



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Freedom of Information Office
Building 31, Room 5B-35
31 Center Drive, MSC 2107
Bethesda, Maryland 20892-2107
phone: (301) 496-5633
fax: (301) 402-4541

Via Email: mdiliberto@judicialwatch.org

May 15, 2023

Meredith Di Liberto
Judicial Watch, Inc.
425 Third Street SW, Suite 800
Washington, DC 20024

Re: NIH FOIA Case No.: 58237; Judicial Watch v. HHS, Case No. 22-cv-03045

Dear Ms. Di Liberto:

This is a complete response to the Freedom of Information Act (FOIA) request that is the subject of the complaint filed in *Judicial Watch v. HHS*, 22-cv-03045, now pending in the U.S. District Court for the District of Columbia. Your FOIA request, dated April 15, 2022, was received by the National Institutes of Health (NIH) on April 28, 2022.

You requested all digital, audio and/or voice recordings, notes, text messages, emails and chat logs of NIH officials involved in and relating to a Zoom meeting that took place on October 20, 2021 at 9:30 AM between NIH officials and officials of the University of Pittsburgh related to fetal tissue research.

We have processed 90 pages responsive to your request, all of which are attached. Also attached are the records produced to you under your *Judicial Watch v. HHS*, 22-cv-03051, litigation, as they are also responsive to this request. I have determined to withhold portions of the enclosed pages under FOIA exemptions (b)(4), (b)(5), (b)(6), (b)(7)(C) and (b)(7)(E). The information being withheld is protected from release pursuant to Exemptions 4, 5, 6, and 7 of the FOIA, 5 U.S.C. § 552 (b)(4), (b)(5), (b)(6), (b)(7)(C) and (b)(7)(E); and sections 5.31 (d), (e), (f), (g)(3) and (g)(5) of the HHS FOIA Regulations, 45 CFR Part 5. Exemption 4 protects from disclosure trade secrets and commercial or financial information that is privileged and confidential. Exemption 5 permits the withholding of internal government records which are pre-decisional and contain staff advice, opinion, and recommendations, as well as documents solicited and received by the President or his immediate White House advisers who have broad and significant responsibility for investigating and formulating the advice to be given to the President. Exemption 6 exempts from disclosure records the release of which would cause a clearly unwarranted invasion of personal privacy. Exemption 7(C) provides protection for law enforcement information for which disclosure could reasonably be expected to constitute an unwarranted invasion of privacy. Exemption 7(E) provides protection to law enforcement information that would disclose techniques and procedures for law enforcement investigations or prosecutions.

Please direct any questions regarding this response to AUSA Moustakas, of the Department of Justice, who can be reached at John.Moustakas@usdoj.gov.

Sincerely,

for Gorka Garcia-Malene
Freedom of Information Act Officer, NIH

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 11/8/2021 7:12:50 PM
To: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; (b) (6), (b) (7)(C)
(b) (6) Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]

Attachments: RE: Please read and acknowledge receipt -- questions about the GUDMAP project

Location: (b) (6)

Start: 11/9/2021 9:30:00 PM
End: 11/9/2021 10:00:00 PM
Show Time As: Busy

Required Attendees: (b) (6), (b) (7)(C) (OIG/OI); Bundesen, Liza (NIH/OD) [E]

Michael Lauer is inviting you to a scheduled ZoomGov meeting.

Join ZoomGov Meeting

(b) (6)

Meeting ID: (b) (6)

Passcode: (b) (6)

One tap mobile

+16692545252, (b) (6) US (San Jose)
+16468287666, (b) (6) US (New York)

Dial by your location

+1 669 254 5252 US (San Jose)
+1 646 828 7666 US (New York)
+1 551 285 1373 US
+1 669 216 1590 US (San Jose)

Meeting ID: (b) (6)

Passcode: (b) (6)

Find your local number: (b) (6)

Join by SIP

(b) (6)

Join by H.323

161.199.138.10 (US West)
161.199.136.10 (US East)

Meeting ID: (b) (6)

Passcode: (b) (6)

From: (b) (6), (b) (7)(C)
Sent: 11/8/2021 6:59:50 PM
To: (b) (6)
CC: Bundesen, Liza (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]; (b) (6)
(b) (6)
Subject: RE: Please read and acknowledge receipt -- questions about the GUDMAP project

Great, that works for me.

Thanks,

(b) (6), (b)
(7)(C)

From: (b) (6)
Sent: Monday, November 8, 2021 1:58 PM
To: (b) (6), (b) (7)(C)
Cc: (b) (6), (b) (7)(C) Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>;
(b) (6)
Subject: RE: Please read and acknowledge receipt -- questions about the GUDMAP project

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

Drs. Lauer and Bundesen are available tomorrow, Tuesday, November 9, 4:30-5pm ET. A meeting invite with Zoom coordinates will be coming your way shortly.

Best,
(b) (6)

(b) (6)

From: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Sent: Sunday, November 7, 2021 3:03 PM
To: (b) (6), (b) (7)(C)
Cc: (b) (6) Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>;
Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Many thanks (b) (6), (b) (7) I'm looping in (b) (6) to find a time that works for all of us.

Mike

From: [REDACTED] (b) (6)
Date: Sunday, November 7, 2021 at 2:08 PM
To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Cc: [REDACTED] (b) (6), (b) (7)(C) "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>, "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
Subject: RE: Please read and acknowledge receipt -- questions about the GUDMAP project

Good Afternoon Mike,

I'm free at any time tomorrow, Tuesday after 1pm, or Wednesday after 2pm. Whatever works best for you and Dr. Bundesen works for me.

Thanks,

[REDACTED] (b) (6), (b) (7)(C)

[REDACTED] (b) (6), (b) (7)(C)



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From: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Sent: Sunday, November 7, 2021 1:36 PM
To: [REDACTED] (b) (6), (b) (7)(C)
Cc: [REDACTED] (b) (6), (b) (7)(C) Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>; Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Subject: FW: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear [REDACTED] (b) (6), (b) (7)(C)

Dr. Bundesen and I would appreciate the opportunity to speak with you. Please let me know if that's OK, and we'll work on setting up a meeting.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
301-496-1096
Michael.Lauer@nih.gov

From: "Rutenbar, Rob A" <RUTENBAR@pitt.edu>

Date: Friday, November 5, 2021 at 12:48 PM

To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>

Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>

Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr. Lauer –

We acknowledge your follow-up email of Friday October 29. We submitted the revised RPPR from Dr. Dhir on November 3, 2021. Please let us know if you have any questions regarding that revised report.

With regard to your request for documentation/information, please be aware that we received a subpoena from HHS OIG requesting similar documentation on October 28, 2021. This was issued by (b) (6), (b) (7)(C). We are happy to provide the requested information to both you and HHS OIG, however, (b) (6), (b) (7)(C) instructed us not to provide the documentation you have requested until he has had the opportunity to speak with you. As such, we have to await further instruction from (b) (6), (b) (7)(C) as to what we can provide and when. He asked that we share his contact information with you. He can be reached by email at (b) (6), (b) (7)(C) and by phone at (b) (6), (b) (7)(C). Please let us know if you have any questions or concerns.

Best, -Rob R

Rob A. Rutenbar
Senior Vice Chancellor for Research
Distinguished Professor of CS & ECE
University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260
Tel: 412-624-9019 Email: rutenbar@pitt.edu
Admin: (b) (6)

From: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Sent: Friday, October 29, 2021 5:04 AM
To: Rutenbar, Rob A <RUTENBAR@pitt.edu>
Cc: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>; Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Thank you again Rob.

We understand that you have an ongoing independent review. Nonetheless, in our September 27, 2021, letter we asked you to provide information and documents as listed below. You should be able to provide us with written responses (as well as actual documents).

These were our requests:

- A copy of the Pittsburgh Biospecimen Core's policies and standard operating procedures related to human fetal tissue.
- For grant [U24DK110791](#), documentation of consent protocols, including a copy of the consent form(s) used, and supporting documentation demonstrating that consent was obtained, such as an attestation from the health care provider(s) or third party supplier(s) that informed consent was obtained at the time of tissue collection.
- A clarification of the tissue collection procedures for the GUDMAP Tissue Collection Site and explain the procedures used for reducing "warm ischemic time."
- An explanation as to whether any tissue was obtained after 25 weeks from any source, such as the International Institute for the Advancement of Medicine. If so, please indicate whether the tissue was from abortions and/or neonatal death and provide copies of the source's protocols for tissue collection procedures.

Please let us know when we can expect to receive these documents / information.

In addition, during our recent Zoom call we noted problems with a recent RPPR submission (October 4 communications attached). When will you submit a revised RPPR?

We look forward to hearing back from you very soon.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
301-496-1096
Michael.Lauer@nih.gov

From: "Rutenbar, Rob A" <RUTENBAR@pitt.edu>
Date: Wednesday, October 27, 2021 at 11:09 AM
To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr Lauer:

Please see attached letter, in response to your inquiry to the University of Pittsburgh of 27 September 2021.

Sincerely
-rob r

Rob A. Rutenbar
Senior Vice Chancellor for Research
Distinguished Professor of CS & ECE
University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260
Tel: 412-624-9019 Email: rutenbar@pitt.edu
Admin: (b) (6)

From: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Date: Monday, September 27, 2021 at 5:14 PM
To: Rob Rutenbar <RUTENBAR@pitt.edu>
Cc: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>, "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
Subject: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr. Rutenbar:

Please see attached.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: 301-496-1096
Email: Michael.Lauer@nih.gov

From: Bundesen, Liza (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3CDED900576A49AEA461D26E93BDDAC3-LBUNDESE]
Sent: 10/19/2021 5:04:57 PM
To: [REDACTED] (b) (6)
Subject: FW: Fetal tissue research-University of Pittsburgh
Attachments: Re: Fetal tissue research-University of Pittsburgh

FYI

From: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Sent: Sunday, October 17, 2021 9:23 AM
To: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Cc: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Subject: FW: Fetal tissue research-University of Pittsburgh

Hi Liza – interesting development (below and attached).

Thanks, Mike

From: "Tabak, Lawrence (NIH/OD) [E]" <lawrence.tabak@nih.gov>
Date: Sunday, October 17, 2021 at 9:18 AM
To: "Berg, Jeremy" <jberg@pitt.edu>
Cc: "Collins, Francis (NIH/OD) [E]" <collinsf@od.nih.gov>, "Burklow, John (NIH/OD) [E]" <burklowj@od.nih.gov>, "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Subject: Re: Fetal tissue research-University of Pittsburgh

Jeremy,

Mike Lauer (added to this thread) will be meeting with your VPR on Wednesday. Based upon the outcome of that meeting, Mike and I are willing to meet with your Chancellor if that is still desired.

Best wishes,
Larry

Lawrence A. Tabak, DDS, PhD
Principal Deputy Director, NIH

From: Jeremy Berg <jberg@pitt.edu>
Date: Saturday, October 16, 2021 at 9:50 AM
To: Francis Collins <collinsf@od.nih.gov>
Cc: "Tabak, Lawrence (NIH/OD) [E]" <lawrence.tabak@nih.gov>, "Burklow, John (NIH/OD) [E]" <burklowj@od.nih.gov>
Subject: Fetal tissue research-University of Pittsburgh

Hi Francis:

I write regarding ongoing efforts to undermine important science using fetal tissue. As you no doubt know, various public universities have been the subject of rotating attacks about research using fetal tissue, sometimes citing NIH support for the research. It is now the University of Pittsburgh turn in the spotlight. The event that triggered this is the publication of a paper (attached) on grafting fetal skin onto rodents supported by an R21 from NIAID (<https://reporter.nih.gov/search/cbh4-6MG-UCNgeeBHC15ew/project-details/9599671>). I provide this only for background as the details do not matter for the issue I am raising.

Pitt's response to concerns raised by state legislators and various news outlets has been to commission an outside review of Pitt's practices and compliance. The University believes that all appropriate practices and laws have been followed. However, this outside review has been met with additional complaints (see <https://www.foxnews.com/us/pittsburgh-investigation-fetal-tissue-probe-cone-silence>).

We have been discussing these issues and it seems that this is an organized attempt to delegitimize science based on fetal tissue rather than to identify misbehavior (although, of course, any misbehavior does create opportunities for outrage). In light of this, we feel that the scientific community would benefit if more institutions could stand together to take some of the power out of the one-at-a-time strategy that appears to be operating.

Our Chancellor Pat Gallagher, former Director of NIST and your Senate confirmation colleague would like the opportunity to discuss this with you or other appropriate individuals at NIH via whatever venue would be preferred (phone, Zoom, in Bethesda).

If this is possible, please let me know the best way to make the appropriate arrangements.

Thank you for your consideration and best wishes for the remainder of your time at NIH and for the next phase.

Best, Jeremy

Jeremy M. Berg, Ph.D.
University of Pittsburgh
Associate Senior Vice Chancellor for Science Strategy and Planning
in the Health Sciences
Professor of Computational and Systems Biology
3550 Terrace Street
Pittsburgh, PA 15213
(412)624-1223

(b) (6) (cell)
jberg@pitt.edu

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 10/17/2021 1:15:26 PM
To: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Jorgenson, Lyric (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbde7d361374981a4d336b6eeb17521-jorgensonla]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
Subject: Re: Fetal tissue research-University of Pittsburgh

So in addition to letting Jeremy know that Mike and I are willing to meet with their Chancellor, I will also indicate that Mike is meeting with the VPR on Wed.

From: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Date: Saturday, October 16, 2021 at 7:28 PM
To: Francis Collins <collinsf@od.nih.gov>, "Tabak, Lawrence (NIH/OD) [E]" <lawrence.tabak@nih.gov>, "Burklow, John (NIH/OD) [E]" <burklowj@od.nih.gov>, "Hallett, Adrienne (NIH/OD) [E]" <adrienne.hallett@nih.gov>, "Jorgenson, Lyric (NIH/OD) [E]" <lyric.jorgenson@nih.gov>, "Myles, Renate (NIH/OD) [E]" <mylesr@mail.nih.gov>, "Wood, Gretchen (NIH/OD) [E]" <woodgs@od.nih.gov>
Cc: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Subject: Re: Fetal tissue research-University of Pittsburgh

Good evening – We have a Zoom meeting scheduled with the Pitt VPR and team this Wednesday, October 20, at 9:30 AM. That's why I'll be late for Exec Comm – I'll join at 10 AM. So the timing works.

Thanks, Mike

From: "Collins, Francis (NIH/OD) [E]" <collinsf@od.nih.gov>
Date: Saturday, October 16, 2021 at 5:36 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <lawrence.tabak@nih.gov>, "Burklow, John (NIH/OD) [E]" <burklowj@od.nih.gov>, "Hallett, Adrienne (NIH/OD) [E]" <adrienne.hallett@nih.gov>, "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>, "Jorgenson, Lyric (NIH/OD) [E]" <lyric.jorgenson@nih.gov>, "Myles, Renate (NIH/OD) [E]" <mylesr@mail.nih.gov>, "Wood, Gretchen (NIH/OD) [E]" <woodgs@od.nih.gov>
Subject: RE: Fetal tissue research-University of Pittsburgh

That sounds right. +Gretchen

FC

From: Tabak, Lawrence (NIH/OD) [E] <lawrence.tabak@nih.gov>
Sent: Saturday, October 16, 2021 2:07 PM
To: Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>; Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: Re: Fetal tissue research-University of Pittsburgh

Francis,

I suggest we discuss at ExCom. In the interim, I recommend that I respond to Jeremy and offer to meet with his Chancellor together with Mike Lauer.

Larry

From: "Burklow, John (NIH/OD) [E]" <burklowj@od.nih.gov>
Date: Saturday, October 16, 2021 at 12:38 PM
To: Francis Collins <collinsf@od.nih.gov>, "Tabak, Lawrence (NIH/OD) [E]" <lawrence.tabak@nih.gov>, "Hallett, Adrienne (NIH/OD) [E]" <adrienne.hallett@nih.gov>, "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>, "Jorgenson, Lyric (NIH/OD) [E]" <lyric.jorgenson@nih.gov>, "Myles, Renate (NIH/OD) [E]" <mylesr@mail.nih.gov>
Subject: Fwd: Fetal tissue research-University of Pittsburgh

+ Renate.

Sent from my iPhone

Begin forwarded message:

From: "Collins, Francis (NIH/OD) [E]" <collinsf@od.nih.gov>
Date: October 16, 2021 at 9:53:00 AM EDT
To: "Tabak, Lawrence (NIH/OD) [E]" <lawrence.tabak@nih.gov>, "Burklow, John (NIH/OD) [E]" <burklowj@od.nih.gov>, "Jorgenson, Lyric (NIH/OD) [E]" <lyric.jorgenson@nih.gov>, "Hallett, Adrienne (NIH/OD) [E]" <adrienne.hallett@nih.gov>, "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Subject: FW: Fetal tissue research-University of Pittsburgh

Adding Lyric, Adrienne, and Mike.

From: Berg, Jeremy <jberg@pitt.edu>
Sent: Saturday, October 16, 2021 9:50 AM
To: Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>
Cc: Tabak, Lawrence (NIH/OD) [E] <lawrence.tabak@nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>
Subject: Fetal tissue research-University of Pittsburgh

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provide this only for background as the details do not matter for the issue I am raising.

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Thank you for your consideration and best wishes for the remainder of your time at NIH and for the next phase.

Best, Jeremy

Jeremy M. Berg, Ph.D.
University of Pittsburgh
Associate Senior Vice Chancellor for Science Strategy and Planning
in the Health Sciences
Professor of Computational and Systems Biology
3550 Terrace Street
Pittsburgh, PA 15213
(412)624-1223
(b) (6)
jberg@pitt.edu<<mailto:jberg@pitt.edu>>

From: Bundesen, Liza (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3CDED900576A49AEA461D26E93BDDAC3-LBUNDESE]
Sent: 11/5/2021 6:09:30 PM
To: [REDACTED] (b) (6)
Subject: FW: Please read and acknowledge receipt -- questions about the GUDMAP project

FYI

From: Rutenbar, Rob A <RUTENBAR@pitt.edu>
Sent: Friday, November 5, 2021 12:49 PM
To: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Cc: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr. Lauer –

We acknowledge your follow-up email of Friday October 29. We submitted the revised RPPR from Dr. Dhir on November 3, 2021. Please let us know if you have any questions regarding that revised report.

With regard to your request for documentation/information, please be aware that we received a subpoena from HHS OIG requesting similar documentation on October 28, 2021. This was issued by [REDACTED] (b) (6), (b) (7)(C). We are happy to provide the requested information to both you and HHS OIG, however, [REDACTED] (b) (6), (b) (7)(C) instructed us not to provide the documentation you have requested until he has had the opportunity to speak with you. As such, we have to await further instruction from [REDACTED] (b) (6), (b) (7)(C) as to what we can provide and when. He asked that we share his contact information with you. He can be reached by email at [REDACTED] (b) (6), (b) (7)(C) and by phone at [REDACTED] (b) (6), (b) (7)(C). Please let us know if you have any questions or concerns.

Best, -Rob R

Rob A. Rutenbar
Senior Vice Chancellor for Research
Distinguished Professor of CS & ECE
University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260
Tel: 412-624-9019 Email: rutenbar@pitt.edu
Admin: [REDACTED] (b) (6)

From: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Sent: Friday, October 29, 2021 5:04 AM
To: Rutenbar, Rob A <RUTENBAR@pitt.edu>
Cc: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>; Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Thank you again Rob.

We understand that you have an ongoing independent review. Nonetheless, in our September 27, 2021, letter we asked you to provide information and documents as listed below. You should be able to provide us with written responses (as well as actual documents).

These were our requests:

- A copy of the Pittsburgh Biospecimen Core's policies and standard operating procedures related to human fetal tissue.
- For grant [U24DK110791](#), documentation of consent protocols, including a copy of the consent form(s) used, and supporting documentation demonstrating that consent was obtained, such as an attestation from the health care provider(s) or third party supplier(s) that informed consent was obtained at the time of tissue collection.
- A clarification of the tissue collection procedures for the GUDMAP Tissue Collection Site and explain the procedures used for reducing "warm ischemic time."
- An explanation as to whether any tissue was obtained after 25 weeks from any source, such as the International Institute for the Advancement of Medicine. If so, please indicate whether the tissue was from abortions and/or neonatal death and provide copies of the source's protocols for tissue collection procedures.

Please let us know when we can expect to receive these documents / information.

In addition, during our recent Zoom call we noted problems with a recent RPPR submission (October 4 communications attached). When will you submit a revised RPPR?

We look forward to hearing back from you very soon.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
301-496-1096
Michael.Lauer@nih.gov

From: "Rutenbar, Rob A" <RUTENBAR@pitt.edu>

Date: Wednesday, October 27, 2021 at 11:09 AM

To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>

Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>

Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr Lauer:

Please see attached letter, in response to your inquiry to the University of Pittsburgh of 27 September 2021.

Sincerely
-rob r

Rob A. Rutenbar
Senior Vice Chancellor for Research
Distinguished Professor of CS & ECE
University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260
Tel: 412-624-9019 Email: rutenbar@pitt.edu
Admin: (b) (6)

From: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Date: Monday, September 27, 2021 at 5:14 PM
To: Rob Rutenbar <RUTENBAR@pitt.edu>
Cc: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>, "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
Subject: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr. Rutenbar:

Please see attached.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: 301-496-1096
Email: Michael.Lauer@nih.gov

From: Bundesen, Liza (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3CDED900576A49AEA461D26E93BDDAC3-LBUNDESE]
Sent: 11/8/2021 7:51:21 PM
To: [REDACTED] (b) (6)
Subject: RE: Please read and acknowledge receipt -- questions about the GUDMAP project

Don't know. Talking to OIG tomorrow afternoon.

From: [REDACTED] (b) (6)
Sent: Monday, November 8, 2021 1:52 PM
To: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Subject: RE: Please read and acknowledge receipt -- questions about the GUDMAP project

Got it. Do we know who requested the investigation? I don't see anything online.

From: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Sent: Monday, November 8, 2021 9:24 AM
To: [REDACTED] (b) (6)
Subject: RE: Please read and acknowledge receipt -- questions about the GUDMAP project

Yes. He forwarded it to the [REDACTED] (b) (5)

From: [REDACTED] (b) (6)
Sent: Monday, November 8, 2021 8:45 AM
To: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Subject: RE: Please read and acknowledge receipt -- questions about the GUDMAP project

Thanks. I should let Lyric & my OSP chain of command know. Do you know who Mike has already told? Was this what you wanted to talk about on Friday?

From: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Sent: Sunday, November 7, 2021 5:10 PM
To: [REDACTED] (b) (6)
Subject: FW: Please read and acknowledge receipt -- questions about the GUDMAP project

FYI

From: Rutenbar, Rob A <RUTENBAR@pitt.edu>
Sent: Friday, November 5, 2021 12:49 PM
To: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Cc: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr. Lauer --

We acknowledge your follow-up email of Friday October 29. We submitted the revised RPPR from Dr. Dhir on November 3, 2021. Please let us know if you have any questions regarding that revised report.

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Best, -Rob R

Rob A. Rutenbar
Senior Vice Chancellor for Research
Distinguished Professor of CS & ECE
University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260
Tel: 412-624-9019 Email: rutenbar@pitt.edu
Admin: (b) (6)

From: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Sent: Friday, October 29, 2021 5:04 AM
To: Rutenbar, Rob A <RUTENBAR@pitt.edu>
Cc: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>; Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

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tissue was from abortions and/or neonatal death and provide copies of the source's protocols for tissue collection procedures.

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We look forward to hearing back from you very soon.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
301-496-1096
Michael.Lauer@nih.gov

From: "Rutenbar, Rob A" <RUTENBAR@pitt.edu>

Date: Wednesday, October 27, 2021 at 11:09 AM

To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>

Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>

Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr Lauer:

Please see attached letter, in response to your inquiry to the University of Pittsburgh of 27 September 2021.

Sincerely

-rob r

Rob A. Rutenbar
Senior Vice Chancellor for Research
Distinguished Professor of CS & ECE
University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260
Tel: 412-624-9019 Email: rutenbar@pitt.edu
Admin: [REDACTED] (b) (6)

From: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>

Date: Monday, September 27, 2021 at 5:14 PM

To: Rob Rutenbar <RUTENBAR@pitt.edu>

Cc: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>, "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>

Subject: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr. Rutenbar:

Please see attached.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: 301-496-1096
Email: Michael.Lauer@nih.gov

From: Bundesen, Liza (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3CDED900576A49AEA461D26E93BDDAC3-LBUNDESE]
Sent: 10/21/2021 3:09:28 PM
To: [REDACTED] (b) (6)
Subject: Notes from call with Pittsburgh
Attachments: For call with Pittsburgh tomorrow; Notes from 10-20-2021 call.docx

From: Bundesen, Liza (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3CDED900576A49AEA461D26E93BDDAC3-LBUNDESE]
Sent: 10/19/2021 8:17:13 PM
To: Lauer, Michael (NIH/NHLBI) [E] [Michael.Lauer@nih.gov]
CC: Bundesen, Liza (NIH/OD) [E] [lbundese@mail.nih.gov]
Subject: For call with Pittsburgh tomorrow
Attachments: Prep for 10-20-2021 call with Pittsburgh.docx; FW: 5 U24 DK110791-05. PI: Dhir, Rajiv --Final RPPR; FRPPR letter DK110791v1.1.pdf; DRAFT GUDMAP Ancillary Questions and Answers_8.25.21 rm ewb (003)_LJ clean.docx; FW: Fetal tissue research-University of Pittsburgh; NIDDK_GUDMAP_8.27.21 Clean with Qs.docx; CUsersGpuckettAppDataLocalTempDDAddin1632259181MI10FAX_20210921_155218 OCR.pdf; Letter to Pittsburgh re GUDMAP 9 27 21.docx; DRAFT GUDMAP Ancillary Questions and Answers_8.25.21 rm ewb (003)_LJ.docx

Hi Mike,

For our call with Pittsburgh tomorrow--in the first attachment, "Prep..." I outlined some discussion topics that we could address, if time permits. As we discussed, we'll give Pittsburgh ample opportunity to share any concerns they may have.

I've also attached the various other background documents for reference:

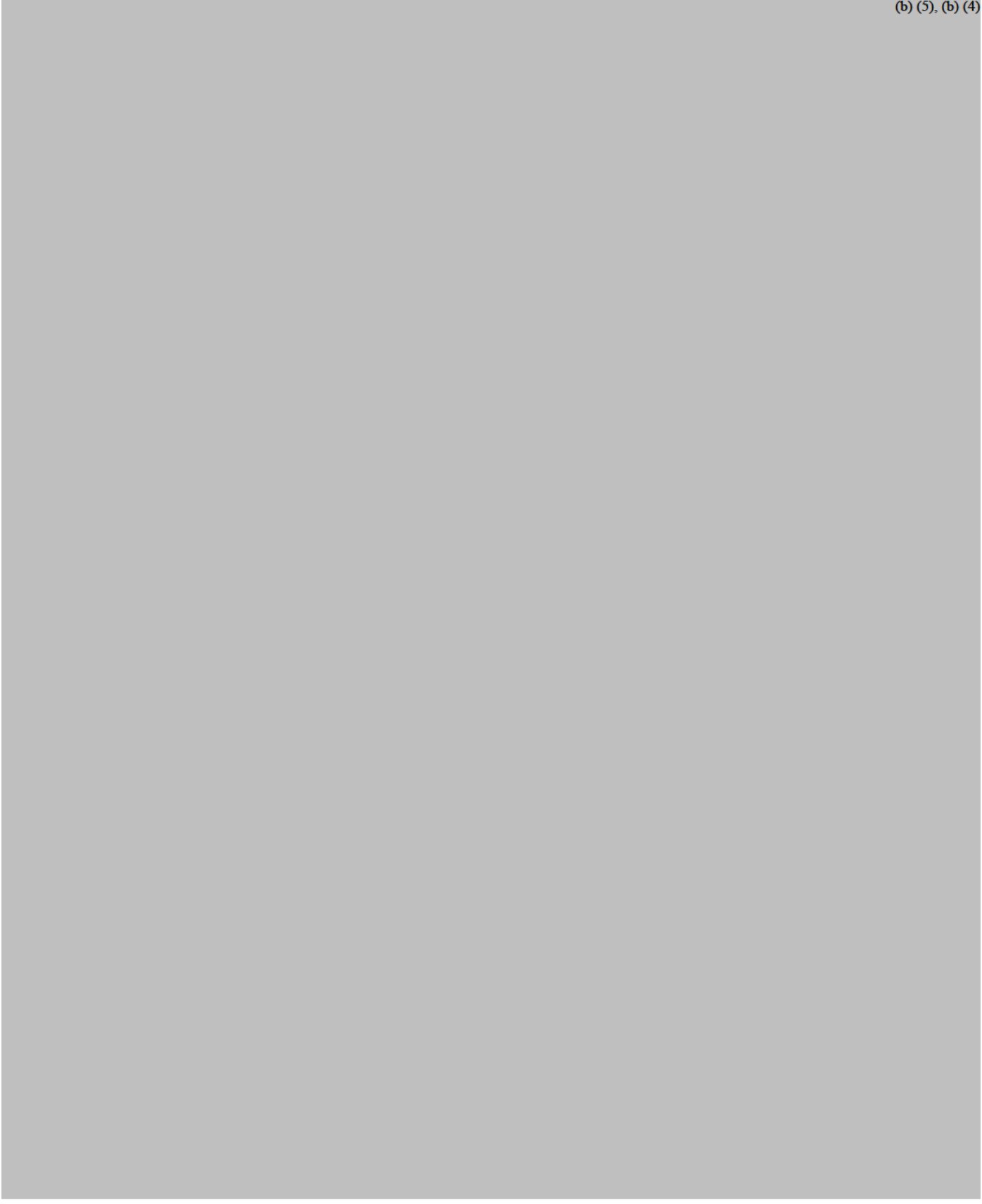
- NIDDK's letter to Pittsburgh re: the request to update the FRPPR and the PI's response, which you elevated to Dr. Rutenbar
- Dr. Berg's recent email
- OCPL's draft targeted fact sheet and Q&A
- Letter from Congress, which we included in our initial email to Pittsburgh
- Our letter to Pittsburgh

I didn't see the need to send these over SEFT.

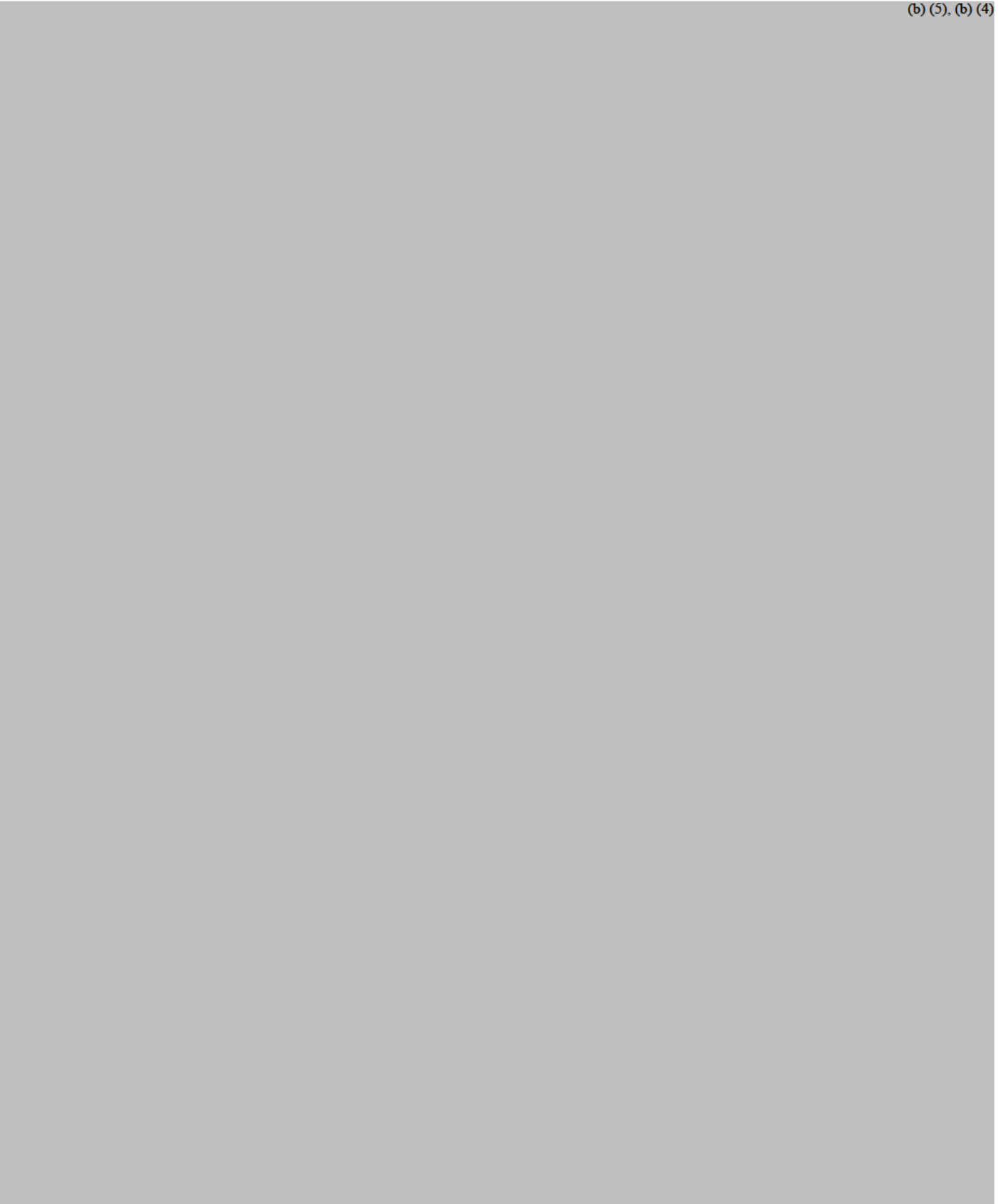
Thanks,
Liza

10-20-2021 Call with Pittsburgh re: GUDMAP Atlas Project, U24 DK110791

(b) (5), (b) (4)



(b) (5), (b) (4)



From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 10/4/2021 7:27:08 PM
To: Rutenbar, Rob A [RUTENBAR@pitt.edu]
CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]
Subject: FW: 5 U24 DK110791-05. PI: Dhir, Rajiv --Final RPPR
Attachments: 5 U24 DK110791-05. PI: Dhir, Rajiv --Final RPPR

Hi Rob

We are elevating this set of communications to you.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: 301-496-1096
Email: Michael.Lauer@nih.gov

From: (b) (6)
Sent: Friday, October 1, 2021 2:40 PM
To: (b) (6)
Cc: Dhir, Rajiv <dhir@pitt.edu>; (b) (6)
(b) (6)
(b) (6)
Subject: FW: 5 U24 DK110791-05. PI: Dhir, Rajiv --Final RPPR

Hello,

As (b) (6) of the University of Pittsburgh, I endorse this communication.

Thanks.

(b) (6)



University of
Pittsburgh

Office of
Sponsored Programs

From: [REDACTED] (b) (6)
Sent: Friday, October 1, 2021 2:08 PM
To: Dhir, Rajiv <dhirr@upmc.edu>; osp@pitt.edu <osp@pitt.edu>
Cc: [REDACTED]
Subject: RE: 5 U24 DK110791-05. PI: Dhir, Rajiv --Final RPPR

Good Afternoon,

All responses should be from your AOR. If you'd like to address any concerns raised in the letter, please go through your AOR.

Thank you,

[REDACTED] (b) (6)

National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health

In accordance with NIH policy, all requests and documents must be submitted by an Authorized Organization Representative (AOR). In eRA Commons the AOR holds the Signing Official Role.

From: Dhir, Rajiv <dhirr@upmc.edu>
Sent: Wednesday, September 29, 2021 2:38 PM
To: [REDACTED] (b) (6) osp@pitt.edu
Cc: [REDACTED]
Subject: Re: 5 U24 DK110791-05. PI: Dhir, Rajiv --Final RPPR

Hi [REDACTED] (b) (6) There was no change from our perspective. If the project PIs had unrealistic expectations; and no idea about the clinical world and were expecting gestational ages like they got from mice; then that really cannot be put on us.

As good team players; we agreed to budgetary and project changes. But that was because of the projects disconnect with reality.

I will be glad to discuss this and rectify as you deem fit. But I do not think we should be viewed as not delivering. We never promised what they thought they were going to get.

Best wishes.
Rajiv

Rajiv Dhir, MD, MBA

Executive Vice Chair and Medical Director of Anatomic Pathology Services at UPMC

Chief of Pathology, Shadyside Hospital

Univ. of Pittsburgh Health Systems

Phone: (412) 623-1321

From: (b) (6)
Sent: Wednesday, September 29, 2021 12:42 PM
To: osp@pitt.edu <osp@pitt.edu>; Dhir, Rajiv <dhirr@upmc.edu>
Cc: (b) (6)
Subject: 5 U24 DK110791-05. PI: Dhir, Rajiv --Final RPPR

Good Afternoon,

We've reviewed the Final RPPR and have some concerns. Please see our letter attached.

Thank you,

(b) (6)

National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health

In accordance with NIH policy, all requests and documents must be submitted by an Authorized Organization Representative (AOR). In eRA Commons the AOR holds the Signing Official Role.

From: [REDACTED] (b) (6)
Sent: 9/29/2021 4:42:12 PM
To: osp@pitt.edu; dhirr@upmc.edu
CC: [REDACTED] (b) (6)
Subject: 5 U24 DK110791-05. PI: Dhir, Rajiv --Final RPPR
Attachments: FRPPR letter DK110791v1.1.pdf

Good Afternoon,

We've reviewed the Final RPPR and have some concerns. Please see our letter attached.

Thank you,

[REDACTED] (b) (6)

National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health

In accordance with NIH policy, all requests and documents must be submitted by an Authorized Organization Representative (AOR). In eRA Commons the AOR holds the Signing Official Role.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institute of Health

National Institute of Diabetes and
Digestive and Kidney Diseases
Bethesda, Maryland 20892

Dear Dr. Dhir/Business Official,

We have had the opportunity to review your submitted final research performance progress report (FRPPR) for U24 DK110791-05.

(b) (4)

Sincerely,

Obtained via FOIA by Judicial Watch, Inc.

(b) (6)

(b) (6)

National Institute of Diabetes and Digestive and
Kidney Diseases
National Institutes of Health

(b) (6)

(b) (6)

National Institute of Diabetes and Digestive and
Kidney Diseases
National Institutes of Health

(b) (5)



(b) (5)



(b) (5)



DRAFT

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 10/17/2021 1:22:53 PM
To: Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]
CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauer]
Subject: FW: Fetal tissue research-University of Pittsburgh
Attachments: Re: Fetal tissue research-University of Pittsburgh

Hi Liza – interesting development (below and attached).

Thanks, Mike

From: "Tabak, Lawrence (NIH/OD) [E]" <lawrence.tabak@nih.gov>
Date: Sunday, October 17, 2021 at 9:18 AM
To: "Berg, Jeremy" <jberg@pitt.edu>
Cc: "Collins, Francis (NIH/OD) [E]" <collinsf@od.nih.gov>, "Burklow, John (NIH/OD) [E]" <burklowj@od.nih.gov>, "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Subject: Re: Fetal tissue research-University of Pittsburgh

Jeremy,

Mike Lauer (added to this thread) will be meeting with your VPR on Wednesday. Based upon the outcome of that meeting, Mike and I are willing to meet with your Chancellor if that is still desired.

Best wishes,
Larry

Lawrence A. Tabak, DDS, PhD
Principal Deputy Director, NIH

From: Jeremy Berg <jberg@pitt.edu>
Date: Saturday, October 16, 2021 at 9:50 AM
To: Francis Collins <collinsf@od.nih.gov>
Cc: "Tabak, Lawrence (NIH/OD) [E]" <lawrence.tabak@nih.gov>, "Burklow, John (NIH/OD) [E]" <burklowj@od.nih.gov>
Subject: Fetal tissue research-University of Pittsburgh

Hi Francis:

I write regarding ongoing efforts to undermine important science using fetal tissue. As you no doubt know, various public universities have been the subject of rotating attacks about research using fetal tissue, sometimes citing NIH support for the research. It is now the University of Pittsburgh turn in the spotlight. The event that triggered this is the publication of a paper (attached) on grafting fetal skin onto rodents supported by an R21 from NIAID (<https://reporter.nih.gov/search/cbh4-6MG-UCNgeeBHC15ew/project->

[details/9599671](#)). I provide this only for background as the details do not matter for the issue I am raising.

Pitt's response to concerns raised by state legislators and various news outlets has been to commission an outside review of Pitt's practices and compliance. The University believes that all appropriate practices and laws have been followed. However, this outside review has been met with additional complaints (see <https://www.foxnews.com/us/pittsburgh-investigation-fetal-tissue-probe-cone-silence>).


We have been discussing these issues and it seems that this is an organized attempt to delegitimize science based on fetal tissue rather than to identify misbehavior (although, of course, any misbehavior does create opportunities for outrage). In light of this, we feel that the scientific community would benefit if more institutions could stand together to take some of the power out of the one-at-a-time strategy that appears to be operating.

Our Chancellor Pat Gallagher, former Director of NIST and your Senate confirmation colleague would like the opportunity to discuss this with you or other appropriate individuals at NIH via whatever venue would be preferred (phone, Zoom, in Bethesda).

If this is possible, please let me know the best way to make the appropriate arrangements.

Thank you for your consideration and best wishes for the remainder of your time at NIH and for the next phase.

Best, Jeremy

Jeremy M. Berg, Ph.D.
University of Pittsburgh
Associate Senior Vice Chancellor for Science Strategy and Planning
in the Health Sciences
Professor of Computational and Systems Biology
3550 Terrace Street
Pittsburgh, PA 15213
(412)624-1223
 (b) (6)
jberg@pitt.edu

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 10/17/2021 1:15:26 PM
To: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Jorgenson, Lyric (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbde7d361374981a4d336b6eeb17521-jorgensonla]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
Subject: Re: Fetal tissue research-University of Pittsburgh

So in addition to letting Jeremy know that Mike and I are willing to meet with their Chancellor, I will also indicate that Mike is meeting with the VPR on Wed.

From: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Date: Saturday, October 16, 2021 at 7:28 PM
To: Francis Collins <collinsf@od.nih.gov>, "Tabak, Lawrence (NIH/OD) [E]" <lawrence.tabak@nih.gov>, "Burklow, John (NIH/OD) [E]" <burklowj@od.nih.gov>, "Hallett, Adrienne (NIH/OD) [E]" <adrienne.hallett@nih.gov>, "Jorgenson, Lyric (NIH/OD) [E]" <lyric.jorgenson@nih.gov>, "Myles, Renate (NIH/OD) [E]" <mylesr@mail.nih.gov>, "Wood, Gretchen (NIH/OD) [E]" <woodgs@od.nih.gov>
Cc: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Subject: Re: Fetal tissue research-University of Pittsburgh

Good evening – We have a Zoom meeting scheduled with the Pitt VPR and team this Wednesday, October 20, at 9:30 AM. That's why I'll be late for Exec Comm – I'll join at 10 AM. So the timing works.

Thanks, Mike

From: "Collins, Francis (NIH/OD) [E]" <collinsf@od.nih.gov>
Date: Saturday, October 16, 2021 at 5:36 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <lawrence.tabak@nih.gov>, "Burklow, John (NIH/OD) [E]" <burklowj@od.nih.gov>, "Hallett, Adrienne (NIH/OD) [E]" <adrienne.hallett@nih.gov>, "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>, "Jorgenson, Lyric (NIH/OD) [E]" <lyric.jorgenson@nih.gov>, "Myles, Renate (NIH/OD) [E]" <mylesr@mail.nih.gov>, "Wood, Gretchen (NIH/OD) [E]" <woodgs@od.nih.gov>
Subject: RE: Fetal tissue research-University of Pittsburgh

That sounds right. +Gretchen

FC

From: Tabak, Lawrence (NIH/OD) [E] <lawrence.tabak@nih.gov>
Sent: Saturday, October 16, 2021 2:07 PM
To: Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>; Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: Re: Fetal tissue research-University of Pittsburgh

Francis,

I suggest we discuss at ExCom. In the interim, I recommend that I respond to Jeremy and offer to meet with his Chancellor together with Mike Lauer.

Larry

From: "Burklow, John (NIH/OD) [E]" <burklowj@od.nih.gov>
Date: Saturday, October 16, 2021 at 12:38 PM
To: Francis Collins <collinsf@od.nih.gov>, "Tabak, Lawrence (NIH/OD) [E]" <lawrence.tabak@nih.gov>, "Hallett, Adrienne (NIH/OD) [E]" <adrienne.hallett@nih.gov>, "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>, "Jorgenson, Lyric (NIH/OD) [E]" <lyric.jorgenson@nih.gov>, "Myles, Renate (NIH/OD) [E]" <mylesr@mail.nih.gov>
Subject: Fwd: Fetal tissue research-University of Pittsburgh

+ Renate.

Sent from my iPhone

Begin forwarded message:

From: "Collins, Francis (NIH/OD) [E]" <collinsf@od.nih.gov>
Date: October 16, 2021 at 9:53:00 AM EDT
To: "Tabak, Lawrence (NIH/OD) [E]" <lawrence.tabak@nih.gov>, "Burklow, John (NIH/OD) [E]" <burklowj@od.nih.gov>, "Jorgenson, Lyric (NIH/OD) [E]" <lyric.jorgenson@nih.gov>, "Hallett, Adrienne (NIH/OD) [E]" <adrienne.hallett@nih.gov>, "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Subject: FW: Fetal tissue research-University of Pittsburgh

Adding Lyric, Adrienne, and Mike.

From: Berg, Jeremy <jberg@pitt.edu>
Sent: Saturday, October 16, 2021 9:50 AM
To: Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>
Cc: Tabak, Lawrence (NIH/OD) [E] <lawrence.tabak@nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>
Subject: Fetal tissue research-University of Pittsburgh

Hi Francis:

I write regarding ongoing efforts to undermine important science using fetal tissue. As you no doubt know, various public universities have been the subject of rotating attacks about research using fetal tissue, sometimes citing NIH support for the research. It is now the University of Pittsburgh turn in the spotlight. The event that triggered this is the publication of a paper (attached) on grafting fetal skin onto rodents supported by an R21 from NIAID (<https://reporter.nih.gov/search/cbh4-6MG-UCNgeeBHC15ew/project-details/9599671>). I

provide this only for background as the details do not matter for the issue I am raising.

Pitt's response to concerns raised by state legislators and various news outlets has been to commission an outside review of Pitt's practices and compliance. The University believes that all appropriate practices and laws have been followed. However, this outside review has been met with additional complaints (see <https://www.foxnews.com/us/pittsburgh-investigation-fetal-tissue-probe-cone-silence>).

We have been discussing these issues and it seems that this is an organized attempt to delegitimize science based on fetal tissue rather than to identify misbehavior (although, of course, any misbehavior does create opportunities for outrage). In light of this, we feel that the scientific community would benefit if more institutions could stand together to take some of the power out of the one-at-a-time strategy that appears to be operating.

Our Chancellor Pat Gallagher, former Director of NIST and your Senate confirmation colleague would like the opportunity to discuss this with you or other appropriate individuals at NIH via whatever venue would be preferred (phone, Zoom, in Bethesda).

If this is possible, please let me know the best way to make the appropriate arrangements.

Thank you for your consideration and best wishes for the remainder of your time at NIH and for the next phase.

Best, Jeremy

Jeremy M. Berg, Ph.D.
University of Pittsburgh
Associate Senior Vice Chancellor for Science Strategy and Planning
in the Health Sciences
Professor of Computational and Systems Biology
3550 Terrace Street
Pittsburgh, PA 15213
(412)624-1223

(b) (6)

jberg@pitt.edu<<mailto:jberg@pitt.edu>>

(b) (5)



(b) (5)



(b) (5)



(b) (5)



Congress of the United States
Washington, DC 20515

September 21, 2021

The Honorable Merrick Garland
United States Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW, Room 1145
Washington, D.C. 20530

The Honorable Xavier Becerra
Secretary of Health & Human Services
U.S. Department of Health & Human Services
200 Independence Avenue SW
Washington, D.C. 20201

The Honorable Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
U.S. Department of Health and Human Services
Building One, Room 244
One Center Drive
Bethesda, MD 20892

Dear Attorney General Garland, Secretary Becerra, and Director Collins,

We are alarmed by public records obtained from the National Institutes of Health (NIH) which show that the University of Pittsburgh (Pitt) may have violated federal law by altering abortion procedures to harvest organs from babies who were old enough to live outside the womb. We ask for a complete investigation into the activities of this organization and a full report of findings and any remedial measures necessary.

The NIH documents detailing Pitt's grant request were obtained in response to a Freedom of Information Act (FOIA) request from the Center for Medical Progress. Between fiscal years 2016 and 2020, NIH awarded approximately \$1.5 million to Pitt for a project related to the GenitoUrinary Developmental Molecular Anatomy Project (GUDMAP) program.¹ The GUDMAP program was intended to provide the scientific and medical community tools to study "congenital diseases of the genitourinary tract (kidneys, bladder, ureter, urethra)" by obtaining such organs from aborted babies for research.² In its application for funding to be a GUDMAP "tissue hub and collection site" Pitt states that its Health Science Tissue Bank (HSTB) has been involved in procuring and disbursing the body parts of aborted babies for years, noting that "the fetal tissue IRB [Institutional Review Board] has been in place since 2005."³ The application contains references in several places regarding the HSTB to the Pitt Institutional Review Board (IRB)⁴ but also states that the IRB forms are in the process of being altered⁵ and the IRB review is pending.⁶

First, Pitt's application raises concern that it has failed to comply with federal law prohibiting the alteration of abortion procedures solely for the purpose of obtaining fetal tissue, which states that an attending physician may have "no part in any decisions as to the timing, method, or procedures used to

¹ Award Letter. Department of Health and Human Services National Institutes of Health. Grant number 1U24DK110791-01. September 12, 2016.

² NIH RePORT Project Details. "University of Pittsburgh as the GUDMAP Tissue Hub and Collection Site." Abstract Text. https://reporter.nih.gov/search/p3w-bb6YsECf3hOTrF_iLA/project-details/9944639/history

³ University of Pittsburgh. Application for Federal Assistance SF 424 (R&R). Page 7. <https://www.centerformedicalprogress.org/wp-content/uploads/2021/08/GUDMAP2015NIHappFOIA.pdf>

⁴ University of Pittsburgh. Application for Federal Assistance SF 424 (R&R). Pages 7, 60, 61, 64.

⁵ University of Pittsburgh. Application for Federal Assistance SF 424 (R&R). Pages 62, 65, 70.

⁶ University of Pittsburgh. Application for Federal Assistance SF 424 (R&R). Page 6.

terminate a pregnancy.”⁷ It is not clear that Pitt has complied with these legal requirements based on the following statements on Pitt’s grant application:

- Pitt states that “ischemia time is minimized” when it obtains fetal tissue.⁸ NIH defines “ischemia” as “time a tissue, organ, or body part remains at body temperature after its blood supply has been reduced or cut off but before it is cooled or reconnected to a blood supply.”⁹ It would be illegal for Pitt to alter the “timing, method, or procedures” of the abortion to minimize ischemia time.
- Pitt states that it “tailor[s] [its] collection processes on a case-by-case basis to maximize the needs of investigators.”¹⁰ It would be illegal for researchers to have any part in the decisions surrounding the obtainment of fetal tissue from elective abortions.

Second, if the organs were harvested from babies born after induced abortion, we are concerned that some of these babies were born alive, could have survived with appropriate care, and may have died as a result of having their organs harvested. Pitt’s application states that it can obtain access to the organs and tissues of unborn babies between 6-24 weeks gestation, but it partners with another organization to obtain unborn babies between 25-42 weeks gestation.¹¹ Babies as young as less than 22 weeks gestation have been known to survive outside the womb with appropriate care.¹² The statements about “warm ischemia” raise questions about the cause of death for these babies. As noted above, Pitt states that it sought to minimize the time between when the blood supply to an organ was reduced and when the organ is cooled or reconnected. If the organs are harvested from a baby born after induced abortion, it is possible the baby was delivered alive, and the removal of the organs was the cause of the baby’s death.

Exploiting the body parts of aborted children for research purposes is repulsive and should stop, regardless of the outcome hoped for by researchers. Research using abortive fetal tissue is unethical, wrong, and has also been proven ineffective. Despite being used in clinical research since the 1920s, fetal tissue has not produced a single clinical treatment.¹³

Based on these considerations, for the federal awards given the project number 1U24DK110791, please provide full and clear responses to the following information requests going back to the beginning of the grant project period to today:

- The number of cases at each gestational age involving abortion, miscarriage, stillbirth, and neonate utilized in the GUDMAP program during the grant project period;

⁷ 45 C.F.R. 46.204(i). This regulation extends to all Federally-funded human fetal tissue research the statutory requirements of 42 U.S.C. 289g-1, which states that, “no alteration of the timing, method, or procedures used to terminate the pregnancy [may be] made solely for the purposes of obtaining the tissue” for “research on the transplantation of human fetal tissue for therapeutic purposes.”

⁸ “JW v HHS NIH July 2021 Records 00642 pg 170.” Judicial Watch. August 3, 2021.

<https://www.judicialwatch.org/documents/hhs-cmp-responsive-records-july-2021-pg-170/>

⁹ Definition of warm ischemia time - NCI Dictionary of Cancer Terms - National Cancer Institute

¹⁰ “JW v HHS NIH July 2021 Records 00642 pg 170.” Judicial Watch. August 3, 2021.

<https://www.judicialwatch.org/documents/hhs-cmp-responsive-records-july-2021-pg-170/>

¹¹ University of Pittsburgh. Application for Federal Assistance SF 424 (R&R). Page 60.

¹² Ahmad, Kaashif A. et al. “Two-Year Neurodevelopmental Outcome of an Infant Born at 21 Weeks’ 4 Days’ Gestation.” *Pediatrics*. November 2017. <https://pediatrics.aappublications.org/content/early/2017/10/31/peds.2017-0103>

¹³ “Final Report.” Select Investigative Panel of the Energy & Commerce Committee. 30 December 2016. Pg. 386.

- Detailed protocols for Dilation & Curettage, Dilation & Evacuation, and Labor Induction followed to obtain fetal tissue for the GUDMAP program;
- The detailed biospecimen collection IRB application and approval for the Health Science Tissue Bank;
- Documentation to verify the physiological status of babies delivered by labor induction upon tissue harvest;
- The number of fetal tissue collection procedures from babies delivered by labor induction;
- Documentation of the number of babies delivered by labor induction that were deceased, and cardiac activity had ceased prior to fetal organ and tissue collection;
- Documentation of when “warm ischemia” time was recorded with reference to death when collecting organs and tissue from abortion, miscarriage, stillbirth, and neonate;
- Documentation on the specific steps that were taken to minimize warm ischemic time when collecting organs and tissue from abortion, miscarriage, stillbirth, and neonate;
- Details on how specimens are collected and transferred to the Tissue Hub and the personnel involved at each step;
- Documentation of how compliance is ensured (including any reporting and oversight mechanisms) with regard to each of the following statutes and regulations:
 - The Partial-Birth Abortion Ban Act (18 U.S.C. 1531);
 - Research protections for pregnant women and fetuses (42 U.S.C. 289g, 289g-1, and 45 C.F.R. 46.204);
 - Research protections for neonates (45 C.F.R. 46.205); and,
 - Prohibitions regarding fetal tissue (42 U.S.C. 289g-2, 45 C.F.R. 46.206).

We appreciate your attention to this matter and look forward to your prompt and thorough response to each of these requests. We ask for a response by the date of October 12, 2021.

Sincerely,



Josh Hawley
United States Senator



Lisa McClain
Member of Congress



Steve Daines
United States Senator



Blaine Luetkemeyer
Member of Congress



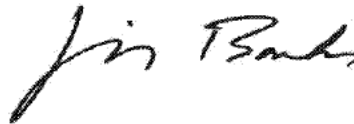
James Lankford
United States Senator



Jim Jordan
Member of Congress



Ted Cruz
United States Senator



Jim Banks
Member of Congress



John Boozman
United States Senator



Christopher H. Smith
Member of Congress



Bill Cassidy, M.D.
United States Senator



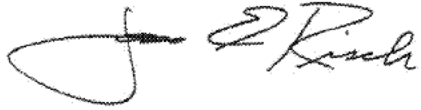
Rodney Davis
Member of Congress



John Thune
United States Senator



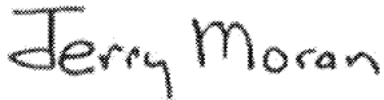
Jake LaTurner
Member of Congress



James E. Risch
United States Senator



Jeff Duncan
Member of Congress



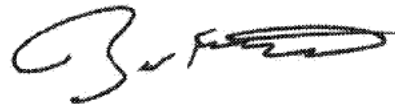
Jerry Moran
United States Senator



Michael Cloud
Member of Congress



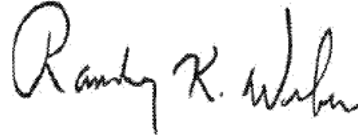
Tom Cotton
United States Senator



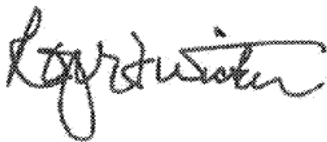
Randy Feenstra
Member of Congress



Marco Rubio
United States Senator



Randy Weber
Member of Congress



Roger F. Wicker
United States Senator



Ralph Norman
Member of Congress



Mike Braun
United States Senator



Brian Babin, D.D. S.
Member of Congress



M. Michael Rounds
United States Senator



Markwayne Mullin
Member of Congress



Cindy Hyde-Smith
United States Senator



Chris Jacobs
Member of Congress



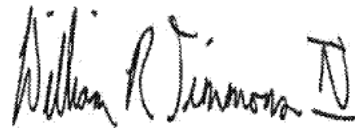
Rick Scott
United States Senator



Glenn "GT" Thompson
Member of Congress



Marsha Blackburn
United States Senator



William R. Timmons, IV
Member of Congress



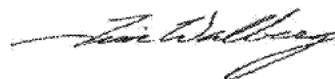
Rand Paul
United States Senator



Ann Wagner
Member of Congress



James M. Inhofe
United States Senator



Tim Walberg
Member of Congress



Steven M. Palazzo
Member of Congress



Paul A. Gosar, D.D.S.
Member of Congress



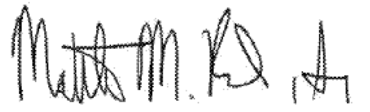
Jake Ellzey
Member of Congress



Steve Womack
Member of Congress



Bruce Westerman
Member of Congress




Matthew Rosendale, Sr.
Member of Congress



Andy Biggs
Member of Congress



Ben Cline
Member of Congress



Michael Guest
Member of Congress



Roger Williams
Member of Congress



Ron Estes
Member of Congress



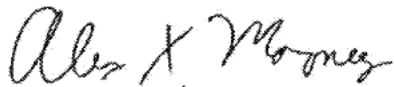
Debbie Lesko
Member of Congress



Madison Cawthorn
Member of Congress



Jody Hice
Member of Congress



Alex X. Mooney
Member of Congress



Scott Franklin
Member of Congress



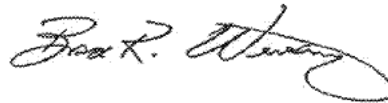
Vicky Hartzler
Member of Congress



Doug LaMalfa
Member of Congress



Darin LaHood
Member of Congress



Brad R. Wenstrup, D.P.M.
Member of Congress



Rick Crawford
Member of Congress



David B. McKinley, P.E.
Member of Congress



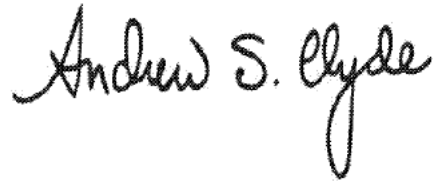
Warren Davidson
Member of Congress



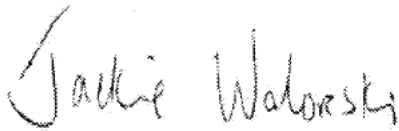
Bob Good
Member of Congress



Trent Kelly
Member of Congress



Andrew S. Clyde
Member of Congress



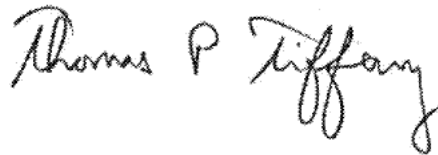
Jackie Walorski
Member of Congress



Lauren Boebert
Member of Congress



Glenn Grothman
Member of Congress



Tom Tiffany
Member of Congress



Kevin Hern
Member of Congress



Daniel Webster
Member of Congress



Doug Lamborn
Member of Congress



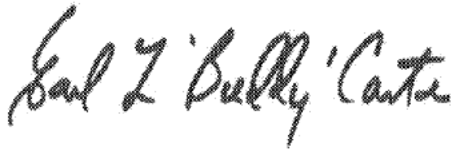
Ronny L. Jackson, M.D.
Member of Congress



Bill Johnson
Member of Congress



Guy Reschenthaler
Member of Congress



Earl L. "Buddy" Carter
Member of Congress



Louie Gohmert
Member of Congress



Mike Kelly
Member of Congress



David Kustoff
Member of Congress



Barry Moore
Member of Congress



Andy Harris, M.D.
Member of Congress



Mary E. Miller
Member of Congress



John Rose
Member of Congress



Chip Roy
Member of Congress



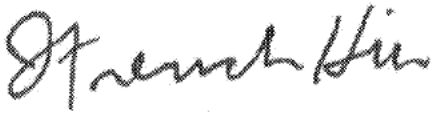
Bill Huizenga
Member of Congress



Billy Long
Member of Congress



Mike Bost
Member of Congress



French Hill
Member of Congress



Michelle Fischbach
Member of Congress



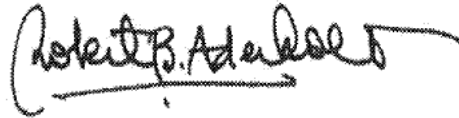
Julia Letlow
Member of Congress



Michael C. Burgess, M.D.
Member of Congress



Mike Johnson
Member of Congress



Robert B. Aderholt
Member of Congress



National Institutes of Health
Bethesda, Maryland 20892

[Confidential]

Date: September 27, 2021

To: Rob A. Rutenbar, PhD
Senior Vice Chancellor for Research
University of Pittsburgh

From: Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Director, NIH Office of Extramural Research

Re: GenitoUrinary Development Molecular Anatomy Project (GUDMAP) Tissue Hub and Collection Site (U24DK110791)

Dear Dr. Rutenbar:

I am sending you this letter in your capacity as Senior Vice Chancellor for Research at the University of Pittsburgh.

It has come to our attention that various media outlets and nonprofit organizations have made allegations about the fetal tissue collection procedures associated with the GenitoUrinary Development Molecular Anatomy Project (GUDMAP) Tissue Hub and Collection Site at the University of Pittsburgh.^{1,2,3,4}

As you are aware, NIH requires that NIH-supported recipient institutions certify that they will comply with the NIH Grants Policy Statement (see section 4.1.14 Human Fetal Tissue Research), which incorporates Federal statutory requirements for research with human fetal tissue. Sections 498A and 498B of the PHS Act (42 U.S.C. 289g-1 and 289g-2) set forth specific requirements and prohibitions on research involving human fetal tissue. Research involving human fetal tissue is also subject to the HHS Regulations for the Protection of Human Subjects (45 CFR Part 46). When an application involving human fetal tissue research is submitted to NIH, the Authorized Organization Representative's signature certifies that researchers using these tissues are in compliance with the PHS Act. When obtaining primary human fetal tissue for research purposes, NIH expects recipients and contractors to maintain appropriate documentation, such as an attestation from the health care provider or a third party supplier, that informed consent was obtained at the time of tissue collection.

1 The Center for Medical Progress: Aborted Infants' Continued Blood Flow Advertised in Racist University of Pittsburgh Grant Application to NIH

2 Judicial Watch: New HHS Documents Reveal Millions in Federal Funding for University of Pittsburgh Human Fetal Organ Harvesting Project Including Viable and Full-Term Babies

3 Fox News: Doctors say Pitt statements point to possibility organs extracted from live fetuses; school denies charge

4 Fox News: Millions in federal money flowed to tissue bank that collected fetal 'heart, gonads, legs, brain': report

The scientific and ethical challenges associated with research utilizing human fetal tissue make it imperative that researchers and their organizations be fully aware of and in compliance with the Federal requirements. In light of this, we are asking that you address the following:

- Please provide a copy of the Pittsburgh Biospecimen Core's policies and standard operating procedures related to human fetal tissue.
- For grant U24DK110791, provide documentation of consent protocols, including a copy of the consent form(s) used, and supporting documentation demonstrating that consent was obtained, such as an attestation from the health care provider(s) or third party supplier(s) that informed consent was obtained at the time of tissue collection.
- Please clarify the tissue collection procedures for the GUDMAP Tissue Collection Site and explain the procedures used for reducing "warm ischemic time."
- Please explain if any tissue was obtained after 25 weeks from any source, such as the International Institute for the Advancement of Medicine. If so, please indicate whether the tissue was from abortions and/or neonatal death and provide copies of the source's protocols for tissue collection procedures."

Please review these issues and confirm that the University of Pittsburgh complied with the policies cited above. If any instances of non-compliance are identified or suspected, please also provide a detailed description of the issue and corrective actions taken or planned.

We would like to receive your written response within the next 30 days. In the interim, we would like to schedule a phone call at your earliest convenience.

Sincerely,

Michael S. Lauer, MD

(b) (5)



(b) (5)




(b) (5)



10-20-2021 Call with Pittsburgh re: GUDMAP Atlas Project, U24 DK110791

(b) (4), (b) (5)



From: [REDACTED] (b) (6)
Sent: 11/8/2021 6:16:08 PM
To: Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]
Subject: RE: Please read and acknowledge receipt -- questions about the GUDMAP project

Ok, thank you. I'll offer tomorrow, 11/9, 4:30-5pm.

Best,
[REDACTED] (b) (6)

[REDACTED] (b) (6)

From: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Sent: Monday, November 8, 2021 1:13 PM
To: [REDACTED] (b) (6)
Subject: RE: Please read and acknowledge receipt -- questions about the GUDMAP project

Hi [REDACTED] (b) (6)

[REDACTED] (b) (6) So,
tomorrow would be preferred.

Thanks,
Liza

From: [REDACTED] (b) (6)
Sent: Monday, November 8, 2021 1:10 PM
To: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Cc: [REDACTED] (b) (6)
Subject: FW: Please read and acknowledge receipt -- questions about the GUDMAP project
Importance: High

Hi Liza,

In continuation of the emails below, Mike is requesting a meeting with [REDACTED] (b) (6), (b) (7)(C) and his availability is any time today, Tuesday after 1pm, or Wednesday after 2pm. Mike is availability as follows.

11/8 (today) - 3:30-4pm
11/9 - 4:30-5pm

Please let me know if any of these options work for you.

Best,

From: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>

Sent: Sunday, November 7, 2021 3:03 PM

To: (b) (6), (b) (7)(C)

Cc: (b) (6), (b) (7)(C) Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>;

Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>

Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Many thanks, (b) (6). I'm looping in (b) (6) to find a time that works for all of us.

Mike

From: (b) (6), (b) (7)(C)

Date: Sunday, November 7, 2021 at 2:08 PM

To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>

Cc: (b) (6), (b) (7)(C) "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>, "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>

Subject: RE: Please read and acknowledge receipt -- questions about the GUDMAP project

Good Afternoon Mike,

I'm free at any time tomorrow, Tuesday after 1pm, or Wednesday after 2pm. Whatever works best for you and Dr. Bundesen works for me.

Thanks,

(b) (6), (b) (7)(C)



OIG Fraud Hotline | 1-800-HHS-TIPS | TIPS.HHS.GOV | TTY 1-800-377-4950

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From: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Sent: Sunday, November 7, 2021 1:36 PM
To: (b) (6), (b) (7)(C)
Cc: (b) (6), (b) (7)(C) Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>; Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Subject: FW: Please read and acknowledge receipt -- questions about the GUDMAP project

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

Dr. Bundesen and I would appreciate the opportunity to speak with you. Please let me know if that's OK, and we'll work on setting up a meeting.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
301-496-1096
Michael.Lauer@nih.gov

From: "Rutenbar, Rob A" <RUTENBAR@pitt.edu>
Date: Friday, November 5, 2021 at 12:48 PM
To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

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Best, -Rob R

Rob A. Rutenbar
Senior Vice Chancellor for Research
Distinguished Professor of CS & ECE
University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260
Tel: 412-624-9019 Email: rutenbar@pitt.edu
Admin: (b) (6)

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We look forward to hearing back from you very soon.

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Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
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Sincerely
-rob r

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Date: Monday, September 27, 2021 at 5:14 PM

To: Rob Rutenbar <RUTENBAR@pitt.edu>

Cc: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>, "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>

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Dear Dr. Rutenbar:

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1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: 301-496-1096
Email: Michael.Lauer@nih.gov

From: [REDACTED] (b) (6)
Sent: 10/19/2021 5:15:22 PM
To: Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]
Subject: RE: Fetal tissue research-University of Pittsburgh

Thanks. Lyric had told me something about this, but it's helpful to see the details.

From: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Sent: Tuesday, October 19, 2021 1:05 PM
To: [REDACTED] (b) (6)
Subject: FW: Fetal tissue research-University of Pittsburgh

FYI

From: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Sent: Sunday, October 17, 2021 9:23 AM
To: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Cc: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Subject: FW: Fetal tissue research-University of Pittsburgh

Hi Liza – interesting development (below and attached).

Thanks, Mike

From: "Tabak, Lawrence (NIH/OD) [E]" <lawrence.tabak@nih.gov>
Date: Sunday, October 17, 2021 at 9:18 AM
To: "Berg, Jeremy" <jberg@pitt.edu>
Cc: "Collins, Francis (NIH/OD) [E]" <collinsf@od.nih.gov>, "Burklow, John (NIH/OD) [E]" <burklowj@od.nih.gov>, "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Subject: Re: Fetal tissue research-University of Pittsburgh

Jeremy,

Mike Lauer (added to this thread) will be meeting with your VPR on Wednesday. Based upon the outcome of that meeting, Mike and I are willing to meet with your Chancellor if that is still desired.

Best wishes,
Larry

Lawrence A. Tabak, DDS, PhD
Principal Deputy Director, NIH

From: Jeremy Berg <jberg@pitt.edu>
Date: Saturday, October 16, 2021 at 9:50 AM
To: Francis Collins <collinsf@od.nih.gov>
Cc: "Tabak, Lawrence (NIH/OD) [E]" <lawrence.tabak@nih.gov>, "Burklow, John (NIH/OD) [E]"

<burklowj@od.nih.gov>

Subject: Fetal tissue research-University of Pittsburgh

Hi Francis:

I write regarding ongoing efforts to undermine important science using fetal tissue. As you no doubt know, various public universities have been the subject of rotating attacks about research using fetal tissue, sometimes citing NIH support for the research. It is now the University of Pittsburgh turn in the spotlight. The event that triggered this is the publication of a paper (attached) on grafting fetal skin onto rodents supported by an R21 from NIAID (<https://reporter.nih.gov/search/cbh4-6MG-UCNgeeBHC15ew/project-details/9599671>). I provide this only for background as the details do not matter for the issue I am raising.

Pitt's response to concerns raised by state legislators and various news outlets has been to commission an outside review of Pitt's practices and compliance. The University believes that all appropriate practices and laws have been followed. However, this outside review has been met with additional complaints (see <https://www.foxnews.com/us/pittsburgh-investigation-fetal-tissue-probe-cone-silence>).

We have been discussing these issues and it seems that this is an organized attempt to delegitimize science based on fetal tissue rather than to identify misbehavior (although, of course, any misbehavior does create opportunities for outrage). In light of this, we feel that the scientific community would benefit if more institutions could stand together to take some of the power out of the one-at-a-time strategy that appears to be operating.

Our Chancellor Pat Gallagher, former Director of NIST and your Senate confirmation colleague would like the opportunity to discuss this with you or other appropriate individuals at NIH via whatever venue would be preferred (phone, Zoom, in Bethesda).

If this is possible, please let me know the best way to make the appropriate arrangements.

Thank you for your consideration and best wishes for the remainder of your time at NIH and for the next phase.

Best, Jeremy

Jeremy M. Berg, Ph.D.
University of Pittsburgh
Associate Senior Vice Chancellor for Science Strategy and Planning

in the Health Sciences
Professor of Computational and Systems Biology
3550 Terrace Street
Pittsburgh, PA 15213
(412)624-1223

(b) (6)

jberg@pitt.edu

From: [REDACTED] (b) (6)
Sent: 11/8/2021 7:12:48 PM
To: [REDACTED] (b) (6), (b) (7)(C) Bundesen, Liza (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]
Subject: Questions about the GUDMAP project
Attachments: RE: Please read and acknowledge receipt -- questions about the GUDMAP project
Location: [REDACTED] (b) (6)
Start: 11/9/2021 9:30:00 PM
End: 11/9/2021 10:00:00 PM
Show Time As: Tentative

Required Attendees: [REDACTED] (b) (6), (b) (7)(C) Bundesen, Liza (NIH/OD) [E]

Michael Lauer is inviting you to a scheduled ZoomGov meeting.

Join ZoomGov Meeting

[REDACTED] (b) (6)

Meeting ID: [REDACTED] (b) (6)
Passcode: [REDACTED] (b) (6)
One tap mobile
+16692545252, [REDACTED] (b) (6) (San Jose)
+16468287666, [REDACTED] (New York)

Dial by your location

+1 669 254 5252 US (San Jose)
+1 646 828 7666 US (New York)
+1 551 285 1373 US
+1 669 216 1590 US (San Jose)

Meeting ID: [REDACTED] (b) (6)
Passcode: [REDACTED] (b) (6)
Find your local number: <https://nih.zoomgov.com/j/amg78iJYO>

Join by SIP

[REDACTED] (b) (6)

Join by H.323

161.199.138.10 (US West)
161.199.136.10 (US East)
Meeting ID: [REDACTED] (b) (6)
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We understand that you have an ongoing independent review. Nonetheless, in our September 27, 2021, letter we asked you to provide information and documents as listed below. You should be able to provide us with written responses (as well as actual documents).

These were our requests:

- A copy of the Pittsburgh Biospecimen Core's policies and standard operating procedures related to human fetal tissue.
- For grant [U24DK110791](#), documentation of consent protocols, including a copy of the consent form(s) used, and supporting documentation demonstrating that consent was obtained, such as an attestation from the health care provider(s) or third party supplier(s) that informed consent was obtained at the time of tissue collection.
- A clarification of the tissue collection procedures for the GUDMAP Tissue Collection Site and explain the procedures used for reducing "warm ischemic time."
- An explanation as to whether any tissue was obtained after 25 weeks from any source, such as the International Institute for the Advancement of Medicine. If so, please indicate whether the tissue was from abortions and/or neonatal death and provide copies of the source's protocols for tissue collection procedures.

Please let us know when we can expect to receive these documents / information.

In addition, during our recent Zoom call we noted problems with a recent RPPR submission (October 4 communications attached). When will you submit a revised RPPR?

We look forward to hearing back from you very soon.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
301-496-1096
Michael.Lauer@nih.gov

From: "Rutenbar, Rob A" <RUTENBAR@pitt.edu>
Date: Wednesday, October 27, 2021 at 11:09 AM
To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr Lauer:

Please see attached letter, in response to your inquiry to the University of Pittsburgh of 27 September 2021.

Sincerely
-rob r

Rob A. Rutenbar
Senior Vice Chancellor for Research
Distinguished Professor of CS & ECE
University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260
Tel: 412-624-9019 Email: rutenbar@pitt.edu
Admin: [REDACTED] (b) (6)

From: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Date: Monday, September 27, 2021 at 5:14 PM
To: Rob Rutenbar <RUTENBAR@pitt.edu>
Cc: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>, "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
Subject: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr. Rutenbar:

Please see attached.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: 301-496-1096
Email: Michael.Lauer@nih.gov

From: [REDACTED] (b) (6)
[REDACTED]
Sent: 11/8/2021 7:12:33 PM
To: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; [REDACTED] (b) (6), (b) (7)(C)
[REDACTED] Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]
Subject: Questions about the GUDMAP project
Attachments: RE: Please read and acknowledge receipt -- questions about the GUDMAP project
Location: [REDACTED] (b) (6)
Start: 11/9/2021 9:30:00 PM
End: 11/9/2021 10:00:00 PM
Show Time As: Busy

Required Attendees: [REDACTED] (b) (6), (b) (7)(C) Bundesen, Liza (NIH/OD) [E]

Michael Lauer is inviting you to a scheduled ZoomGov meeting.

Join ZoomGov Meeting

[REDACTED] (b) (6)

Meeting ID: [REDACTED] (b) (6)
Passcode: [REDACTED] (b) (6)
One tap mobile
+16692545252, [REDACTED] (b) (6) (San Jose)
+16468287666, [REDACTED] (New York)

Dial by your location

+1 669 254 5252 US (San Jose)
+1 646 828 7666 US (New York)
+1 551 285 1373 US
+1 669 216 1590 US (San Jose)

Meeting ID: [REDACTED] (b) (6)
Passcode: [REDACTED] (b) (6)
Find your local number: <https://nih.zoomgov.com/j/amtg78iJYO>

Join by SIP

[REDACTED] (b) (6)

Join by H.323

161.199.138.10 (US West)
161.199.136.10 (US East)
Meeting ID: [REDACTED] (b) (6)
Passcode: [REDACTED] (b) (6)

From: (b) (6), (b) (7)(C)
Sent: 11/8/2021 6:59:50 PM
To: (b) (6)
CC: (b) (6), (b) (7)(C)
(b) (6), (b) (7)(C) Bundesen, Liza (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese] (b) (6)
Subject: RE: Please read and acknowledge receipt -- questions about the GUDMAP project

Great, that works for me.

Thanks,

(b) (6), (b)
(7)(C)

From: (b) (6)
Sent: Monday, November 8, 2021 1:58 PM
To: (b) (6), (b) (7)(C)
Cc: (b) (6), (b) (7)(C) Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>;
(b) (6)
Subject: RE: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear

Drs. Lauer and Bundesen are available tomorrow, Tuesday, November 9, 4:30-5pm ET. A meeting invite with Zoom coordinates will be coming your way shortly.

Best,
(b) (6)

(b) (6)

From: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Sent: Sunday, November 7, 2021 3:03 PM
To: (b) (6), (b) (7)(C)
Cc: (b) (6), (b) (7)(C) Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>;
Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Many thanks (b) (6), I'm looping in (b) (6) to find a time that works for all of us.

Mike

From: (b) (6), (b) (7)(C)
Date: Sunday, November 7, 2021 at 2:08 PM
To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Cc: (b) (6), (b) (7)(C) "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>, "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
Subject: RE: Please read and acknowledge receipt -- questions about the GUDMAP project

Good Afternoon Mike,

I'm free at any time tomorrow, Tuesday after 1pm, or Wednesday after 2pm. Whatever works best for you and Dr. Bundesen works for me.

Thanks,

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)



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From: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Sent: Sunday, November 7, 2021 1:36 PM
To: (b) (6), (b) (7)(C)
Cc: (b) (6), (b) (7)(C) Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>; Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Subject: FW: Please read and acknowledge receipt -- questions about the GUDMAP project

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

Dr. Bundesen and I would appreciate the opportunity to speak with you. Please let me know if that's OK, and we'll work on setting up a meeting.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
301-496-1096
Michael.Lauer@nih.gov

From: "Rutenbar, Rob A" <RUTENBAR@pitt.edu>

Date: Friday, November 5, 2021 at 12:48 PM

To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>

Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>

Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr. Lauer –

We acknowledge your follow-up email of Friday October 29. We submitted the revised RPPR from Dr. Dhir on November 3, 2021. Please let us know if you have any questions regarding that revised report.

With regard to your request for documentation/information, please be aware that we received a subpoena from HHS OIG requesting similar documentation on October 28, 2021. This was issued by (b) (6), (b) (7)(C). We are happy to provide the requested information to both you and HHS OIG, however, (b) (6), (b) (7)(C) instructed us not to provide the documentation you have requested until he has had the opportunity to speak with you. As such, we have to await further instruction from (b) (6), (b) (7)(C) as to what we can provide and when. He asked that we share his contact information with you. He can be reached by email at (b) (6), (b) (7)(C) and by phone at (b) (6), (b) (7)(C). Please let us know if you have any questions or concerns.

Best, -Rob R

Rob A. Rutenbar
Senior Vice Chancellor for Research
Distinguished Professor of CS & ECE
University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260
Tel: 412-624-9019 Email: rutenbar@pitt.edu
Admin: (b) (6)

From: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>

Sent: Friday, October 29, 2021 5:04 AM

To: Rutenbar, Rob A <RUTENBAR@pitt.edu>

Cc: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>; Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>

Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Thank you again Rob.

We understand that you have an ongoing independent review. Nonetheless, in our September 27, 2021, letter we asked you to provide information and documents as listed below. You should be able to provide us with written responses (as well as actual documents).

These were our requests:

- A copy of the Pittsburgh Biospecimen Core's policies and standard operating procedures related to human fetal tissue.
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- A clarification of the tissue collection procedures for the GUDMAP Tissue Collection Site and explain the procedures used for reducing "warm ischemic time."
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Please let us know when we can expect to receive these documents / information.

In addition, during our recent Zoom call we noted problems with a recent RPPR submission (October 4 communications attached). When will you submit a revised RPPR?

We look forward to hearing back from you very soon.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
301-496-1096
Michael.Lauer@nih.gov

From: "Rutenbar, Rob A" <RUTENBAR@pitt.edu>
Date: Wednesday, October 27, 2021 at 11:09 AM
To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr Lauer:

Please see attached letter, in response to your inquiry to the University of Pittsburgh of 27 September 2021.

Sincerely
-rob r

Rob A. Rutenbar
Senior Vice Chancellor for Research
Distinguished Professor of CS & ECE
University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260
Tel: 412-624-9019 Email: rutenbar@pitt.edu
Admin: [REDACTED] (b) (6)

From: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Date: Monday, September 27, 2021 at 5:14 PM
To: Rob Rutenbar <RUTENBAR@pitt.edu>
Cc: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>, "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
Subject: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr. Rutenbar:

Please see attached.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: 301-496-1096
Email: Michael.Lauer@nih.gov

From: Bundesen, Liza (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3CDED900576A49AEA461D26E93BDDAC3-LBUNDESE]
Sent: 10/17/2021 2:11:42 PM
To: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: RE: Fetal tissue research-University of Pittsburgh

Thanks, Mike.

From: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Sent: Sunday, October 17, 2021 9:23 AM
To: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Cc: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Subject: FW: Fetal tissue research-University of Pittsburgh

Hi Liza – interesting development (below and attached).

Thanks, Mike

From: "Tabak, Lawrence (NIH/OD) [E]" <lawrence.tabak@nih.gov>
Date: Sunday, October 17, 2021 at 9:18 AM
To: "Berg, Jeremy" <jberg@pitt.edu>
Cc: "Collins, Francis (NIH/OD) [E]" <collinsf@od.nih.gov>, "Burklow, John (NIH/OD) [E]" <burklowj@od.nih.gov>, "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Subject: Re: Fetal tissue research-University of Pittsburgh

Jeremy,

Mike Lauer (added to this thread) will be meeting with your VPR on Wednesday. Based upon the outcome of that meeting, Mike and I are willing to meet with your Chancellor if that is still desired.

Best wishes,
Larry

Lawrence A. Tabak, DDS, PhD
Principal Deputy Director, NIH

From: Jeremy Berg <jberg@pitt.edu>
Date: Saturday, October 16, 2021 at 9:50 AM
To: Francis Collins <collinsf@od.nih.gov>
Cc: "Tabak, Lawrence (NIH/OD) [E]" <lawrence.tabak@nih.gov>, "Burklow, John (NIH/OD) [E]" <burklowj@od.nih.gov>
Subject: Fetal tissue research-University of Pittsburgh

Hi Francis:

I write regarding ongoing efforts to undermine important science using fetal tissue. As you no doubt know, various public universities have been the subject of rotating attacks

about research using fetal tissue, sometimes citing NIH support for the research. It is now the University of Pittsburgh turn in the spotlight. The event that triggered this is the publication of a paper (attached) on grafting fetal skin onto rodents supported by an R21 from NIAID (<https://reporter.nih.gov/search/cbh4-6MG-UCNgeeBHC15ew/project-details/9599671>). I provide this only for background as the details do not matter for the issue I am raising.

Pitt's response to concerns raised by state legislators and various news outlets has been to commission an outside review of Pitt's practices and compliance. The University believes that all appropriate practices and laws have been followed. However, this outside review has been met with additional complaints (see <https://www.foxnews.com/us/pittsburgh-investigation-fetal-tissue-probe-cone-silence>).

We have been discussing these issues and it seems that this is an organized attempt to delegitimize science based on fetal tissue rather than to identify misbehavior (although, of course, any misbehavior does create opportunities for outrage). In light of this, we feel that the scientific community would benefit if more institutions could stand together to take some of the power out of the one-at-a-time strategy that appears to be operating.

Our Chancellor Pat Gallagher, former Director of NIST and your Senate confirmation colleague would like the opportunity to discuss this with you or other appropriate individuals at NIH via whatever venue would be preferred (phone, Zoom, in Bethesda).

If this is possible, please let me know the best way to make the appropriate arrangements.

Thank you for your consideration and best wishes for the remainder of your time at NIH and for the next phase.

Best, Jeremy

Jeremy M. Berg, Ph.D.
University of Pittsburgh
Associate Senior Vice Chancellor for Science Strategy and Planning
in the Health Sciences
Professor of Computational and Systems Biology
3550 Terrace Street
Pittsburgh, PA 15213
(412)624-1223

(b) (6)

jberg@pitt.edu

From: (b) (6), (b) (7)(C)
Sent: 11/19/2021 12:34:22 PM
To: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]
Subject: RE: Please read and acknowledge receipt -- questions about the GUDMAP project

Good Morning Dr. Lauer,

Thanks for sending. (b) (5), (b) (7)(E)

(b) (5), (b) (7)(E)

Thanks,

(b) (6), (b) (7)(C)

From: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Sent: Friday, November 19, 2021 5:48 AM
To: (b) (6), (b) (7)(C)
Cc: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>; Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Subject: FW: Please read and acknowledge receipt -- questions about the GUDMAP project

Good morning (b) (6), (b) (7) – We just received these materials from Pitt.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
301-496-1096
Michael.Lauer@nih.gov

From: "Rutenbar, Rob A" <RUTENBAR@pitt.edu>
Date: Thursday, November 18, 2021 at 4:55 PM
To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>, "Shekhar, Anantha" <AS1@pitt.edu>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Mike – please find enclosed the materials you requested in your November 10, 2021 email.

Best. -rob

Rob A. Rutenbar
Senior Vice Chancellor for Research
Distinguished Professor of CS & ECE
University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260
Tel: 412-624-9019 Email: rutenbar@pitt.edu
Admin: [REDACTED] (b) (6)

From: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Date: Wednesday, November 10, 2021 at 5:38 AM
To: Rob Rutenbar <RUTENBAR@pitt.edu>
Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>, "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Good morning Rob

Dr. Bundesen and I spoke with OIG [REDACTED] (b) (6), (b) (7)(C) yesterday, and he has given Pitt a green light to respond to NIH requests (please see the second attachment).

We look forward to receiving all requested materials from you soon, no later than COB Thursday, November 18.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
301-496-1096
Michael.Lauer@nih.gov

From: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Date: Friday, October 29, 2021 at 5:04 AM
To: "Rutenbar, Rob A" <RUTENBAR@pitt.edu>
Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>, "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

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- For grant [U24DK110791](#), documentation of consent protocols, including a copy of the consent form(s) used, and supporting documentation demonstrating that consent was obtained, such as an attestation from the health care provider(s) or third party supplier(s) that informed consent was obtained at the time of tissue collection.
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Please let us know when we can expect to receive these documents / information.

In addition, during our recent Zoom call we noted problems with a recent RPPR submission (October 4 communications attached). When will you submit a revised RPPR?

We look forward to hearing back from you very soon.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
301-496-1096
Michael.Lauer@nih.gov

From: "Rutenbar, Rob A" <RUTENBAR@pitt.edu>
Date: Wednesday, October 27, 2021 at 11:09 AM
To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>

Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr Lauer:

Please see attached letter, in response to your inquiry to the University of Pittsburgh of 27 September 2021.

Sincerely
-rob r

Rob A. Rutenbar
Senior Vice Chancellor for Research
Distinguished Professor of CS & ECE
University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260
Tel: 412-624-9019 Email: rutenbar@pitt.edu
Admin: (b) (6)

From: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Date: Monday, September 27, 2021 at 5:14 PM
To: Rob Rutenbar <RUTENBAR@pitt.edu>
Cc: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>, "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
Subject: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr. Rutenbar:

Please see attached.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: 301-496-1096
Email: Michael.Lauer@nih.gov

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 1/20/2022 3:57:24 AM
To: Rutenbar, Rob A [RUTENBAR@pitt.edu]
CC: Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]; Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerml]
Subject: Re: [EXTERNAL] External review of fetal tissue work at Pitt

Many thanks, Rob, we will review and let you know of any questions we have.

Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
301-496-1096
Michael.Lauer@nih.gov

From: (b) (6) on behalf of "Rutenbar, Rob A" <RUTENBAR@pitt.edu>
Date: Wednesday, January 19, 2022 at 11:04 AM
To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Cc: "Bunden, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
Subject: [EXTERNAL] External review of fetal tissue work at Pitt

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dear Dr. Lauer:

Circling back to share the results of an independent, third-party review of the University of Pittsburgh's fetal tissue research protocols and practices. We've also posted these findings, in full, online at <http://humancelltissueresearch.pitt.edu/university-pittsburgh-releases-report-fetal-tissue-research>. Happy to answer questions, should you have any.

Best,
-Rob

Rob A. Rutenbar

Senior Vice Chancellor for Research

Distinguished Professor of CS & ECE

University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260

Tel: 412-624-9019 Email: rutenbar@pitt.edu

Admin: (b) (6)

From: Rutenbar, Rob A [RUTENBAR@pitt.edu]
Sent: 11/10/2021 2:48:40 PM
To: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
CC: Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Mike – we acknowledge receipt of your email, and we will respond by the deadline next week with the requested materials.

Best. -rob

Rob A. Rutenbar
Senior Vice Chancellor for Research
Distinguished Professor of CS & ECE
University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260
Tel: 412-624-9019 Email: rutenbar@pitt.edu
Admin: [REDACTED] (b) (6)

From: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Date: Wednesday, November 10, 2021 at 5:38 AM
To: Rob Rutenbar <RUTENBAR@pitt.edu>
Cc: "Bunden, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>, "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Good morning Rob

Dr. Bundesen and I spoke with OIG [REDACTED] (b) (7)(C) yesterday, and he has given Pitt a green light to respond to NIH requests (please see the second attachment).

We look forward to receiving all requested materials from you soon, no later than COB Thursday, November 18.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
301-496-1096
Michael.Lauer@nih.gov

From: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Date: Friday, October 29, 2021 at 5:04 AM
To: "Rutenbar, Rob A" <RUTENBAR@pitt.edu>
Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>, "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Thank you again Rob.

We understand that you have an ongoing independent review. Nonetheless, in our September 27, 2021, letter we asked you to provide information and documents as listed below. You should be able to provide us with written responses (as well as actual documents).

These were our requests:

- A copy of the Pittsburgh Biospecimen Core's policies and standard operating procedures related to human fetal tissue.
- For grant [U24DK110791](#), documentation of consent protocols, including a copy of the consent form(s) used, and supporting documentation demonstrating that consent was obtained, such as an attestation from the health care provider(s) or third party supplier(s) that informed consent was obtained at the time of tissue collection.
- A clarification of the tissue collection procedures for the GUDMAP Tissue Collection Site and explain the procedures used for reducing "warm ischemic time."
- An explanation as to whether any tissue was obtained after 25 weeks from any source, such as the International Institute for the Advancement of Medicine. If so, please indicate whether the tissue was from abortions and/or neonatal death and provide copies of the source's protocols for tissue collection procedures.

Please let us know when we can expect to receive these documents / information.

In addition, during our recent Zoom call we noted problems with a recent RPPR submission (October 4 communications attached). When will you submit a revised RPPR?

We look forward to hearing back from you very soon.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
301-496-1096
Michael.Lauer@nih.gov

From: "Rutenbar, Rob A" <RUTENBAR@pitt.edu>
Date: Wednesday, October 27, 2021 at 11:09 AM
To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr Lauer:

Please see attached letter, in response to your inquiry to the University of Pittsburgh of 27 September 2021.

Sincerely
-rob r

Rob A. Rutenbar
Senior Vice Chancellor for Research
Distinguished Professor of CS & ECE
University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260
Tel: 412-624-9019 Email: rutenbar@pitt.edu
Admin: (b) (6)

From: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Date: Monday, September 27, 2021 at 5:14 PM
To: Rob Rutenbar <RUTENBAR@pitt.edu>
Cc: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>, "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
Subject: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr. Rutenbar:

Please see attached.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: 301-496-1096
Email: Michael.Lauer@nih.gov

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 11/7/2021 6:36:40 PM
To: Rutenbar, Rob A [RUTENBAR@pitt.edu]
CC: Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]; Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Thank you, Rob, we will follow-up.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
301-496-1096
Michael.Lauer@nih.gov

From: "Rutenbar, Rob A" <RUTENBAR@pitt.edu>
Date: Friday, November 5, 2021 at 12:48 PM
To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr. Lauer –

We acknowledge your follow-up email of Friday October 29. We submitted the revised RPPR from Dr. Dhir on November 3, 2021. Please let us know if you have any questions regarding that revised report.

With regard to your request for documentation/information, please be aware that we received a subpoena from HHS OIG requesting similar documentation on October 28, 2021. This was issued by (b) (7)(C). We are happy to provide the requested information to both you and HHS OIG, however, (b) (7)(C) instructed us not to provide the documentation you have requested until he has had the opportunity to speak with you. As such, we have to await further instruction from (b) (7)(C) as to what we can provide and when. He asked that we share his contact information with you. He can be reached by email at (b) (7)(C) and by phone at (b) (7)(C). Please let us know if you have any questions or concerns.

Best, -Rob R

Rob A. Rutenbar
Senior Vice Chancellor for Research
Distinguished Professor of CS & ECE
University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260
Tel: 412-624-9019 Email: rutenbar@pitt.edu
Admin: [REDACTED] (b) (6)

From: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Sent: Friday, October 29, 2021 5:04 AM
To: Rutenbar, Rob A <RUTENBAR@pitt.edu>
Cc: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>; Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Thank you again Rob.

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Please let us know when we can expect to receive these documents / information.

In addition, during our recent Zoom call we noted problems with a recent RPPR submission (October 4 communications attached). When will you submit a revised RPPR?

We look forward to hearing back from you very soon.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892

301-496-1096

Michael.Lauer@nih.gov

From: "Rutenbar, Rob A" <RUTENBAR@pitt.edu>
Date: Wednesday, October 27, 2021 at 11:09 AM
To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr Lauer:

Please see attached letter, in response to your inquiry to the University of Pittsburgh of 27 September 2021.

Sincerely
-rob r

Rob A. Rutenbar
Senior Vice Chancellor for Research
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Date: Monday, September 27, 2021 at 5:14 PM
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Cc: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>, "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
Subject: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr. Rutenbar:

Please see attached.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research

Obtained via FOIA by Judicial Watch, Inc.

1 Center Drive, Building 1, Room 144

Bethesda, MD 20892

Phone: 301-496-1096

Email: Michael.Lauer@nih.gov

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 10/28/2021 9:53:41 AM
To: Rutenbar, Rob A [RUTENBAR@pitt.edu]
CC: Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]; Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project
Attachments: 2021-10-27 PITT Reply to NIH Letter sent Sept 27[1].pdf

Thank you, Rob, we've received your letter.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
301-496-1096
Michael.Lauer@nih.gov

From: "Rutenbar, Rob A" <RUTENBAR@pitt.edu>
Date: Wednesday, October 27, 2021 at 11:09 AM
To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
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Sincerely
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Date: Monday, September 27, 2021 at 5:14 PM

To: Rob Rutenbar <RUTENBAR@pitt.edu>

Cc: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>, "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>

Subject: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr. Rutenbar:

Please see attached.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: 301-496-1096
Email: Michael.Lauer@nih.gov



University of
Pittsburgh

Office of the Senior Vice Chancellor
for Research

Rob A. Rutenbar
Senior Vice Chancellor for Research

132 Cathedral of Learning
Pittsburgh, PA 15260
412-624-9019
rutenbar@pitt.edu
svcresearch.pitt.edu

October 26, 2021

Michael S. Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892

Dear Dr. Lauer:

Thank you for speaking with me and my colleagues from the University of Pittsburgh on October 20, 2021. The University is aware of the allegations referenced in your letter dated September 27, 2021.

As we discussed during the phone call, the University maintains rigorous protocols and procedures to ensure that researchers comply with all legal requirements and ethical duties related to fetal tissue research. While we have no evidence of non-compliance with any applicable legal requirements, as part of our ongoing commitment to our obligations, we have commissioned the law firm of Hyman, Phelps & McNamara to conduct an independent review of the University's fetal tissue research processes and practices. This firm was selected because of its extensive experience navigating the intersections of health care, research, and regulatory law.

Needless to say, if this review reveals any non-compliance, we will take immediate corrective action and follow up with NIH as necessary. Based on the phone call, it is our understanding that NIH supports this approach, but please let us know if you have any additional questions or concerns.

Sincerely yours,

(b) (6)

Rob Rutenbar, Ph.D.
Senior Vice Chancellor for Research

Pitt Research Offices:

Office of Innovation and Entrepreneurship | Center for Research Computing
Office of Research Protections | Office of Sponsored Programs | Office of Trade Compliance

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 11/19/2021 10:47:07 AM
To: Rutenbar, Rob A [RUTENBAR@pitt.edu]
CC: Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]; (b) (6)
Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project
Attachments: 2021-11 Rutenbar-PITT for Lauer-NIH re GUDMAP.docx.pdf; COLL 00005 Generic Banking of Tissue.docx; Dhir Fetal Tissue Consent (stillbirth) STUDY19020213.pdf; Dhir fetal tissue consent STUDY19020213[1].pdf

Many thanks, Rob, for sending these materials. We will review and let you know if we have any additional questions.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
301-496-1096
Michael.Lauer@nih.gov

From: "Rutenbar, Rob A" <RUTENBAR@pitt.edu>
Date: Thursday, November 18, 2021 at 4:55 PM
To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Cc: "Bunden, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>, (b) (6)
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Mike – please find enclosed the materials you requested in your November 10, 2021 email.

Best. -rob

Rob A. Rutenbar
Senior Vice Chancellor for Research
Distinguished Professor of CS & ECE
University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260
Tel: 412-624-9019 Email: rutenbar@pitt.edu
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Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>, "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>

Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Good morning Rob

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We look forward to receiving all requested materials from you soon, no later than COB Thursday, November 18.

Many thanks, Mike

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Date: Friday, October 29, 2021 at 5:04 AM

To: "Rutenbar, Rob A" <RUTENBAR@pitt.edu>

Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>, "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>

Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

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In addition, during our recent Zoom call we noted problems with a recent RPPR submission (October 4 communications attached). When will you submit a revised RPPR?

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Date: Wednesday, October 27, 2021 at 11:09 AM
To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr Lauer:

Please see attached letter, in response to your inquiry to the University of Pittsburgh of 27 September 2021.

Sincerely
-rob r

Rob A. Rutenbar
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University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260

Tel: 412-624-9019 Email: rutenbar@pitt.edu

Admin: [REDACTED] (b) (6)

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Date: Monday, September 27, 2021 at 5:14 PM
To: Rob Rutenbar <RUTENBAR@pitt.edu>
Cc: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>, "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
Subject: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr. Rutenbar:

Please see attached.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: 301-496-1096
Email: Michael.Lauer@nih.gov



University of
Pittsburgh

Office of the Senior Vice Chancellor
for Research

Rob A. Rutenbar
Senior Vice Chancellor for Research

132 Cathedral of Learning
Pittsburgh, PA 15260
412-624-9019
rutenbar@pitt.edu
research@pitt.edu

November 18, 2021

Michael S. Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892

Dear Dr. Lauer:

In response to your request for information, we have enclosed relevant documentation, including the University's protocol related to banking tissue at the Biospecimen Core (the "Core") and the consent forms utilized during the donation and collection of fetal tissue for grant U24DK110791.

As outlined in the protocol, when the clinical site notifies the Core that fetal tissue is available for pick up, the Core obtains and reviews the patient consent form, and, upon confirming consent is present and complete, picks up the tissue. Neither the Core staff nor any researcher that may utilize the tissue is involved in the clinical procedure resulting in the donation. The donation process is handled entirely by the clinical site and takes place prior to the Core receiving the tissue. We have reviewed our records, which include copies of completed consent forms provided by the clinical sites, and we can confirm that informed consent was obtained by the clinician or their designee at the time of tissue collection for all patients that donated fetal tissue.

As referenced in the original protocol for grant U24DK110791, upon receipt of tissue, the Core works to minimize "warm ischemia time" (i.e., the time between the Core staff receiving the specimen and depositing it into the Core's storage facility). This means that once tissue is made available to the Core, Core staff transport it to the storage facility as quickly as possible and log the time it took to do so.

Once the tissue arrives at the Core, the completed consent is uploaded and the tissue samples are logged. As appropriate, researcher(s) are provided samples from the Core for their research.

Pitt Research Offices:

Office of Innovation and Entrepreneurship | Center for Research Computing
Office of Research Protections | Office of Sponsored Programs

Finally, you asked whether any tissue was obtained after 25 weeks from any source for this grant. We have reviewed our records and we can confirm that no tissue was obtained after 25 weeks from any source.

Please let us know if you have any other questions or requests with which we can assist.

Sincerely,

(b) (6)

Rob A. Rutenbar, Ph.D.

Senior Vice Chancellor for Research

Pitt Biospecimen Core

#1	DOCUMENT CONTROL INFORMATION
-----------	-------------------------------------

Procedure Title	Generic Banking of Tissue Protocol
Document Number	COLL 00005
Version	1.4
Creation/Revision Date	09/08/2021
Location of Procedure	Pitt Biospecimen Core

<u>CONFIRM THAT COLLECTION PROTOCOL DOES NOT HAVE SPECIFIC REQUIREMENTS</u>	
--	--

#2	PURPOSE AND SCOPE
-----------	--------------------------

	<ol style="list-style-type: none"> 1. This protocol is to be followed only when a specific protocol for tissue is not provided by the investigator. Please note that many projects supply specific collection, processing, and storage criteria that must be followed. 2. In order to ensure the integrity and quality of the samples that are being collected, it is necessary to institute standard processing and storage requirements for tissues received within the bank for those specimens that are collected without defined criteria. 3. There are instances when a researcher's protocol will define a portion of the collection, processing, or storage. This procedure is intended to fill in the gaps in those instances.
--	---

#3	RESPONSIBILITY
-----------	-----------------------

	<ol style="list-style-type: none"> 1. All laboratory personnel performing this procedure are required to have the appropriate health and safety training. In addition, all personnel are required to have a complete understanding of the procedure described within this SOP and to receive specific training regarding this procedure if necessary. 2. The Director, Assistant Director, and QA Manager are responsible for implementing this procedure and ensuring that it is followed accurately. 3. All staff are responsible for reporting deviations from this SOP to the QA Manager.
--	--

#4	SAFETY & PRECAUTION
-----------	--------------------------------

	<ol style="list-style-type: none"> 1. Standard Precautions (SAFE00004) for handling biological specimens. 2. Dry Ice (SAFE00005) and Liquid Nitrogen (SAFE00003) safety. 3. Sharps safety: the greatest risks when using sharps with infectious or potentially infectious materials are accidental injection and creation of aerosols. The most
--	--

Pitt Biospecimen Core

	<p>effective method of preventing cuts and sticks is to minimize contact with sharps by recapping when not in use and disposing of them immediately after use. An appropriate sharps disposal container should be available, closable, and puncture resistant. The sharps container should be disposed of properly when two-thirds full.</p>
#5	DEFINITIONS
	<ol style="list-style-type: none"> 1. PBC: Pitt Biospecimen Core 2. BIOS: Biospecimen Inventory and Operations System 3. TP#: Tissue Procurement Number (also referred to as ANON# in BIOS). This number is generated upon creation of an encounter in BIOS.
#6	EQUIPMENT, MATERIALS, & REAGENTS
	<ol style="list-style-type: none"> 1. Equipment <ol style="list-style-type: none"> a. Scale 2. Materials <ol style="list-style-type: none"> a. Cryogenic Storage Bag b. Biospecimen Sheet c. Labeling Marker d. Forceps e. Weigh Paper
#7	STEP-BY-STEP OPERATING PROCEDURE
	<ol style="list-style-type: none"> 1. Don personal protective equipment. <ul style="list-style-type: none"> <input checked="" type="checkbox"/> scrubs <input checked="" type="checkbox"/> gloves; indicate type: Nitrile <input type="checkbox"/> safety goggles <input type="checkbox"/> face shield <input type="checkbox"/> lab coat <input type="checkbox"/> other: _____ 2. <u>Tissue Collection intended for Cryogenic Storage</u> <ol style="list-style-type: none"> a. Excess collection tissue types are defined by the Director of the Pitt Biospecimen Core (PBC) based on need. No patient consent is required. b. Consented Collection: PBC staff will ensure receipt of the signed consent prior to moving forward with tissue collection. c. Identify time and location of procedure and match schedule with consent. d. The Pathology staff will be alerted of targeted specimens based on communication between the PBC and Gross Room. e. Once received by Pathology, clinical needs will be satisfied and Pathology will determine if banking is possible. f. Pathology will notify the PBC stating whether or not there is available tissue for research.

Pitt Biospecimen Core

	<ul style="list-style-type: none"> (1) If tissue is not being released, the PBC will stop pursuing the case. (2) If the specimen is being released to the PBC, create the encounter in BIOS. TP# will be assigned at this time. g. Pathology will do a gross dissection of the tissue to be placed directly into a cryogenic storage bag, hand-labeled with the TP#, and brought to the PBC lab. <ul style="list-style-type: none"> (1) If the specimen does not need further dissection, it is permissible to snap-freeze the specimen and place it into an ultra-low freezer. It can also be transported to the tissue bank on dry ice. h. If a specimen weighs more than 1.5 grams, cut it into smaller sections weighing 0.5-0.75 grams per section. i. Log each discrete specimen into BIOS, with weight and detail. j. Affix barcode labels to the specimen bag. k. Snap-freeze specimens and store in a -80°C freezer.
	<p>3. <u>Tissue Collected for Fresh Disbursement</u></p> <ul style="list-style-type: none"> a. Excess collection tissue types are defined by the Director of the Pitt Biospecimen Core (PBC) based on need. No patient consent is required. b. Consented Collection: PBC staff will ensure receipt of the signed consent prior to moving forward with tissue collection. c. Review OR schedule and Medical Records to flag cases desirable for research. d. The Pathology staff will be alerted of targeted specimens based on communication between the PBC and Gross Room. e. Once received by Pathology, clinical needs will be satisfied and Pathology will determine if banking is possible. f. Pathology will notify the PBC stating whether or not there is available tissue for research. <ul style="list-style-type: none"> (1) If tissue is not being released, no further action is required. (2) If the specimen is being released to the PBC, create the encounter in BIOS. TP# will be assigned at this time. g. Pathology will do a gross dissection of the tissue. h. Retrieve the tissue from Pathology (gross room, frozen section room, etc.). <ul style="list-style-type: none"> (1) Complete applicable sections of the Biospecimens Sheet, with input from Pathology personnel. i. Label the specimen container with the appropriate TP#, place in a biohazard bag, seal the biohazard bag, and transport the tissue back to the PBC lab. j. Log each discrete specimen into BIOS, with weight and detail. k. Affix barcode label to specimen container. l. Notify PI/Research Coordinator that the tissue is ready for pick-up. m. Refrigerate the specimen until picked up.
	<p>4. Any deviation from expected criteria will warrant the completion of a Deviation Management Report (FORM 00004).</p>
#8	QUALITY CONTROL & DOCUMENTATION
<p>1. Deviation Management Record: FORM 00004</p>	

Pitt Biospecimen Core

#9	ATTACHMENTS		
N/A			
#10	TRAINING REQUIREMENTS		
<p>General Training <i>(check all that apply):</i></p> <ul style="list-style-type: none"><input checked="" type="checkbox"/> Liquid Nitrogen Usage & Precautions (SAFE00003)<input checked="" type="checkbox"/> Standard Precautions (SAFE00004)<input checked="" type="checkbox"/> Dry Ice Handling & Usage (SAFE00005)<input type="checkbox"/> Fire Prevention & Preparedness (SAFE00006)<input type="checkbox"/> Dangerous Goods Shipping Training (SAFE00007)<input type="checkbox"/> Formaldehyde Policy (SAFE00010)<input type="checkbox"/> Spill Kit Management (SAFE00025)<input type="checkbox"/> Xylene Monitoring (SAFE00026)<input checked="" type="checkbox"/> Sharps Safety <p>Laboratory-specific training <i>(check all that apply):</i></p> <ul style="list-style-type: none"><input checked="" type="checkbox"/> Review of SDS for chemicals involved in this process/experiment<input checked="" type="checkbox"/> Review of this SOP<input type="checkbox"/> Other: _____ <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"><tr><td style="width: 35%; padding: 5px;">Location Where Records Maintained:</td><td style="padding: 5px;">MediaLab & Personnel File</td></tr></table>		Location Where Records Maintained:	MediaLab & Personnel File
Location Where Records Maintained:	MediaLab & Personnel File		
#11	REFERENCES		
<ul style="list-style-type: none">1. Standard Precautions (SAFE00004)2. Dry Ice Handling & Usage (SAFE00005)3. Liquid Nitrogen Usage & Precautions (SAFE00003)4. Deviation Management Record (FORM00004)			



Magee-Womens Hospital

of the University of Pittsburgh Medical Center

300 Halket Street
Pittsburgh, PA 15213-3180

CONSENT TO ACT AS A PARTICIPANT IN RESEARCH (FETAL TISSUE CONSENT FORM)

TITLE: Fetal Tissue Collection Protocol (Stillbirth > 24 weeks)

PRINCIPAL INVESTIGATOR:

(b) (6)
Magee-Womens Hospital, (b) (6)

Why is this research being done?

Some researchers are performing studies of fetal tissue within the limits of the laws of Pennsylvania. For these studies, the researchers need to use tissue from pregnancies. This protocol allows us to collect and store tissue and facilitate the distribution of fetal tissue samples to those who have approved research protocols.

Who is being asked to take part in this research?

You are being asked to submit tissue for this research study after you have experienced a loss of pregnancy and have consented to a fetal autopsy.

What procedures will be performed for research purposes?

You are being asked to allow researchers at the University of Pittsburgh to use any of the tissue from the pregnancy, as needed, for research projects. We may collect a sample of your urine (about 6 tablespoons) and blood (about 1 tablespoon), if possible, to use for research projects. Your samples may undergo genetic analysis (DNA/RNA), including genotype and phenotype. The tissue and samples may also be used by other researchers. These research studies are approved by an ethics review board (Institutional Review Board or IRB) and are subject to oversight to make sure that they are conducted appropriately and within the laws of the Commonwealth of Pennsylvania and/or the state in which the research is being conducted.

We are also requesting your authorization or permission to review your medical records. We will obtain the following information: data related to pregnancy, tissue and maternal health. Your signed consent form will be placed in your medical record. This research will involve collecting information from your medical records but your identity will only be known to the person (honest broker) collecting this information. Identifiable information will never be provided to any researchers.

Your participation is completely voluntary. If you agree to allow your samples to be included as part of this collection protocol, they will become the property of the University of Pittsburgh. Your medical information and samples will be stored at the University of Pittsburgh and/or at other federal research repositories until such time that the samples are used up or no longer felt to be appropriate for use in research studies. Your voluntary decision to provide these samples and

Page 1 of 4



University Of Pittsburgh
Institutional Review Board

Approval Date: 2/13/2017
Renewal Date: 2/4/2018

IRB #: IRB0702050

identifiable medical information to the inclusion of this study, or to later withdraw from it, will not affect your current or future medical care at UPMC.

Your samples will be stored in a way that will permit the people responsible for the samples (honest brokers) to connect your identity with your samples. However, when your medical information, samples, and data/information about tests done on your samples (including genotype and phenotype) are made available for actual use in research studies, they will be provided to researchers without personal identifiers. Researchers will not be able to connect your identity with the data, samples, or medical information. Your de-identified samples, results (genotype and phenotype) from samples and medical information may also be shared with other federally-funded tissue banks, shared data bases (both unrestricted-access and controlled-access repositories) and researchers, who may also share samples and medical information with other researchers. You will not be contacted when your samples or information are sent to researchers. Note that these samples will be released only after it is ensured proper research approvals are received (i.e. IRB approval). Because it will not be possible to connect your identity with your tissue/biological sample when the sample is being used for research, it will not be possible to inform you of the results of such research.

What are the possible risks, side effects and discomforts of this research?

If you agree to allow us to collect blood, we will collect blood by putting a needle into one of your veins and letting the blood flow into a tube. You may feel some pain and experience some bleeding when the needle goes into your vein. Although rare, there is a risk of fainting and infection from taking blood. You may have a small bruise where the needle went under the skin.

There is a risk of breach of confidentiality. The risks associated with genetic studies include the potential for a breach of confidentiality which could affect future insurability, employability, or reproduction plans, or have a negative impact on family relationships and/or result in paternity suits or stigmatization. However, we have put measures in place to reduce these risks. No information will be given to any researchers that would allow them to identify you in any way. A federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect you from being treated unfairly because of your genes.

What are the possible benefits from taking part in this research?

There is no personal or direct benefit to you from participating in this research. However, a potential benefit to society from this research is a gain in knowledge.

What treatments or procedures are available if I decide not to take part in this research?

You do not have to agree to participate in this study. Your participation is completely voluntary. Your care and benefits will be the same whether you agree to participate in this study or not.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research?

There are no costs to you or your insurance provider for participating in this research (urine sample, blood sample, medical record information, fetal tissue collection). You will be charged in the standard manner for any clinical care/clinical procedures.



Will I be paid if I take part in this research?

You will not be paid for allowing your fetal tissue to be used for research or for your participation. Your samples may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by researchers and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights nor will you share in any money which researchers, the University of Pittsburgh, or their agents may realize. There are no costs to you for participating.

Who will pay if I am injured as a result of participation in this research?

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation.

Who will know about my participation in this research?

The honest brokers will have access to identifiable information linking you to your samples. However, no researchers will be provided with any identifiable information or samples. The University of Pittsburgh Research Conduct and Compliance Office may have access to your records (including your identifiable medical information) for the purposes of monitoring the conduct of this project.

This authorization is valid for an indefinite period of time.

You may withdraw your authorization to review your medical records, and your consent for the collection and use of your fetal tissue, blood, and/or urine. However, once data or samples have been shared with researchers, there will be no way to get the data/samples back as researchers are not provided with any identifiers. To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

How long will records be maintained?

Research records will kept indefinitely but at least 7 years after completion of the research.

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research during the course of this research, and that such future questions will be answered by the researchers listed on the first page of this form. Any questions which I have about my rights as a research participant will be



answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

By signing this form, I agree to participate in this research and provide my authorization to share my medical records, as described above. I agree to donate one or more of the following samples. A copy of this consent form will be given to me.

- ☐ Tissue
- ☐ Urine
- ☐ Blood
- ☐ All of the above

Participant's Signature

Date

Participant's Printed Name

Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research to the above-named individual, and I have discussed the potential benefits and possible risks of the research participation. Any questions the individual has about this research have been answered, and we will always be available to address future questions as they arise.

Printed Name of Person Obtaining Consent

Role in Research

Signature of Person Obtaining Consent

Date





Magee-Womens Hospital

of the University of Pittsburgh Medical Center

300 Halket Street
Pittsburgh, PA 15213-3180

CONSENT TO ACT AS A PARTICIPANT IN RESEARCH (FETAL TISSUE CONSENT FORM)

TITLE: Fetal Tissue Collection Protocol (Spontaneous and Elective Abortions < 24 weeks)

PRINCIPAL INVESTIGATOR:

(b) (6)
Magee-Womens Hospital, (b) (6)

Why is this research being done?

Some researchers are performing studies of fetal tissue within the limits of the laws of Pennsylvania. For these studies, the researchers need to use tissue from pregnancies. This collection protocol allows us to collect and store tissue, and to facilitate the distribution of fetal tissue samples to those who have approved research protocols.

Who is being asked to take part in this research?

You are scheduled to have an elective abortion to end your pregnancy or you have experienced a spontaneous abortion (miscarriage). You have already signed a consent form for the procedure to remove the tissue from your uterus or to be cared for if the tissue passed spontaneously.

What procedures will be performed for research purposes?

You are being asked to allow researchers at the University of Pittsburgh to use any of the tissue from the pregnancy, as needed, for research projects. We may collect a sample of your urine (about 6 tablespoons) and blood (about 1 tablespoon), if possible, to use for research projects. Your samples may undergo genetic analysis (DNA/RNA), including genotype and phenotype. The tissue and samples may also be used by other researchers. These research studies are approved by an ethics review board (Institutional Review Board or IRB) and are subject to oversight to make sure that they are conducted appropriately and within the laws of the Commonwealth of Pennsylvania and/or the state in which the research is being conducted.

We are also requesting your authorization or permission to review your medical records. We will obtain the following information: data related to pregnancy, tissue and maternal health. Your signed consent form will be placed in your medical record. This research will involve collecting information from your medical records but your identity will only be known to the person (honest broker) collecting this information. Identifiable information will never be provided to any researchers.

Your participation is completely voluntary. If you agree to allow your samples to be included as part of this collection protocol, they will become the property of the University of Pittsburgh. Your medical information and samples will be stored at the University of Pittsburgh and/or at other federal research repositories until such time that the samples are used up or no longer felt to be appropriate for use in research studies. Your voluntary decision to provide these samples and identifiable medical information to the inclusion of this study, or to later withdraw from it, will not affect your current or future medical care at UPMC.



Your samples will be stored in a way that will permit the people responsible for the samples (honest brokers) to connect your identity with your samples. However, when your medical information, samples, and data/information about tests done on your samples (including genotype and phenotype) are made available for actual use in research studies, they will be provided to researchers without personal identifiers. Researchers will not be able to connect your identity with the data, samples, or medical information. Your de-identified samples, results (genotype and phenotype) from samples and medical information may also be shared with other federally-funded tissue banks, shared data bases (both unrestricted-access and controlled-access repositories) and researchers, who may also share samples and medical information with other researchers. You will not be contacted when your samples or information are sent to researchers. Note that these samples will be released only after it is ensured proper research approvals are received (i.e. IRB approval). Because it will not be possible to connect your identity with your tissue/biological sample when the sample is being used for research, it will not be possible to inform you of the results of such research.

What are the possible risks, side effects and discomforts of this research?

If you agree to allow us to collect blood, we will collect blood by putting a needle into one of your veins and letting the blood flow into a tube. You may feel some pain and experience some bleeding when the needle goes into your vein. Although rare, there is a risk of fainting and infection from taking blood. You may have a small bruise where the needle went under the skin.

There is a risk of breach of confidentiality. The risks associated with genetic studies include the potential for a breach of confidentiality which could affect future insurability, employability, or reproduction plans, or have a negative impact on family relationships and/or result in paternity suits or stigmatization. However, we have put measures in place to reduce these risks. No information will be given to any researchers that would allow them to identify you in any way. A federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect you from being treated unfairly because of your genes.

What are the possible benefits from taking part in this research?

There is no personal or direct benefit to you from participating in this research. However, a potential benefit to society from this research is a gain in knowledge.

What treatments or procedures are available if I decide not to take part in this research?

You do not have to agree to participate in this study. Your participation is completely voluntary. Your care and benefits will be the same whether you agree to participate in this study or not.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research?

There are no costs to you or your insurance provider for participating in this research (urine sample, blood sample, medical record information, fetal tissue collection). You will be charged in the standard manner for any clinical care/clinical procedures.

Will I be paid if I take part in this research?

You will not be paid for allowing your fetal tissue to be used for research or for your participation. Your samples may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by researchers and the University of Pittsburgh for use in other research or the development of new products. You will



not retain any property rights nor will you share in any money which researchers, the University of Pittsburgh, or their agents may realize. There are no costs to you for participating.

Who will pay if I am injured as a result of participation in this research?

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation.

Who will know about my participation in this research?

The honest brokers will have access to identifiable information linking you to your samples. However, no researchers will be provided with any identifiable information or samples. The University of Pittsburgh Research Conduct and Compliance Office may have access to your records (including your identifiable medical information) for the purposes of monitoring the conduct of this project.

This authorization is valid for an indefinite period of time.

You may withdraw your authorization to review your medical records, and your consent for the collection and use of your fetal tissue, blood, and/or urine. However, once data or samples have been shared with researchers, there will be no way to get the data/samples back as researchers are not provided with any identifiers. To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

How long will records be maintained?

Research records will kept indefinitely but at least 7 years after completion of the research.

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research during the course of this research, and that such future questions will be answered by the researchers listed on the first page of this form. Any questions which I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

By signing this form, I agree to participate in this research and provide my authorization to share my medical records, as described above. I agree to donate one or more of the following samples. A copy of this consent form will be given to me.

☐ Tissue



- ☐ Urine
- ☐ Blood
- ☐ All of the above

Participant's Signature

Date

Participant's Printed Name

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research to the above-named individual, and I have discussed the potential benefits and possible risks of the research participation. Any questions the individual has about this research have been answered, and we will always be available to address future questions as they arise.

Printed Name of Person Obtaining Consent

Role in Research

Signature of Person Obtaining Consent

Date



From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 11/10/2021 10:37:41 AM
To: Rutenbar, Rob A [RUTENBAR@pitt.edu]
CC: Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]; Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project
Attachments: Re: Please read and acknowledge receipt -- questions about the GUDMAP project; OIG Subpoena - Health Sciences Tissue Bank; Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Good morning Rob

Dr. Bundesen and I spoke with OIG (b) (7)(C) yesterday, and he has given Pitt a green light to respond to NIH requests (please see the second attachment).

We look forward to receiving all requested materials from you soon, no later than COB Thursday, November 18.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
301-496-1096
Michael.Lauer@nih.gov

From: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Date: Friday, October 29, 2021 at 5:04 AM
To: "Rutenbar, Rob A" <RUTENBAR@pitt.edu>
Cc: "Bunden, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>, "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Thank you again Rob.

We understand that you have an ongoing independent review. Nonetheless, in our September 27, 2021, letter we asked you to provide information and documents as listed below. You should be able to provide us with written responses (as well as actual documents).

These were our requests:

- A copy of the Pittsburgh Biospecimen Core's policies and standard operating procedures related to human fetal tissue.
- For grant [U24DK110791](#), documentation of consent protocols, including a copy of the consent form(s) used, and supporting documentation demonstrating that consent was obtained, such as

an attestation from the health care provider(s) or third party supplier(s) that informed consent was obtained at the time of tissue collection.

- A clarification of the tissue collection procedures for the GUDMAP Tissue Collection Site and explain the procedures used for reducing "warm ischemic time."
- An explanation as to whether any tissue was obtained after 25 weeks from any source, such as the International Institute for the Advancement of Medicine. If so, please indicate whether the tissue was from abortions and/or neonatal death and provide copies of the source's protocols for tissue collection procedures.

Please let us know when we can expect to receive these documents / information.

In addition, during our recent Zoom call we noted problems with a recent RPPR submission (October 4 communications attached). When will you submit a revised RPPR?

We look forward to hearing back from you very soon.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
301-496-1096
Michael.Lauer@nih.gov

From: "Rutenbar, Rob A" <RUTENBAR@pitt.edu>

Date: Wednesday, October 27, 2021 at 11:09 AM

To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>

Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>

Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr Lauer:

Please see attached letter, in response to your inquiry to the University of Pittsburgh of 27 September 2021.

Sincerely
-rob r

Rob A. Rutenbar
Senior Vice Chancellor for Research
Distinguished Professor of CS & ECE

University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260

Tel: 412-624-9019 Email: rutenbar@pitt.edu

Admin: [REDACTED] (b) (6)

From: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>

Date: Monday, September 27, 2021 at 5:14 PM

To: Rob Rutenbar <RUTENBAR@pitt.edu>

Cc: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>, "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>

Subject: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr. Rutenbar:

Please see attached.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: 301-496-1096
Email: Michael.Lauer@nih.gov

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 10/29/2021 9:04:03 AM
To: Rutenbar, Rob A [RUTENBAR@pitt.edu]
CC: Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]; Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project
Attachments: 2021-10-27 PITT Reply to NIH Letter sent Sept 27[2].pdf; Letter to Pittsburgh re GUDMAP 9 27 21[1].docx; Re: 5 U24 DK110791-05. PI: Dhir, Rajiv --Final RPPR; FW: 5 U24 DK110791-05. PI: Dhir, Rajiv --Final RPPR

Thank you again Rob.

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Michael.Lauer@nih.gov

From: "Rutenbar, Rob A" <RUTENBAR@pitt.edu>
Date: Wednesday, October 27, 2021 at 11:09 AM
To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

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Sincerely
-rob r

Rob A. Rutenbar
Senior Vice Chancellor for Research
Distinguished Professor of CS & ECE
University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260
Tel: 412-624-9019 Email: rutenbar@pitt.edu
Admin: [REDACTED] (b) (6)

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To: Rob Rutenbar <RUTENBAR@pitt.edu>
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Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: 301-496-1096
Email: Michael.Lauer@nih.gov



University of
Pittsburgh

Office of the Senior Vice Chancellor
for Research

Rob A. Rutenbar
Senior Vice Chancellor for Research

132 Cathedral of Learning
Pittsburgh, PA 15260
412-624-9019
rutenbar@pitt.edu
svcresearch.pitt.edu

October 26, 2021

Michael S. Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892

Dear Dr. Lauer:

Thank you for speaking with me and my colleagues from the University of Pittsburgh on October 20, 2021. The University is aware of the allegations referenced in your letter dated September 27, 2021.

As we discussed during the phone call, the University maintains rigorous protocols and procedures to ensure that researchers comply with all legal requirements and ethical duties related to fetal tissue research. While we have no evidence of non-compliance with any applicable legal requirements, as part of our ongoing commitment to our obligations, we have commissioned the law firm of Hyman, Phelps & McNamara to conduct an independent review of the University's fetal tissue research processes and practices. This firm was selected because of its extensive experience navigating the intersections of health care, research, and regulatory law.

Needless to say, if this review reveals any non-compliance, we will take immediate corrective action and follow up with NIH as necessary. Based on the phone call, it is our understanding that NIH supports this approach, but please let us know if you have any additional questions or concerns.

Sincerely yours,

(b) (6)

Rob Rutenbar, Ph.D.
Senior Vice Chancellor for Research

Pitt Research Offices:

Office of Innovation and Entrepreneurship | Center for Research Computing
Office of Research Protections | Office of Sponsored Programs | Office of Trade Compliance



National Institutes of Health
Bethesda, Maryland 20892

[Confidential]

Date: September 27, 2021

To: Rob A. Rutenbar, PhD
Senior Vice Chancellor for Research
University of Pittsburgh

From: Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Director, NIH Office of Extramural Research

Re: GenitoUrinary Development Molecular Anatomy Project (GUDMAP) Tissue Hub and Collection Site (U24DK110791)

Dear Dr. Rutenbar:

I am sending you this letter in your capacity as Senior Vice Chancellor for Research at the University of Pittsburgh.

It has come to our attention that various media outlets and nonprofit organizations have made allegations about the fetal tissue collection procedures associated with the GenitoUrinary Development Molecular Anatomy Project (GUDMAP) Tissue Hub and Collection Site at the University of Pittsburgh.^{1,2,3,4}

As you are aware, NIH requires that NIH-supported recipient institutions certify that they will comply with the NIH Grants Policy Statement (see section 4.1.14 Human Fetal Tissue Research), which incorporates Federal statutory requirements for research with human fetal tissue. Sections 498A and 498B of the PHS Act (42 U.S.C. 289g-1 and 289g-2) set forth specific requirements and prohibitions on research involving human fetal tissue. Research involving human fetal tissue is also subject to the HHS Regulations for the Protection of Human Subjects (45 CFR Part 46). When an application involving human fetal tissue research is submitted to NIH, the Authorized Organization Representative's signature certifies that researchers using these tissues are in compliance with the PHS Act. When obtaining primary human fetal tissue for research purposes, NIH expects recipients and contractors to maintain appropriate documentation, such as an attestation from the health care provider or a third party supplier, that informed consent was obtained at the time of tissue collection.

1 The Center for Medical Progress: Aborted Infants' Continued Blood Flow Advertised in Racist University of Pittsburgh Grant Application to NIH

2 Judicial Watch: New HHS Documents Reveal Millions in Federal Funding for University of Pittsburgh Human Fetal Organ Harvesting Project Including Viable and Full-Term Babies

3 Fox News: Doctors say Pitt statements point to possibility organs extracted from live fetuses; school denies charge

4 Fox News: Millions in federal money flowed to tissue bank that collected fetal 'heart, gonads, legs, brain': report

The scientific and ethical challenges associated with research utilizing human fetal tissue make it imperative that researchers and their organizations be fully aware of and in compliance with the Federal requirements. In light of this, we are asking that you address the following:

- Please provide a copy of the Pittsburgh Biospecimen Core's policies and standard operating procedures related to human fetal tissue.
- For grant U24DK110791, provide documentation of consent protocols, including a copy of the consent form(s) used, and supporting documentation demonstrating that consent was obtained, such as an attestation from the health care provider(s) or third party supplier(s) that informed consent was obtained at the time of tissue collection.
- Please clarify the tissue collection procedures for the GUDMAP Tissue Collection Site and explain the procedures used for reducing "warm ischemic time."
- Please explain if any tissue was obtained after 25 weeks from any source, such as the International Institute for the Advancement of Medicine. If so, please indicate whether the tissue was from abortions and/or neonatal death and provide copies of the source's protocols for tissue collection procedures."

Please review these issues and confirm that the University of Pittsburgh complied with the policies cited above. If any instances of non-compliance are identified or suspected, please also provide a detailed description of the issue and corrective actions taken or planned.

We would like to receive your written response within the next 30 days. In the interim, we would like to schedule a phone call at your earliest convenience.

Sincerely,

Michael S. Lauer, MD

From: Rutenbar, Rob A [RUTENBAR@pitt.edu]
Sent: 10/4/2021 7:56:49 PM
To: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
CC: Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]
Subject: Re: 5 U24 DK110791-05. PI: Dhir, Rajiv --Final RPPR

Mike – we acknowledge receipt, we will take a look. -rob

Rob A. Rutenbar
Senior Vice Chancellor for Research
Distinguished Professor of CS & ECE
University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260
Tel: 412-624-9019 Email: rutenbar@pitt.edu
Admin: (b) (6)

From: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Date: Monday, October 4, 2021 at 3:27 PM
To: Rob Rutenbar <RUTENBAR@pitt.edu>
Cc: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>, "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
Subject: FW: 5 U24 DK110791-05. PI: Dhir, Rajiv --Final RPPR

Hi Rob

We are elevating this set of communications to you.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: 301-496-1096
Email: Michael.Lauer@nih.gov

From: (b) (6)
Sent: Friday, October 1, 2021 2:40 PM
To: (b) (6)
Cc: Dhir, Rajiv <dhir@pitt.edu>; (b) (6)
(b) (6)
Subject: FW: 5 U24 DK110791-05. PI: Dhir, Rajiv --Final RPPR

Hello,

As (b) (6) of the University of Pittsburgh, I endorse this communication.

Thanks.

(b) (6)



University of
Pittsburgh

Office of
Sponsored Programs

From: (b) (6)
Sent: Friday, October 1, 2021 2:08 PM
To: Dhir, Rajiv <dhirr@upmc.edu>; osp@pitt.edu <osp@pitt.edu>
Cc: (b) (6)
Subject: RE: 5 U24 DK110791-05. PI: Dhir, Rajiv --Final RPPR

Good Afternoon,

All responses should be from your AOR. If you'd like to address any concerns raised in the letter, please go through your AOR.

Thank you,

(b) (6)

National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health

In accordance with NIH policy, all requests and documents must be submitted by an Authorized Organization Representative (AOR). In eRA Commons the AOR holds the Signing Official Role.

From: Dhir, Rajiv <dhirr@upmc.edu>
Sent: Wednesday, September 29, 2021 2:38 PM
To: (b) (6) osp@pitt.edu
Cc: (b) (6)
Subject: Re: 5 U24 DK110791-05. PI: Dhir, Rajiv --Final RPPR

Hi (b) (6): There was no change from our perspective. If the project PIs had unrealistic expectations; and no idea about the clinical world and were expecting gestational ages like they got from mice; then that really cannot be put on us.

As good team players; we agreed to budgetary and project changes. But that was because of the projects disconnect with reality.

I will be glad to discuss this and rectify as you deem fit. But I do not think we should be viewed as not delivering. We never promised what they thought they were going to get.

Best wishes.
Rajiv

Rajiv Dhir, MD, MBA

Executive Vice Chair and Medical Director of Anatomic Pathology Services at UPMC

Chief of Pathology, Shadyside Hospital

Univ. of Pittsburgh Health Systems

Phone: (412) 623-1321

From: (b) (6)
Sent: Wednesday, September 29, 2021 12:42 PM
To: osp@pitt.edu <osp@pitt.edu>; Dhir, Rajiv <dhirr@upmc.edu>
Cc: (b) (6)
Subject: 5 U24 DK110791-05. PI: Dhir, Rajiv --Final RPPR

Good Afternoon,

We've reviewed the Final RPPR and have some concerns. Please see our letter attached.

Thank you,

(b) (6)

National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health

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From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 10/4/2021 7:27:08 PM
To: Rutenbar, Rob A [RUTENBAR@pitt.edu]
CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]
Subject: FW: 5 U24 DK110791-05. PI: Dhir, Rajiv --Final RPPR
Attachments: 5 U24 DK110791-05. PI: Dhir, Rajiv --Final RPPR

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Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: 301-496-1096
Email: Michael.Lauer@nih.gov

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To: (b) (6)
Cc: Dhir, Rajiv <dhir@pitt.edu>; (b) (6)
(b) (6)
Subject: FW: 5 U24 DK110791-05. PI: Dhir, Rajiv --Final RPPR

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Thanks.

(b) (6)



University of
Pittsburgh

Office of
Sponsored Programs

From: [REDACTED] (b) (6)
Sent: Friday, October 1, 2021 2:08 PM
To: Dhir, Rajiv <dhirr@upmc.edu>; osp@pitt.edu <osp@pitt.edu>
Cc: [REDACTED] (b) (6)
Subject: RE: 5 U24 DK110791-05. PI: Dhir, Rajiv --Final RPPR

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[REDACTED] (b) (6)

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Sent: Wednesday, September 29, 2021 2:38 PM
To: [REDACTED] (b) (6) osp@pitt.edu
Cc: [REDACTED] (b) (6)
Subject: Re: 5 U24 DK110791-05. PI: Dhir, Rajiv --Final RPPR

Hi [REDACTED] (b) (6): There was no change from our perspective. If the project PIs had unrealistic expectations; and no idea about the clinical world and were expecting gestational ages like they got from mice; then that really cannot be put on us.

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Best wishes.
Rajiv

Rajiv Dhir, MD, MBA

Executive Vice Chair and Medical Director of Anatomic Pathology Services at UPMC

Chief of Pathology, Shadyside Hospital

Univ. of Pittsburgh Health Systems

Phone: (412) 623-1321

From: [REDACTED] (b) (6)

Sent: Wednesday, September 29, 2021 12:42 PM

To: osp@pitt.edu <osp@pitt.edu>; Dhir, Rajiv <dhirr@upmc.edu>

Cc: [REDACTED] (b) (6)

Subject: 5 U24 DK110791-05. PI: Dhir, Rajiv --Final RPPR

Good Afternoon,

We've reviewed the Final RPPR and have some concerns. Please see our letter attached.

Thank you,

[REDACTED] (b) (6)

National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health

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From: (b) (6)/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C2760BC534384D50977C9A2C7AAE50C3-KENLEYC]
Sent: 9/29/2021 4:42:12 PM
To: osp@pitt.edu; dhirr@upmc.edu
CC: (b) (6)/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ca830e5be774c189322ea0f83fab0a3-saduskyab]
Subject: 5 U24 DK110791-05. PI: Dhir, Rajiv --Final RPPR
Attachments: FRPPR letter DK110791v1.1.pdf

Good Afternoon,

We've reviewed the Final RPPR and have some concerns. Please see our letter attached.

Thank you,

(b) (6)

National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health

In accordance with NIH policy, all requests and documents must be submitted by an Authorized Organization Representative (AOR). In eRA Commons the AOR holds the Signing Official Role.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institute of Health

National Institute of Diabetes and
Digestive and Kidney Diseases
Bethesda, Maryland 20892

Dear Dr. Dhir/Business Official,

We have had the opportunity to review your submitted final research performance progress report (FRPPR) for U24 DK110791-05.

(b) (4)

Sincerely,

Obtained via FOIA by Judicial Watch, Inc.

(b) (6)

(b) (6)

National Institute of Diabetes and Digestive and
Kidney Diseases
National Institutes of Health

(b) (6)

(b) (6)

National Institute of Diabetes and Digestive and
Kidney Diseases
National Institutes of Health

From: (b) (7)(C)
Sent: 11/10/2021 10:31:11 AM
To: (b) (6)
CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]
Subject: OIG Subpoena - Health Sciences Tissue Bank

Good Morning (b) (6)

I've had an opportunity to coordinate with NIH. Please feel free to respond to NIH's request and produce any responsive records when your team is ready.

As far as the OIG subpoena production, please respond in accordance with the date on the subpoena or, if necessary, please let me know if an extension of that date will be needed.

Feel free to call if you have any additional questions.

(b) (7)(C)

(b) (7)(C)



OIG Fraud Hotline | 1-800-HHS-TIPS | TIPS.HHS.GOV | TTY 1-800-377-4950

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From: Rutenbar, Rob A [RUTENBAR@pitt.edu]
Sent: 11/5/2021 4:48:43 PM
To: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
CC: Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr. Lauer –

We acknowledge your follow-up email of Friday October 29. We submitted the revised RPPR from Dr. Dhir on November 3, 2021. Please let us know if you have any questions regarding that revised report.

With regard to your request for documentation/information, please be aware that we received a subpoena from HHS OIG requesting similar documentation on October 28, 2021. This was issued by (b) (7)(C). We are happy to provide the requested information to both you and HHS OIG, however, (b) (7)(C) instructed us not to provide the documentation you have requested until he has had the opportunity to speak with you. As such, we have to await further instruction from (b) (7)(C) as to what we can provide and when. He asked that we share his contact information with you. He can be reached by email at (b) (7)(C) and by phone at (b) (7)(C). Please let us know if you have any questions or concerns.

Best, -Rob R

Rob A. Rutenbar
Senior Vice Chancellor for Research
Distinguished Professor of CS & ECE
University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260
Tel: 412-624-9019 Email: rutenbar@pitt.edu
Admin: (b) (6)

From: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Sent: Friday, October 29, 2021 5:04 AM
To: Rutenbar, Rob A <RUTENBAR@pitt.edu>
Cc: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>; Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Thank you again Rob.

We understand that you have an ongoing independent review. Nonetheless, in our September 27, 2021, letter we asked you to provide information and documents as listed below. You should be able to provide us with written responses (as well as actual documents).

These were our requests:

- A copy of the Pittsburgh Biospecimen Core's policies and standard operating procedures related to human fetal tissue.
- For grant [U24DK110791](#), documentation of consent protocols, including a copy of the consent form(s) used, and supporting documentation demonstrating that consent was obtained, such as an attestation from the health care provider(s) or third party supplier(s) that informed consent was obtained at the time of tissue collection.
- A clarification of the tissue collection procedures for the GUDMAP Tissue Collection Site and explain the procedures used for reducing "warm ischemic time."
- An explanation as to whether any tissue was obtained after 25 weeks from any source, such as the International Institute for the Advancement of Medicine. If so, please indicate whether the tissue was from abortions and/or neonatal death and provide copies of the source's protocols for tissue collection procedures.

Please let us know when we can expect to receive these documents / information.

In addition, during our recent Zoom call we noted problems with a recent RPPR submission (October 4 communications attached). When will you submit a revised RPPR?

We look forward to hearing back from you very soon.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
301-496-1096
Michael.Lauer@nih.gov

From: "Rutenbar, Rob A" <RUTENBAR@pitt.edu>
Date: Wednesday, October 27, 2021 at 11:09 AM
To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr Lauer:

Please see attached letter, in response to your inquiry to the University of Pittsburgh of 27 September 2021.

Sincerely
-rob r

Rob A. Rutenbar
Senior Vice Chancellor for Research
Distinguished Professor of CS & ECE
University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260
Tel: 412-624-9019 Email: rutenbar@pitt.edu
Admin: [REDACTED] (b) (6)

From: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Date: Monday, September 27, 2021 at 5:14 PM
To: Rob Rutenbar <RUTENBAR@pitt.edu>
Cc: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>, "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
Subject: Please read and acknowledge receipt -- questions about the GUDMAP project

Dear Dr. Rutenbar:

Please see attached.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: 301-496-1096
Email: Michael.Lauer@nih.gov

From: Rutenbar, Rob A [RUTENBAR@pitt.edu]
Sent: 11/18/2021 9:54:09 PM
To: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
CC: Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]; (b) (6)
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project
Attachments: 2021-11 Rutenbar-PITT for Lauer-NIH re GUDMAP.docx.pdf; COLL 00005 Generic Banking of Tissue.docx; Dhir Fetal Tissue Consent (stillbirth) STUDY19020213.pdf; Dhir fetal tissue consent STUDY19020213.pdf

Mike – please find enclosed the materials you requested in your November 10, 2021 email.

Best. -rob

Rob A. Rutenbar
Senior Vice Chancellor for Research
Distinguished Professor of CS & ECE
University of Pittsburgh | 132 Cathedral | Pittsburgh PA, 15260
Tel: 412-624-9019 Email: rutenbar@pitt.edu
Admin: (b) (6)

From: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Date: Wednesday, November 10, 2021 at 5:38 AM
To: Rob Rutenbar <RUTENBAR@pitt.edu>
Cc: "Bunden, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>, "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Subject: Re: Please read and acknowledge receipt -- questions about the GUDMAP project

Good morning Rob

Dr. Bundesen and I spoke with OIG (b) (7)(C) yesterday, and he has given Pitt a green light to respond to NIH requests (please see the second attachment).

We look forward to receiving all requested materials from you soon, no later than COB Thursday, November 18.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
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301-496-1096
Michael.Lauer@nih.gov

From: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Date: Friday, October 29, 2021 at 5:04 AM
To: "Rutenbar, Rob A" <RUTENBAR@pitt.edu>
Cc: "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>, "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
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Please let us know when we can expect to receive these documents / information.

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To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
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Sincerely
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Cc: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>, "Bundesen, Liza (NIH/OD) [E]" <lbundese@mail.nih.gov>
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Dear Dr. Rutenbar:

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University of
Pittsburgh

Office of the Senior Vice Chancellor
for Research

Rob A. Rutenbar
Senior Vice Chancellor for Research

132 Cathedral of Learning
Pittsburgh, PA 15260
412-624-9019
rutenbar@pitt.edu
research@pitt.edu

November 18, 2021

Michael S. Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892

Dear Dr. Lauer:

In response to your request for information, we have enclosed relevant documentation, including the University's protocol related to banking tissue at the Biospecimen Core (the "Core") and the consent forms utilized during the donation and collection of fetal tissue for grant U24DK110791.

As outlined in the protocol, when the clinical site notifies the Core that fetal tissue is available for pick up, the Core obtains and reviews the patient consent form, and, upon confirming consent is present and complete, picks up the tissue. Neither the Core staff nor any researcher that may utilize the tissue is involved in the clinical procedure resulting in the donation. The donation process is handled entirely by the clinical site and takes place prior to the Core receiving the tissue. We have reviewed our records, which include copies of completed consent forms provided by the clinical sites, and we can confirm that informed consent was obtained by the clinician or their designee at the time of tissue collection for all patients that donated fetal tissue.

As referenced in the original protocol for grant U24DK110791, upon receipt of tissue, the Core works to minimize "warm ischemia time" (i.e., the time between the Core staff receiving the specimen and depositing it into the Core's storage facility). This means that once tissue is made available to the Core, Core staff transport it to the storage facility as quickly as possible and log the time it took to do so.

Once the tissue arrives at the Core, the completed consent is uploaded and the tissue samples are logged. As appropriate, researcher(s) are provided samples from the Core for their research.

Pitt Research Offices:

Office of Innovation and Entrepreneurship | Center for Research Computing
Office of Research Protections | Office of Sponsored Programs

Finally, you asked whether any tissue was obtained after 25 weeks from any source for this grant. We have reviewed our records and we can confirm that no tissue was obtained after 25 weeks from any source.

Please let us know if you have any other questions or requests with which we can assist.

Sincerely,

(b) (6)

Rob A. Rutenbar, Ph.D.

Senior Vice Chancellor for Research

Pitt Biospecimen Core

#1	DOCUMENT CONTROL INFORMATION
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Procedure Title	Generic Banking of Tissue Protocol
Document Number	COLL 00005
Version	1.4
Creation/Revision Date	09/08/2021
Location of Procedure	Pitt Biospecimen Core

<u>CONFIRM THAT COLLECTION PROTOCOL DOES NOT HAVE SPECIFIC REQUIREMENTS</u>	
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#2	PURPOSE AND SCOPE
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	<ol style="list-style-type: none"> 1. This protocol is to be followed only when a specific protocol for tissue is not provided by the investigator. Please note that many projects supply specific collection, processing, and storage criteria that must be followed. 2. In order to ensure the integrity and quality of the samples that are being collected, it is necessary to institute standard processing and storage requirements for tissues received within the bank for those specimens that are collected without defined criteria. 3. There are instances when a researcher's protocol will define a portion of the collection, processing, or storage. This procedure is intended to fill in the gaps in those instances.
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#3	RESPONSIBILITY
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	<ol style="list-style-type: none"> 1. All laboratory personnel performing this procedure are required to have the appropriate health and safety training. In addition, all personnel are required to have a complete understanding of the procedure described within this SOP and to receive specific training regarding this procedure if necessary. 2. The Director, Assistant Director, and QA Manager are responsible for implementing this procedure and ensuring that it is followed accurately. 3. All staff are responsible for reporting deviations from this SOP to the QA Manager.
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#4	SAFETY & PRECAUTION
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	<ol style="list-style-type: none"> 1. Standard Precautions (SAFE00004) for handling biological specimens. 2. Dry Ice (SAFE00005) and Liquid Nitrogen (SAFE00003) safety. 3. Sharps safety: the greatest risks when using sharps with infectious or potentially infectious materials are accidental injection and creation of aerosols. The most
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Pitt Biospecimen Core

<p>effective method of preventing cuts and sticks is to minimize contact with sharps by recapping when not in use and disposing of them immediately after use. An appropriate sharps disposal container should be available, closable, and puncture resistant. The sharps container should be disposed of properly when two-thirds full.</p>	
#5	DEFINITIONS
<ol style="list-style-type: none"> 1. PBC: Pitt Biospecimen Core 2. BIOS: Biospecimen Inventory and Operations System 3. TP#: Tissue Procurement Number (also referred to as ANON# in BIOS). This number is generated upon creation of an encounter in BIOS. 	
#6	EQUIPMENT, MATERIALS, & REAGENTS
<ol style="list-style-type: none"> 1. Equipment <ol style="list-style-type: none"> a. Scale 2. Materials <ol style="list-style-type: none"> a. Cryogenic Storage Bag b. Biospecimen Sheet c. Labeling Marker d. Forceps e. Weigh Paper 	
#7	STEP-BY-STEP OPERATING PROCEDURE
<ol style="list-style-type: none"> 1. Don personal protective equipment. <ul style="list-style-type: none"> <input checked="" type="checkbox"/> scrubs <input checked="" type="checkbox"/> gloves; indicate type: Nitrile <input type="checkbox"/> safety goggles <input type="checkbox"/> face shield <input type="checkbox"/> lab coat <input type="checkbox"/> other: _____ 2. <u>Tissue Collection intended for Cryogenic Storage</u> <ol style="list-style-type: none"> a. Excess collection tissue types are defined by the Director of the Pitt Biospecimen Core (PBC) based on need. No patient consent is required. b. Consented Collection: PBC staff will ensure receipt of the signed consent prior to moving forward with tissue collection. c. Identify time and location of procedure and match schedule with consent. d. The Pathology staff will be alerted of targeted specimens based on communication between the PBC and Gross Room. e. Once received by Pathology, clinical needs will be satisfied and Pathology will determine if banking is possible. f. Pathology will notify the PBC stating whether or not there is available tissue for research. 	

Pitt Biospecimen Core

	<ul style="list-style-type: none">(1) If tissue is not being released, the PBC will stop pursuing the case.(2) If the specimen is being released to the PBC, create the encounter in BIOS. TP# will be assigned at this time.g. Pathology will do a gross dissection of the tissue to be placed directly into a cryogenic storage bag, hand-labeled with the TP#, and brought to the PBC lab.<ul style="list-style-type: none">(1) If the specimen does not need further dissection, it is permissible to snap-freeze the specimen and place it into an ultra-low freezer. It can also be transported to the tissue bank on dry ice.h. If a specimen weighs more than 1.5 grams, cut it into smaller sections weighing 0.5-0.75 grams per section.i. Log each discrete specimen into BIOS, with weight and detail.j. Affix barcode labels to the specimen bag.k. Snap-freeze specimens and store in a -80°C freezer.3. <u>Tissue Collected for Fresh Disbursement</u><ul style="list-style-type: none">a. Excess collection tissue types are defined by the Director of the Pitt Biospecimen Core (PBC) based on need. No patient consent is required.b. Consented Collection: PBC staff will ensure receipt of the signed consent prior to moving forward with tissue collection.c. Review OR schedule and Medical Records to flag cases desirable for research.d. The Pathology staff will be alerted of targeted specimens based on communication between the PBC and Gross Room.e. Once received by Pathology, clinical needs will be satisfied and Pathology will determine if banking is possible.f. Pathology will notify the PBC stating whether or not there is available tissue for research.<ul style="list-style-type: none">(1) If tissue is not being released, no further action is required.(2) If the specimen is being released to the PBC, create the encounter in BIOS. TP# will be assigned at this time.g. Pathology will do a gross dissection of the tissue.h. Retrieve the tissue from Pathology (gross room, frozen section room, etc.).<ul style="list-style-type: none">(1) Complete applicable sections of the Biospecimens Sheet, with input from Pathology personnel.i. Label the specimen container with the appropriate TP#, place in a biohazard bag, seal the biohazard bag, and transport the tissue back to the PBC lab.j. Log each discrete specimen into BIOS, with weight and detail.k. Affix barcode label to specimen container.l. Notify PI/Research Coordinator that the tissue is ready for pick-up.m. Refrigerate the specimen until picked up.4. Any deviation from expected criteria will warrant the completion of a Deviation Management Report (FORM 00004).
#8	QUALITY CONTROL & DOCUMENTATION
1. Deviation Management Record: FORM 00004	

Pitt Biospecimen Core

#9	ATTACHMENTS		
N/A			
#10	TRAINING REQUIREMENTS		
<p>General Training <i>(check all that apply):</i></p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Liquid Nitrogen Usage & Precautions (SAFE00003) <input checked="" type="checkbox"/> Standard Precautions (SAFE00004) <input checked="" type="checkbox"/> Dry Ice Handling & Usage (SAFE00005) <input type="checkbox"/> Fire Prevention & Preparedness (SAFE00006) <input type="checkbox"/> Dangerous Goods Shipping Training (SAFE00007) <input type="checkbox"/> Formaldehyde Policy (SAFE00010) <input type="checkbox"/> Spill Kit Management (SAFE00025) <input type="checkbox"/> Xylene Monitoring (SAFE00026) <input checked="" type="checkbox"/> Sharps Safety <p>Laboratory-specific training <i>(check all that apply):</i></p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Review of SDS for chemicals involved in this process/experiment <input checked="" type="checkbox"/> Review of this SOP <input type="checkbox"/> Other: _____ <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="width: 35%; padding: 5px;">Location Where Records Maintained:</td> <td style="padding: 5px;">MediaLab & Personnel File</td> </tr> </table>		Location Where Records Maintained:	MediaLab & Personnel File
Location Where Records Maintained:	MediaLab & Personnel File		
#11	REFERENCES		
<ol style="list-style-type: none"> 1. Standard Precautions (SAFE00004) 2. Dry Ice Handling & Usage (SAFE00005) 3. Liquid Nitrogen Usage & Precautions (SAFE00003) 4. Deviation Management Record (FORM00004) 			



Magee-Womens Hospital

of the University of Pittsburgh Medical Center

300 Halket Street
Pittsburgh, PA 15213-3180

CONSENT TO ACT AS A PARTICIPANT IN RESEARCH (FETAL TISSUE CONSENT FORM)

TITLE: Fetal Tissue Collection Protocol (Stillbirth > 24 weeks)

PRINCIPAL INVESTIGATOR:

(b) (6)
Magee-Womens Hospital, (b) (6)

Why is this research being done?

Some researchers are performing studies of fetal tissue within the limits of the laws of Pennsylvania. For these studies, the researchers need to use tissue from pregnancies. This protocol allows us to collect and store tissue and facilitate the distribution of fetal tissue samples to those who have approved research protocols.

Who is being asked to take part in this research?

You are being asked to submit tissue for this research study after you have experienced a loss of pregnancy and have consented to a fetal autopsy.

What procedures will be performed for research purposes?

You are being asked to allow researchers at the University of Pittsburgh to use any of the tissue from the pregnancy, as needed, for research projects. We may collect a sample of your urine (about 6 tablespoons) and blood (about 1 tablespoon), if possible, to use for research projects. Your samples may undergo genetic analysis (DNA/RNA), including genotype and phenotype. The tissue and samples may also be used by other researchers. These research studies are approved by an ethics review board (Institutional Review Board or IRB) and are subject to oversight to make sure that they are conducted appropriately and within the laws of the Commonwealth of Pennsylvania and/or the state in which the research is being conducted.

We are also requesting your authorization or permission to review your medical records. We will obtain the following information: data related to pregnancy, tissue and maternal health. Your signed consent form will be placed in your medical record. This research will involve collecting information from your medical records but your identity will only be known to the person (honest broker) collecting this information. Identifiable information will never be provided to any researchers.

Your participation is completely voluntary. If you agree to allow your samples to be included as part of this collection protocol, they will become the property of the University of Pittsburgh. Your medical information and samples will be stored at the University of Pittsburgh and/or at other federal research repositories until such time that the samples are used up or no longer felt to be appropriate for use in research studies. Your voluntary decision to provide these samples and

Page 1 of 4



University Of Pittsburgh
Institutional Review Board

Approval Date: 2/13/2017
Renewal Date: 2/4/2018

IRB #: IRB0702050

identifiable medical information to the inclusion of this study, or to later withdraw from it, will not affect your current or future medical care at UPMC.

Your samples will be stored in a way that will permit the people responsible for the samples (honest brokers) to connect your identity with your samples. However, when your medical information, samples, and data/information about tests done on your samples (including genotype and phenotype) are made available for actual use in research studies, they will be provided to researchers without personal identifiers. Researchers will not be able to connect your identity with the data, samples, or medical information. Your de-identified samples, results (genotype and phenotype) from samples and medical information may also be shared with other federally-funded tissue banks, shared data bases (both unrestricted-access and controlled-access repositories) and researchers, who may also share samples and medical information with other researchers. You will not be contacted when your samples or information are sent to researchers. Note that these samples will be released only after it is ensured proper research approvals are received (i.e. IRB approval). Because it will not be possible to connect your identity with your tissue/biological sample when the sample is being used for research, it will not be possible to inform you of the results of such research.

What are the possible risks, side effects and discomforts of this research?

If you agree to allow us to collect blood, we will collect blood by putting a needle into one of your veins and letting the blood flow into a tube. You may feel some pain and experience some bleeding when the needle goes into your vein. Although rare, there is a risk of fainting and infection from taking blood. You may have a small bruise where the needle went under the skin.

There is a risk of breach of confidentiality. The risks associated with genetic studies include the potential for a breach of confidentiality which could affect future insurability, employability, or reproduction plans, or have a negative impact on family relationships and/or result in paternity suits or stigmatization. However, we have put measures in place to reduce these risks. No information will be given to any researchers that would allow them to identify you in any way. A federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect you from being treated unfairly because of your genes.

What are the possible benefits from taking part in this research?

There is no personal or direct benefit to you from participating in this research. However, a potential benefit to society from this research is a gain in knowledge.

What treatments or procedures are available if I decide not to take part in this research?

You do not have to agree to participate in this study. Your participation is completely voluntary. Your care and benefits will be the same whether you agree to participate in this study or not.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research?

There are no costs to you or your insurance provider for participating in this research (urine sample, blood sample, medical record information, fetal tissue collection). You will be charged in the standard manner for any clinical care/clinical procedures.



Will I be paid if I take part in this research?

You will not be paid for allowing your fetal tissue to be used for research or for your participation. Your samples may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by researchers and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights nor will you share in any money which researchers, the University of Pittsburgh, or their agents may realize. There are no costs to you for participating.

Who will pay if I am injured as a result of participation in this research?

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation.

Who will know about my participation in this research?

The honest brokers will have access to identifiable information linking you to your samples. However, no researchers will be provided with any identifiable information or samples. The University of Pittsburgh Research Conduct and Compliance Office may have access to your records (including your identifiable medical information) for the purposes of monitoring the conduct of this project.

This authorization is valid for an indefinite period of time.

You may withdraw your authorization to review your medical records, and your consent for the collection and use of your fetal tissue, blood, and/or urine. However, once data or samples have been shared with researchers, there will be no way to get the data/samples back as researchers are not provided with any identifiers. To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

How long will records be maintained?

Research records will kept indefinitely but at least 7 years after completion of the research.

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research during the course of this research, and that such future questions will be answered by the researchers listed on the first page of this form. Any questions which I have about my rights as a research participant will be



answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

By signing this form, I agree to participate in this research and provide my authorization to share my medical records, as described above. I agree to donate one or more of the following samples. A copy of this consent form will be given to me.

- ☐ Tissue
- ☐ Urine
- ☐ Blood
- ☐ All of the above

Participant's Signature

Date

Participant's Printed Name

Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research to the above-named individual, and I have discussed the potential benefits and possible risks of the research participation. Any questions the individual has about this research have been answered, and we will always be available to address future questions as they arise.

Printed Name of Person Obtaining Consent

Role in Research

Signature of Person Obtaining Consent

Date





Magee-Womens Hospital

of the University of Pittsburgh Medical Center

300 Halket Street
Pittsburgh, PA 15213-3180

CONSENT TO ACT AS A PARTICIPANT IN RESEARCH (FETAL TISSUE CONSENT FORM)

TITLE: Fetal Tissue Collection Protocol (Spontaneous and Elective Abortions < 24 weeks)

PRINCIPAL INVESTIGATOR:

(b) (6)
Magee-Womens Hospital, (b) (6)

Why is this research being done?

Some researchers are performing studies of fetal tissue within the limits of the laws of Pennsylvania. For these studies, the researchers need to use tissue from pregnancies. This collection protocol allows us to collect and store tissue, and to facilitate the distribution of fetal tissue samples to those who have approved research protocols.

Who is being asked to take part in this research?

You are scheduled to have an elective abortion to end your pregnancy or you have experienced a spontaneous abortion (miscarriage). You have already signed a consent form for the procedure to remove the tissue from your uterus or to be cared for if the tissue passed spontaneously.

What procedures will be performed for research purposes?

You are being asked to allow researchers at the University of Pittsburgh to use any of the tissue from the pregnancy, as needed, for research projects. We may collect a sample of your urine (about 6 tablespoons) and blood (about 1 tablespoon), if possible, to use for research projects. Your samples may undergo genetic analysis (DNA/RNA), including genotype and phenotype. The tissue and samples may also be used by other researchers. These research studies are approved by an ethics review board (Institutional Review Board or IRB) and are subject to oversight to make sure that they are conducted appropriately and within the laws of the Commonwealth of Pennsylvania and/or the state in which the research is being conducted.

We are also requesting your authorization or permission to review your medical records. We will obtain the following information: data related to pregnancy, tissue and maternal health. Your signed consent form will be placed in your medical record. This research will involve collecting information from your medical records but your identity will only be known to the person (honest broker) collecting this information. Identifiable information will never be provided to any researchers.

Your participation is completely voluntary. If you agree to allow your samples to be included as part of this collection protocol, they will become the property of the University of Pittsburgh. Your medical information and samples will be stored at the University of Pittsburgh and/or at other federal research repositories until such time that the samples are used up or no longer felt to be appropriate for use in research studies. Your voluntary decision to provide these samples and identifiable medical information to the inclusion of this study, or to later withdraw from it, will not affect your current or future medical care at UPMC.



Your samples will be stored in a way that will permit the people responsible for the samples (honest brokers) to connect your identity with your samples. However, when your medical information, samples, and data/information about tests done on your samples (including genotype and phenotype) are made available for actual use in research studies, they will be provided to researchers without personal identifiers. Researchers will not be able to connect your identity with the data, samples, or medical information. Your de-identified samples, results (genotype and phenotype) from samples and medical information may also be shared with other federally-funded tissue banks, shared data bases (both unrestricted-access and controlled-access repositories) and researchers, who may also share samples and medical information with other researchers. You will not be contacted when your samples or information are sent to researchers. Note that these samples will be released only after it is ensured proper research approvals are received (i.e. IRB approval). Because it will not be possible to connect your identity with your tissue/biological sample when the sample is being used for research, it will not be possible to inform you of the results of such research.

What are the possible risks, side effects and discomforts of this research?

If you agree to allow us to collect blood, we will collect blood by putting a needle into one of your veins and letting the blood flow into a tube. You may feel some pain and experience some bleeding when the needle goes into your vein. Although rare, there is a risk of fainting and infection from taking blood. You may have a small bruise where the needle went under the skin.

There is a risk of breach of confidentiality. The risks associated with genetic studies include the potential for a breach of confidentiality which could affect future insurability, employability, or reproduction plans, or have a negative impact on family relationships and/or result in paternity suits or stigmatization. However, we have put measures in place to reduce these risks. No information will be given to any researchers that would allow them to identify you in any way. A federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect you from being treated unfairly because of your genes.

What are the possible benefits from taking part in this research?

There is no personal or direct benefit to you from participating in this research. However, a potential benefit to society from this research is a gain in knowledge.

What treatments or procedures are available if I decide not to take part in this research?

You do not have to agree to participate in this study. Your participation is completely voluntary. Your care and benefits will be the same whether you agree to participate in this study or not.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research?

There are no costs to you or your insurance provider for participating in this research (urine sample, blood sample, medical record information, fetal tissue collection). You will be charged in the standard manner for any clinical care/clinical procedures.

Will I be paid if I take part in this research?

You will not be paid for allowing your fetal tissue to be used for research or for your participation. Your samples may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by researchers and the University of Pittsburgh for use in other research or the development of new products. You will



not retain any property rights nor will you share in any money which researchers, the University of Pittsburgh, or their agents may realize. There are no costs to you for participating.

Who will pay if I am injured as a result of participation in this research?

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation.

Who will know about my participation in this research?

The honest brokers will have access to identifiable information linking you to your samples. However, no researchers will be provided with any identifiable information or samples. The University of Pittsburgh Research Conduct and Compliance Office may have access to your records (including your identifiable medical information) for the purposes of monitoring the conduct of this project.

This authorization is valid for an indefinite period of time.

You may withdraw your authorization to review your medical records, and your consent for the collection and use of your fetal tissue, blood, and/or urine. However, once data or samples have been shared with researchers, there will be no way to get the data/samples back as researchers are not provided with any identifiers. To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

How long will records be maintained?

Research records will kept indefinitely but at least 7 years after completion of the research.

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research during the course of this research, and that such future questions will be answered by the researchers listed on the first page of this form. Any questions which I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

By signing this form, I agree to participate in this research and provide my authorization to share my medical records, as described above. I agree to donate one or more of the following samples. A copy of this consent form will be given to me.

☐ Tissue



- ☐ Urine
- ☐ Blood
- ☐ All of the above

Participant's Signature

Date

Participant's Printed Name

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research to the above-named individual, and I have discussed the potential benefits and possible risks of the research participation. Any questions the individual has about this research have been answered, and we will always be available to address future questions as they arise.

Printed Name of Person Obtaining Consent

Role in Research

Signature of Person Obtaining Consent

Date



From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 9/27/2021 9:13:24 PM
To: Rutenbar, Rob A [RUTENBAR@pitt.edu]
CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]
Subject: Please read and acknowledge receipt -- questions about the GUDMAP project
Attachments: Letter to Pittsburgh re GUDMAP 9 27 21.docx;
CUsersGpuckettAppDataLocalTempDDAddin1632259181MI10FAX_20210921_155218.pdf

Dear Dr. Rutenbar:

Please see attached.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: 301-496-1096
Email: Michael.Lauer@nih.gov



National Institutes of Health
Bethesda, Maryland 20892

[Confidential]

Date: September 27, 2021

To: Rob A. Rutenbar, PhD
Senior Vice Chancellor for Research
University of Pittsburgh

From: Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Director, NIH Office of Extramural Research

Re: GenitoUrinary Development Molecular Anatomy Project (GUDMAP) Tissue Hub and Collection Site (U24DK110791)

Dear Dr. Rutenbar:

I am sending you this letter in your capacity as Senior Vice Chancellor for Research at the University of Pittsburgh.

It has come to our attention that various media outlets and nonprofit organizations have made allegations about the fetal tissue collection procedures associated with the GenitoUrinary Development Molecular Anatomy Project (GUDMAP) Tissue Hub and Collection Site at the University of Pittsburgh.^{1,2,3,4}

As you are aware, NIH requires that NIH-supported recipient institutions certify that they will comply with the NIH Grants Policy Statement (see section 4.1.14 Human Fetal Tissue Research), which incorporates Federal statutory requirements for research with human fetal tissue. Sections 498A and 498B of the PHS Act (42 U.S.C. 289g-1 and 289g-2) set forth specific requirements and prohibitions on research involving human fetal tissue. Research involving human fetal tissue is also subject to the HHS Regulations for the Protection of Human Subjects (45 CFR Part 46). When an application involving human fetal tissue research is submitted to NIH, the Authorized Organization Representative's signature certifies that researchers using these tissues are in compliance with the PHS Act. When obtaining primary human fetal tissue for research purposes, NIH expects recipients and contractors to maintain appropriate documentation, such as an attestation from the health care provider or a third party supplier, that informed consent was obtained at the time of tissue collection.

1 The Center for Medical Progress: Aborted Infants' Continued Blood Flow Advertised in Racist University of Pittsburgh Grant Application to NIH

2 Judicial Watch: New HHS Documents Reveal Millions in Federal Funding for University of Pittsburgh Human Fetal Organ Harvesting Project Including Viable and Full-Term Babies

3 Fox News: Doctors say Pitt statements point to possibility organs extracted from live fetuses; school denies charge

4 Fox News: Millions in federal money flowed to tissue bank that collected fetal 'heart, gonads, legs, brain': report

The scientific and ethical challenges associated with research utilizing human fetal tissue make it imperative that researchers and their organizations be fully aware of and in compliance with the Federal requirements. In light of this, we are asking that you address the following:

- Please provide a copy of the Pittsburgh Biospecimen Core's policies and standard operating procedures related to human fetal tissue.
- For grant U24DK110791, provide documentation of consent protocols, including a copy of the consent form(s) used, and supporting documentation demonstrating that consent was obtained, such as an attestation from the health care provider(s) or third party supplier(s) that informed consent was obtained at the time of tissue collection.
- Please clarify the tissue collection procedures for the GUDMAP Tissue Collection Site and explain the procedures used for reducing "warm ischemic time."
- Please explain if any tissue was obtained after 25 weeks from any source, such as the International Institute for the Advancement of Medicine. If so, please indicate whether the tissue was from abortions and/or neonatal death and provide copies of the source's protocols for tissue collection procedures."

Please review these issues and confirm that the University of Pittsburgh complied with the policies cited above. If any instances of non-compliance are identified or suspected, please also provide a detailed description of the issue and corrective actions taken or planned.

We would like to receive your written response within the next 30 days. In the interim, we would like to schedule a phone call at your earliest convenience.

Sincerely,

Michael S. Lauer, MD

Congress of the United States
Washington, DC 20515

September 21, 2021

The Honorable Merrick Garland
United States Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW, Room 1145
Washington, D.C. 20530

The Honorable Xavier Becerra
Secretary of Health & Human Services
U.S. Department of Health & Human Services
200 Independence Avenue SW
Washington, D.C. 20201

The Honorable Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
U.S. Department of Health and Human Services
Building One, Room 244
One Center Drive
Bethesda, MD 20892

Dear Attorney General Garland, Secretary Becerra, and Director Collins,

We are alarmed by public records obtained from the National Institutes of Health (NIH) which show that the University of Pittsburgh (Pitt) may have violated federal law by altering abortion procedures to harvest organs from babies who were old enough to live outside the womb. We ask for a complete investigation into the activities of this organization and a full report of findings and any remedial measures necessary.

The NIH documents detailing Pitt's grant request were obtained in response to a Freedom of Information Act (FOIA) request from the Center for Medical Progress. Between fiscal years 2016 and 2020, NIH awarded approximately \$1.5 million to Pitt for a project related to the GenitoUrinary Developmental Molecular Anatomy Project (GUDMAP) program.¹ The GUDMAP program was intended to provide the scientific and medical community tools to study "congenital diseases of the genitourinary tract (kidneys, bladder, ureter, urethra)" by obtaining such organs from aborted babies for research.² In its application for funding to be a GUDMAP "tissue hub and collection site" Pitt states that its Health Science Tissue Bank (HSTB) has been involved in procuring and disbursing the body parts of aborted babies for years, noting that "the fetal tissue IRB [Institutional Review Board] has been in place since 2005."³ The application contains references in several places regarding the HSTB to the Pitt Institutional Review Board (IRB)⁴ but also states that the IRB forms are in the process of being altered⁵ and the IRB review is pending.⁶

First, Pitt's application raises concern that it has failed to comply with federal law prohibiting the alteration of abortion procedures solely for the purpose of obtaining fetal tissue, which states that an attending physician may have "no part in any decisions as to the timing, method, or procedures used to

¹ Award Letter. Department of Health and Human Services National Institutes of Health. Grant number 1U24DK110791-01. September 12, 2016.

² NIH RePORT Project Details. "University of Pittsburgh as the GUDMAP Tissue Hub and Collection Site." Abstract Text. https://reporter.nih.gov/search/p3w-bb6YsECf3hOTrF_iLA/project-details/9944639/history

³ University of Pittsburgh. Application for Federal Assistance SF 424 (R&R). Page 7. <https://www.centerformedicalprogress.org/wp-content/uploads/2021/08/GUDMAP2015NIHappFOIA.pdf>

⁴ University of Pittsburgh. Application for Federal Assistance SF 424 (R&R). Pages 7, 60, 61, 64.

⁵ University of Pittsburgh. Application for Federal Assistance SF 424 (R&R). Pages 62, 65, 70.

⁶ University of Pittsburgh. Application for Federal Assistance SF 424 (R&R). Page 6.

terminate a pregnancy.”⁷ It is not clear that Pitt has complied with these legal requirements based on the following statements on Pitt’s grant application:

- Pitt states that “ischemia time is minimized” when it obtains fetal tissue.⁸ NIH defines “ischemia” as “time a tissue, organ, or body part remains at body temperature after its blood supply has been reduced or cut off but before it is cooled or reconnected to a blood supply.”⁹ It would be illegal for Pitt to alter the “timing, method, or procedures” of the abortion to minimize ischemia time.
- Pitt states that it “tailor[s] [its] collection processes on a case-by-case basis to maximize the needs of investigators.”¹⁰ It would be illegal for researchers to have any part in the decisions surrounding the obtainment of fetal tissue from elective abortions.

Second, if the organs were harvested from babies born after induced abortion, we are concerned that some of these babies were born alive, could have survived with appropriate care, and may have died as a result of having their organs harvested. Pitt’s application states that it can obtain access to the organs and tissues of unborn babies between 6-24 weeks gestation, but it partners with another organization to obtain unborn babies between 25-42 weeks gestation.¹¹ Babies as young as less than 22 weeks gestation have been known to survive outside the womb with appropriate care.¹² The statements about “warm ischemia” raise questions about the cause of death for these babies. As noted above, Pitt states that it sought to minimize the time between when the blood supply to an organ was reduced and when the organ is cooled or reconnected. If the organs are harvested from a baby born after induced abortion, it is possible the baby was delivered alive, and the removal of the organs was the cause of the baby’s death.

Exploiting the body parts of aborted children for research purposes is repulsive and should stop, regardless of the outcome hoped for by researchers. Research using abortive fetal tissue is unethical, wrong, and has also been proven ineffective. Despite being used in clinical research since the 1920s, fetal tissue has not produced a single clinical treatment.¹³

Based on these considerations, for the federal awards given the project number 1U24DK110791, please provide full and clear responses to the following information requests going back to the beginning of the grant project period to today:

- The number of cases at each gestational age involving abortion, miscarriage, stillbirth, and neonate utilized in the GUDMAP program during the grant project period;

⁷ 45 C.F.R. 46.204(i). This regulation extends to all Federally-funded human fetal tissue research the statutory requirements of 42 U.S.C. 289g-1, which states that, “no alteration of the timing, method, or procedures used to terminate the pregnancy [may be] made solely for the purposes of obtaining the tissue” for “research on the transplantation of human fetal tissue for therapeutic purposes.”

⁸ “JW v HHS NIH July 2021 Records 00642 pg 170.” Judicial Watch. August 3, 2021.

<https://www.judicialwatch.org/documents/hhs-cmp-responsive-records-july-2021-pg-170/>

⁹ Definition of warm ischemia time - NCI Dictionary of Cancer Terms - National Cancer Institute

¹⁰ “JW v HHS NIH July 2021 Records 00642 pg 170.” Judicial Watch. August 3, 2021.

<https://www.judicialwatch.org/documents/hhs-cmp-responsive-records-july-2021-pg-170/>

¹¹ University of Pittsburgh. Application for Federal Assistance SF 424 (R&R). Page 60.

¹² Ahmad, Kaashif A. et al. “Two-Year Neurodevelopmental Outcome of an Infant Born at 21 Weeks’ 4 Days’ Gestation.” *Pediatrics*. November 2017. <https://pediatrics.aappublications.org/content/early/2017/10/31/peds.2017-0103>

¹³ “Final Report.” Select Investigative Panel of the Energy & Commerce Committee. 30 December 2016. Pg. 386.

- Detailed protocols for Dilation & Curettage, Dilation & Evacuation, and Labor Induction followed to obtain fetal tissue for the GUDMAP program;
- The detailed biospecimen collection IRB application and approval for the Health Science Tissue Bank;
- Documentation to verify the physiological status of babies delivered by labor induction upon tissue harvest;
- The number of fetal tissue collection procedures from babies delivered by labor induction;
- Documentation of the number of babies delivered by labor induction that were deceased, and cardiac activity had ceased prior to fetal organ and tissue collection;
- Documentation of when “warm ischemia” time was recorded with reference to death when collecting organs and tissue from abortion, miscarriage, stillbirth, and neonate;
- Documentation on the specific steps that were taken to minimize warm ischemic time when collecting organs and tissue from abortion, miscarriage, stillbirth, and neonate;
- Details on how specimens are collected and transferred to the Tissue Hub and the personnel involved at each step;
- Documentation of how compliance is ensured (including any reporting and oversight mechanisms) with regard to each of the following statutes and regulations:
 - The Partial-Birth Abortion Ban Act (18 U.S.C. 1531);
 - Research protections for pregnant women and fetuses (42 U.S.C. 289g, 289g-1, and 45 C.F.R. 46.204);
 - Research protections for neonates (45 C.F.R. 46.205); and,
 - Prohibitions regarding fetal tissue (42 U.S.C. 289g-2, 45 C.F.R. 46.206).

We appreciate your attention to this matter and look forward to your prompt and thorough response to each of these requests. We ask for a response by the date of October 12, 2021.

Sincerely,



Josh Hawley
United States Senator



Lisa McClain
Member of Congress



Steve Daines
United States Senator



Blaine Luetkemeyer
Member of Congress



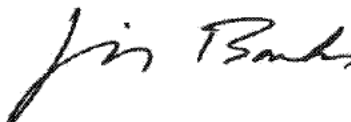
James Lankford
United States Senator



Jim Jordan
Member of Congress



Ted Cruz
United States Senator




Jim Banks
Member of Congress



John Boozman
United States Senator



Christopher H. Smith
Member of Congress



Bill Cassidy, M.D.
United States Senator



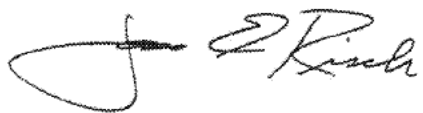
Rodney Davis
Member of Congress



John Thune
United States Senator



Jake LaTurner
Member of Congress



James E. Risch
United States Senator



Jeff Duncan
Member of Congress



Jerry Moran
United States Senator



Michael Cloud
Member of Congress



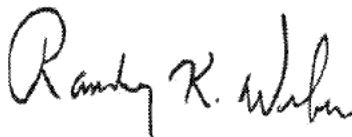
Tom Cotton
United States Senator



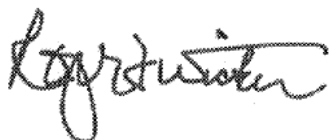
Randy Feenstra
Member of Congress



Marco Rubio
United States Senator



Randy Weber
Member of Congress



Roger F. Wicker
United States Senator



Ralph Norman
Member of Congress



Mike Braun
United States Senator



Brian Babin, D.D. S.
Member of Congress



M. Michael Rounds
United States Senator



Markwayne Mullin
Member of Congress



Cindy Hyde-Smith
United States Senator



Chris Jacobs
Member of Congress



Rick Scott
United States Senator



Glenn "GT" Thompson
Member of Congress



Marsha Blackburn
United States Senator



William R. Timmons, IV
Member of Congress



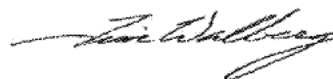
Rand Paul
United States Senator



Ann Wagner
Member of Congress



James M. Inhofe
United States Senator



Tim Walberg
Member of Congress



Steven M. Palazzo
Member of Congress



Paul A. Gosar, D.D.S.
Member of Congress



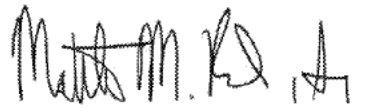
Jake Ellzey
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Steve Womack
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Bruce Westerman
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Matthew Rosendale, Sr.
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Andy Biggs
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Ben Cline
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Madison Cawthorn
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Jody Hice
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Alex X. Mooney
Member of Congress



Scott Franklin
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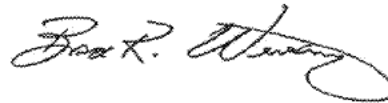
Vicky Hartzler
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Darin LaHood
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Brad R. Wenstrup, D.P.M.
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Rick Crawford
Member of Congress



David B. McKinley, P.E.
Member of Congress



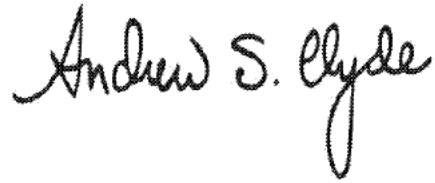
Warren Davidson
Member of Congress



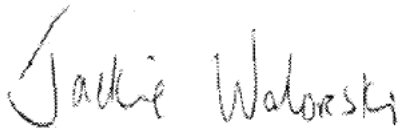
Bob Good
Member of Congress



Trent Kelly
Member of Congress



Andrew S. Clyde
Member of Congress



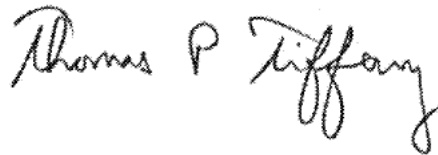
Jackie Walorski
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Lauren Boebert
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Tom Tiffany
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Kevin Hern
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Daniel Webster
Member of Congress



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Ronny L. Jackson, M.D.
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Bill Johnson
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Guy Reschenthaler
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Earl L. "Buddy" Carter
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Louie Gohmert
Member of Congress



Mike Kelly
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David Kustoff
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Barry Moore
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Andy Harris, M.D.
Member of Congress



Mary E. Miller
Member of Congress



John Rose
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Chip Roy
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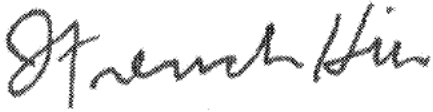
Bill Huizenga
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Billy Long
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Mike Bost
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French Hill
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Michelle Fischbach
Member of Congress



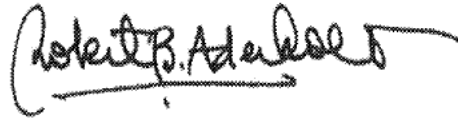
Julia Letlow
Member of Congress



Michael C. Burgess, M.D.
Member of Congress



Mike Johnson
Member of Congress



Robert B. Aderholt
Member of Congress

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 10/17/2021 2:47:13 PM
To: Berg, Jeremy [jberg@pitt.edu]
CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: Re: Fetal tissue research-University of Pittsburgh

Hi Jeremy – I recommend you connect with your colleague Rob Rutenbar.

Thanks, Mike

From: "Berg, Jeremy" <jberg@pitt.edu>
Date: Sunday, October 17, 2021 at 9:42 AM
To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
Subject: Re: Fetal tissue research-University of Pittsburgh

Thanks, Mike. Can you tell me the time of the scheduled meeting?

Best, Jeremy

Jeremy M. Berg, Ph.D.
University of Pittsburgh
Associate Senior Vice Chancellor for Science Strategy and Planning
in the Health Sciences
Professor of Computational and Systems Biology
3550 Terrace Street
Pittsburgh, PA 15213
(412)624-1223
(b) (6) (cell)
jberg@pitt.edu

From: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Date: Sunday, October 17, 2021 at 9:35 AM
To: Tabak, Lawrence (NIH/OD) [E] <lawrence.tabak@nih.gov>, Berg, Jeremy <jberg@pitt.edu>
Cc: Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>, Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Subject: Re: Fetal tissue research-University of Pittsburgh

The meeting is already scheduled – you can check in with [Rob Rutenbar](#).

Thanks, Mike

From: "Tabak, Lawrence (NIH/OD) [E]" <lawrence.tabak@nih.gov>
Date: Sunday, October 17, 2021 at 9:29 AM

To: "Berg, Jeremy" <jberg@pitt.edu>

Cc: "Burklow, John (NIH/OD) [E]" <burklowj@od.nih.gov>, "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>

Subject: Re: Fetal tissue research-University of Pittsburgh

Mike indicated that it is arranged (dropping FC to bcc line).

Larry

From: Jeremy Berg <jberg@pitt.edu>

Date: Sunday, October 17, 2021 at 9:27 AM

To: "Tabak, Lawrence (NIH/OD) [E]" <lawrence.tabak@nih.gov>

Cc: Francis Collins <collinsf@od.nih.gov>, "Burklow, John (NIH/OD) [E]" <burklowj@od.nih.gov>, "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>

Subject: Re: Fetal tissue research-University of Pittsburgh

Thanks, Larry. Has this meeting been arranged or is this still to be done?

Best, Jeremy

Jeremy M. Berg, Ph.D.

University of Pittsburgh

Associate Senior Vice Chancellor for Science Strategy and Planning
in the Health Sciences

Professor of Computational and Systems Biology

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(412)624-1223

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jberg@pitt.edu

From: Tabak, Lawrence (NIH/OD) [E] <lawrence.tabak@nih.gov>

Date: Sunday, October 17, 2021 at 9:18 AM

To: Berg, Jeremy <jberg@pitt.edu>

Cc: Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>, Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>, Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>

Subject: Re: Fetal tissue research-University of Pittsburgh

Jeremy,

Mike Lauer (added to this thread) will be meeting with your VPR on Wednesday. Based upon the outcome of that meeting, Mike and I are willing to meet with your Chancellor if that is still desired.

Best wishes,

Larry

Lawrence A. Tabak, DDS, PhD

Principal Deputy Director, NIH

From: Jeremy Berg <jberg@pitt.edu>
Date: Saturday, October 16, 2021 at 9:50 AM
To: Francis Collins <collinsf@od.nih.gov>
Cc: "Tabak, Lawrence (NIH/OD) [E]" <lawrence.tabak@nih.gov>, "Burklow, John (NIH/OD) [E]" <burklowj@od.nih.gov>
Subject: Fetal tissue research-University of Pittsburgh

Hi Francis:

I write regarding ongoing efforts to undermine important science using fetal tissue. As you no doubt know, various public universities have been the subject of rotating attacks about research using fetal tissue, sometimes citing NIH support for the research. It is now the University of Pittsburgh turn in the spotlight. The event that triggered this is the publication of a paper (attached) on grafting fetal skin onto rodents supported by an R21 from NIAID (<https://reporter.nih.gov/search/cbh4-6MG-UCNgeeBHC15ew/project-details/9599671>). I provide this only for background as the details do not matter for the issue I am raising.

Pitt's response to concerns raised by state legislators and various news outlets has been to commission an outside review of Pitt's practices and compliance. The University believes that all appropriate practices and laws have been followed. However, this outside review has been met with additional complaints (see <https://www.foxnews.com/us/pittsburgh-investigation-fetal-tissue-probe-cone-silence>).

We have been discussing these issues and it seems that this is an organized attempt to delegitimize science based on fetal tissue rather than to identify misbehavior (although, of course, any misbehavior does create opportunities for outrage). In light of this, we feel that the scientific community would benefit if more institutions could stand together to take some of the power out of the one-at-a-time strategy that appears to be operating.

Our Chancellor Pat Gallagher, former Director of NIST and your Senate confirmation colleague would like the opportunity to discuss this with you or other appropriate individuals at NIH via whatever venue would be preferred (phone, Zoom, in Bethesda).

If this is possible, please let me know the best way to make the appropriate arrangements.

Thank you for your consideration and best wishes for the remainder of your time at NIH and for the next phase.

Best, Jeremy

Jeremy M. Berg, Ph.D.
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