



Bob Ferguson
ATTORNEY GENERAL OF WASHINGTON

Administration Division

PO Box 40100 • Olympia WA 98504-0100 • (360) 753-6200

MEMORANDUM

DATE: November 12, 2015

TO: Bob Ferguson, Attorney General

FROM: Paige Dietrich, Deputy Attorney General
Kristen Mitchell, Senior Assistant Attorney General

SUBJECT: **Review of Legal Issues Related to Legislators' Letters
Regarding Planned Parenthood**

I. QUESTION PRESENTED

In response to letters received from various members of the Washington State Legislature on July 22 and 29, 2015,¹ you asked us to conduct a review of the allegations made in the letters. The two letters request that the Attorney General investigate all Planned Parenthood Federation of America affiliates in Washington for alleged violations of state and federal law. Specifically, the letter asks whether Planned Parenthood affiliates in Washington perform partial-birth abortions and, second, whether any Washington affiliate sells fetal tissue for profit, rather than simply recovering costs.

II. BRIEF ANSWER

The procedures described in the Center for Medical Progress videos that aired and in the letters this office received from legislators do not meet the definition of partial-birth abortion. We found no indication that procedures performed by Planned Parenthood are anything other than performance of a legally authorized medical procedure.

The sale of fetal tissue is unlawful. Planned Parenthood, however, does not sell fetal tissue. While federal law permits Planned Parenthood to recover costs associated with fetal tissue donations for research purposes, the organization does not recover such costs. It only accepts mailing materials provided by the fetal tissue repository for transport of the tissue. We found no basis to believe that Planned Parenthood is selling fetal tissue or profiting from fetal tissue donations.

¹ Letter dated July 22, 2015 from 34 members of the Washington State House of Representatives; Letter dated July 29, 2015 from 10 members of the Washington State Senate. Copies of letters attached.

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III. SUMMARY OF THE ISSUES AND BACKGROUND

In July 2015, a group called the Center for Medical Progress began releasing undercover videos purportedly showing Planned Parenthood officials discussing the sale of fetal tissue obtained during abortions. The videos received significant press coverage and the U.S. Congress and a number of states initiated investigations of Planned Parenthood. Each video identifies the Planned Parenthood employees recorded and the date and location of the video. None of the videos were recorded in Washington state.

Planned Parenthood of Greater Washington and North Idaho (PPGWNI) has nine health centers in Eastern Washington. One of the health centers has an agreement to donate fetal tissue to the University of Washington School of Medicine, which manages and operates the Birth Defects Research Laboratory (UW BDRL). The UW BDRL receives, stores and provides fetal tissue for research purposes. The National Institutes of Health (NIH), a medical research agency within the U.S. Department of Health and Human Services, funds the laboratory.

The NIH requires that the program adhere to strict guidelines for tissue donation and storage, and the repository may provide tissue only for academic or non-profit research. The NIH requirements prohibit the UW BDRL from having any interaction with commercialized research enterprises. PPGWNI has an agreement with the UW BDRL to donate fetal tissue in compliance with federal laws for research involving human subjects, including 42 U.S.C. § 289g-1(b) and 45 CFR § 46.204, the terms of the NIH grant, and the conditions of approval from the University of Washington Institutional Review Board.

We have completed a review of the available information related to the allegations, gathering information from PPGWNI and the UW BDRL. We reviewed the Center for Medical Progress videos and transcripts made publicly available. The Center for Medical Progress has published many videos, some described as edited and others described as “full” or unedited. The videos and associated transcripts appear to be extensively edited. The transcripts are not formal or professional and contain noted deletions, editorial comments, and redactions. As mentioned above, none of the videos were recorded in Washington state.²

We spoke with Karl Eastlund, President and CEO of PPGWNI, who explained their procedures, provided copies of consent forms, and provided an affidavit supporting his explanation of PPGWNI’s agreement with UW BDRL and procedures relevant to this inquiry.³ In addition, staff at the University of Washington and UW BDRL provided information, including copies of consent forms, the agreement with PPGWNI, and pertinent federal law related to the UW BDRL, as well as information about the NIH. The University of Washington also provided a copy of a

² Incidentally, if a recording were made in Washington under similar circumstances, the act could violate Washington state law, which requires consent before recording a private conversation. RCW 9.73.030.

³ Affidavit of Karl Eastlund, dated October 8, 2015. Copy attached. We also spoke with officials of the other Planned Parenthood affiliates in Washington to confirm that they do not donate fetal tissue.

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letter from the Vice Dean for Research and Graduate Education to Senator Mike Padden, explaining its program and its value to medical research.⁴

Both entities cooperated fully. They answered our questions and provided information at our request.

IV. PLANNED PARENTHOOD PROCEDURES

The July 2015 letters ask the Attorney General to investigate potential violations of state and federal law. In Washington state, abortion is a legal medical procedure and “the state may not deny or interfere with a woman’s right to choose to have an abortion prior to viability of the fetus, or to protect her life or health.” RCW 9.02.110, Initiative Measure No. 120, approved November 5, 1991.

A. Consent to Donate Fetal Tissue for Research

The Planned Parenthood health centers follow protocols to obtain informed consent for abortions. Federal law addresses the type of informed consent required for fetal tissue donation. 42 U.S.C. § 289g-1(b). Pursuant to the requirements for the NIH grant, no monetary or other type of inducement may be offered a woman to terminate a pregnancy. 45 CFR § 46.204(h). Typically, women seeking an abortion speak with health center medical providers twice prior to the procedure. If a woman decides to have the abortion, she is counselled a second time about options and risks and then formally consents to the abortion in writing.⁵ Once the decision to abort is made, the fetal tissue will either be discarded or donated for research. By a separate process, following consent to the abortion, the woman is then informed about the option to donate and the risks associated with donation, and informed consent is obtained.⁶

B. Partial-Birth Abortion

Both letters ask for investigation into whether Planned Parenthood affiliates have performed partial-birth abortions. Partial-birth abortions are criminalized by federal law. 18 U.S.C. § 1531(a). A partial-birth abortion is defined as an abortion in which the entire fetal head or trunk is outside the body of the mother at the time the physician performs the act that kills the fetus. 18 U.S.C. § 1531(b)(1). Even prior to the federal ban, state law barred partial-birth abortions in Washington by requiring medical resuscitation in the event of a partial-birth. RCW 18.71.240. With respect to fetal tissue donation, federal law prohibits a change in the timing and method of procedures used to terminate the pregnancy solely for the purpose of obtaining the tissue. 42 U.S.C. § 289g-1(b)(2), 45 CFR § 46.204(i).

⁴ John T. Slattery, Ph.D., Vice Dean for Research and Graduate Education, University of Washington, School of Medicine, letter to Senator Mike Padden, dated September 17, 2015. Copy attached.

⁵ Consent forms. Copies attached.

⁶ Consent forms. Copies attached.

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November 12, 2015

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Turning a fetus in the womb, as described in the July 29, 2015 letter, does not meet the definition of a partial-birth abortion under federal law. Similarly, none of the videos or transcripts publicized by the Center for Medical Progress contain any description of a procedure that would meet the federal definition of a partial-birth abortion. Based upon information provided by both PPGWNI and the UW BDRL, there are no changes to abortion procedure by the PPGWNI health center, even if fetal tissue is to be donated. To the contrary, in order to comply with federal law and the NIH grant, there can be no changes to the procedure. 42 U.S.C. § 289g-1(b) and 45 CFR § 46.204(i).

There has been no information presented to indicate that partial-birth abortions have been performed at any Planned Parenthood health center in Washington, and Mr. Eastlund has offered a sworn affidavit attesting that PPGWNI health centers do not perform partial-birth abortions.

C. Sale of Donated Fetal Tissue

The letters also express concern that Planned Parenthood may be in violation of federal law prohibiting sale of human body parts. Research on fetal tissue is legal and widespread.⁷ Federal law does prohibit payment of “valuable consideration” for donated fetal tissue, but allows “reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.” 42 U.S.C. § 289g-2(a) and (e)(3).

As described above, one PPGWNI health center donates fetal tissue. It only donates to the UW BDRL, which is funded by the NIH. PPGWNI accepts shipping materials from the UW BDRL, but does not seek or receive any form of reimbursement by the UW BDRL.⁸ There have been no specific facts alleged, nor did our inquiry result in any indication that PPGWNI sells fetal tissue or profits from fetal tissue donation.

V. CONCLUSION

Our review found no information to support any of the alleged violations of Washington or federal law by Planned Parenthood or the UW BDRL. This concludes our review of this matter.

PLD/KM/jlg

⁷ Slattery letter. Copy enclosed.

⁸ Affidavit of Eastlund. Copy enclosed.

Memorandum Enclosure – Footnote 1

Copies of Letters to the Attorney General
From Members of Washington State Legislature

State of
Washington
House of
Representatives



July 22, 2015

The Honorable Bob Ferguson
Attorney General, State of Washington
PO Box 40100
Olympia, WA 98504

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2015 JUL 28 A 8:25

ATTORNEY GENERAL
OF
WASHINGTON

Dear Attorney General Ferguson,

Recent reports have surfaced alleging improper, unethical, and illegal actions relating to the trafficking of human organs and body parts by some Planned Parenthood Federation of America affiliates. The actions outlined in recent media reports describe employees extracting organs and body parts from aborted babies and maintaining them for sale or transfer. Additionally, Dr. Deborah Nucatola, the Senior Medical Director for Planned Parenthood Federation of America, is seen in one video graphically describing performing partial-birth abortion procedures to preserve high-value organs. If these practices are occurring in Washington it would be a violation of both state and federal law – and completely unacceptable.

Federal law states, "It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce." Further, Congress passed a ban on partial-birth abortion, which the president signed, and the U.S. Supreme Court upheld. Again, any procedure to this effect would be illegal.

Therefore, on behalf of our constituents and the people of our state, we are formally asking you to investigate all Planned Parenthood Federation of America affiliates operating in Washington State for violations of all applicable state and federal laws pertaining to the trafficking of human organs and body parts, and to take the necessary injunctive action to end said practices.

Investigations have been initiated in multiple states to ensure their Planned Parenthood Federation of America affiliates are in compliance with the law. We further ask your office to coordinate with both Gov. Jay Inslee and his Secretary of Health, Dr. John Wiesman, to do the same in Washington.

Finally, regardless of personal views of legalized abortion, a civilized society cannot tolerate unethical medical practices such as the harvesting of human organs for monetary gain. We appreciate your attention to this matter and look forward to your prompt response.

Sincerely,

A handwritten signature in black ink, appearing to read "Drew MacEwen".

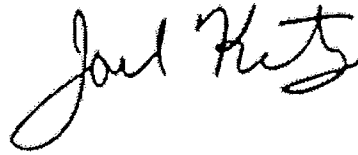
Representative Drew MacEwen
35th District

A handwritten signature in black ink, appearing to read "Dan Griffey".

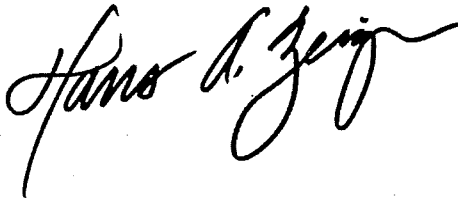
Representative Dan Griffey
35th District



Representative Dan Kristiansen
39th District



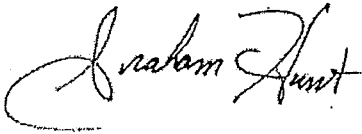
Representative Joel Kretz
7th District



Representative Hans Zeiger
25th District




Representative Lynda Wilson
17th District



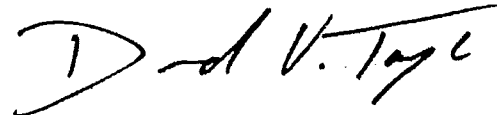
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2nd District



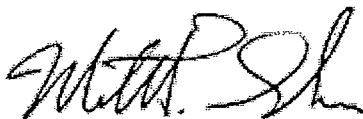
Representative Bob McCaslin
4th District



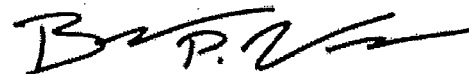
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14th District



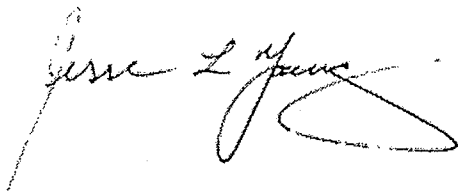
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15th District



Representative Matt Shea
4th District



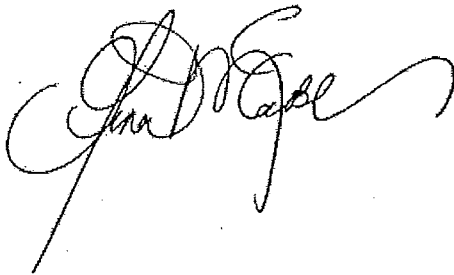
Representative Brandon Vick
18th District



Representative Jesse Young
26th District



Representative Mark Harmsworth
44th District



Representative Gina McCabe
14th District



Representative Kevin Parker
6th District



Representative Elizabeth Scott
39th District



Representative Maureen Walsh
16th District



Representative Joe Schmick
9th District



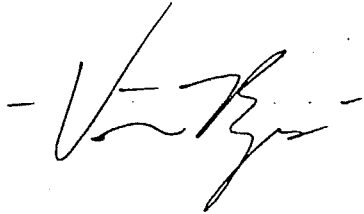
Representative Cary Condotta
12th District



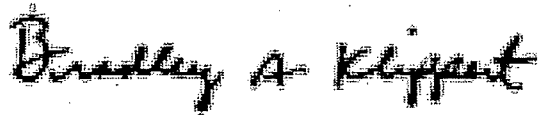
Representative Mark Hargrove
47th District



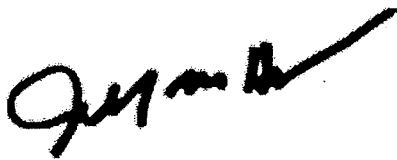
Representative Luanne Van Werven
42nd District




Representative Vincent Buys
42nd District



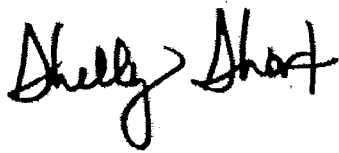
Representative Brad Klippert
8th District



Representative Jeff Holy
6th District



Representative Tom Dent
13th District



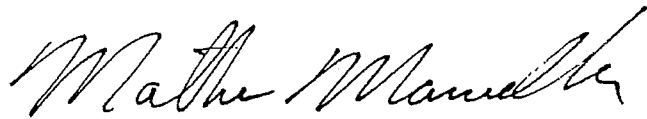
Representative Shelly Short
7th District



Representative Dick Muri
28th District



Representative Paul Harris
17th District



Representative Matt Manweller
13th District



Representative Liz Pike
18th District



Representative Jay Rodne
5th District



Representative Dave Hayes
10th District



Representative Norma Smith
10th District

cc: Governor Jay Inslee
Secretary John Wiesman, Department of Health



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Washington State Legislature

ATTORNEY GENERAL
OF

July 29, 2015 WASHINGTON

The Honorable Bob Ferguson
Washington State Attorney General
PO Box 40100
Olympia, WA 98504

Dear Attorney General Ferguson,

Sometimes as an elected official an issue comes up which is so grotesque, so grisly, it can challenge our civility and cause us to reflect upon the moral fabric of our society. We refer to recent reports relating to the trafficking of human body parts by affiliates of Planned Parenthood Federation of America which are so horrific in nature it demands our attention.

Federal law prohibits the selling of human body parts. Furthermore, federal law prohibits partial-birth abortion, where an unborn baby is intentionally turned to the breech position to ensure delivery of the body happens before delivery of the head. Evidence is mounting that Planned Parenthood is in violation of both laws. According to Planned Parenthood Doctor Deborah Nuctola partial-birth abortion is "not a medical term, it doesn't exist in reality."

Bargaining over the price of dead babies and altering the abortion procedure to make the harvesting of organs easier is horrid beyond belief. As a result, many states have begun investigations into potential violations of state and federal laws. The state of Washington should join them.

This is an issue which should transcend whatever personal views we as elected officials may have on the issue of abortion. The laws on these issues are well established and clear. We respectfully request your investigation into these matters. Thank you for your consideration.

Sincerely,

Senator Judy Warnick
13th Legislative District

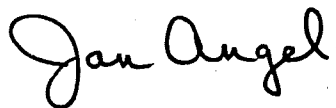
Senator Jim Hargrove
24th Legislative District

Senator Mike Padden
4th Legislative District

Senator Mark Miloscia
30th Legislative District

Senator Ann Rivers
18th Legislative District

Senator Randi Becker
2nd Legislative District



Senator Jan Angel
26th Legislative District



Senator Don Benton
17th Legislative District



Senator Jim Honeyford
15th Legislative District



Senator Bruce Dammeier
25th Legislative District

Memorandum Enclosure – Footnote 3

Affidavit of Karl Eastlund, dated October 8, 2015

Planned Parenthood of Greater Washington and North Idaho

AFFIDAVIT

I, KARL EASTLUND, have personal knowledge of the information contained in this affidavit:

1. I am the President and Chief Executive Officer for Planned Parenthood of Greater Washington and North Idaho (PPGWNl). I have held this position for four years. I joined PPGWNl in 2003, as the Chief Financial Officer and also served as the Chief Operating Officer from 2004 to 2011.

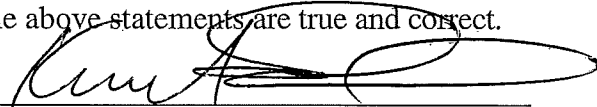
2. PPGWNl operates nine clinics in Eastern Washington that serve women in Washington and Idaho.

3. Only one PPGWNl clinic collects donations of fetal tissue. The only organization to which PPGWNl donates fetal tissue is the University of Washington Birth Defects Research Laboratory.

4. The only form of cost recovery PPGWNl receives from the University of Washington Birth Defects Research Laboratory for fetal tissue donations is shipping materials. PPGWNl does not receive any other compensation nor valuable consideration for donation of fetal tissue.

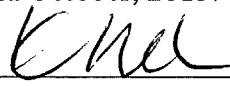
5. PPGWNl does not change the timing or procedure for abortions in cases where fetal tissue is donated. PPGWNl does not perform partial birth abortions.

I, KARL EASTLUND, declare that the above statements are true and correct.


KARL EASTLUND

SIGNED OR ATTESTED before me this 8 of October, 2015.




Notary Public in and for the State of
Washington.
My commission expires: 4/15/2016

Memorandum Enclosure – Footnote 4

Letter to Senator Mike Padden
From John T. Slattery, Ph.D., dated September 17, 2015

UW Medicine

UW SCHOOL
OF MEDICINE

September 17, 2015

Senator Mike Padden
Washington State Senate
4th Legislative District
106 Irving Newhouse Building
PO Box 40404
Olympia, WA 98504-0404
Mike.Padden@leg.wa.gov

Dear Senator Padden,

Thank you for your August 25, 2015 letter, outlining your concerns about the distribution of human fetal tissue by abortion providers to third party companies for the purpose of research. I write to you as vice dean for research and graduate education for the University of Washington School of Medicine (UWSOM) to explain our role as a research institution in receiving and distributing fetal tissue and to assure you that the UWSOM is fully compliant with all applicable federal, state and local laws.

The UW School of Medicine operates the Birth Defects Research Laboratory (BDRL), which is a nationally recognized lab for birth-defects research that serves as the major national resource for the collection and distribution of human fetal tissue for use by non-commercial research entities. The BDRL is directly funded by the National Institutes of Health (NIH) to collect, identify and provide fetal tissue for research purposes solely for use by academic and non-profit research facilities around the country. The BDRL adheres to very strict NIH requirements in receiving donated fetal tissue, which prohibit the BDRL from having any interaction with commercialized research enterprises and requires all recipients of fetal tissue from the BDRL to qualify as an academic or non-profit research entity.

The following provides additional background information on the BDRL and the process it follows for collecting fetal tissue and distributing the tissue for research purposes.

The BDRL plays a key role in medical research by academic and non-profit entities around the country and has operated for 51 years. The current NIH program supporting fetal tissue donation and research has been in place since 2010 and the BDRL receives approximately \$440,000 per year from the NIH for laboratory operations to collect, review and distribute donated fetal tissue. The BDRL receives donated tissue from both medically necessary procedures and voluntary pregnancy terminations and has entered into agreements with seven stand-alone reproductive health clinics and three hospitals within the state of Washington to collect tissue.

Office of Research and Graduate Education

The BDRL operates under strict conditions that expressly require tissue to be donated on a completely voluntary basis. Accordingly, the donating clinics and hospitals must ensure that: 1) consent of the woman for any related procedure, including an abortion, is obtained prior to the consent for the fetal tissue donation; 2) there is no alteration of the timing or method of the procedure solely for purposes of obtaining the tissue; and 3) there is no compensation for the donation of the tissue provided to either the donor or the clinic/hospital.

These requirements are based on the federal rules for research involving human subjects, including the terms of the NIH grant and the conditions of approval from the University of Washington's (UW) Institutional Review Board (IRB), which reviews and approves UW research involving human participants to assure protection of their safety, rights and welfare. In order to ensure compliance with these requirements, the BDRL conducts an annual review of the consent and donation process at the providing clinics and hospitals. The BDRL provides updated training materials to the clinics and hospitals to ensure that employees are following the consent and donation guidelines on a regular basis.

It is worth emphasizing that, during the process, the patient is presented with the option to donate fetal tissue for research only after the patient has been informed that the procedure is medically necessary or the patient has made the independent decision to terminate the pregnancy. If the patient agrees to donate tissue to research, an extensive written informed consent is obtained, either by the clinic counselor or a member of the BDRL research team. The consent forms accompany the transmittal of the tissue from the clinic or hospital to the BDRL.

The donating clinics and hospitals do not profit from providing donated fetal tissue to the BDRL. As allowed by federal law, the clinics and hospitals are reimbursed for costs associated with obtaining the fetal tissue for research. These costs include on-line training of staff regarding the protection of human subject research participants; the copying of medical records and radiological images; and purchasing of reagents, shipping materials, or copying of research consent forms. These providers receive no other compensation for the donation of fetal tissues.

Upon receipt of the donated tissue, the BDRL examines the donated fetal tissue to determine the most impactful use the tissue may have for research purposes and places it in its tissue storage bank (repository). The BDRL then makes the de-identified fetal tissue available to appropriately qualified researchers. In operating the repository and making the tissue available for researchers, the BDRL must follow the terms and requirements of the NIH grant.

First, as noted above, the BDRL only provides tissue to non-profit research or academic institutions. It does not provide tissue to independent for-profit organizations or third party organizations (brokers) seeking fetal tissue for research. Moreover, researchers who receive tissue from the BDRL must agree not to distribute the tissue to any third party without prior authorization.

Second, the BDRL does not sell tissue to researchers. It charges a processing fee of \$200 to cover operational costs incurred and not covered by the NIH grant. This cost recovery charge has remained the same since 2007.

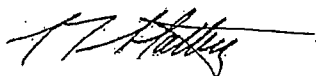
Third, the BDRL requires researchers to provide documentation of approval from their institution's own Institutional Review Board (IRB) for the research they are conducting. These research institutions therefore hold themselves to the same federal standards in the use of fetal tissue for research.

Locally, the BDRL makes tissue available to researchers at the UW, the Fred Hutchinson Cancer Research Center, Seattle Children's Hospital and the Paul G. Allen Brain Institute. The BDRL also distributes to multiple academic research facilities across the country. There are approximately 60 investigators nationwide who receive tissue samples. External recipients include academic centers working to prevent such birth abnormalities as hypoplastic left heart syndrome.

Within the UWSoM, the BDRL's distribution of fetal tissue donations includes the Institute for Stem Cell & Regenerative Medicine where researchers are working on regenerating damaged heart muscles and the Department of Pediatrics and Medical Genetics where researchers are working to understand and prevent newborn brain malformations including Dandy Walker Syndrome and Joubert Syndrome. Other recipients include researchers who are working on solving macular degeneration with retina regeneration.

These examples demonstrate the wide and significant range of academic research supported by the BDRL. Because these research initiatives rely upon donated fetal tissue from the BDRL, the BDRL takes great care in maintaining compliance with federal and state requirements and with the terms and conditions of the NIH grant in the donation and dispersing of fetal tissue. The UWSoM will continue to maintain our compliance with rigorous efforts in order to ensure this crucial research continues. I hope this information has been helpful in understanding the UWSoM role in the receipt and distribution of fetal tissue and how the BDRL operates. If you have any questions or concerns please do not hesitate to contact me at (206) 543-6116 or jts@uw.edu.

Sincerely,



John T. Slattery, Ph.D.
Vice Dean for Research and Graduate Education
University of Washington, School of Medicine

cc: Ian M. Goodhew
Michael McCliment

Memorandum Enclosures – Footnotes 5 & 6

Consent Forms
Planned Parenthood and University of Washington



Planned Parenthood of Greater Washington and North Idaho
123 E Indiana Ave, Spokane, WA 99207 1.866.904.7721

REQUEST FOR SURGERY OR SPECIAL PROCEDURE AND ACKNOWLEDGEMENT OF RECEIPT OF NOTICE OF HEALTH INFORMATION PRIVACY PRACTICES

Before you give your consent, be sure you understand the information given below. If you have any questions, we will be happy to talk about them with you. You may ask for a copy of this form.

I understand that I must tell the staff if language interpreter services are necessary to my understanding of the written or spoken information given during my health care visits. I understand that free interpretive services may not be immediately available and Planned Parenthood may need to refer me to another health care facility to provide the services necessary for my care.

I will be given information about the test(s), treatments, service(s)/procedure(s)/ surgery to be provided, including the benefits, risks, possible problems/complications and alternate choices. I was given *written patient information* and/or a copy of the Planned Parenthood Client Information for Informed Consent sheet. It was reviewed with me.

I understand that with any service/procedure/surgery, there is also the possibility of side effects. I understand that I should ask questions about anything I do not understand. I understand that a clinician is available to answer any questions I may have.

No guarantee about the results from this service/procedure/surgery has been given to me. I know that it is my choice whether or not to have this service/procedure/surgery. I know that I can change my mind about receiving this service at Planned Parenthood at any time.

I will be given referrals for further diagnosis or treatment if necessary. I understand that if referral is needed, I will assume responsibility for obtaining and paying for this care. I will be told how to get care in case of an emergency.

If there is an unexpected complication during the service/procedure/surgery, I request and authorize the clinician and authorized Planned Parenthood staff to do whatever is necessary to preserve my health and welfare.

In the event I need more pain medication to safely continue or complete the procedure, I request and authorize Planned Parenthood staff to give me medications they believe necessary. This may include medications to reduce pain and/or anxiety. I understand every medication carries a small risk. I understand the clinician will only use medications if s/he believes it is clinically indicated.

I request that a person authorized by Planned Parenthood provide appropriate evaluation, testing, and treatment (including a birth control drug or device, if I request it) and perform the following service(s)/procedure(s)/surgery:

NAME:

DOB:

PPGWNI #:

CL 00.012.02 (04/15)

- ☐ In-Clinic Suction Abortion (CL 01.003, In-Clinic Abortion CIIC) - Removal of uterine pregnancy less than 14 weeks gestational age by mechanical method.
- ☐ In-Clinic Dilation & Evacuation (D&E) Abortion (CL 01.003, In-Clinic Abortion CIIC) - Removal of uterine pregnancy at 14 weeks or greater gestational age by mechanical method.
- ☐ Osmotic Dilator Insertion prior to Surgical Abortion (CL 01.003, In-Clinic Abortion CIIC) - Short thin rods placed in the cervix (opening of uterus) to stretch the opening before the abortion procedure.
- ☐ The Abortion Pill (CL 01.010, Using the Abortion Pill CIIC) - Prescription medicine taken to stop pregnancy development and cause passage of uterine pregnancy up to 10 weeks (70 days) gestational age.
- ☐ Uterine Aspiration (CL 01.015, Aspiration After Abortion CIIC) - Removal of blood or remaining pregnancy tissue from uterus following abortion.
- ☐ Treatment of Miscarriage with a Suction Procedure (CL 13.001, Treatment of Miscarriage - Suction Procedure CIIC) - Removal of remaining pregnancy tissue from uterus following an early pregnancy loss.
- ☐ Treatment of Miscarriage with Abortion Pill (CL 13.004, Treat of Miscarriage with the Abortion Pill CIIC) - Prescription medicine taken to cause passage of pregnancy tissue following an early pregnancy loss.
- ☐ Analgesia/Sedation (CL 01.001, Sedation CIIC) - for the relief of pain and anxiety during abortion procedure.
- ☐ Colposcopy (CL 04.001, Colposcopy and Biopsy CIIC) - Use of microscope to look for abnormal cells on cervix (opening of uterus).
- ☐ Cervical Biopsy and Endocervical Sampling (ECS) (CL 04.001, Colposcopy and Biopsy CIIC) - Removal of small piece(s) of tissue on cervix to check for abnormalities.
- ☐ Endometrial Biopsy (CL 08.001, Endometrial Biopsy CIIC) - Removal of cells from lining of uterus to check for abnormalities.
- ☐ Vulvar Biopsy (CL 09.009, Vulvar Biopsy CIIC) - Removal of small piece of tissue from the lips of vagina to check for abnormalities.
- ☐ Cryotherapy of Cervix (CL 04.002, Cryotherapy CIIC) - Freezing of top layer of cervix (opening of uterus) to treat abnormal cells.
- ☐ Loop Electrode Excision Procedure (LEEP) (CL 04.003, LEEP CIIC) - A small electrical wire loop used to remove abnormal tissue from the cervix.
- ☐ Intrauterine Contraceptives (IUC) Insertion (CL 06.001, IUC CIIC) - Placement of ☐ Mirena ☐ Liletta ☐ Skyla ☐ Paragard into uterus to prevent pregnancy.
- ☐ Intrauterine Contraceptive (IUC) Removal (CL 06.004, Removing Your (IUC) When the String is Missing CIIC) - Removal of ☐ Mirena ☐ Liletta ☐ Skyla ☐ Paragard from uterus when the string is missing.
- ☐ Contraceptive Implant Insertion (CL 06.009, Single Rod Implant (Implanon) CIIC) - After a shot of numbing medicine, birth control device (flexible 1 1/2" rod) is placed under skin of upper arm to prevent pregnancy.
- ☐ Contraceptive Implant Removal (CL 06.011, Removal of Single Rod Implant (Implanon) CIIC) - After a shot of numbing medicine, small cut is made in skin and the birth control device is removed through it.

NAME:

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CL 00.012.02 (04/15)

- ☐ Hysteroscopic Tubal Sterilization (Essure®) (CL 05.004, Hysteroscopic Tubal Sterilization (Essure®) CIIC) – A method of permanent birth control. A tiny device, called a microinsert, is used to close the opening of each of the fallopian tubes (the tubes that carry the eggs from the ovaries to the uterus).
- ☐ Vasectomy (CL 05.001, Vasectomy) – A method of permanent birth control. After a shot of numbing medicine, the vas deferens are cut or blocked.
- ☐ Breast Cyst Aspiration (CL 03.005, Breast Cyst Aspiration CIIC) – Use of a thin needle to remove the fluid from a fluid filled lump in the breast.
- ☐ Treatment of Bartholin's Duct Abscess (I & D) (CL 08.002, Treatment of Bartholin's Duct Abscess CIIC) – Small cut made to infected area to drain fluid from it.
- ☐ Skin Biopsy (CL 12.001, Skin Biopsy CIIC) – Removal of a very small piece of skin to check for disease or remove the problem.
- ☐ Other: _____

I understand that if tests for certain sexually transmitted infections are positive, reporting of positive results to public health agencies is required by law.

I understand that confidentiality will be maintained as described in Planned Parenthood of Greater Washington and North Idaho's *Notice of Health Information Privacy Practices*. I consent to the use and disclosure of my health information as described in *Notice of Health Information Privacy Practices*.

I hereby acknowledge receipt of Planned Parenthood of Greater Washington and North Idaho's notice of health information privacy practices

Client Signature

Date

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature

Date

☐ CHECK HERE IF CLIENT'S GUARDIAN OR RELATIVE IS LEGALLY REQUIRED TO SIGN BELOW.

Signature of any other person consenting

Date

Relationship to client

I witness the fact that the client's legal guardian (or person consenting in her/his behalf) received the above mentioned information and said she/he read and understood same.

Witness signature

Date

NAME:

DOB:

PPGWN I #:



Planned Parenthood of Greater Washington and North Idaho
123 E Indiana Ave, Spokane, WA 99207 1866.904.7721

Client Information for Informed Consent

In-Clinic Abortion

What is an in-clinic abortion?

The way an abortion is done depends on how long a person has been pregnant. This is figured out by counting from the first day of the last period or by ultrasound. There are 2 kinds of in-clinic abortion.

- **In-clinic suction abortion:** suction is used to take the pregnancy out of the uterus.
- **In-clinic D&E abortion:** both suction and surgical tools are used to take the pregnancy out of the uterus.

At Planned Parenthood of Greater Washington and North Idaho, we offer both kinds of in-clinic abortion.

Before having an in-clinic abortion, you need to know the most common benefits, risks, side effects, and other choices you have. We are happy to answer any questions you have.

What are the benefits of in-clinic abortion?

- It is a safe and effective way to end a pregnancy.

How well does in-clinic abortion work?

- It almost always works – over 99% of the time.

What are the risks of in-clinic abortion?

Abortion is very safe. But, there are risks with any medical procedure. Your risk may be higher if you had a C-section or other surgery on your uterus.

Risks of an in-clinic abortion are

- **The pregnancy doesn't end** — Sometimes the in-clinic abortion does not end the pregnancy. If the pregnancy is still in the uterus, you may need a suction procedure.
- **Incomplete abortion** — This means some of the pregnancy may be left inside the uterus. This may lead to heavy bleeding, infection, or both. If this happens, you may need a suction procedure, other tests or treatments.
- **Blood clots in the uterus** — Clots may cause cramping and belly pain. If this happens, you may need a suction procedure.
- **Heavy bleeding** — This may require treatment with medicine, a suction procedure, blood transfusion, and/or surgery — including possible hysterectomy (removal of the uterus).
- **Infection of the uterus** — Most infections can be treated with medicines. But, there is a small chance that you may need a suction procedure. You may have to go to the hospital, or even have other surgery to treat the infection.
- **Injury to the cervix (opening to the uterus)** — This may be treated with medicine or rarely with stitches.
- **Injury to the uterus or other organs** — A surgical tool may go through the wall of the uterus, which could damage organs inside the body like the intestines, bladder, or blood vessels. Treatment may mean just watching and waiting for a while or surgery on your belly. There is a small chance that hysterectomy (removal of the uterus) may be needed. Afterwards, scars may develop inside the uterus, which may need to be treated.
- **Allergic reaction** — Some women may be allergic to the medicines that are used.
- **Death** — Death from an in-clinic abortion is very rare. The risk of death from an abortion goes up the longer you are pregnant. When an abortion is done when a woman is less than 20 weeks pregnant (about 4 ½ months), the risk of death from childbirth is higher than the risk of abortion. After 20 weeks of pregnancy, the risks are about the same.

What are the side effects of in-clinic abortion?

Side effects don't usually last long and don't need to be treated.

- Light or medium bleeding
- Cramping

NAME:

DATE:

PPGWN1#:

CL 01.003.02 (07/15)

Besides an in-clinic abortion, what other choices do I have?

If you are pregnant, you have 3 options to think about — abortion, adoption, and parenting.

If you choose abortion and are early enough in the pregnancy, you may be able to use the abortion pill.

We can talk about any of these options with you, and help you with whatever you decide to do.

What will be done to get me ready for the in-clinic abortion?

You will have some lab tests, an ultrasound to help tell how long you've been pregnant, and a brief physical exam.

Pain Medicine — We will tell you about pain medicines that can be used.

Opening your cervix — Your cervix may need to be opened before your abortion. If so, you will be given separate information about the medicine and/or steps that will be taken to open your cervix.

What will happen to me during the in-clinic abortion?

You will be given medicine to make you more comfortable. You may get medicine to numb your cervix.

After the pain medicine begins to work, your doctor or nurse will decide if your cervix is open enough. If your cervix needs to be opened more, your doctor or nurse will stretch it.

When your cervix is open enough, your uterus will be emptied with suction. A small plastic tube will be put into your uterus and connected to a hand-held or electric suction machine. Surgical tools may be put into the uterus through the cervix. The way it is done will depend on how long you've been pregnant.

You may feel cramping during and after the in-clinic abortion, as your uterus gets smaller. What has been removed will be looked at to help make sure the in-clinic abortion is finished.

What will happen to me after the in-clinic abortion?

You will spend time in a recovery area to rest. We will also watch to see if you are OK. You will be given instructions on what to expect, how to care for yourself and reasons to contact us. We will talk about birth control plans with you, unless this was already done.

Most people are ready to leave in about 15 to 45 minutes.

What else do I need to know?

Having a wide range of feelings is normal. Most women feel relieved and do not regret their decision. Others may feel sadness, guilt, or regret after an abortion, just as they may after having a baby. If your mood keeps you from doing the things you usually do each day, call us. We can help or send you to someone who can.

No promise can be made about the outcome of your in-clinic abortion. In the unlikely event that you need emergency medical care that cannot be provided at Planned Parenthood, you will be responsible for paying for it. This is the case even if Planned Parenthood sends you to a hospital because of a problem.

Your health is important to us. If you have any questions or concerns, please call us at 1.866.904.7721
We are happy to help you.

☐ I am having an in-clinic suction abortion

☐ I am having an in-clinic D&E abortion

Client Signature

Date

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature

Date

NAME:

DATE:

PPGWNl#:

CL 01.003.02 (07/15)



Planned Parenthood of Greater Washington and North Idaho
123 E Indiana Ave, Spokane, WA 99207 1.866.804.7721

Client Information for Informed Consent **Anesthesia**

What is anesthesia?

Anesthesia (an-iss-tea-zha) is medicine to make you comfortable during a surgery or procedure. There are many types of anesthesia.

Before you choose to have any type of anesthesia, you need to know your choices and the most common benefits, side effects, risks, and alternatives. We have listed them here for you. We are happy to answer any questions you have.

NO MATTER WHICH ANESTHESIA YOU CHOOSE, tell us if you have

- breathing problems
- heart problems
- used prescription medicines that can cause sleepiness
- any allergies to medicines or drugs
- taken any diet pills, street drugs or alcohol in the last 2 weeks

If you are found to be at increased risk for problems on the day of your appointment, you cannot be given moderate or deep sedation. You may not be given minimal sedation.

MINIMAL SEDATION

Minimal sedation is medicine that you swallow or is injected into a muscle. You will not fall asleep but you may feel more relaxed. These medicines may lessen anxiety and/or pain. If you choose this type of anesthesia, you may eat a light meal before your appointment.

What are the risks of minimal sedation?

Although the medicines used for minimal sedation are safe, there are problems that can occur. You may become sleepier than expected or even fall completely asleep. This could happen because of

- the types of medicine you are given
- your health
- any drugs or medicine you took
- a reaction you may have to the medicines

Major problems that can happen include

- allergic reaction to the medicine

What are the benefits of minimal sedation?

Minimal sedation is safe. It may lessen your pain and anxiety.

MODERATE SEDATION – also called IV sedation

Moderate sedation is medicine that is given directly into your vein. You will not fall asleep but you will feel more relaxed. You will get instructions about when to stop eating and drinking before moderate sedation is given.

What are the risks of moderate sedation?

Although the medicines used for moderate sedation are safe, there are problems that can occur. You may have swelling at the injection site (phlebitis). You may become sleepier than expected or even fall completely asleep.

This could happen because of

- the types of medicine you are given
- your health
- any drugs or medicine you took
- a reaction you may have to the medicines

NAME:

DATE:

PPGWN1#:

CL 02.001.00 (03/15)

Major problems that can happen include

- allergic reactions
- damage to or failure of the heart, lungs, liver, kidneys, and/or brain
- death

What are the benefits of moderate sedation?

Moderate sedation is safe. It may lessen your pain and anxiety. It may keep you from remembering parts of the procedure later on.

MONITORED ANESTHESIA CARE (MAC)

MAC is medicine that is given by a special doctor or nurse directly into your vein. You will fall asleep before your procedure. You will have little or no memory of it. You will get instructions about when to stop eating and drinking before deep sedation is given. You may be given oxygen to breathe.

What are the risks of MAC?

Although MAC is safe, there are problems that can occur. You may have swelling at the injection site (phlebitis). Major problems that can happen include

- allergic reactions
- damage to or failure of the heart, lungs, liver, kidneys, and/or brain
- loss of consciousness
- death

What are the benefits of MAC?

MAC is safe. It will lessen your pain and anxiety. It may keep you from remembering most or all of the procedure later on.

If you have problems during or after anesthesia, you may be sent to a hospital or emergency room. This is rare.

After your sedation

The effects of sedation can last for several hours. Do not drive, operate heavy machinery, or make important decisions for at least 24 hours after sedation.

You **MUST** not drive. You must leave the health center with a responsible adult who will drive or ride other transportation with you.

What are my other choices?

There many types of anesthesia. We have listed the types that are available to you at our health center. You may choose to have a different type of anesthesia, or no anesthesia at all. We can discuss these options with you. And we can help you with whatever decision you make.

I choose

- ☐ minimal sedation
- ☐ moderate sedation
- ☐ MAC

Signature of Client

Date

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature

Date

NAME:

DATE:

PPGWN#:

CL 02.001.00 (03/15)



Planned Parenthood of Greater Washington and North Idaho
123 E Indiana Ave, Spokane, WA 99207 1.886.904.7721

MEDICAL INFORMATION RELEASE FORM

_____/_____/_____/_____/_____/_____
Patient's Last Name First Name M. Initial Date of Birth

Other name(s) medical records may be under. _____

MAIL RECORDS TO: Medical Records Department, 123 E. Indiana Ave., Spokane, WA 99207

FAX RECORDS TO: 1.509.248.3644

FROM: _____ TO: _____

READ CAREFULLY

I understand my medical records may contain information regarding sexually transmitted diseases, including HIV/AIDS, and information regarding abortion services. Release of this information is voluntary and is protected by State Law. I hereby release Planned Parenthood of Greater Washington and North Idaho and its staff from all legal responsibility that may arise from the release of medical information hereby authorized. I authorize you to release the following information to the physician/clinic indicated above. I understand that I have the right to revoke or cancel this authorization, in writing, at any time.

- ☐ My CURRENT MEDICAL RECORD, including past history, testing or treatment for sexually transmitted diseases, drug or alcohol abuse, abortion, and/or mental illness, INCLUDING information pertaining to HIV testing and AIDS.
- ☐ My medical record, INCLUDING my past history, testing, and treatment for sexually transmitted diseases, drug or alcohol abuse, and/or mental illness, EXCEPT for information pertaining to HIV testing and AIDS and/or abortion.
- ☐ My medical record, BUT NOT information relating to my past history, testing or treatment for sexually transmitted diseases, drug or alcohol abuse, and/or mental illness, or information pertaining to HIV testing and AIDS and abortion.
- ☐ OTHER: _____

Signature

_____/_____/_____
Date

NAME:

DOB:

PPGWN I #:

VALID FOR 90 DAYS FROM DATE SIGNED.

CL 00.014.00 (03/15)

UNIVERSITY OF WASHINGTON
BIRTH DEFECTS RESEARCH LABORATORY

H-

Consent Form for the Donation of Embryonic or Fetal Tissue

RECEIVED
Human Subjects Division

Investigators:

Ian A. Glass, MD	Professor, Pediatrics	(206) 616-9278
Vivienne Souter	Ob/Gyn	(206) 616-9278
Julie Taylor	Research Scientist, Pediatrics	(206) 616-9278
Theresa Naluai-Cecchini	Research Scientist, Pediatrics	(206) 616-9278

MAY 20 2015

UW

Researcher's Statement:

The purpose of this consent form is to give you the information you will need to help you to decide whether to be in this study. Please read the form carefully. You may ask questions about what we will ask you to do, the risks, the benefits, your rights as a volunteer, or anything else about the research on this form that is not clear. When all your questions have been answered you can decide if you want to be in this study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

We are asking you to donate embryonic or fetal tissue to a tissue storage bank (repository). The purpose of our research is to study birth defects and other diseases, now and in the future. We use tissues from fetuses and embryos in this research. With these donated tissues, we can study the causes of birth defects and how organs and tissues develop normally or abnormally. We can look at the causes and treatment of cancer and understand more about certain brain disorders such as Alzheimer's and Parkinson's disease. We can also study the effects of medications or drugs on the growing brain, what may cause blindness, and study HIV infection. Research using donated tissues can take place in many areas of science.

STUDY PROCEDURES

You are being asked to donate tissue to a repository (tissue storage bank) since you have made the decision on your own to have clinical care related to fetal loss, miscarriage or decided to have an abortion. The timing or procedures for your medical care will not be changed to allow us to collect this tissue. If your doctor or hospital needs to look at the tissue they will be able to. We will only take tissue that your doctor or hospital does not need for your care or treatment. If you give your permission we may want to talk to your doctor about your medical history and about anything we learn that is important for your healthcare. Your doctor may put this information on your medical record.

Sometimes the fetal tissue will be collected from an intact fetus. Incisions like those used in autopsy will be made to collect the tissue or organs for research. Then the incisions will be closed. If you and your doctor have discussed having an autopsy performed, please know that donating to research will not effect this decision. We will collect tissue only after the Pathologist has completed their exam and taken enough tissue to make a diagnosis.

We send tissue to scientists at other hospitals and schools. Examples of tissue collected and sent to scientists for study are: brain, liver, kidney, ovary or testis, eyes, and skin. Please note this is not the complete list of tissue or organs collected and sent to researchers. The tissue may be used in research and/or for education purposes. Tissue is never used for commercial purposes. The Birth Defects Research Lab will be unable to return any remains unless you choose to make private arrangements. If the termination is due to a birth defect or abnormality, we may request additional medical records but we would only access them for one year.

APPROVED

MAY 21 2015

Genetic research involves any analysis used to look at a person's genetic make-up. Sometimes a person's genetic make-up may cause disease, birth defects, or cause an increased chance of developing a certain condition. Genetic tests can be performed on blood, cheek cells, or saliva. We will examine your DNA (deoxyribonucleic acid), RNA (ribonucleic acid), proteins, or other chemicals in cells that indicate genetic condition. While these tests can confirm a diagnosis or help predict the chance a person will develop a disease or condition in the future, there is no one test that detects all genetic disease. It is possible that we may discover a previously unknown genetic condition. We expect research analysis will take up to 5 years to complete and will not be clinically useful to you.

RISKS, STRESS, OR DISCOMFORT

You may experience emotional distress while you are trying to decide if you want to donate tissue for research. You may experience some pain with the blood draw and in rare cases develop a bruise at the site of the blood draw. Rarely, an infection may develop. It is possible that we, or an outside investigator, may discover a previously unknown genetic disorder.

BENEFITS

We expect that the studies will take many years to complete. If you donate tissue, blood, or saliva it will not directly benefit you; but we hope the information gained by researchers will help future generations.

SOURCE OF FUNDING

Dr. Ian Glass and the study team is receiving payment from the study sponsor the National Institute of Child Health and Human Development for the time spent completing study-related duties.

CONFIDENTIALITY OF RESEARCH INFORMATION

We have a Certificate of Confidentiality from the National Institute of Health of Child and Human Development. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information. We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a family member can share your information or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the University of Washington, the funding National Institute of Health, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- someone who is accused of a crime, if he or she believes that our research records be used for defense.

Although we will make every effort to keep your information confidential, no system for protecting your confidentiality can be completely secure. It is possible that someone might discover that you are in this study, or might obtain information about you. University and government offices sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk or harm.

We will identify the tissue and information about you with a study code. The link between the study code and the consent form with your name is kept in a separate secure area accessible only to the researchers involved in this study. This link will be kept for one year. Written and electronic records of work will be kept indefinitely, but it will not be possible to learn who you are from these records. If we send your tissue to researchers who are not part of the Birth Defects Research Laboratory we will not send them your name.

OTHER INFORMATION

We will provide a copy of the signed consent the pathology lab or clinic; this document lets them know you authorize the release of the tissue to us for research. We will not include a copy of the optional medical health information and it will not contain the study ID. The study ID is assigned after we bring the sample to the lab; they will not be able to link your name and the study ID. We will not pay you to be in this study. We will not pay you for donating the tissue. You don't have to donate tissue if you don't want to. You will have the same medical care you would have if you choose to donate tissue or not donate. Donated blood/saliva and tissue cannot be returned and may be stored indefinitely. We will not tell you which researchers might use this tissue or what the donated tissue will be used for; some researchers may perform whole genome wild analysis of your DNA. Researchers who receive our samples may submit de-identified information about the samples to a national database such as the database of Genotypes and Phenotypes (dbGaP). Researchers who receive our samples may submit de-identified information about the samples to an open access (public) scientific databases, for example the National Institutes of Health's (NIH) National Center for Biotechnology Information (NCBI) and the National Human Genome Research Institute (NHGRI). In order for researchers to share test results, the National Institutes of Health (NIH) and other central repositories have developed special data banks that collect the results of whole genome studies. The NIH and other data banks will store your genetic information and give it to other qualified research to do more studies. Qualified researches that can access the national database can be from the government, or academic, and not-for-profit institutions. We do not think that there will be further risks to your privacy and confidentiality by sharing your whole genome analysis with these databanks; however, we cannot predict how genetic information will be used in the future. Your name and other identifiable information will never be given to them. There are many safeguards in place to protect your information while it is stored in repositories and used for research.

There is a small chance that your genetic information could be shared with others by mistake. In the unlikely event that your information was mistakenly shared and linked with a medical condition you have it could affect your ability to get or keep some kinds of insurance. There is also the risk that data could be released to the public, employers, or law enforcement agencies. If family members were to see this information it could also affect them. This could hurt family relationships. It is possible that you could be identified from the sample if someone has another sample from you. The two samples could be matched to identify you from the sample given for this repository.

You will not receive any results from allowing your data to be placed in a national database. You do not have to participate in sharing your genetic information with the national databases and can withdraw your consent at any time. There will be no consequence for withdrawing consent. However, data that has already been sent to researchers cannot be retrieved from those researchers.

If you have questions about the research you can call Dr. Ian Glass or Laboratory staff at (206) 616-9278

Printed Name of person obtaining consent Signature of person obtaining consent Date

Subject's Statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research I can ask one of the researchers listed above. If I have questions about my rights as a research subject I can call the Human Subjects Division at (206) 543-0098. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Please mark the following choices:

<input type="checkbox"/> YES <input type="checkbox"/> NO	You may keep my fetal DNA samples and medical records, indefinitely.
<input type="checkbox"/> YES <input type="checkbox"/> NO	I will allow other researchers to submit fetal DNA information to a national database such as the database of Genotypes and Phenotypes (dbGaP) and open access (public) scientific databases such as NIH's National Center for Biotechnology Information and National Human Genome Research Institute.
<input type="checkbox"/> YES <input type="checkbox"/> NO	I agree to contact my family members about this research, if requested.

Printed Name of Subject Signature of Subject Date

Copies to: Subject
 Investigator's files

H-

Age: _____

Date of **last** menstrual period _____

Age at **first** menstrual period _____

Is it regular? ____ YES or ____ NO

of Pregnancies (including this pregnancy) _____

of Terminations (including this pregnancy) _____

of Miscarriages (including this pregnancy) _____

Medications (name/dosage/frequency):
(please include prescription and over-the counter)

Recreational Drug Use:

during this pregnancy only

Last use / How Often?

☐ Alcohol _____

☐ Tobacco/Cigarettes _____

☐ Marijuana _____

☐ Other (specify) _____

Ethnicity/Race: _____

Health History: (please indicate by circling)

☐ Heart Disease Self or Family

☐ congenital

☐ other

☐ High Blood Pressure Self or Family

☐ medication-regulated

☐ with pregnancy only

☐ Diabetes Self or Family

☐ insulin-dependent

☐ gestational diabetes

Age at diagnosis _____

☐ Epilepsy Self or Family

☐ medication-regulated

☐ Cancer Self or Family

☐ Birth Defect and/or Self or Family
Genetic Disorder **including this pregnancy**

☐ Other Self or Family

Provider to complete this section:

Fetal Anomalies
<div style="text-align: center; margin-bottom: 10px;"> Yes _____ No _____ </div> <div style="margin-bottom: 10px;"> Specify: _____ _____ </div> <div> Referring Physician _____ </div>

Ultrasound Measurements	Procedure	Fetal Tissue Measurement
Date _____ <div style="display: flex; justify-content: space-between; align-items: center;"> <div>▫ CRL</div> <div>_____ mm/cm</div> </div> <div style="display: flex; justify-content: space-between; align-items: center;"> <div>▫ BPD</div> <div>_____ mm/cm</div> </div> <div style="display: flex; justify-content: space-between; align-items: center;"> <div>▫ Gest. Sac</div> <div>_____ mm/cm</div> </div> <div style="display: flex; justify-content: space-between; align-items: center;"> <div>▫ FL</div> <div>_____ mm/cm</div> </div>	Procedure Date: _____ Procedure End Time: _____	<div style="display: flex; justify-content: space-between; align-items: center;"> <div>▫ FF</div> <div>_____ mm</div> </div> <div style="display: flex; justify-content: space-between; align-items: center; margin-top: 10px;"> <div>▫ Other</div> <div>_____</div> </div>

Dissection Date: _____

Dissection Time: _____

UNIVERSITY OF WASHINGTON
BIRTH DEFECTS RESEARCH LABORATORY

H-

Consent Form for the Donation of Embryonic or Fetal Tissue

RECEIVED
Human Subjects Division

MAY 20 2015

UW

Investigators:

Ian A. Glass, MD

Vivienne Souter, MD

Julie Taylor

Theresa Nalwai-Cecchini

Professor, Pediatrics

Ob/Gyn

Research Scientist, Pediatrics

Research Scientist, Pediatrics

(206) 616-9278

(206) 616-9278

(206) 616-9278

(206) 616-9278

Researcher's Statement:

The purpose of this consent form is to give you the information you will need to help you to decide whether to be in this study. Please read the form carefully. You may ask questions about what we will ask you to do, the risks, the benefits, your rights as a volunteer, or anything else about the research on this form that is not clear. When all your questions have been answered you can decide if you want to be in this study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

We are asking you to donate embryonic or fetal tissue to a tissue storage bank (repository). The purpose of our research is to study birth defects and other diseases, now and in the future. We use tissues from fetuses and embryos in this research. With these donated tissues, we can study the causes of birth defects and how organs and tissues develop normally or abnormally. We can look at the causes and treatment of cancer and understand more about certain brain disorders such as Alzheimer's and Parkinson's disease. We can also study the effects of medications or drugs on the growing brain, what may cause blindness, and study HIV infection. Research using donated tissues can take place in many areas of science.

STUDY PROCEDURES

You are being asked to donate tissue to a repository (tissue storage bank) since you have made the decision on your own to have clinical care related to fetal loss, miscarriage or decided to have an abortion. The timing or procedures for your medical care will not be changed to allow us to collect this tissue. If your doctor or hospital needs to look at the tissue they will be able to. We will only take tissue that your doctor or hospital does not need for your care or treatment. If you give your permission we may want to talk to your doctor about your medical history and about anything we learn that is important for your healthcare. Your doctor may put this information on your medical record. We send tissue to scientists at other hospitals and schools. Examples of tissue collected and sent to scientists for study are: brain, liver, kidney, ovary or testis, eyes, and skin. Please note this is not the complete list of tissue or organs collected and sent to researchers. The tissue may be used in research and/or for education purposes. Tissue is never used for commercial purposes. The Birth Defects Research Lab will be unable to return any remains unless you choose to make private arrangements. If the termination is due to a birth defect or abnormality, we may request additional medical records but would only look at them for one year.

Genetic research involves any analysis used to look at a person's genetic make-up. Sometimes a person's genetic make-up may cause disease, birth defects, or cause an increased chance of developing a certain condition. Genetic tests can be performed on blood, cheek cells, or saliva. We will examine your DNA (deoxyribonucleic acid), RNA (ribonucleic acid), proteins, or other chemicals in cells that indicate genetic

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condition. While these tests can confirm a diagnosis or help predict the chance a person will develop a disease or condition in the future, there is no one test that detects all genetic disease. It is possible that we may discover a previously unknown genetic condition. We expect research analysis will take up to 5 years to complete and will not be clinically useful to you.

RISKS, STRESS, OR DISCOMFORT

You may experience emotional distress while you are trying to decide if you want to donate tissue for research. You may experience some pain with the blood draw and in rare cases develop a bruise at the site of the blood draw. Rarely, an infection may develop. It is possible that we, or an outside investigator, may discover a previously unknown genetic disorder.

BENEFITS

We expect that the studies will take many years to complete. If you donate tissue, blood, or saliva it will not directly benefit you but we hope the information gained by researchers will help future generations.

SOURCE OF FUNDING

Dr. Ian Glass and the study team is receiving payment from the study sponsor the National Institute of Child Health and Human Development for the time spent completing study-related duties.

CONFIDENTIALITY OF RESEARCH INFORMATION

We have a Certificate of Confidentiality from the National Institute of Health of Child and Human Development. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information. We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a family member can share your information or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the University of Washington, the funding National Institute of Health, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA.

Although we will make every effort to keep your information confidential, no system for protecting your confidentiality can be completely secure. It is possible that someone might discover that you are in this study, or might obtain information about you. University and government offices sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk or harm.

We will identify the tissue and information about you with a study code. The link between the study code and the consent form with your name is kept in a separate secure area accessible only to the researchers involved

in this study. This link will be kept for one year. Written and electronic records of work will be kept indefinitely, but it will not be possible to learn who you are from these records. If we send your tissue to researchers who are not part of the Birth Defects Research Laboratory we will not send them your name.

OTHER INFORMATION

We will provide a copy of the signed consent the pathology lab or clinic; this document lets them know you authorize the release of the tissue to us for research. We will not include a copy of the optional medical health information and it will not contain the study ID. The study ID is assigned after we bring the sample to the lab, they will not be able to link your name and the study ID. We will not pay you to be in this study. We will not pay you for donating the tissue. You don't have to donate tissue if you don't want to. You will have the same medical care you would have if you choose to donate tissue or not donate. Donated tissue cannot be returned and may be stored indefinitely. We will not tell you which researchers might use this tissue or what the donated tissue will be used for; some researchers may perform whole genome wild analysis of your DNA. Researchers who receive our samples may submit de-identified information about the samples to a national database such as the database of Genotypes and Phenotypes (dbGaP). Researchers who receive our samples may submit de-identified information about the samples to an open access (public) scientific databases, for example the National Institutes of Health's (NIH) National Center for Biotechnology Information (NCBI) and the National Human Genome Research Institute (NHGRI). In order for researchers to share test results, the NIH and other central repositories have developed special data banks that collect the results of whole genome studies. The NIH and other data banks will store your genetic information and give it to other qualified research to do more studies. Qualified researches that can access the national database can be from the government, or academic, and not-for-profit institutions. We do not think that there will be further risks to your privacy and confidentiality by sharing your whole genome analysis with these databanks; however, we cannot predict how genetic information will be used in the future. Your name and other identifiable information will never be given to them. There are many safeguards in place to protect your information while it is stored in repositories and used for research.

There is a small chance that your genetic information could be shared with others by mistake. In the unlikely event that your information was mistakenly shared and linked with a medical condition you have it could affect your ability to get or keep some kinds of insurance. There is also the risk that data could be released to the public, employers, or law enforcement agencies. If family members were to see this information it could also affect them. This could hurt family relationships. It is possible that you could be identified from the sample if someone has another sample from you. The two samples could be matched to identify you from the sample given for this repository.

You will not receive any results from allowing your data to be placed in a national database. You do not have to participate in sharing your genetic information with the national databases and can withdraw your consent at any time. There will be no consequence for withdrawing consent. However, data that has already been sent to researchers cannot be retrieved from those researchers.

If you have questions about the research you can call Dr. Ian Glass or Laboratory staff at (206) 616-9278.

Printed Name of person obtaining consent

Signature of person obtaining consent

Date

SUBJECT'S STATEMENT

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research I can ask one of the researchers listed above. If I have questions about my rights as a research subject I can call the Human Subjects Division at (206) 543-0098. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Please mark the following choices:

<input type="checkbox"/> YES <input type="checkbox"/> NO	You may keep my fetal DNA samples and medical records, indefinitely.
<input type="checkbox"/> YES <input type="checkbox"/> NO	I will allow other researchers to submit fetal DNA information to national databases such as the database of Genotypes and Phenotypes (dbGaP) and open access (public) scientific databases such as NIH's National Center for Biotechnology Information and National Human Genome Research Institute.
<input type="checkbox"/> YES <input type="checkbox"/> NO	I agree to contact my family members about this research, if requested.

Printed Name of Subject

Signature of Subject

Date

Copies to: Subject
 Investigator's files

H-

OPTIONAL information:

Age: _____

Date of last menstrual period _____

Age at first menstrual period _____

Is it regular? ____ YES or ____ NO

of Pregnancies (including this pregnancy) _____

of Terminations (including this pregnancy) _____

of Miscarriages (including this pregnancy) _____

Medications (name/dosage/frequency):
(please include prescription and over-the counter)

Recreational Drug Use:

during this pregnancy only

Last use / How Often?

- ☐ Alcohol _____
- ☐ Tobacco/Cigarettes _____
- ☐ Marijuana _____
- ☐ Methamphetamine _____
- ☐ Cocaine _____
- ☐ Heroin _____
- ☐ Other (specify) _____
- _____

Ethnicity/Race: _____

Health History: (please indicate by circling)

- ☐ Heart Disease Self or Family
☐ congenital
☐ other
- ☐ High Blood Pressure Self or Family
☐ medication-regulated
☐ with pregnancy only
- ☐ Diabetes Self or Family
☐ insulin-dependent
☐ gestational diabetes
Age at diagnosis _____
- ☐ Epilepsy Self or Family
☐ medication-regulated

☐ Cancer Self or Family

☐ Birth Defect and/or Self or Family
Genetic Disorder **including this pregnancy**

☐ Other Self or Family

Provider to complete this section:

Fetal Anomalies
<p>Yes _____ No _____</p> <p>Specify: _____</p> <p>_____</p> <p>Referring Physician _____</p>

Ultrasound Measurements	Procedure	Fetal Tissue Measurement
<p>Date _____</p> <p>□ CRL _____ mm/cm</p> <p>□ BPD _____ mm/cm</p> <p>□ Gest. Sac _____ mm/cm</p> <p>□ FL _____ mm/cm</p>	<p>Procedure Date: _____</p> <p>Procedure End Time: _____</p>	<p>□ FF _____ mm</p> <p>□ Other _____</p>

Dissection Date: _____

Dissection Time: _____