



## Changes to NIH Requirements Regarding Proposed Human Fetal Tissue (HFT) Research

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.

Changes for grants proposing to use HFT are effective for **due dates on or after 9/25/2019**.

- **Detailed budget** required even if less than \$250,000 in all budget periods. Modular budgets cannot be used for applications proposing use of HFT.
- Budget **must include an 'other cost' line item for 'Human Fetal Tissue Costs'** even if the cost is zero (e.g. donated or existing). The line item name must be exactly as shown because NIH electronic systems will be using validations looking for this text string.
- **Budget justification** must include a detailed justification including the quantity, type(s), and source(s) of the HFT, including the stage of fetal development. This information should be included if costs for the HFT are assigned to the grant or if HFT is acquired under the grant at no cost.
- A new section is required in the **Research Strategy** document, which must be headed: Human Fetal Tissue Research Approach. Page limits will not be changed to accommodate this additional information requirement.
- **Cover letter** is required with a statement that HFT is being used in the proposed research project. This is required regardless of whether human subjects are involved in the project or whether there are costs associated with the human fetal tissue.

**Funded Grants:** the addition of HFT to a funded grant is a change in scope and will require the submission of a competing revised application.

**Training awards and individual fellowships:** may not propose HFT research.

See [NOT-OD-19-128](#) for complete details, including information about contracts.

If you have any questions, please [contact OSRS](#).