

**DOCUMENT GENERATION SYSTEM (DGS) SOLICITATION AND CONTRACT LANGUAGE ON
HUMAN FETAL TISSUE**

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.

DOCUMENT GENERATION SYSTEM (DGS) SOLICITATION AND CONTRACT LANGUAGE ON HUMAN FETAL TISSUE

- 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: <http://www.hhs.gov/ohrp/policy/ohrregulations.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.

Human 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.

DOCUMENT GENERATION SYSTEM (DGS) SOLICITATION AND CONTRACT LANGUAGE ON HUMAN FETAL TISSUE

- 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's Representative (COR) in monthly progress reports.

The Contractor shall comply with the following terms and conditions:

- a) The Contractor shall comply with all HHS/NIH policies specific to HFT.
- b) 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.
- c) 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.
- d) 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.
- e) HFT was not obtained or acquired for valuable consideration, as such term is defined in 42 USC § 289g-2.
- f) 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 Human Fetal Tissue from elective abortions after contract award

DOCUMENT GENERATION SYSTEM (DGS) SOLICITATION AND CONTRACT LANGUAGE ON HUMAN FETAL TISSUE

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 information identified below in their justification request which will undergo review by the Ethics Advisory Board. The Government will not execute a modification to the contract without the recommendation of the Ethics Advisory Board to fund the proposed 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 Ethics Advisory Board.
- The contractor must include the following in the justification:
 - 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).
 - Indicate the methods used to determine that no alternatives to HFT can be used (including, but not limited to, literature review and preliminary experiments)
 - Conduct and describe results from a literature review used to provide justifications.
 - Describe plans for the treatment of HFT and the disposal of HFT when research is complete.
 - 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

DOCUMENT GENERATION SYSTEM (DGS) SOLICITATION AND CONTRACT LANGUAGE ON HUMAN FETAL TISSUE

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

- 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.
- HFT Compliance Assurance: The contractor shall provide a letter signed by the PD/PI 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.

As applicable, the Contractor shall make available, for audit by the Secretary, HHS, the physician statements and informed consents required by 42 USC 289g-1(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Contractor.

SECTION J.

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

TECHNICAL PROPOSAL ATTACHMENTS

Attachment 19:

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 template](#)

**DOCUMENT GENERATION SYSTEM (DGS) SOLICITATION AND CONTRACT LANGUAGE ON
HUMAN FETAL TISSUE**

SECTION L

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

The Contracting Officer shall submit an HFT justification, HFT Compliance Assurance, and a draft Informed Consent form from each from all offerors still being considered for award to the Ethics Advisory Board for review and recommend whether, in light of ethical consideration, NIH should fund the research project.

f. 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

f. 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:

**DOCUMENT GENERATION SYSTEM (DGS) SOLICITATION AND CONTRACT LANGUAGE ON
HUMAN FETAL TISSUE**

§46.204 Research involving pregnant women or fetuses.

~ (a) - (g)

- g. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
- h. 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
- i. 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.

- j. 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.
- k. 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:

<http://www.hhs.gov/ohrp/policy/ohrpreulations.pdf>.

Furthermore, per NOT-OD-16-033, 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.

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.

DOCUMENT GENERATION SYSTEM (DGS) SOLICITATION AND CONTRACT LANGUAGE ON HUMAN FETAL TISSUE

HUMAN FETAL TISSUE OBTAINED from ELECTIVE ABORTIONS

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. The HFT justification, HFT Compliance Assurance, and a draft Informed Consent form from all offerors still being considered for award to the Ethics Advisory Board for review and recommend whether, in light of ethical consideration, NIH should fund the research project. (refer to Section M., Mandatory Qualification Criteria).

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 Ethics Advisory Board.
- The Offeror must include the following in the justification:
 - 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).
 - Indicate the methods used to determine that no alternatives to HFT can be used (including, but not limited to, literature review and preliminary experiments)
 - Conduct and describe results from a literature review used to provide justifications.
 - Describe plans for the treatment of HFT and the disposal of HFT when research is complete.
 - 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

DOCUMENT GENERATION SYSTEM (DGS) SOLICITATION AND CONTRACT LANGUAGE ON HUMAN FETAL TISSUE

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.

- 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.
- HFT Compliance Assurance: Offeror shall provide a letter signed by the PD/PI 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.

SECTION M

****Use below for Solicitations that involve the use of Human Fetal Tissue ****

As authorized by 42 U.S.C. 217a, section 222 and section 492A of the Public Health Service (PHS) Act, as amended, a Human Fetal Tissue Research Ethics Advisory Board will review research involving the proposed use of Human Fetal Tissue (HFT) and the policies respecting these activities to ensure that it is utilized for research only when scientifically justifiable, and in the least amount possible to achieve the scientific outcomes. The Ethics Advisory Board will consider the use of alternative models, and review and verify the core ethical principles and procedures used in the process to obtain written voluntary informed consent for the donation of the tissue and recommend whether, in light of the ethical considerations, NIH should proceed with funding of the research project. The ethical considerations the Ethics Advisory Board will consider are those related to whether the nature of the research involved is such that it is unethical to conduct or support the research.

The Ethics Advisory Board will review the HFT justification, HFT Compliance Assurance, and draft Informed Consent form from all offerors still being considered for award. The Government will not make an award to an offeror who is not recommended for funding by Ethics Advisory Board. The recommendation of Ethics Advisory Board’s review of HFT justification is not subject to further review.

**DOCUMENT GENERATION SYSTEM (DGS) SOLICITATION AND CONTRACT LANGUAGE ON
HUMAN FETAL TISSUE**

****(INCLUDE BELOW, WHEN MANDATORY QUALIFICATION CRITERIA ARE USED.

ADDITIONAL INFORMATION ABOUT THIS ITEM:

1. The documentation which supports that the qualification criterion has been met MUST be contained in the offeror's proposal. The Contracting Officer should decide and indicate below whether the offeror will be required to either put all the qualification information into one area of the proposal or to provide an index in the proposal that will direct reviewers to the specific area of the proposal that addresses a particular mandatory qualification. Additionally, if the mandatory criteria must be met at some time other than at the time of Final Proposal Revisions, the CO should modify the language below.
2. **For Solicitations that include SECTION 508 COMPLIANCE requirements:** See HHSAR 315.304. A solicitation for EIT products and services (including EIT deliverables such as electronic documents and **reports** , unless the EIN products and/or services are incidental the project) shall include a separate technical evaluation factor (which may be in the form of a technical evaluation criterion or a **mandatory qualification criterion (but not both)** , as appropriate) developed by the CO, PO, and OPDIV Section 508 Coordinator to determine vendor compliance with applicable Section 508 accessibility standards. For a list of Section 508 Coordinators, See the OCIO Section 508 SharePoint site at: <http://sps.nihcio.nih.gov/OCIO/NIH/508/default.aspx> under "Documents," then "508 Contacts."

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **First Paragraph:** Select from the bracketed information, that which best describes the way the Contracting Officer would like to see the qualification information presented in the proposal. Delete the sentence that does not apply.
2. **Second Paragraph:** If it is anticipated that the contract will be awarded WITHOUT discussions, make sure that you select the phrase "Technical Proposals" from the drop-down box.
3. **Text Box:**
 - Include the specific qualification criterion that must be met.
 - When the Contracting Officer determines that **SECTION 508 COMPLIANCE** will be evaluated as a Mandatory Qualification Criterion, the HHS Section 508 Product Assessment Template should be used for evaluation purposes.)****

8. MANDATORY QUALIFICATION CRITERIA

Listed below are mandatory qualification criteria. THE OFFEROR SHALL [INCLUDE ALL INFORMATION WHICH DOCUMENTS AND/OR SUPPORTS THE QUALIFICATION CRITERIA IN ONE CLEARLY MARKED SECTION OF ITS TECHNICAL PROPOSAL. [PROVIDE AN INDEX WITHIN ITS TECHNICAL PROPOSAL WHICH DIRECTS THE REVIEWER(S) TO THE SPECIFIC AREA(S) OF THE TECHNICAL PROPOSAL THAT ADDRESS A PARTICULAR MANDATORY

**DOCUMENT GENERATION SYSTEM (DGS) SOLICITATION AND CONTRACT LANGUAGE ON
HUMAN FETAL TISSUE**

QUALIFICATION.]

The qualification criteria establishes conditions that must be met at the time of receipt of the proposal by the Contracting Officer for your proposal to be considered further.

Justification for the use of Human Fetal Tissue (HFT) obtained from elective abortions, HFT Compliance Assurance, and draft Informed Consent form.
--

**DOCUMENT GENERATION SYSTEM (DGS) SOLICITATION AND CONTRACT LANGUAGE ON
HUMAN FETAL TISSUE**

Section J. Attachment

HUMAN FETAL TISSUE OBTAINED FROM ELECTIVE ABORTIONS JUSTIFICATION

Offerors shall address each of the following topic areas:

- 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).
- Indicate the methods used to determine that no alternatives to HFT can be used (including, but not limited to, literature review and preliminary experiments)
- Conduct and describe results from a literature review used to provide justifications.
- Describe plans for the treatment of HFT and the disposal of HFT when research is complete.
- 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.
- 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.
- HFT Compliance Assurance: Offeror shall provide a letter signed by the PD/PI 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.