NIH PUBLISHES REVISED GRANTS POLICY STATEMENT (GPS rev. December 2019) FOR FY 2020

Dec 20, 2019

NOT-OD-20-043 announced the publication of the updated NIH Grants Policy Statement (NIHGPS, rev. December 2019). The updated GPS applies to all NIH grants and cooperative agreements with budget periods beginning on or after October 1, 2019 and supersedes the NIH GPS, rev. October 2018 as a standard term and condition of award. Prior versions of the GPS will remain available as a standard term and condition of NIH grants and cooperative agreements with budget periods that began before October 1, 2019.

Significant changes include, but are not limited to:

Section 2.3.5 Types of Funding Opportunity Announcements ? introduction of Notices of Special Interest (NOSI), which highlights a specific topic of interest and directs applicants to one or more active FOAs (usually a parent announcement) to apply for the initiative described.

Sections 2.3.7.11 and 4.1.14.2 Human Fetal Tissue from Elective Abortions (HFT) ? requires applicants proposing use of HFT to provide justification for the use of HFT, details regarding procurement and costs, and information about how HFT will be used. Reiteration of Sections 498A and 498B of the PHS Act (42 U.S.C. 289g-1 and 289g-2) specific requirements and prohibitions on research involving human fetal tissue and how HHS Regulations for Protection of Human Subjects 45 CFR 46.204 and 46.206 may be specifically relevant to such research. The requirement expects grantees and contractors to maintain appropriate documentation and required informed consent and acknowledgement that human fetal tissue was not received or transferred for valuable consideration.

Section 4.1.3.1 Policy on Dissemination of NIH-Funded Clinical Trial Information ? additional language requiring recipients of NIH funding who conduct non-exempt human subjects research that is subject to the revised Common Rule and is a clinical trial, as defined in 45 CFR 46.102(b), be aware that for each trial one IRB-approved consent form must be posted on a designated public federal website in accordance with 45 CFR 46.116(h) after recruitment closes and no later than 60 days after the last study visit by any subject as required by the protocol.

Section 4.1.27 Research Misconduct ? clarifies institution?s responsibilities in handling suspected or confirmed research misconduct in NIH-funded research and requirement for recipient and subrecipient institutions (foreign or domestic) to hold assurances with the HHS Office of Research Integrity (ORI) and follow procedures to communicate matters related to research misconduct proceedings to the NIH and ORI.

Section 4.2.1-12 Appropriations Mandates ? updated per 2019 Appropriations.

Section 11.3.13.1 Statement of Appointment ? the requirement of the Open Researcher and Contributor Identifiers (ORCID) is added to 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: T03, T15, T32, T34, T37, T42, T90/R90, TL1, TL4, TU2, K12/ KL2, R25, R38, RL5, and RL9. **Appointments will not be accepted unless an ORCID is linked to an individual’s Personal Profile in the eRA Commons.**

Section 12.4.1 Application ? beginning with receipt dates on or after January 25, 2020, the requirement for an ORCID will be enforced at the time of application for individual fellowship (F series) and career development (K series) awards. **eRA system validations will check for ORCIDs and applications will not be accepted unless an ORCID is linked to the PD/PI’s eRA Commons Personal Profile.**

NIH will continue to publish interim grants policy changes, each change will be described including applicability, effective date and language to implement any changes as a term or condition of awards. Check the NIH UPDATES or NEWS pages for highlights on Notices that announce the implementation of future policy changes.

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