New NIH Requirements for Research with Human Fetal Tissue effective 9/25/2019

In June 2019, HHS released a statement on changes to regulations and the NIH Grants Policy Statement (GPS) related to research involving human fetal tissue (HFT).


Research involving 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:

- 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).

Currently awarded NIH funded research projects are not affected during their currently approved project period. However, new research grant applications or current research projects in the competitive renewal process that propose to use HFT from elective abortions must meet specific requirements in applications for: the cover letter, research plan, budget justification, and budget details.

Adding HFT to an already funded project is considered a change of scope & requires a competing revision application which also must follow NOT-OD-19-028 guidance.
These requirements are in addition to the existing NIH Grants Policy Statement on Human Fetal Tissue Research (4.1.14) and NIH expectations to obtain informed consent (NOT-OD-16-033).

NOT-OD-19-028 includes terms and conditions that will be added to agreements awarded with HFT or that add HFT, on or after Sept. 25, 2019.

Application/Proposal Budget Change Requirements

Research Strategy Approach section must include a detailed justification for use of HFT using this heading “Human Fetal tissue Justification”.

Research Proposals

- Must use R&R Budget Form, (modular budget forms are not allowed)
- Provide detailed budgets for cost of acquisition of HFT,
- Describe and document the quantity, type, and source of HFT, in the budget justification,
- Include certification that valuable consideration has not been provided for acquisition of HFT.

Donated or Existing HFT: Indicate HFT line Item Costs as a value of $0.00.

Complex grant applications (with an overall budget and multiple project/core budgets): Include HFT both in the overall budget form/justification and each project/core budget in which HFT use is occurring (even if there is no HFT cost).

R&D Contract Proposals:

- Describe & document the quantity, type, and source of the HFT in the budget justification section of the proposal.
- Provide a line item budget cost for acquisition of HFT or indicate cost is $0.00 if using donated or existing HFT.

If you are working on a proposal application that includes HFT, review detailed instructions within NOT-OD-19-128. NIH will NOT review applications that do not address all of the required information, including the detailed budget.

Resources

- NIH Grants Policy Statement Human Fetal Tissue Research 4.1.14
- NIH: NOT-OD-16-033 – Informed Consent for Human Fetal Tissue Research
- HHS June 5, 2019 Statement