NIH Guide Notice: Changes to NIH Requirements Regarding Proposed Human Fetal Tissue Research

On July 26, the NIH issued a Guide Notice (NOT-OD-19-128) to inform the extramural research community of upcoming HHS requirements regarding research supported by the NIH that involves the proposed use of human fetal tissue (HFT) obtained from elective abortions.

Changes outlined below will apply to competitive applications for grants and cooperative agreements submitted for due dates on or after September 25, 2019. Training awards and individual fellowships, may not propose research using HFT (T15, T32, T34, T35, T36, T37, T90/R90, TL1, TL4, F05, F30, F31, F32, F33, F37, F38, F99, K12, D43, D71).

Note: These requirements are in addition to the existing requirements as detailed in the NIH Grants Policy Statement (4.1.14).

For competing grant applications, NIH will require applicants/contract offerors to do the following:

- *In the Approach section of the Research Strategy*, applicants must justify the need for use of HFT, and it must be described with a heading titled, "Human Fetal Tissue Justification." Description should be "sufficiently detailed to permit meaningful evaluation by NIH". The justification must include:
    1) **Why the research goals cannot be accomplished using an alternative to HFT** (examples include: induced pluripotent cells not developed from HFT or organoids not developed form HFT, animal models, in-vitro models not developed from HFT, computational models, etc.)
    2) Description of the **methods used to determine that no alternatives** to HFT can be used (literature review, preliminary experiments, etc.)
    3) Conduct and describe results from a **literature review** that is used to provide this justification
    4) Describe plans for treatment of HFT and how it will be disposed when research is finished
    5) Describe planned written, voluntary, **informed consent process** for cell/tissue donation; or provide a description and document of the process that was used if the cells were already obtained
        - Include a sample of IRB-approved informed consent form when submitting the application
        - The informed consent for donation of HFT must include language that acknowledges informed consent to donate HFT was obtained by someone other than the person who obtained informed consent for abortion,

occurred after the informed consent for abortion, and will not affect the methods of abortion.

- Acknowledge that **no financial incentives** were used at any level of the process to incentivize abortion or the donation of HFT (signed by both the woman and the person obtaining informed consent)

Budget changes

- **NIH will not be accepting modular budgets for applications**. The new policy will require all applicants for research involving HFT to use the Research & Related (R&R) Budget Form. In using this form, applicants must provide the detailed budgets **(e.g. line-item costs)** for the cost of acquisition of HFT, and also sufficiently describe and document in the budget justification the quantity, type, and source of the HFT
    1) Same policy applies for contract proposals
- ***Applications that do not address all of the required information, including the detailed budget, will be withdrawn from consideration.***

Peer Review

- For grants and contracts, evaluation of the scientific appropriateness/justification of the use of HFT *will be allowed to affect individual score* in the Approach section
- **Applications involving HFT that fall within a fundable scoring range will be assessed for policy compliance by an ethics advisory boards as promulgated by HHS**
    1) Committee will assess the compliance with the policy requirements described in this Notice
    2) Additional consideration will be given to the scientific justification and consideration of alternatives for the use of HFT
    3) The committee will review and verify the core ethical principals and procedures used in the process for obtaining written voluntary informed consent for the donation of the tissue
    4) will recommend whether NIH should fund the research project

Terms and Conditions

List of terms and conditions that will be **added** to all grants and cooperate agreements awarded with HFT on or after September 25. The recipient institution must assure:

- PD/PI is complying with all applicable laws and HHS/NIH policies
- Informed consents were obtained and signed
- NIH award recipient has documentation from the donating organization assuring adherence to the requirements of the informed consent process

- ***NIH awardee will acquire this assurance for <u>each year</u> 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 (8.4.2)***

<u>Changes to Application instructions</u>

- ***Page limits will not be increased to accommodate these requirements.***
- Added sections for these specific policy changes. For example:
  - Under the introductory part of the Research strategy section, there will be a new section titled "Note for Applications Proposing the Use of the HFT"
  - In the Approach subsection, there will be a new bullet point - "Human Fetal Tissue Research Approach" for applicants to describe and justify the use of HFT as described in this notice

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NOTE: This is a brief overview of the policy changes in NIH requirements regarding proposed human fetal tissue research. FASEB will continue to analyze the details of the document and provide updates where appropriate.