RN, BSN, CCRC
Research Director
Planned Parenthood
4600 Gulf Freeway
Houston, TX 77023
PH: 713-831-6561
This message contains information which may be confidential and privileged. Unless you are the addressee (or authorized to receive for the addressee), you many not use, copy or disclose to anyone the message or any information contained in the message. If you have received the message in error, please advise the sender by replying and delete the message

From: Parikh, Supriya [mailto:Supriya.Parikh@bcm.edu]
Sent: Monday, October 20, 2014 8:34 AM
To: Farrell, Melissa
Cc: Paust, Silke
Subject: Pediatrics Research Proposal- Dr Paust/Baylor College of Medicine
Importance: High

Dear Ms. Farrell:

I work with Dr Paust on the pediatrics protocol involving the use of fetal tissue to create humanized mice.

I wanted to follow up once more to see if it would be possible to set a time to touch base over the phone sometime this week. I have spoken to our local IRB and need your approval/guidance before I proceed.

Look forward to hearing from you.

Thanks,
Supriya

Supriya G. Parikh
Research Resources Office
Feigin Center - Suite# 1590
Phone:832-824-3379; Fax: 832-825-4107
Email: sxparikh@texaschildrens.org<mailto:sxparikh@texaschildrens.org>

From: Farrell, Melissa [mailto:Melissa.Farrell@ppgulfcoast.org]
Sent: Monday, September 08, 2014 5:11 PM
To: Paust, Silke; Parikh, Supriya
Subject: RE: IRB Pediatrics BCM

Hello Silke,

Pardon my delayed reply. Your emails are being routed to my junk folder somehow. Yes, please have Supriya contact me.

Missy

[cid:image001.jpg@01CFEC6E.B328FFC0]
Melissa Farrell, RN, BSN, CCRC
Research Director
Planned Parenthood
4600 Gulf Freeway
Houston, TX 77023
PH: 713-831-6561
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From: Paust, Silke [mailto:Silke.Paust@bcm.edu]
Sent: Tuesday, August 26, 2014 3:38 PM
To: Farrell, Melissa; Parikh, Supriya
Subject: Fwd: IRB Pediatrics BCM

Hello Melissa,

I hope this email finds you well. I would like to introduce Supriya Parikh from our Pediatrics-Research Resources Office. She will take over the finalizing of the IRB.

Would it be ok if she contacted you with any questions she may be having?

DX-77

I just completed a phone call with my counterpart at the national office at 1pm. Please see responses below in RED:

Missy

Planned Parenthood
Care. No matter what.
Melissa Farrell, RN, BSN, CCRC
Research Director
Planned Parenthood
4600 Gulf Freeway
Houston, TX 77023
PH: 713-831-6561

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---

From: Parikh, Supriya [mailto:Supriya.Parikh@bcm.edu]
Sent: Wednesday, October 22, 2014 1:23 PM
To: Paust, Silke; Farrell, Melissa
Cc: Damron, Allison Rebecca
Subject: RE: Pediatrics Research Proposal- Dr Paust/Baylor College of Medicine
Importance: High

Dear Ms. Farrell:

I just wanted to touch base to see if you'd heard back from the PPFA group?

Thank you in advance for all your help!
Supriya

From: Parikh, Supriya
Sent: Monday, October 20, 2014 3:10 PM
To: Paust, Silke; Farrell, Melissa
Cc: Damron, Allison Rebecca; Bomgaars, Lisa (LBOMGAARS@texaschildrens.org)
Subject: RE: Pediatrics Research Proposal- Dr Paust/Baylor College of Medicine

Dear Ms. Farrell:

Thank you so much for the productive phone call. I spoke with Dr Paust after our phone call ended and she was really excited to know we had made so much progress. I have outlined some of her comments/feedback below in red:

Key Discussion Items **(Assigned party)**:

- Check with PPFA if we can use the generic tissue procurement consent or do we need a site-specific IRB approved consent form **(Ms. Farrell)** – *Generic Information/Release/Acknowledgement form is acceptable. Please move forward with submission of the attached form to the IRB for approval.*

- Develop a budget/contract describing the scope of work and approximate time/effort it will take to execute the study. Ms. Farrell will send us a sample contract she executed with UT Galveston. **(Ms. Farrell/Dr Paust)** – *I can't provide this yet as the details of the project that need to be referenced in the contract are still being negotiated. We will need to make specific reference to the fact no remuneration for specimens will occur. Administrative costs only will be included in a budget.*
- Dr Paust needs to provide a description of how the tissue should be collected, processed, stored, and transported.

1. *RESPONSE: Dr Paust would like the fetal cadaveric tissue transported on ice to our site. However, she would like to know if Planned Parenthood would be willing to separate out and send the brain, thymus, spleen and liver and how much would this process cost us? PPGC is unable to dissect the tissue per request. It is also important to understand PPGC performs D&E's so that there's disarticulation versus a whole fetus.*

- Discuss the new gestational age calculation per TX state regulations with Dr Paust. Ms. Farrell will provide us with the new gestation age calculation formula. **(Ms. Farrell/Dr Paust)** *The new state limit is 20 weeks post fertilization so 21.6wks LMP, which is how we calculate and our ultrasound machines are calibrated. Therefore, we could collect samples between 20-21.6wks*
- Ms. Farrell would like to have Dr Paust and her team over for a meeting before the study is ready to get started.

RESPONSE: Dr Paust agrees with the idea.

Thanks,
Supriya

-----Original Message-----
From: Paust, Silke
Sent: Monday, October 20, 2014 2:09 PM
To: Farrell, Melissa; Parikh, Supriya
Subject: RE: Pediatrics Research Proposal- Dr Paust/Baylor College of Medicine

Hello,

I just called the number on the invite, but got Melissa's voice mail. Should I be part of this call?

Best wishes,

Silke

Silke Paust Ph.D.
Assistant Professor
Center for Human Immunobiology
Department of Pediatrics
Section of Allergy, Immunology, & Rheumatology Feigin Center FC 330.12
1102 Bates, Houston TX 77030
Texas Children's Hospital
Baylor College of Medicine

Phone: 832-824-2588
Fax: 832-825-1260
email: silke.paust@bcm.edu

From: Farrell, Melissa [Melissa.Farrell@ppgulfcoast.org]
Sent: Monday, October 20, 2014 2:04 PM
To: Parikh, Supriya
Cc: Paust, Silke
Subject: RE: Pediatrics Research Proposal- Dr Paust/Baylor College of Medicine

DX-78

TISSUE SUPPLY AND BIOLOGICAL SPECIMEN AGREEMENT
Between
PLANNED PARENTHOOD GULF COAST, INC.
And
University _____

This Tissue Supply and Biological Specimen Agreement is entered into and made effective on _____ by and between ~~Dr. Baylor~~ Baylor College of Medicine ("Baylor") with offices at One Baylor Plaza, Houston, TX 77030 and Planned Parenthood Gulf Coast, Inc. with offices at 4600 Gulf Freeway, Houston, TX 77023.

WHEREAS, ~~Dr. Baylor~~_____ and Planned Parenthood desire to amend the Agreement as set forth in this Amendment and its Attachments, if any.

WHEREAS, ~~Dr. Baylor~~_____ desires to utilize biological specimens (i.e. blood and urine) and donated fetal tissue for staining, culture, and isolation of cell lines. The difference in growth, adhesion, and invasion will be compared between normal (elective abortus) and abnormal (spontaneous abortus) tissue and between control tissues. No tissue will be used to perform stem cell isolation or stem cell experimentation.

WHEREAS, Planned Parenthood has access to such tissue and, with appropriate informed consent, can supply such tissue to ~~Dr. Baylor~~_____.

NOW THEREFORE, the parties agree as follows:

1. **SUPPLY OF TISSUE AND BIOLOGICAL SPECIMENS**

During the period of this Agreement:

a. Planned Parenthood shall supply donated tissue to ~~Dr. Baylor~~_____ for the isolation of cell lines. Tissue will be collected at the site by personnel, and after it has been examined by the appropriate Planned Parenthood staff, it will be released to ~~Dr. Baylor~~_____.
b. Planned Parenthood shall supply biological specimens (i.e. blood and urine) collected during standard of care procedures.

2. **PAYMENT**

a. ~~Dr. Baylor~~_____ will make no direct payments for the tissue, which will be donated for research purposes after informed consent is obtained from patients by Planned Parenthood personnel.
b. Annually each October for the life of this agreement, ~~Dr. Baylor~~_____ will make a payment of $5,750 to Planned Parenthood Gulf Coast for 25 executed informed consents and associated fees as detailed below to be obtained the proximal year between October and September. This funding will be renewed annually.

i. ~~Dr. Baylor~~_____ will reimburse Planned Parenthood $50 for staff time expense involved in obtaining consent and relevant study documentation. This includes consents for which no sample is obtained. Planned Parenthood will consent up to 500 patients.

ii. ~~Dr. Baylor~~_____ will reimburse Planned Parenthood $100 per executed informed consent for sterile procedure room set-up and sample collection including but not limited to strip machines, sterile equipment, rinse hosing with sterile water, and biological sample collections to be performed by Planned Parenthood staff.

iii. ~~Dr. Baylor~~_____ will reimburse Planned Parenthood an annual administrative fee of $2000 which includes Surgical Services and Research Management oversight, consent storage, and supply storage. This list is not all inclusive.

c. If within the course of the study the need arises for additional subject enrollment beyond 25 within a year, this number can be increased with mutual agreement by both parties. Planned Parenthood will invoice ~~Dr. Baylor~~_____ for these additional costs on a monthly basis. ~~Dr. Baylor~~_____ will pay invoices within 30 days of receipt. Failure to pay invoices will result in immediate halt of study enrollment.

d. ~~Any~~ Ttraining of two staff members shall accrue a fee separate from the annual administrative fee. Dr. Baylor_____ will reimburse Planned Parenthood $3000~~1,500~~ for expenses related to staff time utilized in CITI Training required by the UTMB Institutional Review Board[1]. This reimbursement will be paid by ~~Dr.~~ Baylor_____ upon receipt of certificates of training by Planned Parenthood Staff.

3. OWNERSHIP

a. ~~Dr. Baylor~~_____ shall own all rights relating to the cells or cell lines derived from the donated tissue. This includes the cells themselves and any patents or inventions using or derived from the cells or cell lines.

4. REPORTS

a. ~~Dr. Baylor~~_____ shall supply reports to Planned Parenthood on an annual basis regarding the progress of the project and disposition of the tissue, including annual IRB review and revised, IRB approved consent forms.[2]

5. TERM AND TERMINATION

a. Unless terminated earlier, the Term of this Agreement shall expire upon written notice from ~~Dr. Baylor~~_____ that the project is complete.

b. Either party may terminate this Agreement at any time upon delivery of sixty days (60) notice of such termination.

6. INDEMINIFICATION

a. ~~Dr. Baylor~~_____ agrees to indemnify, defend and hold Planned Parenthood harmless from and against any and all lawsuits, claims, actions, demands, or liabilities (including reasonable attorney's fees) which may be made against or

512.482.9059

incurred by Planned Parenthood involving the supply of tissue to ~~Dr.~~ Baylor_____ except in case involving informed consent. ~~Dr.~~ Baylor_____ relies entirely upon Planned Parenthood to obtain such consent.

In witness whereof, the duly authorized representatives of each of the parties hereto have executed this Amendment.

PLANNED PARENTHOOD GULF COAST, INC.

BY_____ DATE _____
PPGC CEO

BaylorUNIVERSITY _____

BY_____ DATE _____
Michael B. Dilling Ph.D., CLP~~Dr.~~

Read and Understood by:

Dr. Silke Paust

07.31.2012.9060

TISSUE SUPPLY AND BIOLOGICAL SPECIMEN AGREEMENT
Between
PLANNED PARENTHOOD GULF COAST, INC.
And
~~University~~ Baylor College of Medicine

This Tissue Supply and Biological Specimen Agreement is entered into and made effective on ~~_____~~ 7/1/15 by and between Baylor College of Medicine ("Baylor") with offices at One Baylor Plaza, Houston, TX 77030 and Planned Parenthood Gulf Coast, Inc. (Institution) with offices at 4600 Gulf Freeway, Houston, TX 77023.

WHEREAS, Baylor~~_____~~ and Planned Parenthood desire to ~~amend~~ enter into this agreement to govern the relationship between the parties and to define the conditions under which Institution will perform services and supply biologic materials; ~~the Agreement as set forth in this Amendment and its Attachments, if any.~~

WHEREAS, Baylor~~_____~~ desires to utilize biological specimens (i.e. blood and urine) and donated fetal tissue for staining, culture, and isolation of cell lines. The difference in growth, adhesion, and invasion will be compared between normal (elective abortus) and abnormal (spontaneous abortus) tissue and between control tissues. No tissue will be used to perform stem cell isolation or stem cell experimentation.

WHEREAS, Planned Parenthood has access to such tissue and, with appropriate informed consent, can supply such tissue to Baylor~~_____~~.

NOW THEREFORE, the parties agree as follows:

1. SUPPLY OF TISSUE AND BIOLOGICAL SPECIMENS

During the period of this Agreement:

a. Planned Parenthood shall supply donated tissue to Baylor~~_____~~ for the isolation of cell lines. Tissue will be collected at the site by personnel, and after it has been examined by the appropriate Planned Parenthood staff, it will be released to Baylor.~~_____~~.
b. Planned Parenthood shall supply biological specimens (i.e. blood and urine) collected during standard of care procedures.

2. PAYMENT

a. Baylor~~_____~~ will make no direct payments for the tissue, which will be donated for research purposes after informed consent is obtained from patients by Planned Parenthood personnel.
b. Annually each October for the life of this agreement, Baylor~~_____~~ will make an advanced payment of $5,750 to Planned Parenthood Gulf Coast, Inc. for 25 executed informed consents and associated fees as detailed below to be

obtained the proximal year between October and September. This funding ~~will~~ may be be renewed annually upon mutual agreement by both parties.

i. ~~Dr.~~ Baylor_____ will reimburse Planned Parenthood $50 for staff time expense involved in obtaining consent and relevant study documentation. This includes consents for which no sample is obtained. Planned Parenthood will consent up to ~~500~~ 100 patients.

ii. ~~Dr.~~ Baylor_____ will reimburse Planned Parenthood $100 per executed informed consent for sterile procedure room set-up and sample collection including but not limited to strip machines, sterile equipment, rinse hosing with sterile water, and biological sample collections to be performed by Planned Parenthood staff.

iii. ~~Dr.~~ Baylor_____ will reimburse Planned Parenthood an annual administrative fee of $2000 which includes Surgical Services and Research Management oversight, consent storage, and supply storage. This list is not all inclusive.

c. If within the course of the study the need arises for additional subject enrollment beyond 25 within a year, this number can be increased with mutual agreement by both parties. Planned Parenthood will invoice ~~Dr.~~ Baylor_____ for these additional costs on a monthly basis. ~~Dr.~~ Baylor_____ will pay invoices within 30 days of receipt. Failure to pay invoices will result in immediate halt of study enrollment.

d. ~~Any~~ Ttraining of two staff members shall accrue a fee separate from the annual administrative fee. ~~Dr.~~ Baylor_____ will reimburse Planned Parenthood $3000~~1,500~~ for expenses related to staff time utilized in CITI Training required by ~~the UTMB Institutional Review Board~~[1]Baylor and the Baylor IRB. This reimbursement will be paid by ~~Dr.~~ Baylor_____ upon receipt of certificates of training by Planned Parenthood Staff.

3. OWNERSHIP

a. ~~Dr.~~ Baylor_____ shall own all rights relating to the cells or cell lines derived from the donated tissue. This includes the cells themselves and any patents or inventions using or derived from the cells or cell lines.

4. REPORTS

a. ~~Dr.~~ Baylor_____ shall supply reports to Planned Parenthood on an annual basis regarding the progress of the project and disposition of the tissue, including annual IRB review and revised, IRB approved consent forms.[2]

5. TERM AND TERMINATION

a. Unless terminated earlier, the Term of this Agreement shall expire upon written notice from ~~Dr.~~ Baylor_____ that the project is complete.

b. Either party may terminate this Agreement at any time upon delivery of sixty days (60) notice of such termination.

6. INDEMINIFICATION

a. ~~Dr.~~ Baylor_____ agrees to indemnify, defend and hold Planned Parenthood harmless from and against any and all lawsuits, claims, actions, demands, or liabilities (including reasonable attorney's fees) which may be made against or incurred by Planned Parenthood involving the supply of tissue to ~~Dr.~~ Baylor _____ except in case involving informed consent. ~~Dr.~~ Baylor_____ relies entirely upon Planned Parenthood to obtain such consent.

In witness whereof, the duly authorized representatives of each of the parties hereto have executed this Amendment.

PLANNED PARENTHOOD GULF COAST, INC.

BY_____ DATE _____
PPGC CEO

Baylor~~UNIVERSITY~~ _____

BY_____ DATE _____
Michael B. Dilling Ph.D., CLP~~Dr.~~_____

Read and Understood by:

Dr. Silke Paust

07/31/2012.9063

TISSUE SUPPLY AND BIOLOGICAL SPECIMEN AGREEMENT
Between
PLANNED PARENTHOOD GULF COAST, INC.
And
University _____

This Tissue Supply and Biological Specimen Agreement is entered into and made effective on _____ by and between Dr. _____ with offices at _____ and Planned Parenthood Gulf Coast, Inc. with offices at 4600 Gulf Freeway, Houston, TX 77023.

WHEREAS, Dr. _____ and Planned Parenthood desire to amend the Agreement as set forth in this Amendment and its Attachments, if any.

WHEREAS, Dr. _____ desires to utilize biological specimens (i.e. blood and urine) and donated fetal tissue for staining, culture, and isolation of cell lines. The difference in growth, adhesion, and invasion will be compared between normal (elective abortus) and abnormal (spontaneous abortus) tissue and between control tissues. No tissue will be used to perform stem cell isolation or stem cell experimentation.

WHEREAS, Planned Parenthood has access to such tissue and, with appropriate informed consent, can supply such tissue to Dr. _____.

NOW THEREFORE, the parties agree as follows:

1. SUPPLY OF TISSUE AND BIOLOGICAL SPECIMENS

During the period of this Agreement:

a. Planned Parenthood shall supply donated tissue to Dr. _____ for the isolation of cell lines. Tissue will be collected at the site by personnel, and after it has been examined by the appropriate Planned Parenthood staff, it will be released to Dr. _____.
b. Planned Parenthood shall supply biological specimens (i.e. blood and urine) collected during standard of care procedures.

2. PAYMENT

a. Dr. _____ will make no direct payments for the tissue, which will be donated for research purposes after informed consent is obtained from patients by Planned Parenthood personnel.
b. Annually each October for the life of this agreement, Dr. _____ will make a payment of $5,750 to Planned Parenthood Gulf Coast for 25 executed informed consents and associated fees as detailed below to be obtained the proximal year between October and September. This funding will be renewed annually.
    i. Dr. _____ will reimburse Planned Parenthood $50 for staff time expense involved in obtaining consent and relevant study documentation.

This includes consents for which no sample is obtained. Planned Parenthood will consent up to 500 patients.

ii. Dr. _____ will reimburse Planned Parenthood $100 per executed informed consent for sterile procedure room set-up and sample collection including but not limited to strip machines, sterile equipment, rinse hosing with sterile water, and biological sample collections to be performed by Planned Parenthood staff.

iii. Dr. _____ will reimburse Planned Parenthood an annual administrative fee of $2000 which includes Surgical Services and Research Management oversight, consent storage, and supply storage. This list is not all inclusive.

c. If within the course of the study the need arises for additional subject enrollment beyond 25 within a year, this number can be increased with mutual agreement by both parties. Planned Parenthood will invoice Dr. _____ for these additional costs on a monthly basis. Dr. _____ will pay invoices within 30 days of receipt. Failure to pay invoices will result in immediate halt of study enrollment.

d. Any training of staff members shall accrue a fee separate from the annual administrative fee. Dr. _____ will reimburse Planned Parenthood $1,500 for expenses related to staff time utilized in CITI Training required by the UTMB Institutional Review Board. This reimbursement will be paid by Dr. _____ upon receipt of certificates of training by Planned Parenthood Staff.

3. **OWNERSHIP**

a. Dr. _____ shall own all rights relating to the cells or cell lines derived from the donated tissue. This includes the cells themselves and any patents or inventions using or derived from the cells or cell lines.

4. **REPORTS**

a. Dr. _____ shall supply reports to Planned Parenthood on an annual basis regarding the progress of the project and disposition of the tissue, including annual IRB review and revised, IRB approved consent forms.

5. **TERM AND TERMINATION**

a. Unless terminated earlier, the Term of this Agreement shall expire upon written notice from Dr. _____ that the project is complete.

b. Either party may terminate this Agreement at any time upon delivery of sixty days (60) notice of such termination.

6. **INDEMINIFICATION**

a. Dr. _____ agrees to indemnify, defend and hold Planned Parenthood harmless from and against any and all lawsuits, claims, actions, demands, or liabilities (including reasonable attorney's fees) which may be made against or incurred by Planned Parenthood involving the supply of tissue to Dr. _____ except in case involving informed consent. Dr. _____ relies entirely upon Planned Parenthood to obtain such consent.

In witness whereof, the duly authorized representatives of each of the parties hereto have executed this Amendment.

PLANNED PARENTHOOD GULF COAST, INC.

BY_____ DATE _____
PPGC **CEO**

UNIVERSITY _____

BY_____ DATE _____
Dr. _____

DX-79

On Nov 17, 2014, at 12:01 PM, "Farrell, Melissa" <Melissa.Farrell@ppgulfcoast.org> wrote:

Thank you!

<image001.jpg>
Melissa Farrell, RN, BSN, CCRC
Research Director
Planned Parenthood
4600 Gulf Freeway
Houston, TX 77023
PH: 713-831-6561

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From: Parikh, Supriya [mailto:Supriya.Parikh@bcm.edu]
Sent: Monday, November 17, 2014 10:31 AM
To: Farrell, Melissa
Cc: Paust, Silke
Subject: FW: Pediatrics Research Proposal- Dr Paust/Baylor College of Medicine- IRB Approval Obtained
Importance: High

Ms. Farrell:

Hope all is well with you.

First, I would like to thank you for your support through our IRB review process.

We heard back from the IRB today and like we discussed, the study does not constitute human subject's research. The rationale behind this determination is outlined in the exemption memo attached.

Our IRB proposal for your outlining the study procedures/objectives is also attached for your reference.

Lastly, I submitted the clinical consent you provided for tissue donation (attached) to BCM IRB and it was deemed acceptable for use.

As of today, my role on this study has ended but please feel free to contact me should any questions arise.

Dr Paust will be in touch with you to plan to study logistics and budget etc.

It was truly a pleasure working with you

From: **Parikh, Supriya** Supriya.Parikh@bcm.edu
Subject: FW: Pediatrics Research Proposal- Dr Paust/Baylor College of Medicine- IRB Approval Obtained
Date: November 17, 2014 at 10:30 AM
To: Farrell, Melissa (Melissa.Farrell@ppgulfcoast.org) Melissa.Farrell@ppgulfcoast.org
Cc: **Paust, Silke** Silke.Paust@bcm.edu

Ms. Farrell:

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First, I would like to thank you for your support through our IRB review process.

We heard back from the IRB today and like we discussed, the study does not constitute human subject's research. The rationale behind this determination is outlined in the exemption memo attached.

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As of today, my role on this study has ended but please feel free to contact me should any questions arise.

Dr Paust will be in touch with you to plan to study logistics and budget etc.

It was truly a pleasure working with you.

Happy Holidays in advance!
Supriya

Supriya G. Parikh
Research Resources Office
Feigin Center - Suite# 1590
Phone:832-824-3379; Fax: 832-825-4107
Email: sxparikh@texaschildrens.org

From: Farrell, Melissa [mailto:Melissa.Farrell@ppgulfcoast.org]
Sent: Wednesday, October 22, 2014 1:52 PM
To: Parikh, Supriya; Paust, Silke
Cc: Damron, Allison Rebecca
Subject: RE: Pediatrics Research Proposal- Dr Paust/Baylor College of Medicine

Dear Supriya,

DX-80

From: **Paust, Silke** paust@bcm.edu
Subject: Re: Pediatrics Research Proposal- Dr Paust/Baylor College of Medicine- IRB Approval Obtained
Date: October 13, 2015 at 2:59 PM
To: Farrell, Melissa Melissa.Farrell@ppgulfcoast.org

Hello Melissa,

I hope you are well and had a great weekend.

In light of recent events, do we need to make changes to our contract?

I still very much believe in the value of my NIH funded studies, and would very much like to proceed if that is possible. Could you please let me know.

Best wishes,

Silke

Silke Paust Ph.D.
Assistant Professor
Baylor College of Medicine
Center for Human Immunobiology
Department of Pediatrics
Texas Children's Hospital
Feigin Center FC 320.12
1102 Bates, Houston TX 77030

Phone: 832-824-2588
Fax: 832-825-1260
email: silke.paust@bcm.edu

DX-80(a)

From: **Paust, Silke** paust@bcm.edu
Subject: Re: Pediatrics Research Proposal- Dr Paust/Baylor College of Medicine- IRB Approval Obtained
Date: October 13, 2015 at 2:59 PM
To: Farrell, Melissa Melissa.Farrell@ppgulfcoast.org

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In light of recent events, do we need to make changes to our contract?

I still very much believe in the value of my NIH funded studies, and would very much like to proceed if that is possible. Could you please let me know.

Best wishes,

Silke

Silke Paust Ph.D.
Assistant Professor
Baylor College of Medicine
Center for Human Immunobiology
Department of Pediatrics
Texas Children's Hospital
Feigin Center FC 320.12
1102 Bates, Houston TX 77030

Phone: 832-824-2588
Fax: 832-825-1260
email: silke.paust@bcm.edu

From: **Paust, Silke** Silke.Paust@bcm.edu
Subject: Fwd: RE: Pediatrics Research Proposal- Dr Paust/Baylor College of Medicine- IRB Approval Obtained
Date: November 4, 2015 at 2:35 PM
To: Orange, Jordan Scott orange@bcm.edu

Please see below. I feel this is quite some misdirected anger and this will definitively affect my research.

Sent from Outlook

From: Farrell, Melissa <melissa.farrell@ppgulfcoast.org>
Sent: Wednesday, November 4, 2015 2:29 PM
Subject: RE: Pediatrics Research Proposal- Dr Paust/Baylor College of Medicine- IRB Approval Obtained
To: Paust, Silke <silke.paust@bcm.edu>
Cc: Gottlieb, Kathryn (Katie Beth) <kathrynkatiebeth.gottlieb@ppgulfcoast.org>, Tafolla, Rochelle <rochelle.tafolla@ppgulfcoast.org>

Silke,

To clarify: we do not have a valid contract, and I did not offer you a contract. I previously provided some exemplar language that should have been included in any contract regarding fetal tissue with the expectation that BCM Grants and Contracts or a BCM attorney would draft a complete contract for both parties to review.

PPGC will not commit to engage in any fetal tissue research endeavors at this time.

I encourage all academic researchers to escalate their need for donated fetal tissue to their department chair, IRB chairs, chancellors, etc. Academic institutions in Texas cannot remain publically silent regarding their need for donated fetal tissue in research, yet have expectations that research collaboration with Planned Parenthood will remain intact.

Missy

Planned Parenthood
Care. No matter what.
Melissa Farrell, RN, BSN, CCRC
Research Director
Planned Parenthood
4600 Gulf Freeway
Houston, TX 77023
PH: 713-831-6561

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From: Paust, Silke [mailto:Silke.Paust@bcm.edu]
Sent: Tuesday, October 13, 2015 2:59 PM
To: Farrell, Melissa
Subject: Re: Pediatrics Research Proposal- Dr Paust/Baylor College of Medicine- IRB Approval Obtained

Hello Melissa,

DX-81

TEXAS DEPARTMENT OF PUBLIC SAFETY
TEXAS RANGER DIVISION

REPORT OF INVESTIGATION

THIS REPORT IS THE PROPERTY OF TEXAS DPS-TEXAS RANGER DIVISION. NEITHER IT NOR ITS CONTENTS MAY BE DISSEMINATED OUTSIDE THE AGENCY TO WHICH LOANED.

1. PROH THE PURCHASE/SALE HUMAN ORGANS 48.02 PC MA
2. HARRIS COUNTY, HOUSTON, TX, US
3. STATE OF TEXAS
4. 08/10/2015 (Monday)

REPORT OWNER:	DARON PARKER, RANGER 9146 , HOUSTON	FILE STATUS:	ACTIVE
DIVISION:	RA-2015-00269	TYPE:	CRIMINAL
RANGER:	CA09146150810172028A		

SYNOPSIS:

3. 11/09/2015 Report Writer: DARON PARKER, RANGER 9146, HOUSTON
11/18/2015 Approved by: 9487 KIP WESTMORELAND, LIEUTENANT

On 10-22-2015, Texas Ranger Daron PARKER, Houston Police Department Homicide Division Sergeant Chris HASSIG, and members of the Harris County District Attorney's (HCDA) Office toured the Gulf Coast Planned Parenthood (GCPP) Building in Houston, Harris County, Texas. Also present were GCPP legal representatives. The GCPP building tour provided an overview regarding GCPP day to day operations. The tour included a surgical center and laboratory presentation and the explanation of standard practices which occurred during abortion procedures performed. More specifically, abortion procedures performed at the GCPP when the fetal tissue was utilized for scientific studies.

DETAILS:

3.1 On 10-22-2015, at approximately 5:00 PM, Texas Ranger Daron PARKER, Houston Police Department Homicide Division Sergeant Chris HASSIG (Investigator 2.2), Harris County Assistant District Attorneys Anshu MITCHELL (Investigator 1.2), Inger CHANDLER (Investigator 2.1), and Melissa HERVEY (Investigator 1.3) toured the Gulf Coast Planned Parenthood (GCPP) Building, located at 4600 Gulf Freeway in Houston, Harris County, Texas.

3.2 Also present was GCPP Legal Counsel Katie Beth GOTLIEB and Criminal Defense Attorney Josh SCHAFFER. GOTLIEB advised she would guide the GCPP building tour and provide an overview regarding GCPP day to day operations. The tour would include a surgical center and laboratory presentation

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and the explanation of standard practices which occurred during abortion procedures performed at GCPP building.

3.3 GOTLIEB began by showing the group the security station located in the center of a large open area on the first floor near the front door. GOTLIEB explained that everyone was required to show identification at the security station which was occupied by a receptionist. GCPP employed off duty police officers to work security at the building while it was open. Most of the GCPP building required key card access. The GCPP was the largest Planned Parenthood Center in the United States. GCPP offices administrative staff for 30 counties in Texas and the entire state of Louisiana.

3.4 GOTLIEB stated service departments within GCPP included Research, Laboratory, Health, and Family Planning. The ambulatory surgical center, which was where the abortion procedures were performed, was located in the building. The Center for Choice, which was a separate corporation, operated the ambulatory surgical center.

3.5 GOTLIEB next took the group to the research center. GOTLIEB explained GCPP had the largest research center in the nation. Long time Baylor employee, Missy FARRELL, was the Research Director. FARRELL had been instrumental in building the current research program. The vast majority of studies conducted at GCPP were in-vitro diagnostic device studies. GCPP conducted studies focused on sexually transmitted diseases. The Roush Medical Product Company was currently conducting a study on sexually transmitted diseases at the GCPP.

3.6 GOTLIEB stated it was explained to the patient that GCPP was conducting a research study. A patient participating in the study would consent to a tube of the patient's urine specimen being utilized for research. The patient would then be awarded with a $50.00 gift card, or possibly the fee for the STD test would be waived. The award was dependent upon what Roush had set up with GCPP. GCPP preferred this type of research as it did not require the long term cooperation of the patient.

3.7 GOTLIEB stated on her last well woman's exam at GCPP, she

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participated in a research study. A researcher was testing a new type of brush utilized during Pap smear examinations. She was offered a $20.00 gift card for participating in the study, but declined it. The studies were frequently conducted at Planned Parenthood affiliate locations as well.

3.8 ADA HERVEY asked if GCPP or the entity conducting the study provided the gift cards. GOTLIEB affirmed the entity conducting the study provided the gift cards. ADA HERVEY asked if GCPP personnel handed the gift cards out. GOTLIEB affirmed GCPP personnel did hand out the aforementioned gift cards. GOTLIEB added that she believed the gift cards displayed a GCPP logo on them. It was very common for GCPP to place the GCPP logo on various distributed items.

3.9 GOTLIEB described family planning as a fully functioning OB-GYN office which included services for men. Family planning worked in conjunction with the research department.

3.10 GOTLIEB then showed the group the location of offices located in Laboratory, Health, and Family Planning departments. GOTLIEB provided brief overviews of the services provided in the aforementioned departments.

3.11 GOTLIEB then took the group to the Center for Choice. GOTLIEB advised that the Center for Choice was also referred to as the Ambulatory Surgical Center.

3.12 GOTLIEB explained that the GCPP abortion procedure was a two day process. On day one, a mandatory ultrasound procedure was performed requiring the patient to look at the ultrasound screen, and listen to the heartbeat. Next, a doctor read a standard GCPP script discussing the procedure. Lastly, day one ended with abortion procedure education, alternatives, and counseling. Day two, prior to the abortion procedure, the patient reviewed and signed final consent documents.

3.13 The patient was then taken to the surgical area and changed into a surgical gown. An IV was then started on the patient, the abortion procedure was performed, and lastly the patient was taken into a recovery room. In the event the patient resided 100 or more miles away from the nearest

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Planned Parenthood clinic, exceptions could be made and the procedure could be performed in one day.

3.14 GOTLIEB stated one of the abortion methods utilized at GCPP included dilation and evacuation. Dilation and evacuation involved dilating the cervix with a laminaria, and utilizing forceps to disarticulate and remove the fetus in pieces. GOTLIEB described the fetuses as fragile and having soft tissue. GOTLIEB elaborated that the fetuses easily came apart and the calvarium (head) was usually crushed during the procedure.

3.15 GOTLIEB then took the group into the secured area of the Center for Choice's Ambulatory Surgical Center. GOTLIEB showed the group operating rooms utilized for abortion procedures.

3.16 ADA MITCHELL asked at what point during the process a patient consented to a fetal tissue study. GOTLIEB advised that once a patient signed the final consent forms, and paid for the abortion procedure, the patient would be informed about the fetal tissue study. Additional consent forms would be signed.

3.17 ADA MITCHELL asked if the patient was told what would happen to the fetal tissue. GOTLIEB stated patients often asked what happened to the fetal tissue regardless of a study. Patients were informed a licensed medical waste company took the fetal tissue and incinerated it. GOTLIEB advised that the last collected fetal tissue specimen collected by GCPP for a scientific study was on 07-26-2011, for the University of Texas Medical Branch. GCPP was recently approached by the Baylor College of Medicine and Rice University for fetal tissue studies. The Institutional Review Board had not yet given approval for the Baylor or Rice studies.

3.18 ADA MITCHELL asked GOTLIEB how GCPP benefited from participating in a fetal tissue study. GOTLIEB replied that patients on a frequent basis asked what happened to the fetal tissue. The patients were told the fetal tissue would be incinerated. Patients often requested the fetal tissue be utilized for research. GOTLIEB elaborated that the patients liked it, and it was broadly seen as very valuable

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research.

3.19 GOTLIEB stated utilizing sterile items could add a noticeable amount of time to the abortion procedure. GOTLIEB itemized that additional consent forms were necessary, medical device tubing required replacement, the use of sterile Pyrex receptacles was required, and finally the release of the fetal tissue to the entity conducting the scientific research.

3.20 ADA MITCHELL asked if procedures were altered to obtain intact fetuses when collecting for a scientific study. GOTLIEB replied that obtaining an intact fetus was not possible utilizing the dilation and evacuation method. On average, the fetuses were extracted in at least three or more pieces. The calvarium was usually crushed during the procedure, as it was the largest part of the fetus. Studies had been conducted in the past on orbits and eyes. Despite the damage to the calvarium, the eyes could often still be obtained intact.

3.21 ADA MITCHELL asked if it was possible for a patient's cervix to dilate more than expected. GOTLIEB stated dilating more than expected was possible. In the event a patient has had multiple vaginal deliveries, this could happen. The only way to obtain an intact fetus was via a partial birth abortion. GCPP did not perform partial birth abortions. GOTLIEB advised the possibility of a live birth abortion increased when the cervix dilated more than expected. A live birth abortion had never occurred at GCPP. Utilizing the vacuum aspiration method prior to 12 weeks made the possibility of a live birth remote.

3.22 GOTLIEB then took the group to one of the Ambulatory Surgical Center's surgery rooms. Ranger PARKER observed the surgery room to have an operating table, crash cart, an ultrasound device, and the aspiration vacuum.

3.23 GOTLIEB described the aspiration vacuum as functioning similar to a breast pump. GOTLIEB described that during an abortion procedure, the fetal tissue emptied into a jar connected to the aspiration vacuum by a tube. GOTLIEB reiterated that during a scientific study the tubing

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required replacement.

3.24 GOTLIEB then took the group to the Ambulatory Surgical Center's products of conception laboratory. The laboratory was located between the two surgery rooms and was equipped with pass-through windows leading to each of the surgery rooms. Subsequent to the abortion procedure, the jar containing the products of conception (fetal tissue) was passed through the pass-through window. The fetal tissue was then rinsed in a sieve. The fetal tissue was then placed in a Pyrex dish located on a lighted x-ray box and examined and inspected by the doctor. A Laboratory Technician then bagged the fetal tissue and placed it in the freezer. In the event GCPP was participating in a scientific study, the packaged fetal tissue would remain in a sink in the laboratory. At the end of the workday, the fetal tissue was taken by the entity conducting the study.

3.25 Also located in the laboratory was a secured standard upright freezer. GOTLIEB unlocked the freezer and showed Ranger PARKER a biohazard bag containing a small jar containing fetal tissue and two vials of blood. The biohazard bag of fetal tissue would also include the placenta. The items in the bag were labeled with a patient's name.

3.26 GOTLIEB advised that the medical waste disposal company picked up the products of conception once per week. A medical waste disposal company had already obtained products of conception on that particular day. There was a minimal amount of products of conception in the freezer that day, based on the aforementioned medical waste pick up.

3.27 Ranger PARKER asked if there was any other procedure which had not been mentioned when collecting fetal tissue for a scientific study. GOTLIEB advised during the UTMB study, a UTMB representative would stay in the laboratory area on the days that patients were enrolled in the study. GOTLIEB recalled this occurring once or twice a month during the UTMB study. GOTLIEB stated the fetal tissue was required to be placed in a sterile sieve, containing gauze, and subsequently then into a sterilized Pyrex container. Specific doctors performed abortions on specific gestational

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ages. An abortion procedure from start to finish ordinarily took no longer than 30 minutes.

3.28 ADA MITCHELL asked GOTLIEB if GCPP line itemed charges into an invoice for the additional costs for a study, to include additional time for consent procedures, sterilization of instruments, etc. A cost analysis had been conducted on the time it took to complete an abortion procedure that involves a scientific study. GOTLIEB stated results indicated that standard additional costs for an abortion procedure involving a scientific study were approximately $25.00 more. This particular cost analysis was dated, but did not give a specific date it was conducted. This cost was recently increased to $50.00 as it was decided that GCPP was not recouping its costs. GOTLIEB advised to her knowledge the costs were not line itemed. However, if additional time or measures were taken, GCPP would likely have increased the invoiced amount.

3.29 GOTLIEB advised the entities conducting the most recent scientific studies were invoiced at $50.00 per patient consent. The consenting process was the most time consuming element of the process. The total invoiced costs of the recent scientific studies, which included consent and procedural charges, totaled $150.00.

3.30 SCHAFFER advised, while referring to the covert investigation conducted by David DALEIDEN (Physical Description 1.1), the proposed $1600.00 fee was what indicated to GCPP that DALEIDEN was not legitimate.

3.31 GOTLIEB then showed the group a small room with a larger crash cart. The crash cart contained sterilized tools to include forceps and speculums. Ranger PARKER observed each individual tool was contained in a cellophane package.

3.32 GOTLIEB then briefly showed the group a recovery room with several recliner type chairs and other medical equipment. GOTLIEB stated the patient stayed in the recovery room until the staff was satisfied the patient was suitable to leave. The average recovery time was approximately 20 minutes. The patient was required to have someone drive them home from the clinic as an abortion procedure required anesthetic.

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3.33 ADA MITCHELL advised GOTLIEB and SCHAFFER that GCPP would likely be receiving Grand Jury subpoenas for documents regarding participation in scientific studies. SCHAFFER advised that GCPP would cooperate with the HCDA's Office. SCHAFFER also added that GCPP personnel would also cooperate, if asked, regarding the fraudulent identification presented to GCPP at the time the covert videos were made.

3.34 The site visit was concluded, and the group exited the GCPP Offices at approximately 7:00 PM.

END OF REPORT