

# NIH Update

OFFICE OF POLICY FOR EXTRAMURAL RESEARCH  
ADMINISTRATION, OER, NIH



National Institutes of Health

# FY 2020 NIH GRANTS POLICY STATEMENT

**The updated NIH GPS will be available early in Fiscal Year 2020.**

- The revised Grants Policy Statement will be applicable to all NIH grants and cooperative agreements with budget periods beginning on or after October 1, 2019.

Until publication, NIH will continue to publish interim grants policy changes through the issuance of NIH Guide Notices via the NIH Guide for Grants and Contracts.

*Stay tuned for additional information!!!*



# NIH POLICY ON OTHER SUPPORT

- Other Support has long been defined in the NIH Grants Policy Statement ([1.2 Definitions](#) and [2.5.1 Just-in-Time](#))
  - “All financial resources, whether Federal, non-Federal, commercial or organizational, available in direct support of an individual's research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards.”
- NIH issued [NOT-OD-19-114](#) to clarify the existing Other Support requirements
- Our Goal: Facilitate the transparency of all research activities, both domestic and foreign not merely financial.



# IDENTIFYING FOREIGN COMPONENTS

Key measures for identifying foreign components are as follows:

- Is a portion of the project being conducted outside the US?
  - No – not a foreign component
  - Yes – are the activities being conducted outside of the US significant?
  - Indicators include:
    - collaborations with investigators at a foreign site anticipated to result in co-authorship;
    - use of facilities or instrumentation at a foreign site; or
    - receipt of financial support or resources from a foreign entity.
- Foreign components require NIH *prior* approval



# WHAT ABOUT FCOI?

- Requirements found in 42 CFR Part 50, Subpart F
- Investigators must disclose their significant financial interests to their institution
- This requirement includes financial interests received from a foreign entity
- Separate and distinct from other support and foreign components



# CHANGES TO NIH REQUIREMENTS REGARDING PROPOSED HFT RESEARCH

- For **competing applications and competing revisions submitted after Sept. 25, 2019**, NIH will require applicants/contract offerors to address HFT requirements by providing a justification of the use of HFT, details regarding procurement and costs, and information about how the applicant/contract officer will use HFT.
- 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 TO NIH REQUIREMENTS REGARDING PROPOSED HFT RESEARCH

- Applications that do not address all of the required information, including the detailed (non-modular) budget as specifically instructed, will be administratively withdrawn and not reviewed.
  - Specific guidelines for information and forms that must be included in applications are specified in the Guide Notices.
    - Note: If HFT are 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**.
- Applications and proposals involving HFT that fall within a fundable scoring range will be assessed by an [ethics advisory board](#) comprised of scientists, bio-ethicists and others as specified in section 492A of the Public Health Service Act.





# REQUIREMENT FOR ORCID ID BEGINNING IN FY 2020

- In **October 2019**, the requirement for ORCID identifiers will be incorporated into the appointment process for trainees, scholars, and participants supported by institutional research training, career development, and research education awards that require appointments through the xTrain system, including the following:
  - T03, T15, T32, T34, T35, T37, T42, T90/R90, TL1, TL4, TU2, K12/KL2, R25, R38, RL5, RL9
- Beginning with receipt dates on or after **January 25, 2020**, the requirement for ORCID identifiers will be enforced at the time of application for individual fellowship and career development awards, including the following:
  - F05, F30, F31, F32, F33, F37, F38, F99/K00, FI2, K01, K02, K05, K07, K08, K18, K22, K23, K24, K25, K26, K38, K43, K76, K99/R00





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