## SECTION H

****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE RESEARCH INVOLVING HUMAN FETAL TISSUE.)****

### RESEARCH INVOLVING HUMAN FETAL TISSUE

Research involving Human Fetal Tissue (HFT) must be conducted in accordance with applicable Federal, State and local laws, regulations, and policies. Selected Federal statutes, regulations, and policies are provided below:
42 U.S.C. 289g-1 and 289g-2 set forth specific requirements and prohibitions on research involving human fetal tissue. For example, among other prohibitions, 42 U.S.C. 289g-2 provides:

"Prohibitions regarding human fetal tissue:

a. Purchase of tissue

It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce."

The full text of 42 U.S.C. 289g-1 is available at:
http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap6A-subchapIII-partH-sec289g-1.htm

The full text of 42 U.S.C. 289g-2 is available at:
http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap6A-subchapIII-partH-sec289g-2.htm

Research involving HFT is also subject to the HHS Regulations for the Protection of Human Subjects (45 CFR 46 Subparts A and B). The following provisions may be specifically relevant:
§46.204 Research involving pregnant women or fetuses.
~ (a) - (g)

h. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
i. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
j. Individuals engaged in the research will have no part in determining the viability of a neonate.

§46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

a. Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.
b. If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

The full text of the HHS Regulations for the Protection of Human Subjects is available at: https://www.hhs.gov/ohrp/sites/default/files/ohrp/policy/ohrpregulations.pdf .
Furthermore, per NOT-OD-16-033, when obtaining primary HFT for research purposes, The Contractor shall 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.

**Non-Transplantation Research on Fetal Tissue Obtained from Elective Abortions**

The Contractor shall adhere to NIH Policy NOT-OD-19-128 on all contracts that involves the use of HFT obtained from elective abortions. The HFT is defined as research involving the study, analysis, or use of primary HFT, cells, and derivatives, and human fetal primary cell cultures obtained from elective abortions and includes the following (the definition implements the statute (42 U.S.C. Chapter 6A, Subchapter III, Part H, Sec. 289):

- human fetal primary or secondary cell cultures, whether derived by the investigator or obtained from a vendor.
- animal models incorporating HFT from elective abortions, including obtaining such models from a vendor.
- derivative products from elective abortion tissues or cells such as protein or nucleic acid extracts.
- any human extra-embryonic cells and tissue, such as umbilical cord tissue, cord blood, placenta, amniotic fluid, and chorionic villi, if obtained from the process of elective abortion.

The definition of research involving HFT **does not** include the following:

- human fetal primary or secondary cell cultures, if cells were not derived from an elective abortion.
- already-established (as of June 5, 2019) human fetal cell lines (e.g. induced pluripotent stem cell lines from human fetal tissue, immortalized cell lines, differentiated cell lines).

- derivative products from human fetal tissue or cells (e.g. DNA, RNA, protein) **if not derived** from elective abortion.
- human extra-embryonic cells and tissue, including, but not limited to, umbilical cord tissue, cord blood, placenta, amniotic fluid, and chorionic villi **if not derived** from elective abortion.
- human fetal cells present in maternal blood or other maternal sources
- embryonic stem cells or embryonic cell lines.
- research on transplantation of HFT for therapeutic purposes (because of the statutory provision(s) addressing such research).

To assure compliance with all applicable laws and HHS/NIH policies concerning the acquisition and use of HFT obtained from elective abortions, the Contractor shall submit detailed information addressing the use of HFT to Contracting Officer Representative (COR) in monthly progress reports.

The Contractor shall comply with the following terms and conditions:

1. The Contractor shall comply with all HHS/NIH policies specific to HFT.
2. The Contractor shall justify the continued use of HFT obtained from elective abortions in their monthly progress reports by describing the ongoing scientific necessity for the use of HFT.
3. Informed consents for use of HFT in research, containing certain statements/representations that acknowledges informed consent for donation of HFT was obtained by someone other than the person who obtained the informed consent for abortion, occurred after the informed consent for abortion, and will not affect the method of abortion; no enticements, benefits, or financial incentives were used at any level of the process to incentivize abortion or the donation of HFT; and the informed consent will be signed by both the woman and the person who obtains the informed consent.
4. The Contractor shall maintain documentation from the HFT donating organization assuring adherence to the requirements of the informed consent process and documentation that HFT was not obtained or acquired for valuable consideration. The Contractor will acquire this assurance for each year of the award HFT research is conducted for the life of the award and maintain this documentation in accordance with the NIH Record Retention and Access policy.
5. HFT was not obtained or acquired for valuable consideration, as such term is defined in 42 USC § 289g-2.
6. The treatment of HFT, and the disposal of HFT when research is complete, shall be consistent with the plans outlined in the HFT proposal justification.

**Requests to Add New or Additional Non-Transplantation Research on Human Fetal Tissue from Elective Abortions after Contract Award:**

The Contractor shall submit a justification request to the Contracting Officer and COR to modify the contract to add either new or additional sources of HFT obtained from elective abortions. The Contractor shall include the following information in the justification package:

- Use the specific heading: "Human Fetal Tissue Obtained from Elective Abortions Justification". The justification should be in detail for review by NIH.
- The Contractor must include the following in the justification:
    i. Indicate why the research goals cannot be accomplished using an alternative to HFT (including, but not limited to, induced pluripotent cells not developed from HFT, organoids not developed from HFT, neonatal human tissue, human tissue obtained from adults, HFT not derived from elective abortion, animal models, and *in vitro* models that are not developed from HFT, and computational models).
    ii. Indicate the methods used to determine that no alternatives to HFT can be used (including, but not limited to, literature review and preliminary experiments).
    iii. Describe results from a literature review used to provide justifications.
    iv. Describe plans for the treatment of HFT and the disposal of HFT when research is complete.
    v. Describe planned written, voluntary, informed consent process for cell/tissue donation, or description and documentation of process if cells/tissue were already obtained. Include a draft informed consent form for planned use under the proposed research. The informed consent for donation of HFT for use in research requires language that acknowledges informed consent for donation of HFT was obtained by someone other than the person who obtained the informed consent for abortion, occurred after the informed consent for abortion, and will not affect the method of abortion; no enticements, benefits, or financial incentives were used at any level of the process to incentivize abortion or the donation of HFT; and to be signed by both the woman and the person who obtains the informed consent.
    vi. Budget Justification: Describe and document the quantity, type, and source of the HFT, and include a line item cost for the acquisition of HFT or indicate the cost is $0 if using donated or existing HFT.
    vii. HFT Compliance Assurance: The Contractor shall provide a letter signed by the Program Director/Principal Investigator assuring the HFT donating organization or clinic adheres to the requirements of the informed consent process and documentation that HFT was not obtained or acquired for valuable consideration.

Research using HFT shall be in compliance with all applicable federal, state, or local laws, regulations, and policies, including 42 USC 289g-1 and g-2, the HHS Regulations for the Protection of Human Subjects (45 CFR 46 Subparts A and B), NOT-OD-16-033, and NOT-OD-19-128.

**Research on Transplantation of Human Fetal Tissue**

Sections 498A and 498B of the PHS Act (42 U.S.C. 289g-1 and 289g-2) contain additional requirements for research on the transplantation of human fetal tissue for therapeutic purposes conducted or supported by NIH. Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local laws as well as the following NIH guidance.
Under section 498A, the official who signs the application is certifying that the research on transplantation of human fetal tissue will adhere to the following provisions. The woman who donates the fetal tissue must sign a statement declaring that the donation is being made:

- for therapeutic transplantation research
- without any restriction regarding the identity of individuals who may receive the transplantation, and
- without the donor knowing the identity of the recipient.

The attending physician must sign a statement that they have:

- obtained the tissue in accordance with the donor's signed statement and
- fully disclosed to the donor their intent, if any, to use the tissue in research and any known medical risks to the donor or risks to her privacy associated with the donation that are in addition to risks associated with the woman's medical care.

In the case of tissue obtained pursuant to an induced abortion, the physician's statement also must state that they:

- obtained the woman's consent for the abortion before requesting or obtaining consent for the tissue to be used;
- did not alter the timing, method, or procedures used to terminate the pregnancy solely for the purpose of obtaining the tissue for research; and
- performed the abortion in accordance with applicable State and local laws.

The Program Director/Principal Investigator (PD/PI) must sign a statement certifying that they are aware that the tissue is human fetal tissue obtained in a spontaneous or induced abortion, or pursuant to a stillbirth and that the tissue was donated for research purposes. The PD/PI also must certify that this information has been shared with others who have responsibilities regarding the research and, before eliciting informed consent from the transplantation recipient, will obtain written acknowledgment that the patient is aware of the aforementioned information. The PD/PI must certify in writing that they have had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy.

In submitting an application to NIH, the individual that signs the application is certifying that, if research on the transplantation of human fetal tissue is conducted under the grant-supported project, the organization will make available for audit by the HHS Secretary or designee, the physician statements, the PD/PI's statements, and informed consents required by subsections 498A(b)(2) and (c) of the PHS Act or will ensure HHS access to those records, if maintained by an entity other than the recipient. This requirement is in addition to the requirements concerning human subjects in research.

## SECTION J

****(USE BELOW IN ALL SOLICITATIONS THAT INVOLVE HUMAN FETAL TISSUE.) ****

**TECHNICAL PROPOSAL ATTACHMENTS**

Attachment 14: Human Fetal Tissue Obtained from Elective Abortions Justification

NIH requires offerors to address Human Fetal Tissue (HFT) requirements by providing a justification for the use of HFT obtained from elective abortions, details regarding procurement and costs, and information about how the offeror will use HFT obtained from elective abortions.

Link to Form:
https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j.

## SECTION L

****(USE BELOW WHEN HUMAN FETAL TISSUE WILL BE INVOLVED IN SOLICITATION)****

g. **Research Involving Human Fetal Tissue**

Research involving Human Fetal Tissue (HFT) must be conducted in accordance with applicable Federal, State and local laws, regulations, and policies. Selected Federal statutes, regulations, and policies are provided below:

42 U.S.C. 289g-1 and 289g-2 set forth specific requirements and prohibitions on research involving human fetal tissue. For example, among other prohibitions, 42 U.S.C. 289g-2 provides:

"Prohibitions regarding Human Fetal Tissue:

a. Purchase of tissue

It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce."

The full text of 42 U.S.C. 289g-1 is available at: http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap6A-subchapIII-partH-sec289g-1.htm .

The full text of 42 U.S.C. 289g-2 is available at: http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap6A-subchapIII-partH-sec289g-2.htm .

Research involving HFT is also subject to the HHS Regulations for the Protection of Human Subjects (45 CFR 46 Subparts A and B). The following provisions may be specifically relevant:

§46.204 Research involving pregnant women or fetuses.
~ (a) - (g)

h. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
i. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
j. Individuals engaged in the research will have no part in determining the viability of a neonate.

§46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

a. Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.
b. If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

The full text of the HHS Regulations for the Protection of Human Subjects is available at: https://www.hhs.gov/ohrp/sites/default/files/ohrp/policy/ohrpregulations.pdf .

Furthermore, per NOT-OD-16-033 at: https://grants.nih.gov/grants/guide/notice-files/not-od-16-033.html , when obtaining primary HFT for research purposes, NIH expects offerors 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.

**Non-Transplantation Research on Fetal Tissue Obtained from Elective Abortions**

a. By signing the face page of the proposal, the offeror (authorized institutional official) certifies that the research involving HFT is in compliance with applicable federal, state, or local laws, regulations, and policies, including 42 USC 289g-1 and g-2, the HHS Regulations for the Protection of Human Subjects (45 CFR 46 Subparts A and B), and NOT-OD-16-033.

   Offerors shall include a justification for its use as a separate attachment (see Section J for a link to the template used for the justification) and include an HFT Compliance Assurance and draft Informed Consent form as described below. Offerors shall address HFT requirements as outlined in NOT-OD-19-128. Offerors who fail to include a justification for the use of HFT obtained from elective abortions, an HFT Compliance Assurance, and a draft Informed Consent form, will be non-responsive to the solicitation and withdrawn from further consideration.

Offerors shall include the following information in the justification package:

- Use the specific heading: “Human Fetal Tissue Obtained from Elective Abortions Justification”. The justification should be in detail for review by NIH.
- The Offeror must include the following in the justification:
  1. Indicate why the research goals cannot be accomplished using an alternative to HFT (including, but not limited to, induced pluripotent cells not developed from HFT, organoids not developed from HFT, neonatal human tissue, human tissue obtained from adults, HFT not derived from elective abortion,

animal models, and *in vitro* models that are not developed from HFT, and computational models).

2. Indicate the methods used to determine that no alternatives to HFT can be used (including, but not limited to, literature review and preliminary experiments).
3. Describe results from a literature review used to provide justifications.
4. Describe plans for the treatment of HFT and the disposal of HFT when research is complete.
5. Describe planned written, voluntary, informed consent process for cell/tissue donation, or description and documentation of process if cells/tissue were already obtained. Include a draft informed consent form for planned use under the proposed research. The informed consent for donation of HFT for use in research requires language that acknowledges informed consent for donation of HFT was obtained by someone other than the person who obtained the informed consent for abortion, occurred after the informed consent for abortion, and will not affect the method of abortion; no enticements, benefits, or financial incentives were used at any level of the process to incentivize abortion or the donation of HFT; and to be signed by both the woman and the person who obtains the informed consent.
6. Budget Justification: Describe and document the quantity, type, and source of the HFT, and include a line item cost for the acquisition of HFT or indicate the cost is $0 if using donated or existing HFT. The line item cost shall also be included in the offeror's separate Business proposal.
7. HFT Compliance Assurance: Offeror shall provide a letter signed by the Program Director/Principal Investigator assuring the HFT donating organization or clinic adheres to the requirements of the informed consent process and documentation that HFT was not obtained or acquired for valuable consideration.

Research using HFT shall be in compliance with all applicable federal, state, or local laws, regulations, and policies, including 42 USC 289g-1 and g-2, the HHS Regulations for the Protection of Human Subjects (45 CFR 46 Subparts A and B), NOT-OD-16-033, and NOT-OD-19-128.

**Research on Transplantation of Human Fetal Tissue**

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Under section 498A, the official who signs the application is certifying that the research on transplantation of human fetal tissue will adhere to the following provisions. The woman who donates the fetal tissue must sign a statement declaring that the donation is being made:

- for therapeutic transplantation research
- without any restriction regarding the identity of individuals who may receive the transplantation, and
- without the donor knowing the identity of the recipient.

The attending physician must sign a statement that they have:

- obtained the tissue in accordance with the donor's signed statement and
- fully disclosed to the donor their intent, if any, to use the tissue in research and any known medical risks to the donor or risks to her privacy associated with the donation that are in addition to risks associated with the woman's medical care.

In the case of tissue obtained pursuant to an induced abortion, the physician's statement also must state that they:

- obtained the woman's consent for the abortion before requesting or obtaining consent for the tissue to be used;
- did not alter the timing, method, or procedures used to terminate the pregnancy solely for the purpose of obtaining the tissue for research; and
- performed the abortion in accordance with applicable State and local laws.

The Program Director/Principal Investigator (PD/PI) must sign a statement certifying that they are aware that the tissue is human fetal tissue obtained in a spontaneous or induced abortion, or pursuant to a stillbirth and that the tissue was donated for research purposes. The PD/PI also must certify that this information has been shared with others who have responsibilities regarding the research and, before eliciting informed consent from the transplantation recipient, will obtain written acknowledgment that the patient is aware of the aforementioned information. The PD/PI must certify in writing that they have had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy.

In submitting an application to NIH, the individual that signs the application is certifying that, if research on the transplantation of human fetal tissue is conducted under the grant-supported project, the organization will make available for audit by the HHS Secretary or designee, the physician statements, the PD/PI's statements, and informed consents required by subsections 498A(b)(2) and (c) of the PHS Act or will ensure HHS access to those records, if maintained by an entity other than the recipient. This requirement is in addition to the requirements concerning human subjects in research.

**Section J Attachment**

**HUMAN FETAL TISSUE OBTAINED FROM ELECTIVE ABORTIONS JUSTIFICATION**

**Offerors shall address each of the following topic areas:**

1. Indicate why the research goals cannot be accomplished using an alternative to Human Fetal Tissue (HFT) (including, but not limited to, induced pluripotent cells not developed from HFT, organoids not developed from HFT, neonatal human tissue, human tissue obtained from adults, HFT not derived from elective abortion, animal models, and *in vitro* models that are not developed from HFT, and computational models).
2. Indicate the methods used to determine that no alternatives to HFT can be used (including, but not limited to, literature review and preliminary experiments)
3. Describe results from a literature review used to provide justifications.
4. Describe plans for the treatment of HFT and the disposal of HFT when research is complete.
5. Describe planned written, voluntary, informed consent process for cell/tissue donation, or description and documentation of process if cells/tissue were already obtained. Include a draft informed consent form for planned use under the proposed research. The informed consent for donation of HFT for use in research requires language that acknowledges informed consent for donation of HFT was obtained by someone other than the person who obtained the informed consent for abortion, occurred after the informed consent for abortion, and will not affect the method of abortion; no enticements, benefits, or financial incentives were used at any level of the process to incentivize abortion or the donation of HFT; and

to be signed by both the woman and the person who obtains the informed consent.

6. Budget Justification: Describe and document the quantity, type, and source of the HFT, and include a line item cost for the acquisition of HFT or indicate the cost is $0 if using donated or existing HFT. The line item cost shall also be included in the offeror's separate Business proposal.
7. HFT Compliance Assurance: Offeror shall provide a letter signed by the Program Director/Principal Investigator assuring the HFT donating organization or clinic adheres to the requirements of the informed consent process and documentation that HFT was not obtained or acquired for valuable consideration.