NIH PROPOSALS WITH HUMAN FETAL TISSUE (HFT)

Revised December 8, 2021

OVERVIEW

NIH Notice Regarding Requirements for Proposed Human Fetal Tissue Research: NOT-OD-19-128.
All verbiage within text boxes are copied directly from NIH SF424 guidance.

Applications proposing HFT that do not address these requirements will be administratively withdrawn. For further information on HFT policy refer to the NIH Grants Policy Statement, Section 2.3.7.11 Human Fetal Tissue from Elective Abortions, Section 4.1.14 Human Fetal Tissue Research and Section 4.1.14.2 Human Fetal Tissue from Elective Abortions.

SUPPLEMENTAL INSTRUCTIONS FOR HFT

SF 424 (R&R) Form

Cover Letter must be included and must include a statement that the proposed studies involve HFT.

Cover Page Supplement

4. Human Fetal Tissue Section

Does the proposed project involve human fetal tissue from elective abortions?

This field is required.

If the proposed project involves the use of human fetal tissue obtained from elective abortions (HFT), check "Yes" and complete the rest of the "Human Fetal Tissue" section.

If the proposed project does not involve the use of human fetal tissue obtained from elective abortions (HFT), check "No" and skip the rest of the "Human Fetal Tissue" section.

Additional Instructions for Multi-project:
Overall Component: If the use of human fetal tissue obtained from elective abortions (HFT) are proposed in any Component, then you must answer "Yes."

If the answer is "yes" then provide the HFT Compliance Assurance:

If the proposed project involves the use of human fetal tissue obtained from elective abortions (HFT), the applicant must 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 documenting that HFT was not obtained or acquired for valuable consideration. The PDF-formatted letter must be named 'HFTComplianceAssurance.pdf'.

If the answer is "yes" then provide the HFT Sample IRB Consent Form

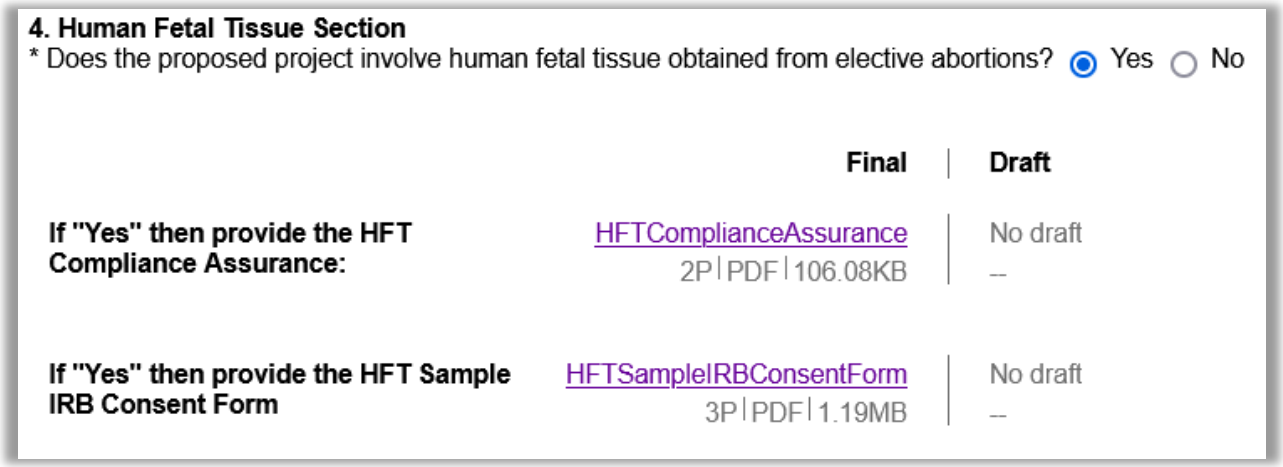
If the proposed project involves the use of human fetal tissue obtained from elective abortions (HFT), provide a blank sample of the IRB-approved consent form. The PDF-formatted form must be a blank sample and named 'HFTSampleIRBConsentForm.pdf'.

o The informed consent for use of HFT from elective abortions 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, that informed consent for donation of HFT occurred after the informed consent for abortion was obtained will not affect the method of abortion, and that no enticements, benefits, or financial incentives were used at any level of the process to incentivize abortion or the donation of HFT. The form must be signed by both the woman and the person who obtains the informed consent.

For further information on HFT policy refer to the NIH Grants Policy Statement, Section 2.3.7.11 Human Fetal Tissue from Elective Abortions, Section 4.1.14 Human Fetal Tissue Research and Section 4.1.14.2 Human Fetal Tissue from Elective Abortions.

Section 4 – Human Fetal Tissue Section: If 'yes' selected, naming convention of files uploaded must match SF424 instructions.

- **HFTComplianceAssurance.pdf**
- **HFTSampleIRBConsentForm.pdf**



4. Human Fetal Tissue Section

* Does the proposed project involve human fetal tissue obtained from elective abortions? (●) Yes ( ) No

	Final	Draft
If "Yes" then provide the HFT Compliance Assurance:	HFTComplianceAssurance 2P | PDF | 106.08KB	No draft --
If "Yes" then provide the HFT Sample IRB Consent Form	HFTSampleIRBConsentForm 3P | PDF | 1.19MB	No draft --

R&R Budget Form

Special Instructions for Applications Proposing the Use of Human Fetal Tissue*: If the use of human fetal tissue obtained from elective abortions (HFT) (as defined in the NIH Grants Policy Statement) is included in the proposed application, regardless of whether costs will be incurred, it must be noted as a single line item here. The line item must be titled "Human Fetal Tissue Costs" (without quotation marks, but following exact phrase and spacing). The line item must only be used for HFT costs and cannot include or be combined with any "Other" costs. If no cost will be incurred (e.g. if HFT will be donated), enter "0" in the "Funds Requested" column. Details regarding HFT must be specified in the Budget Justification attachment (L), pursuant to the instructions.*

- **Budget Type:** Regardless of direct cost requested, the R&R Budget Form must be used. The Modular Budget Form is not allowed.
- **Section F.8-17:** Must include a "Human Fetal Tissues Costs" line regardless of whether or not costs will be incurred to obtain HFT.
  - Do not include or combine this line with any other costs.
  - If no costs will be incurred, enter "0" in the "Funds Requested" column
- **Budget Justification:** Clearly label HFT justification and include a detailed justification including the quantity, types and sources of the HFT, including the stage of fetal development. This information must be included for the HFT are assigned to the grant or if the HFT is acquired under the grant at no cost. If no cost would be incurred enter '0'.

Special Instructions for Applications Proposing the Use of Human Fetal Tissue*: If the use of human fetal tissue obtained from elective abortions (HFT) (as defined in the NIH Grants Policy Statement) is included in the proposed application include a detailed justification including the quantity, type(s), and source(s) of the HFT, including the stage of fetal development. This information must be included if costs for the HFT are assigned to the grant or if the HFT is acquired under the grant at no costs. The HFT justification must be clearly labeled in the budget justification attachment.*

Research Plan

Research Strategy – Approach Section:

- Use the **specific heading**: "Human Fetal Tissue Research Approach"
- Describe the proposed characteristics, procurement, and procedures for the research use of HFT. The description should be sufficiently detailed to permit meaningful evaluation by NIH.

- Justify the use of HFT in the proposed research by indicating the following:
  - Why the research goals cannot be accomplished by using an alternative to HFT.
  - What methods were used (e.g. literature review, preliminary data) to determine that alternatives could not be used.
  - Results from a literature review used to provide justifications.
  - Plans for the treatment of HFT and the disposal of HFT when research is complete.
  - Description of planned written, voluntary, informed consent process for cell/tissue donation, or description and documentation of process if cells/tissue were already obtained.