DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Voice - (800) 368-1019
TDD - (202) 619-3257
Fax - (202) 619-3818
http://www.hhs.gov/ocr

Office for Civil Rights
200 Independence Avenue, S.W.,
Room 509F
Washington, DC 20201

August 9, 2017

(b)(6);(b)(7)(C)

RE: OCR Transaction Number: 16-222823: (b)(6);(b)(7)(C) vs. Planned Parenthood

Dear (b)(6);(b)(7)(

Thank you for your correspondence to the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR).

OCR enforces the Privacy, Security, and Breach Notification Rules, and also Federal civil rights laws which prohibit discrimination in the delivery of health and human services because of race, color, national origin, disability, age, and under certain circumstances, sex and religion.

We have reviewed your complaint against Planned Parenthood, and have determined that OCR will not investigate your allegations. Therefore, OCR is closing this complaint with no further action, effective the date of this letter.

OCR's determination as stated in this applies only to the allegations in this complaint that were reviewed by OCR.

Under the Freedom of Information Act, we may be required to release this letter and other information about this case upon request by the public. In the event OCR receives such a request, we will make every effort, as permitted by law, to protect information that identifies individuals or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

We regret we are unable to assist you further. Thank you.

Sincerely yours,

Sarah C. Brown
Associate Deputy Director for Regional Operations

English	If you speak a non-English language, call 1-800–368–1019 (TTY: 1-800-537-7697), and you will be connected to an interpreter who will assist you with this document at no cost.
Español - Spanish	Si usted habla español marque 1-800-368-1019 (o a la línea de teléfono por texto TTY 1-800-537-7697) y su llamada será conectada con un intérprete que le asistirá con este documento sin costo alguno.
中文 - Chinese	如果你讲中文，请拨打1-800-368-1019（打字电话：1-800-537-7697), 你将被连接到一位讲同语种的翻译员为你提供免费服务。
Tiếng Việt - Vietnamese	Nếu bạn nói tiếng Việt, xin gọi 1-800-368-1019 (TTY: 1-800-537-7697), và bạn sẽ được kết nối với một thông dịch viên, người này sẽ hỗ trợ bạn với tài liệu này miễn phí.
한국어 - Korean	한국어를 하시면 1-800-368-1019 (청각 장애용: 1-800-537-7697) 로 연락 주세요. 통역관과 연결해서 당신의 서류를 무료로 도와 드리겠습니다.
Tagalog (Filipino)	Kung ikaw ay nagsasalita nang Tagalog, tumawag sa 1-800-368-1019 (TTY: 1-800-537-7697) para makonek sa tagapagsalin na tutulong sa iyo sa dokumentong ito na walang bayad.
Русский - Russian	Если вы говорите по- русски, наберите 1-800-368-1019. Для клиентов с ограниченными слуховыми и речевыми возможностями: 1-800-537-7697), и вас соединят с русскоговорящим переводчиком, который вам поможет с этим документом безвозмездно.

Form Approved: OMB No. 0990-0269.
See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE FOR CIVIL RIGHTS (OCR)

HEALTH INFORMATION PRIVACY COMPLAINT

YOUR FIRST NAME	YOUR LAST NAME
(b)(6);(b)(7)(C)	(b)(6);(b)(7)(C)
HOME / CELL PHONE (Please include area code)	WORK PHONE (Please include area code)
(b)(6);(b)(7)(C)	

STREET ADDRESS	CITY
(b)(6);(b)(7)(C)	(b)(6);(b)(7)(C)

STATE	ZIP	E-MAIL ADDRESS (If available)
(b)(6);(b)(7)(C)	(b)(6);(b)(7)(C)	(b)(6);(b)(7)(C)

Are you filing this complaint for someone else? ☐ Yes ☒ No

If Yes, whose health information privacy rights do you believe were violated?

FIRST NAME	LAST NAME

Who (or what agency or organization, e.g., provider, health plan) do you believe violated your (or someone else's) health information privacy rights or committed another violation of the Privacy Rule?

PERSON/AGENCY/ORGANIZATION

Planned Parenthood of Metropolitan New Jersey

STREET ADDRESS	CITY
560 Martin Luther King Blvd.	East Orange

STATE	ZIP	PHONE (Please include area code)
New Jersey	07018	(973) 674-4343

When do you believe that the violation of health information privacy rights occurred?

LIST DATE(S)

10/08/0015

Describe briefly what happened. How and why do you believe your (or someone else's) health information privacy rights were violated, or the privacy rule otherwise was violated? Please be as specific as possible. (Attach additional pages as needed)

I received a letter on 10/16/15 that stated that there was a problem with an abnormal pap/hpv test. This letter also had my planned parenthood file ID number on it. The problem is I was never serviced by them since 2014. This letter had no unit number on the address at which anyone in my complex could have obtained this information as it being left in the lobby, and with my address and ID number that Planned Parenthood released in hand they could portray as me. Secondly the person who actually was serviced has NO IDEA that there is a health concern that needs to be addressed and lastly, when I called they have no record or idea how protocol was not followed and my information along with misinformation about me was sent out. They also raised concern when I was instructed to destroy the letter which is the only evidence I have of this occurrence. I feel embarrassed, anxious, concerned

This field may be truncated due to size limit. See the "Allegation Description" file in the case folder.

Please sign and date this complaint. You do not need to sign if submitting this form by email because submission by email represents your signature.

SIGNATURE	DATE *(mm/dd/yyyy)*
(b)(6);(b)(7)(C)	10/29/2015

Filing a complaint with OCR is voluntary. However, without the information requested above, OCR may be unable to proceed with your complaint. We collect this information under authority of the Privacy Rule issued pursuant to the Health Insurance Portability and Accountability Act of 1996. We will use the information you provide to determine if we have jurisdiction and, if so, how we will process your complaint. Information submitted on this form is treated confidentially and is protected under the provisions of the Privacy Act of 1974. Names or other identifying information about individuals are disclosed when it is necessary for investigation of possible health information privacy violations, for internal systems operations, or for routine uses, which include disclosure of information outside the Department for purposes associated with health information privacy compliance and as permitted by law. It is illegal for a covered entity to intimidate, threaten, coerce, discriminate or retaliate against you for filing this complaint or for taking any other action to enforce your rights under the Privacy Rule. You are not required to use this form. You also may write a letter or submit a complaint electronically with the same information. To submit an electronic complaint, go to OCR's Web site at:
www.hhs.gov/ocr/privacy/hipaa/complaints/index.html. To mail a complaint see reverse page for OCR Regional addresses.

The remaining information on this form is optional. Failure to answer these voluntary questions will not affect OCR's decision to process your complaint.

Do you need special accommodations for us to communicate with you about this complaint? (Check all that apply)

☐ Braille ☐ Large Print ☐ Cassette tape ☐ Computer diskette ☐ Electronic mail ☐ TDD

☐ Sign language interpreter (specify language): _____

☐ Foreign language interpreter (specify language): _____ ☐ Other: _____

If we cannot reach you directly, is there someone we can contact to help us reach you?

FIRST NAME	LAST NAME
HOME / CELL PHONE (Please include area code)	WORK PHONE (Please include area code)
STREET ADDRESS	CITY

STATE	ZIP	E-MAIL ADDRESS (If available)

Have you filed your complaint anywhere else? If so, please provide the following. (Attach additional pages as needed)

PERSON/AGENCY/ORGANIZATION/ COURT NAME(S)

DATE(S) FILED	CASE NUMBER(S) (If known)

To help us better serve the public, please provide the following information for the person you believe had their health information privacy rights violated (you or the person on whose behalf you are filing).

ETHNICITY (select one)

☐ Hispanic or Latino

☐ Not Hispanic or Latino

RACE (select one or more)

☐ American Indian or Alaska Native ☐ Asian ☐ Native Hawaiian or Other Pacific Islander

☐ Black or African American ☐ White ☐ Other (specify): _____

PRIMARY LANGUAGE SPOKEN (if other then English) _____

How did you learn about the Office for Civil Rights?

☒ HHS Website/Internet Search ☐ Family/Friend/Associate ☐ Religious/Community Org ☐ Lawyer/Legal Org ☐ Phone Directory ☐ Employer

☐ Fed/State/Local Gov ☐ Healthcare Provider/Health Plan ☐ Conference/OCR Brochure ☐ Other (specify): _____

To mail a complaint, please type or print, and return completed complaint to the OCR Regional Address based on the region where the alleged violation took place. If you need assistance completing this form, contact the appropriate region listed below.

Region I - CT, ME, MA, NH, RI, VT
Office for Civil Rights, DHHS
JFK Federal Building - Room 1875
Boston, MA 02203
(617) 565-1340; (617) 565-1343 (TDD)
(617) 565-3809 FAX

Region II - NJ, NY, PR, VI
Office for Civil Rights, DHHS
26 Federal Plaza - Suite 3312
New York, NY 10278
(212) 264-3313; (212) 264-2355 (TDD)
(212) 264-3039 FAX

Region III - DE, DC, MD, PA, VA, WV
Office for Civil Rights, DHHS
150 S. Independence Mall West - Suite 372
Philadelphia, PA 19106-3499
(215) 861-4441; (215) 861-4440 (TDD)
(215) 861-4431 FAX

Region IV - AL, FL, GA, KY, MS, NC, SC, TN
Office for Civil Rights, DHHS
61 Forsyth Street, SW. - Suite 16T70
Atlanta, GA 30303-8909
(404) 562-7886; (404) 562-7884 (TDD)
(404) 562-7881 FAX

Region V - IL, IN, MI, MN, OH, WI
Office for Civil Rights, DHHS
233 N. Michigan Ave. - Suite 240
Chicago, IL 60601
(312) 886-2359; (312) 353-5693 (TDD)
(312) 886-1807 FAX

Region VI - AR, LA, NM, OK, TX
Office for Civil Rights, DHHS
1301 Young Street - Suite 1169
Dallas, TX 75202
(214) 767-4056; (214) 767-8940 (TDD)
(214) 767-0432 FAX

Region VII - IA, KS, MO, NE
Office for Civil Rights, DHHS
601 East 12th Street - Room 248
Kansas City, MO 64106
(816) 426-7277; (816) 426-7065 (TDD)
(816) 426-3686 FAX

Region VIII - CO, MT, ND, SD, UT, WY
Office for Civil Rights, DHHS
999 18th Street, Suite 417
Denver, CO 80202
(303) 844-2024; (303) 844-3439 (TDD)
(303) 844-2025 FAX

Region IX - AZ, CA, HI, NV, AS, GU, The U.S. Affiliated Pacific Island Jurisdictions
Office for Civil Rights, DHHS
90 7th Street, Suite 4-100
San Francisco, CA 94103
(415) 437-8310; (415) 437-8311 (TDD)
(415) 437-8329 FAX

Region X - AK, ID, OR, WA
Office for Civil Rights, DHHS
701 Fifth Avenue, Suite 1600, MS - 11
Seattle, WA 98104
(206) 615-2290; (206) 615-2296 (TDD)
(206) 615-2297 FAX

Burden Statement

Public reporting burden for the collection of information on this complaint form is estimated to average 45 minutes per response, including the time for reviewing instructions, gathering the data needed and entering and reviewing the information on the completed complaint form. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: HHS/OS Reports Clearance Officer, Office of Information Resources Management, 200 Independence Ave. S.W., Room 531H, Washington, D.C. 20201. **Please do not mail complaint form to this address.**

COMPLAINANT CONSENT FORM

The Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) has the authority to collect and receive material and information about you, including personnel and medical records, which are relevant to its investigation of your complaint.

To investigate your complaint, OCR may need to reveal your identity or identifying information about you to persons at the entity or agency under investigation or to other persons, agencies, or entities.

The Privacy Act of 1974 protects certain federal records that contain personally identifiable information about you and, with your consent, allows OCR to use your name or other personal information, if necessary, to investigate your complaint.

Consent is voluntary, and it is not always needed in order to investigate your complaint; however, failure to give consent is likely to impede the investigation of your complaint and may result in the closure of your case.

Additionally, OCR may disclose information, including medical records and other personal information, which it has gathered during the course of its investigation in order to comply with a request under the Freedom of Information Act (FOIA) and may refer your complaint to another appropriate agency.

Under FOIA, OCR may be required to release information regarding the investigation of your complaint; however, we will make every effort, as permitted by law, to protect information that identifies individuals or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

Please read and review the documents entitled, *Notice to Complainants and Other Individuals Asked to Supply Information to the Office for Civil Rights* and *Protecting Personal Information in Complaint Investigations* for further information regarding how OCR may obtain, use, and disclose your information while investigating your complaint.

In order to expedite the investigation of your complaint if it is accepted by OCR, please read, sign, and return one copy of this consent form to OCR with your complaint. Please make one copy for your records.

- As a complainant, I understand that in the course of the investigation of my complaint it may become necessary for OCR to reveal my identity or identifying information about me to persons at the entity or agency under investigation or to other persons, agencies, or entities.

- I am also aware of the obligations of OCR to honor requests under the Freedom of Information Act (FOIA). I understand that it may be necessary for OCR to disclose information, including personally identifying information, which it has gathered as part of its investigation of my complaint.

- In addition, I understand that as a complainant I am covered by the Department of Health and Human Services' (HHS) regulations which protect any individual from being intimidated, threatened, coerced, retaliated against, or discriminated against because he/she has made a complaint, testified, assisted, or participated in any manner in any mediation, investigation, hearing, proceeding, or other part of HHS' investigation, conciliation, or enforcement process.

After reading the above information, please check ONLY ONE of the following boxes:

[X] **CONSENT:** I have read, understand, and agree to the above and give permission to OCR to reveal my identity or identifying information about me in my case file to persons at the entity or agency under investigation or to other relevant persons, agencies, or entities during any part of HHS' investigation, conciliation, or enforcement process.

[ ] **CONSENT DENIED:** I have read and I understand the above and do not give permission to OCR to reveal my identity or identifying information about me. I understand that this denial of consent is likely to impede the investigation of my complaint and may result in closure of the investigation.

Signature: (b)(6);(b)(7)(C) Date: 10/29/2015

**Please sign and date this complaint. You do not need to sign if submitting this form by email because submission by email represents your signature.*

Name (Please print): (b)(6);(b)(7)(C)

Address: (b)(6);(b)(7)(C)

Telephone Number (b)(6);(b)(7)(C)

NOTICE TO COMPLAINANTS AND OTHER INDIVIDUALS ASKED TO SUPPLY INFORMATION TO THE OFFICE FOR CIVIL RIGHTS

Privacy Act

The Privacy Act of 1974 (5 U.S.C. §552a) requires OCR to notify individuals whom it asks to supply information that:

— OCR is authorized to solicit information under:
(i) Federal laws barring discrimination by recipients of Federal financial assistance on grounds of race, color, national origin, disability, age, sex, religion under programs and activities receiving Federal financial assistance from the U.S. Department of Health and Human Services (HHS), including, but not limited to, Title VI of the Civil Rights Act of 1964 (42 U.S.C. §2000d et seq.), Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. §794), the Age Discrimination Act of 1975 (42 U.S.C. §6101 et seq.), Title IX of the Education Amendments of 1972 (20 U.S.C. §1681 et seq.), and Sections 794 and 855 of the Public Health Service Act (42 U.S.C. §§295m and 296g);
(ii) Titles VI and XVI of the Public Health Service Act (42 U.S.C. §§291 et seq. and 300s et seq.) and 42 C.F.R. Part 124, Subpart G (Community Service obligations of Hill-Burton facilities);
(iii) 45 C.F.R. Part 85, as it implements Section 504 of the Rehabilitation Act in programs conducted by HHS; and
(iv) Title II of the Americans with Disabilities Act (42 U.S.C. §12131 et seq.) and Department of Justice regulations at 28 C.F.R. Part 35, which give HHS "designated agency" authority to investigate and resolve disability discrimination complaints against certain public entities, defined as health and service agencies of state and local governments, regardless of whether they receive federal financial assistance.
(v) The Standards for the Privacy of Individually Identifiable Health Information (The Privacy Rule) at 45 C.F.R. Part 160 and Subparts A and E of Part 164, which enforce the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 U.S.C. §1320d-2).

OCR will request information for the purpose of determining and securing compliance with the Federal laws listed above. Disclosure of this requested information to OCR by individuals who are not recipients of federal financial assistance is voluntary; however, even individuals who voluntarily disclose information are subject to prosecution and penalties under 18 U.S.C. § 1001 for making false statements.

Additionally, although disclosure is voluntary for individuals who are not recipients of federal financial assistance, failure to provide OCR with requested information may preclude OCR from making a compliance determination or enforcing the laws above.

OCR has the authority to disclose personal information collected during an investigation without the individual's consent for the following routine uses:

(i) to make disclosures to OCR contractors who are required to maintain Privacy Act safeguards with respect to such records;
(ii) for disclosure to a congressional office from the record of an individual in response to an inquiry made at the request of the individual;
(iii) to make disclosures to the Department of Justice to permit effective defense of litigation; and
(iv) to make disclosures to the appropriate agency in the event that records maintained by OCR to carry out its functions indicate a violation or potential violation of law.

Under 5 U.S.C. §552a(k)(2) and the HHS Privacy Act regulations at 45 C.F.R. §5b.11 OCR complaint records have been exempted as investigatory material compiled for law enforcement purposes from certain Privacy Act access, amendment, correction and notification requirements.

Freedom of Information Act

A complainant, the recipient or any member of the public may request release of OCR records under the Freedom of Information Act (5 U.S.C. §552) (FOIA) and HHS regulations at 45 C.F.R. Part 5.

Fraud and False Statements

Federal law, at 18 U.S.C. §1001, authorizes prosecution and penalties of fine or imprisonment for conviction of "whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations or makes or uses any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry".

PROTECTING PERSONAL INFORMATION IN COMPLAINT INVESTIGATIONS

To investigate your complaint, the Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) will collect information from different sources. Depending on the type of complaint, we may need to get copies of your medical records, or other information that is personal to you. This Fact Sheet explains how OCR protects your personal information that is part of your case file.

HOW DOES OCR PROTECT MY PERSONAL INFORMATION?

OCR is required by law to protect your personal information. The Privacy Act of 1974 protects Federal records about an individual containing personally identifiable information, including, but not limited to, the individual's medical history, education, financial transactions, and criminal or employment history that contains an individual's name or other identifying information.

Because of the Privacy Act, OCR will use your name or other personal information with a signed consent and only when it is necessary to complete the investigation of your complaint or to enforce civil rights laws or when it is otherwise permitted by law.

Consent is voluntary, and it is not always needed in order to investigate your complaint; however, failure to give consent is likely to impede the investigation of your complaint and may result in the closure of your case.

CAN I SEE MY OCR FILE?

Under the Freedom of Information Act (FOIA), you can request a copy of your case file once your case has been closed; however, OCR can withhold information from you in order to protect the identities of witnesses and other sources of information.

CAN OCR GIVE MY FILE TO ANY ONE ELSE?

If a complaint indicates a violation or a potential violation of law, OCR can refer the complaint to another appropriate agency without your permission.

If you file a complaint with OCR, and we decide we cannot help you, we may refer your complaint to another agency such as the Department of Justice.

CAN ANYONE ELSE SEE THE INFORMATION IN MY FILE?

Access to OCR's files and records is controlled by the Freedom of Information Act (FOIA). Under FOIA, OCR may be required to release information about this case upon public request. In the event that OCR receives such a request, we will make every effort,

as permitted by law, to protect information that identifies individuals, or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

If OCR receives protected health information about you in connection with a HIPAA Privacy Rule investigation or compliance review, we will only share this information with individuals outside of HHS if necessary for our compliance efforts or if we are required to do so by another law.

DOES IT COST ANYTHING FOR ME (OR SOMEONE ELSE) TO OBTAIN A COPY OF MY FILE?

In most cases, the first two hours spent searching for document(s) you request under the Freedom of Information Act and the first 100 pages are free. Additional search time or copying time may result in a cost for which you will be responsible. If you wish to limit the search time and number of pages to a maximum of two hours and 100 pages; please specify this in your request. You may also set a specific cost limit, for example, cost not to exceed $100.00.

If you have any questions about this complaint and consent package,
Please contact OCR at http://www.hhs.gov/ocr/office/about/contactus/index.html

OR

Contact your OCR Regional Office
(see Regional Office contact information on page 2 of the Complaint Form)

I received a letter on 10/16/15 that stated that there was a problem with an abnormal pap/hpv test. This letter also had my planned parenthood file ID number on it. The problem is I was never serviced by them since 2014. This letter had no unit number on the address at which anyone in my complex could have obtained this information as it being left in the lobby, and with my address and ID number that Planned Parenthood released in hand they could portray as me. Secondly the person who actually was serviced has NO IDEA that there is a health concern that needs to be addressed and lastly, when I called they have no record or idea how protocol was not followed and my information along with misinformation about me was sent out. They also raised concern when I was instructed to destroy the letter which is the only evidence I have of this occurrence. I feel embarrassed, anxious, concerned and humiliated especially since I have no idea how many of these mistaken letters actually went out and I would like this issue addressed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

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TDD - (202) 619-3257
Fax - (202) 619-3818
http://www.hhs.gov/ocr

Office for Civil Rights
200 Independence Avenue, S.W.,
Room 509F
Washington, DC 20201

February 11, 2016

Privacy Officer
Planned Parenthood of Metropolitan New Jersey
560 Martin Luther King Blvd.
East Orange, NJ 07018

Re: OCR Transaction Number: 16-223418

Dear Privacy Officer:

On October 29, 2015, the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR), received a complaint alleging that Planned Parenthood of Metropolitan New Jersey, the covered entity, has violated the Federal Standards for Privacy of Individually Identifiable Health Information and/or the Security Standards for the Protection of Electronic Protected Health Information (45 C.F.R. Parts 160 and 164, Subparts A, C, and E, the Privacy and Security Rules). Specifically, the complainant, (b)(6);(b)(7)(C) alleges that on October 16, 2015, she received a letter from the covered entity, which contained the protected health information (PHI) of another patient, under the complainant's name and identity number. This allegation could reflect a violation of 45 C.F.R. § 164.530(c).

OCR enforces the Privacy, Security, and Breach Notification Rules, and also Federal civil rights laws which prohibit discrimination in the delivery of health and human services because of race, color, national origin, disability, age, and under certain circumstances, sex and religion.

In this matter, the complainant alleges that the covered entity does not employ reasonable safeguards to prevent impermissible disclosures of protected health information (PHI). A covered entity must maintain reasonable and appropriate administrative, technical, and physical safeguards to prevent intentional or unintentional use or disclosure of PHI in violation of the Privacy Rule and to limit its incidental use and disclosure pursuant to otherwise permitted or required use or disclosure. 45 C.F.R. §164.530(c).

Pursuant to its authority under 45 C.F.R. §§ 160.304(a) and (b), OCR has determined to resolve this matter through the provision of technical assistance to Planned Parenthood of Metropolitan New Jersey. To that end, OCR has enclosed material explaining the Privacy Rule provisions related to Reasonable Safeguards.

You are encouraged to review these materials closely and to share them with your staff as part of the Health Insurance Portability and Accountability Act (HIPAA) training you provide to your workforce. You are also encouraged to assess and determine whether there may have been any noncompliance as alleged by the complainant in this matter, and, if so, to take the steps necessary to ensure such noncompliance does not occur in the future. In

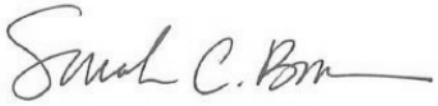
addition, OCR encourages you to review the facts of this individual's complaint and provide the individual the appropriate written response swiftly if necessary to comply with the requirements of the Privacy Rule. Should OCR receive a similar allegation of noncompliance against Planned Parenthood of Metropolitan New Jersey in the future, OCR may initiate an investigation of that matter. In addition, please note that, after a period of six months has passed, OCR may initiate and conduct a compliance review of Planned Parenthood of Metropolitan New Jersey related to your compliance with the Privacy Rule's provisions related to Reasonable Safeguards.

Based on the foregoing, OCR is closing this case without further action, effective the date of this letter. OCR's determination as stated in this letter applies only to the allegations in this complaint that were reviewed by OCR.

Under the Freedom of Information Act, we may be required to release this letter and other information about this case upon request by the public. In the event OCR receives such a request, we will make every effort, as permitted by law, to protect information that identifies individuals or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

If you have any questions regarding this matter, please contact Priya Sampath, Investigator, at (202) 619-2886 (Voice) or (202) 619-3257 (TDD).

Sincerely yours,



Sarah C. Brown
Associate Deputy Director for Regional Operations

Enclosure: Reasonable Safeguards

Reasonable Safeguards

45 C.F.R. § 164.530 (c)

A covered entity must have in place appropriate administrative, technical, and physical safeguards that protect against uses and disclosures not permitted by the Privacy Rule, as well as that limit incidental uses or disclosures. See 45 C.F.R. §164.530 (c). It is not expected that a covered entity's safeguards guarantee the privacy of protected health information from any and all potential risks. Reasonable safeguards will vary from covered entity to covered entity depending on factors, such as the size of the covered entity and the nature of its business. In implementing reasonable safeguards, covered entities should analyze their own needs and circumstances, such as the nature of the protected health information it holds, and assess the potential risks to patients' privacy. Covered entities should also take into account the potential effects on patient care and may consider other issues, such as the financial and administrative burden of implementing particular safeguards.

Many health care providers and professionals have long made it a practice to ensure reasonable safeguards for individuals' health information – for instance:

- By speaking quietly when discussing a patient's condition with family members in a waiting room or other public area;
- By avoiding using patients' names in public hallways and elevators, and posting signs to remind employees to protect patient confidentiality;
- By isolating or locking file cabinets or records rooms; or
- By providing additional security, such as passwords, on computers maintaining personal information.

Protection of patient confidentiality is an important practice for many health care and health information management professionals; covered entities can build upon those codes of conduct to develop the reasonable safeguards required by the Privacy Rule.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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Office for Civil Rights
200 Independence Avenue, S.W.,
Room 509F
Washington, DC 20201

February 11, 2016

(b)(6);(b)(7)(C)

Re: OCR Transaction Number: 16-223418

Dear (b)(6);(b)(7)(C):

On October 29, 2015, the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR), received your complaint alleging that Planned Parenthood of Metropolitan New Jersey, the covered entity, has violated the Federal Standards for Privacy of Individually Identifiable Health Information and/or the Security Standards for the Protection of Electronic Protected Health Information (45 C.F.R. Parts 160 and 164, Subparts A, C, and E, the Privacy and Security Rules). Specifically, you allege that on October 16, 2015, you received a letter from the covered entity, which contained the protected health information (PHI) of another patient, under your name and identity number. This allegation could reflect a violation of 45 C.F.R. § 164.530(c).

Thank you for bringing this matter to OCR's attention. Your complaint is an integral part of OCR's enforcement efforts.

OCR enforces the Privacy, Security, and Breach Notification Rules, and also Federal civil rights laws which prohibit discrimination in the delivery of health and human services because of race, color, national origin, disability, age, and under certain circumstances, sex and religion.

A covered entity must maintain reasonable and appropriate administrative, technical, and physical safeguards to prevent intentional or unintentional use or disclosure of protected health information (PHI) in violation of the Privacy Rule and to limit its incidental use and disclosure pursuant to otherwise permitted or required use or disclosure. 45 C.F.R. §164.530(c). For example, such safeguards might include shredding documents containing protected health information before discarding them, securing medical records with lock and key or pass code, and limiting access to keys or pass codes.

We have carefully reviewed your complaint against Planned Parenthood of Metropolitan New Jersey, and have determined to resolve this matter through the provision of technical assistance to Planned Parenthood of Metropolitan New Jersey. Should OCR receive a similar allegation of noncompliance against Planned Parenthood of Metropolitan New Jersey in the future, OCR may initiate an investigation of that matter.

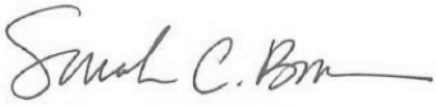
For your informational purposes, OCR has enclosed material regarding the Privacy Rule provisions related to Safeguards.

Based on the foregoing, OCR is closing this case without further action, effective the date of this letter. OCR's determination as stated in this letter applies only to the allegations in this complaint that were reviewed by OCR.

Under the Freedom of Information Act, we may be required to release this letter and other information about this case upon request by the public. In the event OCR receives such a request, we will make every effort, as permitted by law, to protect information that identifies individuals or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

If you have any questions about this matter, please contact Centralized Case Management Operations at (800) 368-1019 or (202) 619-3257 (TDD).

Sincerely,



Sarah C. Brown
Associate Deputy Director for Regional Operations

Enclosure: Reasonable Safeguards

Reasonable Safeguards

45 C.F.R. § 164.530 (c)

A covered entity must have in place appropriate administrative, technical, and physical safeguards that protect against uses and disclosures not permitted by the Privacy Rule, as well as that limit incidental uses or disclosures. See 45 C.F.R. §164.530 (c). It is not expected that a covered entity's safeguards guarantee the privacy of protected health information from any and all potential risks. Reasonable safeguards will vary from covered entity to covered entity depending on factors, such as the size of the covered entity and the nature of its business. In implementing reasonable safeguards, covered entities should analyze their own needs and circumstances, such as the nature of the protected health information it holds, and assess the potential risks to patients' privacy. Covered entities should also take into account the potential effects on patient care and may consider other issues, such as the financial and administrative burden of implementing particular safeguards.

Many health care providers and professionals have long made it a practice to ensure reasonable safeguards for individuals' health information – for instance:

- By speaking quietly when discussing a patient's condition with family members in a waiting room or other public area;
- By avoiding using patients' names in public hallways and elevators, and posting signs to remind employees to protect patient confidentiality;
- By isolating or locking file cabinets or records rooms; or
- By providing additional security, such as passwords, on computers maintaining personal information.

Protection of patient confidentiality is an important practice for many health care and health information management professionals; covered entities can build upon those codes of conduct to develop the reasonable safeguards required by the Privacy Rule.

English	If you speak a non-English language, call 1-800–368–1019 (TTY: 1-800-537-7697), and you will be connected to an interpreter who will assist you with this document at no cost.
Español - Spanish	Si usted habla español marque 1-800-368-1019 (o a la línea de teléfono por texto TTY 1-800-537-7697) y su llamada será conectada con un intérprete que le asistirá con este documento sin costo alguno.
中文 - Chinese	如果你讲中文，请拨打1-800-368-1019（打字电话：1-800-537-7697), 你将被连接到一位讲同语种的翻译员为你提供免费服务。
Tiếng Việt - Vietnamese	Nếu bạn nói tiếng Việt, xin gọi 1-800-368-1019 (TTY: 1-800-537-7697), và bạn sẽ được kết nối với một thông dịch viên, người này sẽ hỗ trợ bạn với tài liệu này miễn phí.
한국어 - Korean	한국어를 하시면 1-800-368-1019 (청각 장애용: 1-800-537-7697) 로 연락 주세요. 통역관과 연결해서 당신의 서류를 무료로 도와 드리겠습니다.
Tagalog (Filipino)	Kung ikaw ay nagsasalita nang Tagalog, tumawag sa 1-800-368-1019 (TTY: 1-800-537-7697) para makonek sa tagapagsalin na tutulong sa iyo sa dokumentong ito na walang bayad.
Русский - Russian	Если вы говорите по- русски, наберите 1-800-368-1019. Для клиентов с ограниченными слуховыми и речевыми возможностями: 1-800-537-7697), и вас соединят с русскоговорящим переводчиком, который вам поможет с этим документом безвозмездно.

Form Approved: OMB No. 0990-0269.
See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE FOR CIVIL RIGHTS (OCR)

HEALTH INFORMATION PRIVACY COMPLAINT

YOUR FIRST NAME	YOUR LAST NAME
(b)(6);(b)(7)(	(b)(6);(b)(7)(C)
HOME / CELL PHONE (Please include area code)	WORK PHONE (Please include area code)

STREET ADDRESS	CITY
(b)(6);(b)(7)(C)	(b)(6);(b)(7)(C)

STATE	ZIP	E-MAIL ADDRESS (If available)
(b)(6);(b)(7)(C)	(b)(6);(b)(7)	(b)(6);(b)(7)(C)

Are you filing this complaint for someone else? ☐ Yes ☒ No

If Yes, whose health information privacy rights do you believe were violated?

FIRST NAME	LAST NAME

Who (or what agency or organization, e.g., provider, health plan) do you believe violated your (or someone else's) health information privacy rights or committed another violation of the Privacy Rule?

PERSON/AGENCY/ORGANIZATION

(b)(6);(b)(7)(C)

STREET ADDRESS	CITY
(b)(6);(b)(7)(C)	(b)(6);(b)(7)(C)

STATE	ZIP	PHONE (Please include area code)
(b)(6);(b)(7)(C)	(b)(6);(b)(7)(C)	

When do you believe that the violation of health information privacy rights occurred?

LIST DATE(S)

01/18/0016

Describe briefly what happened. How and why do you believe your (or someone else's) health information privacy rights were violated, or the privacy rule otherwise was violated? Please be as specific as possible. (Attach additional pages as needed)

I received a text message from the (b)(6);(b)(7)(C) the husband of the complainant (b)(6);(b)(7)(C) My sons father in regard to some abortion procedures that I had received in the past. She is a current employee at the planned parenthood office where the procedures were performed. No other way this information could have been given to him. Being that she is employed with PPH of Southwestern MI. This is the only way he could have knowledge of such medical procedures. He and I never discussed my medical history and I wouldn't give her permission verbal/written or otherwise to disclose this private information with him or anyone else. My family nor the males in each situation were unaware of the procedures and wouldn't have the knowledge to give him this information. The common denominator is (b)(6);(b)(7)(C) I would like to see that she receives punishment for violating my

This field may be truncated due to size limit. See the "Allegation Description" file in the case folder.

Please sign and date this complaint. You do not need to sign if submitting this form by email because submission by email represents your signature.

SIGNATURE	DATE *(mm/dd/yyyy)*
(b)(6);(b)(7)(C)	01/19/2016

Filing a complaint with OCR is voluntary. However, without the information requested above, OCR may be unable to proceed with your complaint. We collect this information under authority of the Privacy Rule issued pursuant to the Health Insurance Portability and Accountability Act of 1996. We will use the information you provide to determine if we have jurisdiction and, if so, how we will process your complaint. Information submitted on this form is treated confidentially and is protected under the provisions of the Privacy Act of 1974. Names or other identifying information about individuals are disclosed when it is necessary for investigation of possible health information privacy violations, for internal systems operations, or for routine uses, which include disclosure of information outside the Department for purposes associated with health information privacy compliance and as permitted by law. It is illegal for a covered entity to intimidate, threaten, coerce, discriminate or retaliate against you for filing this complaint or for taking any other action to enforce your rights under the Privacy Rule. You are not required to use this form. You also may write a letter or submit a complaint electronically with the same information. To submit an electronic complaint, go to OCR's Web site at:
www.hhs.gov/ocr/privacy/hipaa/complaints/index.html. To mail a complaint see reverse page for OCR Regional addresses.

The remaining information on this form is optional. Failure to answer these voluntary questions will not affect OCR's decision to process your complaint.

Do you need special accommodations for us to communicate with you about this complaint? (Check all that apply)

☐ Braille ☐ Large Print ☐ Cassette tape ☐ Computer diskette ☐ Electronic mail ☐ TDD

☐ Sign language interpreter (specify language): _____

☐ Foreign language interpreter (specify language): _____ ☐ Other: _____

If we cannot reach you directly, is there someone we can contact to help us reach you?

FIRST NAME	LAST NAME
HOME / CELL PHONE (Please include area code)	WORK PHONE (Please include area code)

STREET ADDRESS	CITY

STATE	ZIP	E-MAIL ADDRESS (If available)

Have you filed your complaint anywhere else? If so, please provide the following. (Attach additional pages as needed)

PERSON/AGENCY/ORGANIZATION/ COURT NAME(S)

DATE(S) FILED	CASE NUMBER(S) (If known)

To help us better serve the public, please provide the following information for the person you believe had their health information privacy rights violated (you or the person on whose behalf you are filing).

ETHNICITY (select one)

☐ Hispanic or Latino

☒ Not Hispanic or Latino

RACE (select one or more)

☐ American Indian or Alaska Native ☐ Asian ☐ Native Hawaiian or Other Pacific Islander

☒ Black or African American ☐ White ☐ Other (specify): _____

PRIMARY LANGUAGE SPOKEN (if other then English) _____

How did you learn about the Office for Civil Rights?

☒ HHS Website/Internet Search ☐ Family/Friend/Associate ☐ Religious/Community Org ☐ Lawyer/Legal Org ☐ Phone Directory ☐ Employer

☐ Fed/State/Local Gov ☐ Healthcare Provider/Health Plan ☐ Conference/OCR Brochure ☐ Other (specify): _____

To mail a complaint, please type or print, and return completed complaint to the OCR Regional Address based on the region where the alleged violation took place. If you need assistance completing this form, contact the appropriate region listed below.

Region I - CT, ME, MA, NH, RI, VT
Office for Civil Rights, DHHS
JFK Federal Building - Room 1875
Boston, MA 02203
(617) 565-1340; (617) 565-1343 (TDD)
(617) 565-3809 FAX

Region II - NJ, NY, PR, VI
Office for Civil Rights, DHHS
26 Federal Plaza - Suite 3312
New York, NY 10278
(212) 264-3313; (212) 264-2355 (TDD)
(212) 264-3039 FAX

Region III - DE, DC, MD, PA, VA, WV
Office for Civil Rights, DHHS
150 S. Independence Mall West - Suite 372
Philadelphia, PA 19106-3499
(215) 861-4441; (215) 861-4440 (TDD)
(215) 861-4431 FAX

Region IV - AL, FL, GA, KY, MS, NC, SC, TN
Office for Civil Rights, DHHS
61 Forsyth Street, SW. - Suite 16T70
Atlanta, GA 30303-8909
(404) 562-7886; (404) 562-7884 (TDD)
(404) 562-7881 FAX

Region V - IL, IN, MI, MN, OH, WI
Office for Civil Rights, DHHS
233 N. Michigan Ave. - Suite 240
Chicago, IL 60601
(312) 886-2359; (312) 353-5693 (TDD)
(312) 886-1807 FAX

Region VI - AR, LA, NM, OK, TX
Office for Civil Rights, DHHS
1301 Young Street - Suite 1169
Dallas, TX 75202
(214) 767-4056; (214) 767-8940 (TDD)
(214) 767-0432 FAX

Region VII - IA, KS, MO, NE
Office for Civil Rights, DHHS
601 East 12th Street - Room 248
Kansas City, MO 64106
(816) 426-7277; (816) 426-7065 (TDD)
(816) 426-3686 FAX

Region VIII - CO, MT, ND, SD, UT, WY
Office for Civil Rights, DHHS
999 18th Street, Suite 417
Denver, CO 80202
(303) 844-2024; (303) 844-3439 (TDD)
(303) 844-2025 FAX

Region IX - AZ, CA, HI, NV, AS, GU, The U.S. Affiliated Pacific Island Jurisdictions
Office for Civil Rights, DHHS
90 7th Street, Suite 4-100
San Francisco, CA 94103
(415) 437-8310; (415) 437-8311 (TDD)
(415) 437-8329 FAX

Region X - AK, ID, OR, WA
Office for Civil Rights, DHHS
701 Fifth Avenue, Suite 1600, MS - 11
Seattle, WA 98104
(206) 615-2290; (206) 615-2296 (TDD)
(206) 615-2297 FAX

Burden Statement

Public reporting burden for the collection of information on this complaint form is estimated to average 45 minutes per response, including the time for reviewing instructions, gathering the data needed and entering and reviewing the information on the completed complaint form. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: HHS/OS Reports Clearance Officer, Office of Information Resources Management, 200 Independence Ave. S.W., Room 531H, Washington, D.C. 20201. **Please do not mail complaint form to this address.**

COMPLAINANT CONSENT FORM

The Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) has the authority to collect and receive material and information about you, including personnel and medical records, which are relevant to its investigation of your complaint.

To investigate your complaint, OCR may need to reveal your identity or identifying information about you to persons at the entity or agency under investigation or to other persons, agencies, or entities.

The Privacy Act of 1974 protects certain federal records that contain personally identifiable information about you and, with your consent, allows OCR to use your name or other personal information, if necessary, to investigate your complaint.

Consent is voluntary, and it is not always needed in order to investigate your complaint; however, failure to give consent is likely to impede the investigation of your complaint and may result in the closure of your case.

Additionally, OCR may disclose information, including medical records and other personal information, which it has gathered during the course of its investigation in order to comply with a request under the Freedom of Information Act (FOIA) and may refer your complaint to another appropriate agency.

Under FOIA, OCR may be required to release information regarding the investigation of your complaint; however, we will make every effort, as permitted by law, to protect information that identifies individuals or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

Please read and review the documents entitled, *Notice to Complainants and Other Individuals Asked to Supply Information to the Office for Civil Rights* and *Protecting Personal Information in Complaint Investigations* for further information regarding how OCR may obtain, use, and disclose your information while investigating your complaint.

In order to expedite the investigation of your complaint if it is accepted by OCR, please read, sign, and return one copy of this consent form to OCR with your complaint. Please make one copy for your records.

- As a complainant, I understand that in the course of the investigation of my complaint it may become necessary for OCR to reveal my identity or identifying information about me to persons at the entity or agency under investigation or to other persons, agencies, or entities.

- I am also aware of the obligations of OCR to honor requests under the Freedom of Information Act (FOIA). I understand that it may be necessary for OCR to disclose information, including personally identifying information, which it has gathered as part of its investigation of my complaint.

- In addition, I understand that as a complainant I am covered by the Department of Health and Human Services' (HHS) regulations which protect any individual from being intimidated, threatened, coerced, retaliated against, or discriminated against because he/she has made a complaint, testified, assisted, or participated in any manner in any mediation, investigation, hearing, proceeding, or other part of HHS' investigation, conciliation, or enforcement process.

After reading the above information, please check ONLY ONE of the following boxes:

[X] **CONSENT:** I have read, understand, and agree to the above and give permission to OCR to reveal my identity or identifying information about me in my case file to persons at the entity or agency under investigation or to other relevant persons, agencies, or entities during any part of HHS' investigation, conciliation, or enforcement process.

[ ] **CONSENT DENIED:** I have read and I understand the above and do not give permission to OCR to reveal my identity or identifying information about me. I understand that this denial of consent is likely to impede the investigation of my complaint and may result in closure of the investigation.

Signature: (b)(6);(b)(7)(C) Date: 01/19/2016

**Please sign and date this complaint. You do not need to sign if submitting this form by email because submission by email represents your signature.*

Name (Please print): (b)(6);(b)(7)(C)

Address: (b)(6);(b)(7)(C)

Telephone Number: _____

NOTICE TO COMPLAINANTS AND OTHER INDIVIDUALS ASKED TO SUPPLY INFORMATION TO THE OFFICE FOR CIVIL RIGHTS

Privacy Act

The Privacy Act of 1974 (5 U.S.C. §552a) requires OCR to notify individuals whom it asks to supply information that:

— OCR is authorized to solicit information under:
(i) Federal laws barring discrimination by recipients of Federal financial assistance on grounds of race, color, national origin, disability, age, sex, religion under programs and activities receiving Federal financial assistance from the U.S. Department of Health and Human Services (HHS), including, but not limited to, Title VI of the Civil Rights Act of 1964 (42 U.S.C. §2000d et seq.), Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. §794), the Age Discrimination Act of 1975 (42 U.S.C. §6101 et seq.), Title IX of the Education Amendments of 1972 (20 U.S.C. §1681 et seq.), and Sections 794 and 855 of the Public Health Service Act (42 U.S.C. §§295m and 296g);
(ii) Titles VI and XVI of the Public Health Service Act (42 U.S.C. §§291 et seq. and 300s et seq.) and 42 C.F.R. Part 124, Subpart G (Community Service obligations of Hill-Burton facilities);
(iii) 45 C.F.R. Part 85, as it implements Section 504 of the Rehabilitation Act in programs conducted by HHS; and
(iv) Title II of the Americans with Disabilities Act (42 U.S.C. §12131 et seq.) and Department of Justice regulations at 28 C.F.R. Part 35, which give HHS "designated agency" authority to investigate and resolve disability discrimination complaints against certain public entities, defined as health and service agencies of state and local governments, regardless of whether they receive federal financial assistance.
(v) The Standards for the Privacy of Individually Identifiable Health Information (The Privacy Rule) at 45 C.F.R. Part 160 and Subparts A and E of Part 164, which enforce the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 U.S.C. §1320d-2).

OCR will request information for the purpose of determining and securing compliance with the Federal laws listed above. Disclosure of this requested information to OCR by individuals who are not recipients of federal financial assistance is voluntary; however, even individuals who voluntarily disclose information are subject to prosecution and penalties under 18 U.S.C. § 1001 for making false statements.

Additionally, although disclosure is voluntary for individuals who are not recipients of federal financial assistance, failure to provide OCR with requested information may preclude OCR from making a compliance determination or enforcing the laws above.

OCR has the authority to disclose personal information collected during an investigation without the individual's consent for the following routine uses:

(i) to make disclosures to OCR contractors who are required to maintain Privacy Act safeguards with respect to such records;
(ii) for disclosure to a congressional office from the record of an individual in response to an inquiry made at the request of the individual;
(iii) to make disclosures to the Department of Justice to permit effective defense of litigation; and
(iv) to make disclosures to the appropriate agency in the event that records maintained by OCR to carry out its functions indicate a violation or potential violation of law.

Under 5 U.S.C. §552a(k)(2) and the HHS Privacy Act regulations at 45 C.F.R. §5b.11 OCR complaint records have been exempted as investigatory material compiled for law enforcement purposes from certain Privacy Act access, amendment, correction and notification requirements.

Freedom of Information Act

A complainant, the recipient or any member of the public may request release of OCR records under the Freedom of Information Act (5 U.S.C. §552) (FOIA) and HHS regulations at 45 C.F.R. Part 5.

Fraud and False Statements

Federal law, at 18 U.S.C. §1001, authorizes prosecution and penalties of fine or imprisonment for conviction of "whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations or makes or uses any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry".

PROTECTING PERSONAL INFORMATION IN COMPLAINT INVESTIGATIONS

To investigate your complaint, the Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) will collect information from different sources. Depending on the type of complaint, we may need to get copies of your medical records, or other information that is personal to you. This Fact Sheet explains how OCR protects your personal information that is part of your case file.

HOW DOES OCR PROTECT MY PERSONAL INFORMATION?

OCR is required by law to protect your personal information. The Privacy Act of 1974 protects Federal records about an individual containing personally identifiable information, including, but not limited to, the individual's medical history, education, financial transactions, and criminal or employment history that contains an individual's name or other identifying information.

Because of the Privacy Act, OCR will use your name or other personal information with a signed consent and only when it is necessary to complete the investigation of your complaint or to enforce civil rights laws or when it is otherwise permitted by law.

Consent is voluntary, and it is not always needed in order to investigate your complaint; however, failure to give consent is likely to impede the investigation of your complaint and may result in the closure of your case.

CAN I SEE MY OCR FILE?

Under the Freedom of Information Act (FOIA), you can request a copy of your case file once your case has been closed; however, OCR can withhold information from you in order to protect the identities of witnesses and other sources of information.

CAN OCR GIVE MY FILE TO ANY ONE ELSE?

If a complaint indicates a violation or a potential violation of law, OCR can refer the complaint to another appropriate agency without your permission.

If you file a complaint with OCR, and we decide we cannot help you, we may refer your complaint to another agency such as the Department of Justice.

CAN ANYONE ELSE SEE THE INFORMATION IN MY FILE?

Access to OCR's files and records is controlled by the Freedom of Information Act (FOIA). Under FOIA, OCR may be required to release information about this case upon public request. In the event that OCR receives such a request, we will make every effort,

as permitted by law, to protect information that identifies individuals, or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

If OCR receives protected health information about you in connection with a HIPAA Privacy Rule investigation or compliance review, we will only share this information with individuals outside of HHS if necessary for our compliance efforts or if we are required to do so by another law.

DOES IT COST ANYTHING FOR ME (OR SOMEONE ELSE) TO OBTAIN A COPY OF MY FILE?

In most cases, the first two hours spent searching for document(s) you request under the Freedom of Information Act and the first 100 pages are free. Additional search time or copying time may result in a cost for which you will be responsible. If you wish to limit the search time and number of pages to a maximum of two hours and 100 pages; please specify this in your request. You may also set a specific cost limit, for example, cost not to exceed $100.00.

If you have any questions about this complaint and consent package,
Please contact OCR at http://www.hhs.gov/ocr/office/about/contactus/index.html

OR

Contact your OCR Regional Office
(see Regional Office contact information on page 2 of the Complaint Form)

I received a text message from the (b)(6);(b)(7)(the husband of the complainant (b)(6);(b)(7)(C) My sons father in regard to some abortion procedures that I had received in the past. She is a current employee at the planned parenthood office where the procedures were performed. No other way this information could have been given to him. Being that she is employed with PPH of Southwestern MI. This is the only way he could have knowledge of such medical procedures. He and I never discussed my medical history and I wouldn't give her permission verbal/written or otherwise to disclose this private information with him or anyone else. My family nor the males in each situation were unaware of the procedures and wouldn't have the knowledge to give him this information. The common denominator is (b)(6);(b)(7)(C) I would like to see that she receives punishment for violating my right to privacy when I signed the HIPPA forms with the staff members at PPSWM. As an employee she has been informed and should have been properly trained in regard to exposing medical information to others without a need to know or permission from the patient. If she has violated my right to privacy she may have done the same to other patients whose medical records she has access to in her daily duties.

Dear (b)(6);(b)(7)(C)

On January 19, 2016, you submitted a Health Information Privacy Complaint to my office. Your complaint has been assigned to me, Investigator Hilden, for case processing.

Please provide the addressed of the Planned Parenthood Southwestern Michigan office where (b)(6);(b)(7)(C) is employed.

Also, please provide a telephone number where you may be reached should I have additions questions.

In an effort to update your contact information and to focus our investigative efforts, we are requesting that you call or respond to this email by March 7, 2016. When contacting the investigator, please remember to clearly state your name and the transaction number that we have given your file. The transaction number is located in the subject line. If you know longer with to pursue this complaint, please contact me and advise that you wish to withdraw your complaint.

Thank you.

Investigator Hilden
Office for Civil Rights (OCR), Midwest Region
Chicago Office
Telephone: (312) 353-9688
Fax: (312) 886-1807
Email: Alyce.Hilden@hhs.gov

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Chicago Office
233 North Michigan Avenue, Suite 240
Chicago, IL 60601

Kansas City Office
601 East 12th Street, Room 353
Kansas City, MO 64106

Office for Civil Rights
Midwest Region
Website: http://www.hhs.gov/ocr
Voice - (800) 368-1019
TDD - (800) 537-7697

March 28, 2016

(b)(6);(b)(7)(C)

Re: (b)(6);(b)(7)(C) v. Planned Parenthood of Southwestern Michigan/Starr Andrew-Snell
OCR Transaction Number: 16-229005

Dear (b)(6);(b)(7)(C)

On January 19, 2016, the U.S. Department of Health and Human Services, Office for Civil Rights (OCR), Region V, received your complaint in the above-captioned matter.

I have been trying to contact you to interview you about your complaint. On February 29, 2016, I sent you an email asking you to contact me. To date, you have not contacted me.

In an effort to update your contact information and to focus our investigative efforts, we are requesting that you call the OCR Investigator listed below within ten (10) calendar days (i.e., **April 7, 2016**). When contacting the investigator, please remember to clearly state your name and the transaction number that we have given your file. The transaction number is located above. If we do not hear from you within the specified time frame, we will assume you are no longer interested in pursuing this matter and we will close your case.

Your complaint has been assigned to me, Investigator Hilden, for case processing. You may reach me at (312) 353-9688 (Voice) or at (312) 353-5693 (TTY). Thank you.

Sincerely,

Investigator Hilden

Investigator Hilden

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Chicago Office
233 North Michigan Avenue, Suite 240
Chicago, IL 60601

Kansas City Office
601 East 12th Street, Room 353
Kansas City, MO 64106

Office for Civil Rights
Midwest Region
Website: http://www.hhs.gov/ocr
Voice - (800) 368-1019
TDD - (800) 537-7697

April 8, 2016

(b)(6);(b)(7)(C)

Re: (b)(6);(b)(7)(C) Planned Parenthood of Southwestern Michigan/Starr Andrew-Snell
OCR Transaction Number: 16-229005

Dear (b)(6);(b)(7)(C)

On March 28, 2016, OCR sent you a letter asking that you contact us if you wish to continue pursuing the above-captioned complaint. You were informed that if you did not contact our office by April 7, 2016, we would assume you are no longer interested in pursuing this matter and we would close your complaint. To date, OCR has not received a response from you. Therefore, OCR is closing your complaint without further action, effective the date of this letter.

If you have any questions regarding OCR's disposition of your complaint, please call our office at the above-listed telephone numbers. Thank you.

Sincerely,

Celeste H. Davis, J.D.
Regional Manager

(b)(5)

From: (b)(6);(b)(7)(C)
Sent: Tuesday, December 08, 2015 1:24 PM
To: OCR Mail
Subject: Violation

To whom it may concern
I I(b)(6);(b)(7)(C) feel as if I've been violated by planned parenthood canton Ohio campus

The incident took place on December 8 2015
At approximately at 12:30pm

An employee called me to give me test results, but before revealing my lab results she never asked no one to verify any information , so my friend told her she wasn't I(b)(6);(b)(7)(C) and her responds was relay the message to I

I can't express how upset I am at this moment I feel so violated I called the office and spoke with an adminstration but I feel as if no one is taking me serious at all

The location is in canton Ohio
2663 cleveland ave nw 44709
330 456 7191phone

My information
(b)(6);(b)(7)(C)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Voice - (800) 368-1019
TDD - (202) 619-3257
Fax - (202) 619-3818
http://www.hhs.gov/ocr

Office for Civil Rights
200 Independence Avenue, S.W.,
Room 509F
Washington, DC 20201

August 9, 2017

(b)(6);(b)(7)(C)

Re: OCR Transaction Number: 16-229029
(b)(6);(b)(7)(C) vs. Planned Parenthood Canton Health Center

Dear (b)(6);(b)(7)(C),

On December 10, 2015, the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR), received your complaint alleging that Planned Parenthood Canton Health Center, the covered entity, has violated the Federal Standards for Privacy of Individually Identifiable Health Information and/or the Security Standards for the Protection of Electronic Protected Health Information (45 C.F.R. Parts 160 and 164, Subparts A, C, and E, the Privacy and Security Rules). Specifically, you allege that an employee for Planned Parenthood Canton Health Center located at 2663 Cleveland Ave, NW, Canton, Ohio called the complainant to provide her lab results without verification of identity. As a result, your friend received your information. This allegation could reflect a violation of 45 C.F.R. § 164.530(c).

Thank you for bringing this matter to OCR's attention. Your complaint is an integral part of OCR's enforcement efforts.

OCR enforces the Privacy, Security, and Breach Notification Rules, and also Federal civil rights laws which prohibit discrimination in the delivery of health and human services because of race, color, national origin, disability, age, and under certain circumstances, sex and religion.

A covered entity must maintain reasonable and appropriate administrative, technical, and physical safeguards to prevent intentional or unintentional use or disclosure of protected health information (PHI) in violation of the Privacy Rule and to limit its incidental use and disclosure pursuant to otherwise permitted or required use or disclosure. 45 C.F.R. §164.530(c). For example, such safeguards might include shredding documents containing protected health information before discarding them, securing medical records with lock and key or pass code, and limiting access to keys or pass codes.

We have carefully reviewed your complaint against Planned Parenthood Canton Health Center and have determined to resolve this matter through the provision of technical assistance to Planned Parenthood Canton Health Center. Should OCR receive a similar allegation of noncompliance against Planned Parenthood Canton Health Center in the future, OCR may initiate an investigation of that matter.

For your informational purposes, OCR has enclosed material regarding the Privacy Rule provisions related to Safeguards.

Based on the foregoing, OCR is closing this case without further action, effective the date of this letter. OCR's determination as stated in this letter applies only to the allegations in this complaint that were reviewed by OCR.

Under the Freedom of Information Act, we may be required to release this letter and other information about this case upon request by the public. In the event OCR receives such a request, we will make every effort, as permitted by law, to protect information that identifies individuals or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

If you have any questions about this matter, please contact Centralized Case Management Operations at (800) 368-1019 or (202) 619-3257 (TDD).

Sincerely yours,

Sarah C. Brown
Associate Deputy Director for Regional Operations

Enclosure: Reasonable Safeguards

Reasonable Safeguards

45 C.F.R. § 164.530 (c)

A covered entity must have in place appropriate administrative, technical, and physical safeguards that protect against uses and disclosures not permitted by the Privacy Rule, as well as that limit incidental uses or disclosures. See 45 C.F.R. §164.530 (c). It is not expected that a covered entity's safeguards guarantee the privacy of protected health information from any and all potential risks. Reasonable safeguards will vary from covered entity to covered entity depending on factors, such as the size of the covered entity and the nature of its business. In implementing reasonable safeguards, covered entities should analyze their own needs and circumstances, such as the nature of the protected health information it holds, and assess the potential risks to patients' privacy. Covered entities should also take into account the potential effects on patient care and may consider other issues, such as the financial and administrative burden of implementing particular safeguards.

Many health care providers and professionals have long made it a practice to ensure reasonable safeguards for individuals' health information – for instance:

- By speaking quietly when discussing a patient's condition with family members in a waiting room or other public area;
- By avoiding using patients' names in public hallways and elevators, and posting signs to remind employees to protect patient confidentiality;
- By isolating or locking file cabinets or records rooms; or
- By providing additional security, such as passwords, on computers maintaining personal information.

Protection of patient confidentiality is an important practice for many health care and health information management professionals; covered entities can build upon those codes of conduct to develop the reasonable safeguards required by the Privacy Rule.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Voice - (800) 368-1019
TDD - (202) 619-3257
Fax - (202) 619-3818
http://www.hhs.gov/ocr

Office for Civil Rights
200 Independence Avenue, S.W.,
Room 509F
Washington, DC 20201

April 4, 2016

Mrs. Cecile Richards
President
Planned Parenthood Canton Health Center
2663 Cleveland Ave NW
Canton, OH 44709

Re: OCR Transaction Number: 16-229029
(b)(6);(b)(7)(C) vs. Planned Parenthood Canton Health Center

Dear Mrs. Richards,

On December 10, 2015, the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR), received a complaint alleging that Planned Parenthood Canton Health Center, the covered entity, has violated the Federal Standards for Privacy of Individually Identifiable Health Information and/or the Security Standards for the Protection of Electronic Protected Health Information (45 C.F.R. Parts 160 and 164, Subparts A, C, and E, the Privacy and Security Rules). Specifically, the complainant alleges that an employee for Planned Parenthood Canton Health Center located at 2663 Cleveland Ave, NW, Canton, Ohio called the complainant to provide her lab results without verification of identity. As a result, the Complainant's friend received Complainant's information. This allegation could reflect a violation of 45 C.F.R. § 164.530(c).

OCR enforces the Privacy, Security, and Breach Notification Rules, and also Federal civil rights laws which prohibit discrimination in the delivery of health and human services because of race, color, national origin, disability, age, and under certain circumstances, sex and religion.

In this matter, the complainant alleges that the covered entity does not employ reasonable safeguards to prevent impermissible disclosures of protected health information (PHI). A covered entity must maintain reasonable and appropriate administrative, technical, and physical safeguards to prevent intentional or unintentional use or disclosure of PHI in violation of the Privacy Rule and to limit its incidental use and disclosure pursuant to otherwise permitted or required use or disclosure. 45 C.F.R. §164.530(c).

Pursuant to its authority under 45 C.F.R. §§ 160.304(a) and (b), OCR has determined to resolve this matter through the provision of technical assistance to Planned Parenthood Canton Health Center. To that end, OCR has enclosed material explaining the Privacy Rule provisions related to Reasonable Safeguards.

You are encouraged to review these materials closely and to share them with your staff as part of the Health Insurance Portability and Accountability Act (HIPAA) training you provide

to your workforce. You are also encouraged to assess and determine whether there may have been any noncompliance as alleged by the complainant in this matter, and, if so, to take the steps necessary to ensure such noncompliance does not occur in the future. In addition, OCR encourages you to review the facts of this individual's complaint and provide the individual the appropriate written response swiftly if necessary to comply with the requirements of the Privacy Rule. Should OCR receive a similar allegation of noncompliance against Planned Parenthood Canton Health Center in the future, OCR may initiate an investigation of that matter. In addition, please note that, after a period of six months has passed, OCR may initiate and conduct a compliance review of Planned Parenthood Canton Health Center related to your compliance with the Privacy Rule's provisions related to Reasonable Safeguards.

Based on the foregoing, OCR is closing this case without further action, effective the date of this letter. OCR's determination as stated in this letter applies only to the allegations in this complaint that were reviewed by OCR.

Under the Freedom of Information Act, we may be required to release this letter and other information about this case upon request by the public. In the event OCR receives such a request, we will make every effort, as permitted by law, to protect information that identifies individuals or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

If you have any questions about this matter, please contact Centralized Case Management Operations at (800) 368-1019 or (202) 619-3257 (TDD).

Sincerely yours,

Sarah C. Brown
Associate Deputy Director for Regional Operations

Enclosure: Reasonable Safeguards

Reasonable Safeguards

45 C.F.R. § 164.530 (c)

A covered entity must have in place appropriate administrative, technical, and physical safeguards that protect against uses and disclosures not permitted by the Privacy Rule, as well as that limit incidental uses or disclosures. See 45 C.F.R. §164.530 (c). It is not expected that a covered entity's safeguards guarantee the privacy of protected health information from any and all potential risks. Reasonable safeguards will vary from covered entity to covered entity depending on factors, such as the size of the covered entity and the nature of its business. In implementing reasonable safeguards, covered entities should analyze their own needs and circumstances, such as the nature of the protected health information it holds, and assess the potential risks to patients' privacy. Covered entities should also take into account the potential effects on patient care and may consider other issues, such as the financial and administrative burden of implementing particular safeguards.

Many health care providers and professionals have long made it a practice to ensure reasonable safeguards for individuals' health information – for instance:

- By speaking quietly when discussing a patient's condition with family members in a waiting room or other public area;
- By avoiding using patients' names in public hallways and elevators, and posting signs to remind employees to protect patient confidentiality;
- By isolating or locking file cabinets or records rooms; or
- By providing additional security, such as passwords, on computers maintaining personal information.

Protection of patient confidentiality is an important practice for many health care and health information management professionals; covered entities can build upon those codes of conduct to develop the reasonable safeguards required by the Privacy Rule.

Form Approved: OMB No. 0990-0269.
See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE FOR CIVIL RIGHTS (OCR)

HEALTH INFORMATION PRIVACY COMPLAINT

YOUR FIRST NAME	YOUR LAST NAME
(b)(6);(b)(7)(C)	(b)(6);(b)(7)(C)
HOME / CELL PHONE (Please include area code)	WORK PHONE (Please include area code)
(b)(6);(b)(7)(C)	
STREET ADDRESS	CITY
(b)(6);(b)(7)(C)	(b)(6);(b)
STATE	ZIP	E-MAIL ADDRESS (If available)
(b)(6);(b)(7)(C)	(b)(6);(b)(7	(b)(6);(b)(7)(C)

Are you filing this complaint for someone else? [X] Yes [ ] No

If Yes, whose health information privacy rights do you believe were violated?

FIRST NAME	LAST NAME
(b)(6);(b)(7)(C)	(b)(6);(b)(7)(C)

Who (or what agency or organization, e.g., provider, health plan) do you believe violated your (or someone else's) health information privacy rights or committed another violation of the Privacy Rule?

PERSON/AGENCY/ORGANIZATION

Planned Parenthood of the Great Northwest

STREET ADDRESS	CITY
2001 E Madison Street, PO Box 24165 Seattle, WA 98124-0165	Seattle

STATE	ZIP	PHONE (Please include area code)
Washington	98122-2959	(877) 320-7619

When do you believe that the violation of health information privacy rights occurred?

LIST DATE(S)

02/02/2016

Describe briefly what happened. How and why do you believe your (or someone else's) health information privacy rights were violated, or the privacy rule otherwise was violated? Please be as specific as possible. (Attach additional pages as needed)

(b)(6);(b)(7)(C) was seen at Planned Parenthood on 12/10/2015, at that time she requested nothing be sent to mailing address since she was under the age of 18 and did not want her parents to know that she had gone to Planned Parenthood.

On 02/02/16 Planned Parenthood sent a paper bill to her mailing address that not only had the encounter/office visit listed, but also what she had been tested for. This was in direct violation of the HIPPA act since she had requested nothing be sent to mailing address in order to keep her medical records private.

This field may be truncated due to size limit. See the "Allegation Description" file in the case folder.

Please sign and date this complaint. You do not need to sign if submitting this form by email because submission by email represents your signature.

SIGNATURE	DATE *(mm/dd/yyyy)*
(b)(6);(b)(7)(C)	02/26/2016

Filing a complaint with OCR is voluntary. However, without the information requested above, OCR may be unable to proceed with your complaint. We collect this information under authority of the Privacy Rule issued pursuant to the Health Insurance Portability and Accountability Act of 1996. We will use the information you provide to determine if we have jurisdiction and, if so, how we will process your complaint. Information submitted on this form is treated confidentially and is protected under the provisions of the Privacy Act of 1974. Names or other identifying information about individuals are disclosed when it is necessary for investigation of possible health information privacy violations, for internal systems operations, or for routine uses, which include disclosure of information outside the Department for purposes associated with health information privacy compliance and as permitted by law. It is illegal for a covered entity to intimidate, threaten, coerce, discriminate or retaliate against you for filing this complaint or for taking any other action to enforce your rights under the Privacy Rule. You are not required to use this form. You also may write a letter or submit a complaint electronically with the same information. To submit an electronic complaint, go to OCR's Web site at:
www.hhs.gov/ocr/privacy/hipaa/complaints/index.html. To mail a complaint see reverse page for OCR Regional addresses.

The remaining information on this form is optional. Failure to answer these voluntary questions will not affect OCR's decision to process your complaint.

Do you need special accommodations for us to communicate with you about this complaint? (Check all that apply)

☐ Braille ☐ Large Print ☐ Cassette tape ☐ Computer diskette ☐ Electronic mail ☐ TDD

☐ Sign language interpreter (specify language): _____

☐ Foreign language interpreter (specify language): _____ ☐ Other: _____

If we cannot reach you directly, is there someone we can contact to help us reach you?

FIRST NAME	LAST NAME
HOME / CELL PHONE (Please include area code)	WORK PHONE (Please include area code)

STREET ADDRESS	CITY

STATE	ZIP	E-MAIL ADDRESS (If available)

Have you filed your complaint anywhere else? If so, please provide the following. (Attach additional pages as needed)

PERSON/AGENCY/ORGANIZATION/ COURT NAME(S)

DATE(S) FILED	CASE NUMBER(S) (If known)

To help us better serve the public, please provide the following information for the person you believe had their health information privacy rights violated (you or the person on whose behalf you are filing).

ETHNICITY (select one)

☐ Hispanic or Latino

☐ Not Hispanic or Latino

RACE (select one or more)

☐ American Indian or Alaska Native ☐ Asian ☐ Native Hawaiian or Other Pacific Islander

☐ Black or African American ☒ White ☐ Other (specify): _____

PRIMARY LANGUAGE SPOKEN (if other then English) _____

How did you learn about the Office for Civil Rights?

☐ HHS Website/Internet Search ☐ Family/Friend/Associate ☐ Religious/Community Org ☐ Lawyer/Legal Org ☐ Phone Directory ☐ Employer

☐ Fed/State/Local Gov ☐ Healthcare Provider/Health Plan ☐ Conference/OCR Brochure ☒ Other (specify): work place HIPPA

To mail a complaint, please type or print, and return completed complaint to the OCR Regional Address based on the region where the alleged violation took place. If you need assistance completing this form, contact the appropriate region listed below.

Region I - CT, ME, MA, NH, RI, VT
Office for Civil Rights, DHHS
JFK Federal Building - Room 1875
Boston, MA 02203
(617) 565-1340; (617) 565-1343 (TDD)
(617) 565-3809 FAX

Region II - NJ, NY, PR, VI
Office for Civil Rights, DHHS
26 Federal Plaza - Suite 3312
New York, NY 10278
(212) 264-3313; (212) 264-2355 (TDD)
(212) 264-3039 FAX

Region III - DE, DC, MD, PA, VA, WV
Office for Civil Rights, DHHS
150 S. Independence Mall West - Suite 372
Philadelphia, PA 19106-3499
(215) 861-4441; (215) 861-4440 (TDD)
(215) 861-4431 FAX

Region IV - AL, FL, GA, KY, MS, NC, SC, TN
Office for Civil Rights, DHHS
61 Forsyth Street, SW. - Suite 16T70
Atlanta, GA 30303-8909
(404) 562-7886; (404) 562-7884 (TDD)
(404) 562-7881 FAX

Region V - IL, IN, MI, MN, OH, WI
Office for Civil Rights, DHHS
233 N. Michigan Ave. - Suite 240
Chicago, IL 60601
(312) 886-2359; (312) 353-5693 (TDD)
(312) 886-1807 FAX

Region VI - AR, LA, NM, OK, TX
Office for Civil Rights, DHHS
1301 Young Street - Suite 1169
Dallas, TX 75202
(214) 767-4056; (214) 767-8940 (TDD)
(214) 767-0432 FAX

Region VII - IA, KS, MO, NE
Office for Civil Rights, DHHS
601 East 12th Street - Room 248
Kansas City, MO 64106
(816) 426-7277; (816) 426-7065 (TDD)
(816) 426-3686 FAX

Region VIII - CO, MT, ND, SD, UT, WY
Office for Civil Rights, DHHS
999 18th Street, Suite 417
Denver, CO 80202
(303) 844-2024; (303) 844-3439 (TDD)
(303) 844-2025 FAX

Region IX - AZ, CA, HI, NV, AS, GU, The U.S. Affiliated Pacific Island Jurisdictions
Office for Civil Rights, DHHS
90 7th Street, Suite 4-100
San Francisco, CA 94103
(415) 437-8310; (415) 437-8311 (TDD)
(415) 437-8329 FAX

Region X - AK, ID, OR, WA
Office for Civil Rights, DHHS
701 Fifth Avenue, Suite 1600, MS - 11
Seattle, WA 98104
(206) 615-2290; (206) 615-2296 (TDD)
(206) 615-2297 FAX

Burden Statement

Public reporting burden for the collection of information on this complaint form is estimated to average 45 minutes per response, including the time for reviewing instructions, gathering the data needed and entering and reviewing the information on the completed complaint form. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: HHS/OS Reports Clearance Officer, Office of Information Resources Management, 200 Independence Ave. S.W., Room 531H, Washington, D.C. 20201. **Please do not mail complaint form to this address.**

COMPLAINANT CONSENT FORM

The Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) has the authority to collect and receive material and information about you, including personnel and medical records, which are relevant to its investigation of your complaint.

To investigate your complaint, OCR may need to reveal your identity or identifying information about you to persons at the entity or agency under investigation or to other persons, agencies, or entities.

The Privacy Act of 1974 protects certain federal records that contain personally identifiable information about you and, with your consent, allows OCR to use your name or other personal information, if necessary, to investigate your complaint.

Consent is voluntary, and it is not always needed in order to investigate your complaint; however, failure to give consent is likely to impede the investigation of your complaint and may result in the closure of your case.

Additionally, OCR may disclose information, including medical records and other personal information, which it has gathered during the course of its investigation in order to comply with a request under the Freedom of Information Act (FOIA) and may refer your complaint to another appropriate agency.

Under FOIA, OCR may be required to release information regarding the investigation of your complaint; however, we will make every effort, as permitted by law, to protect information that identifies individuals or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

Please read and review the documents entitled, *Notice to Complainants and Other Individuals Asked to Supply Information to the Office for Civil Rights* and *Protecting Personal Information in Complaint Investigations* for further information regarding how OCR may obtain, use, and disclose your information while investigating your complaint.

In order to expedite the investigation of your complaint if it is accepted by OCR, please read, sign, and return one copy of this consent form to OCR with your complaint. Please make one copy for your records.

- As a complainant, I understand that in the course of the investigation of my complaint it may become necessary for OCR to reveal my identity or identifying information about me to persons at the entity or agency under investigation or to other persons, agencies, or entities.

- I am also aware of the obligations of OCR to honor requests under the Freedom of Information Act (FOIA). I understand that it may be necessary for OCR to disclose information, including personally identifying information, which it has gathered as part of its investigation of my complaint.

- In addition, I understand that as a complainant I am covered by the Department of Health and Human Services' (HHS) regulations which protect any individual from being intimidated, threatened, coerced, retaliated against, or discriminated against because he/she has made a complaint, testified, assisted, or participated in any manner in any mediation, investigation, hearing, proceeding, or other part of HHS' investigation, conciliation, or enforcement process.

After reading the above information, please check ONLY ONE of the following boxes:

[X] **CONSENT:** I have read, understand, and agree to the above and give permission to OCR to reveal my identity or identifying information about me in my case file to persons at the entity or agency under investigation or to other relevant persons, agencies, or entities during any part of HHS' investigation, conciliation, or enforcement process.

[ ] **CONSENT DENIED:** I have read and I understand the above and do not give permission to OCR to reveal my identity or identifying information about me. I understand that this denial of consent is likely to impede the investigation of my complaint and may result in closure of the investigation.

Signature: (b)(6);(b)(7)(C) Date: 02/26/2016

**Please sign and date this complaint. You do not need to sign if submitting this form by email because submission by email represents your signature.*

Name (Please print): (b)(6);(b)(7)(C)

Address: (b)(6);(b)(7)(C)

Telephone Number: (b)(6);(b)(7)(C)

NOTICE TO COMPLAINANTS AND OTHER INDIVIDUALS ASKED TO SUPPLY INFORMATION TO THE OFFICE FOR CIVIL RIGHTS

Privacy Act

The Privacy Act of 1974 (5 U.S.C. §552a) requires OCR to notify individuals whom it asks to supply information that:

— OCR is authorized to solicit information under:
(i) Federal laws barring discrimination by recipients of Federal financial assistance on grounds of race, color, national origin, disability, age, sex, religion under programs and activities receiving Federal financial assistance from the U.S. Department of Health and Human Services (HHS), including, but not limited to, Title VI of the Civil Rights Act of 1964 (42 U.S.C. §2000d et seq.), Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. §794), the Age Discrimination Act of 1975 (42 U.S.C. §6101 et seq.), Title IX of the Education Amendments of 1972 (20 U.S.C. §1681 et seq.), and Sections 794 and 855 of the Public Health Service Act (42 U.S.C. §§295m and 296g);
(ii) Titles VI and XVI of the Public Health Service Act (42 U.S.C. §§291 et seq. and 300s et seq.) and 42 C.F.R. Part 124, Subpart G (Community Service obligations of Hill-Burton facilities);
(iii) 45 C.F.R. Part 85, as it implements Section 504 of the Rehabilitation Act in programs conducted by HHS; and
(iv) Title II of the Americans with Disabilities Act (42 U.S.C. §12131 et seq.) and Department of Justice regulations at 28 C.F.R. Part 35, which give HHS "designated agency" authority to investigate and resolve disability discrimination complaints against certain public entities, defined as health and service agencies of state and local governments, regardless of whether they receive federal financial assistance.
(v) The Standards for the Privacy of Individually Identifiable Health Information (The Privacy Rule) at 45 C.F.R. Part 160 and Subparts A and E of Part 164, which enforce the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 U.S.C. §1320d-2).

OCR will request information for the purpose of determining and securing compliance with the Federal laws listed above. Disclosure of this requested information to OCR by individuals who are not recipients of federal financial assistance is voluntary; however, even individuals who voluntarily disclose information are subject to prosecution and penalties under 18 U.S.C. § 1001 for making false statements.

Additionally, although disclosure is voluntary for individuals who are not recipients of federal financial assistance, failure to provide OCR with requested information may preclude OCR from making a compliance determination or enforcing the laws above.

OCR has the authority to disclose personal information collected during an investigation without the individual's consent for the following routine uses:

(i) to make disclosures to OCR contractors who are required to maintain Privacy Act safeguards with respect to such records;
(ii) for disclosure to a congressional office from the record of an individual in response to an inquiry made at the request of the individual;
(iii) to make disclosures to the Department of Justice to permit effective defense of litigation; and
(iv) to make disclosures to the appropriate agency in the event that records maintained by OCR to carry out its functions indicate a violation or potential violation of law.

Under 5 U.S.C. §552a(k)(2) and the HHS Privacy Act regulations at 45 C.F.R. §5b.11 OCR complaint records have been exempted as investigatory material compiled for law enforcement purposes from certain Privacy Act access, amendment, correction and notification requirements.

Freedom of Information Act

A complainant, the recipient or any member of the public may request release of OCR records under the Freedom of Information Act (5 U.S.C. §552) (FOIA) and HHS regulations at 45 C.F.R. Part 5.

Fraud and False Statements

Federal law, at 18 U.S.C. §1001, authorizes prosecution and penalties of fine or imprisonment for conviction of "whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations or makes or uses any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry".

PROTECTING PERSONAL INFORMATION IN COMPLAINT INVESTIGATIONS

To investigate your complaint, the Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) will collect information from different sources. Depending on the type of complaint, we may need to get copies of your medical records, or other information that is personal to you. This Fact Sheet explains how OCR protects your personal information that is part of your case file.

HOW DOES OCR PROTECT MY PERSONAL INFORMATION?

OCR is required by law to protect your personal information. The Privacy Act of 1974 protects Federal records about an individual containing personally identifiable information, including, but not limited to, the individual's medical history, education, financial transactions, and criminal or employment history that contains an individual's name or other identifying information.

Because of the Privacy Act, OCR will use your name or other personal information with a signed consent and only when it is necessary to complete the investigation of your complaint or to enforce civil rights laws or when it is otherwise permitted by law.

Consent is voluntary, and it is not always needed in order to investigate your complaint; however, failure to give consent is likely to impede the investigation of your complaint and may result in the closure of your case.

CAN I SEE MY OCR FILE?

Under the Freedom of Information Act (FOIA), you can request a copy of your case file once your case has been closed; however, OCR can withhold information from you in order to protect the identities of witnesses and other sources of information.

CAN OCR GIVE MY FILE TO ANY ONE ELSE?

If a complaint indicates a violation or a potential violation of law, OCR can refer the complaint to another appropriate agency without your permission.

If you file a complaint with OCR, and we decide we cannot help you, we may refer your complaint to another agency such as the Department of Justice.

CAN ANYONE ELSE SEE THE INFORMATION IN MY FILE?

Access to OCR's files and records is controlled by the Freedom of Information Act (FOIA). Under FOIA, OCR may be required to release information about this case upon public request. In the event that OCR receives such a request, we will make every effort,

as permitted by law, to protect information that identifies individuals, or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

If OCR receives protected health information about you in connection with a HIPAA Privacy Rule investigation or compliance review, we will only share this information with individuals outside of HHS if necessary for our compliance efforts or if we are required to do so by another law.

DOES IT COST ANYTHING FOR ME (OR SOMEONE ELSE) TO OBTAIN A COPY OF MY FILE?

In most cases, the first two hours spent searching for document(s) you request under the Freedom of Information Act and the first 100 pages are free. Additional search time or copying time may result in a cost for which you will be responsible. If you wish to limit the search time and number of pages to a maximum of two hours and 100 pages; please specify this in your request. You may also set a specific cost limit, for example, cost not to exceed $100.00.

If you have any questions about this complaint and consent package,
Please contact OCR at http://www.hhs.gov/ocr/office/about/contactus/index.html

OR

Contact your OCR Regional Office
(see Regional Office contact information on page 2 of the Complaint Form)

(b)(6);(b)(7)(C) was seen at Planned Parenthood on 12/10/2015, at that time she requested nothing be sent to mailing address since she was under the age of 18 and did not want her parents to know that she had gone to Planned Parenthood.

On 02/02/16 Planned Parenthood sent a paper bill to her mailing address that not only had the encounter/office visit listed, but also what she had been tested for. This was in direct violation of the HIPPA act since she had requested nothing be sent to mailing address in order to keep her medical records private.

I called Planned Parenthood financial services on 2/26/16 and spoke with (b)(6); (she did not give me a last name) who confirmed that they had on record that nothing was to be sent to (b)(6);(b) (the patients) mailing address due to confidentiality issues.

Due to this violation (b)(6);(b)(personal medical information was mailed to the home address where anyone could see it.

Please let me know the outcome of your investigation, I am very concerned that others may have been violated by Planned Parenthood and need to warn them if you are unable to fix this violation.

Thank you,

(b)(6);(b)(7)(C)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Voice - (202) 619-0403
TDD - (202) 619-3257
Fax - (202) 619-3818
http://www.hhs.gov/ocr

Office for Civil Rights
200 Independence Avenue,
S.W., Room 506F
Washington, DC 20201

May 25, 2016

(b)(6);(b)(7)(C)

Our Transaction Number: CU-16-232450

(b)(6);(b)(7)(C) vs. Planned Parenthood of Great Northwest

Dear (b)(6);(b)(7)(C):

On February 26, 2016, the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR), received your complaint alleging that Planned Parenthood of the Great Northwest, the covered entity, has violated the Federal Standards for Privacy of Individually Identifiable Health Information and/or the Security Standards for the Protection of Electronic Protected Health Information (45 C.F.R. Parts 160 and 164, Subparts A, C, and E, the Privacy and Security Rules).

OCR enforces the Privacy, Security, and Breach Notification Rules, and also Federal civil rights laws which prohibit discrimination in the delivery of health and human services because of race, color, national origin, disability, age, and under certain circumstances, sex and religion.

We have reviewed your complaint and have determined that OCR will not investigate your allegations. Therefore, OCR is closing this complaint with no further action, effective the date of this letter.

OCR's determination as stated in this applies only to the allegations in this complaint that were reviewed by OCR.

Under the Freedom of Information Act, we may be required to release this letter and other information about this case upon request by the public. In the event OCR receives such a request, we will make every effort, as permitted by law, to protect information that identifies individuals or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

We regret we are unable to assist you further. Thank you.

Sincerely,

Peggy Lee

Peggy Lee
Interim Director CCMO

English	If you speak a non-English language, call 1-800–368–1019 (TTY: 1-800-537-7697), and you will be connected to an interpreter who will assist you with this document at no cost.
Español - Spanish	Si usted habla español marque 1-800-368-1019 (o a la línea de teléfono por texto TTY 1-800-537-7697) y su llamada será conectada con un intérprete que le asistirá con este documento sin costo alguno.
中文 - Chinese	如果你讲中文，请拨打1-800-368-1019（打字电话：1-800-537-7697），你将被连接到一位讲同语种的翻译员为你提供免费服务。
Tiếng Việt - Vietnamese	Nếu bạn nói tiếng Việt, xin gọi 1-800-368-1019 (TTY: 1-800-537-7697), và bạn sẽ được kết nối với một thông dịch viên, người này sẽ hỗ trợ bạn với tài liệu này miễn phí.
한국어 - Korean	한국어를 하시면 1-800-368-1019 (청각 장애용: 1-800-537-7697) 로 연락 주세요. 통역관과 연결해서 당신의 서류를 무료로 도와 드리겠습니다.
Tagalog (Filipino)	Kung ikaw ay nagsasalita nang Tagalog, tumawag sa 1-800-368-1019 (TTY: 1-800-537-7697) para makonek sa tagapagsalin na tutulong sa iyo sa dokumentong ito na walang bayad.
Русский - Russian	Если вы говорите по- русски, наберите 1-800-368-1019. Для клиентов с ограниченными слуховыми и речевыми возможностями: 1-800-537-7697), и вас соединят с русскоговорящим переводчиком, который вам поможет с этим документом безвозмездно.

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6115

Majority (202) 225–2927

Minority (202) 225–3641

VIA EMAIL

June 1, 2016

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

Dear Director Samuels:

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

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

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

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

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

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

I. BACKGROUND

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

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

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

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

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[2] *See* Attachment A.

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

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

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

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

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

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

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

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

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

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

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

II. THE HIPAA PRIVACY RULE

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

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

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

III. THE CONTRACTS BETWEEN STEMEXPRESS AND THE ABORTION CLINICS

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

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

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

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

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

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

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

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

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

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

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

1. Cadaveric organ, eye or tissue transplantation

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

2. Research

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

3. Violations Preceding "Consent"

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CONCLUSION

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

Sincerely yours,

Marsha Blackburn
Chair
Select Investigative Panel

Attachment(s)

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

[32] 45 C.F.R. § 160.103.

Attachment A

Letter to HHS Office for Human Research Protections

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6115

Majority (202) 225–2927

Minority (202) 225–3641

VIA EMAIL

June 1, 2016

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

Dear Director Menikoff:

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

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

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

Background

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Informed Consent

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

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

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

> Research using donated tissue and blood is currently underway to uncover the causes of and ultimately find cures for things like: Heart Disease, Diabetes, Parkinson's Disease, Sickle Cell Anemia, Leukemia, Lymphoma, Cancer, Spinal Cord Disease, and more. . . .
>
> The benefits of consenting to donation today include furthering medical research in finding cures for disease like diabetes, leukemia, lymphoma, Parkinson's disease and more.

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

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[1] 45 CFR 46 §116.

[2] *Id.*

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

Coercion or Undue Influence

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

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

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

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

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

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[4] 45 CFR 46 §110(4) and (7)(b).

[5] *Id.*

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

IRB

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

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

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

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

> (1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
>
> (2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
>
> (3) Records of continuing review activities.
>
> (4) Copies of all correspondence between the IRB and the investigators . . . .[8]

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

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

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

While regulation of IRBs does not fall under the auspices of OHRP, it may interest you to know that, in March of 2012, the Food and Drug Administration ("FDA") issued a warning letter to BioMed IRB, citing: A failure to fulfill membership requirements; failure to prepare, maintain, and follow adequate written procedures for conducting the review of research, including initial and continuing review; and keeping minutes that were not sufficient to show attendance at the meetings, actions taken by the IRB, the vote on these actions including the number of members voting for, against, and abstaining, the basis for requiring changes in or disapproving research, and a written summary of the discussion of controverted issues and their resolution. As a result, the FDA ruled it "will withhold approval of all new studies subject to 21 CFR Part 56 and reviewed by the IRB; and [n]o new subjects are to be enrolled in any ongoing studies subject to 21 CFR Part 56 and approved by the IRB."[11] That ban was lifted in January 2013.[12]

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

Respectfully yours,

Marsha Blackburn
Chair, Select Investigative Panel

cc: Rep. Jan Schakowsky
Ranking Member

[10] Email from Fred Fox, Executive Director, Biomedical Research Institute of America, to Select Panel staff, Apr. 4, 2016.
[11] Letter from Mary A. Malarkey, Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, to Fred Fox, Executive Director, Biomedical Research Institute of America dba BioMed IRB, Mar. 29, 2012.
[12] Letter from Mary A. Malarkey, Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, to Fred Fox, Executive Director, Biomedical Research Institute of America dba BioMed IRB, Jan. 16, 2013.

Attachment B

Clinic Procedures & Policies

Attachment C

Researcher Procurement Record

Attachment D

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

Attachment E

Updated Task Assignment: Procurement Schedule
Wednesday, 3/20/13

Attachment F

Navigating the Task Board

Attachment G

StemExpress Emails

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

Ok.

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

Best,
Redacted

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

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

Redacted

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

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

just fyi

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

Hi,

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

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

Best,
Redacted

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

Hello,

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

Thank you,

Redacted

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

Hi Redacted

How is the pancreas forecast today - any possible procurements?

Best,
Redacted

Sent from my iPhone

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

Hi Redacted

There is one sample left on (b)(4) (the trisomy + normal). We have a trisomy patient scheduled this week and could try to procure the brain sample for you, but the PO would have to be edited to reflect the cost of the potential trisomy sample, or we could create a new PO for 1 trisomy sample.

There is also one sample left on (b)(4)

Thank you,

Redacted

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

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

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

Attachment H

Consenting Patients

Attachment I

Procurement Technician Compensation Policy for Tissue and Blood Procurement

Attachment J

StemExpress Services Agreement with Planned Parenthood Shasta Pacific

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

Purchase Order No (b)(4)

Purchase Order No.

Purchase Order No

Purchase Order No

StemExpress Invoice # (b)(4)

(b)(4)

(b)(4);(b)(6);(b)(7)(C)