### NIH Update

OFFICE OF POLICY FOR EXTRAMURAL RESEARCH ADMINISTRATION, OER, NIH





#### NIH FY 2020 Budget News

As of Dec. 20, 2019, NIH is funded under the Further Consolidated Appropriations Act, 2020 (<u>H.R.1865</u>).

- NIH Budget for FY 2020 is \$41.68 billion, a 6.65% increase over FY 2019
- Specific increases for All of Us, the BRAIN Initiative, Alzheimer's Research and the Childhood Cancer Data Initiative
- NIH Fiscal Policy and Legislative Mandates updates for awards in FY2020 are forthcoming.
- Executive Schedule has been updated effective 1/5/20. Executive Level II is now \$197,300. Guide notice regarding salary cap forthcoming.





### FY 2020 NIH GRANTS POLICY STATEMENT

#### The updated NIH GPS has been published!

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

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





### New NIH "FORMS-F" Application Forms and Instructions

#### For Due Dates on or after May 25, 2020:

The following application forms include substantive changes (i.e., new/deleted/modified fields). All other forms include only an OMB expiration date change.

- PHS 398 Career Development Award Supplemental Form
- PHS 398 Cover Page Supplement
- PHS Assignment Request form
- PHS Fellowship Supplemental Form
- PHS Human Subjects and Clinical Trials Information
- SBIR/STTR Information

See <u>High-level Summary of Form Changes in FORMS-F Application Packages</u> for a full list of form changes. We will notify the community if we determine additional changes are needed.

For due dates on or before May 24, 2020, applicants must continue to use the application form packages and instructions (FORMS-E) posted with our funding opportunity announcements despite the expiration dates noted on each form.





## NIH Current Policy on Other Support

Other Support is defined in the NIH Grants Policy Statement (1.2 <u>Definitions</u> and 2.5.1 <u>Just-in-Time</u>), which was updated in December 2019

• "All resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant. This includes resource and/or financial support from all foreign and domestic entities, including but not limited to, financial support for laboratory personnel, and provision of high-value materials that are not freely available (e.g., biologics, chemical, model systems, technology, etc.)."

Our Goal: Facilitate the transparency and reporting 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 <u>from elective abortions</u> 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 <u>ethics advisory board</u> 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





If these dates or location don't work for you, consider the

Fall 2020 NIH Regional Seminar in Nashville, TN ~ Oct. 28-30

Registration opens late January. More info & Listserv at https://grants.nih.gov/news/contact-in-person/seminars.htm.