NIH Update

Federal Demonstration Partnership

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National Institutes of Health

NIH FY 2019 Budget News

- NIH is funded under the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, (Public Law 115-245) signed by President Trump on September 28, 2018.

- NIHs FY 2019 budget amount is $39.3 billion which represents a 5.6 percent increase over the FY 2018 final funding level.

- 2019 Legislative Mandates posted **NOT-OD-19-030**.

NRSA FY 19 Stipends

NIH announced stipend levels for trainees and fellows supported by Kirschstein NRSA awards in FY 2019.

Tuition and Fees

- *Undergraduate and Predoctoral Trainees and Fellows:*
  - *60% of requested amount up to $16,000 per year*
  - *60% of requested amount up to $21,000 per year (enrolled in a program that supports formally combined, dual-degree training)*
- *Postdoctoral Trainees and Fellows:*
  - *60% of requested amount up to $4,500 per year.*
  - *60% of requested amount up to $16,000 per year (If the trainee or fellow is enrolled in formal degree-granting training)*

Training Related Expenses (Training Grant) and Institutional Allowance (Fellowship)

- *Postdoctoral Fellows and Trainees:* $10,850

Institutional Allowance for Federal and For-Profit Individual Fellows

- *Postdoctoral Fellows:* $9,750

See NOT-OD-19-036 for additional information.

NRSA Postdoctoral FY 19 Stipends

Career Level	Years of Experience	Stipend for FY 2019	Monthly Stipend
Predoctoral	ALL	$24,816	$2,068
Postdoctoral	0	$50,004	$4,167
	1	$50,376	$4,198
	2	$50,760	$4,230
	3	$52,896	$4,408
	4	$54,756	$4,563
	5	$56,880	$4,740
	6	$59,100	$4,925
	7 or More	$61,308	$5,109

Policy Updates

Extension of Comment Period on Draft Report: Reducing Administrative Burden to Researchers for Animal Care and Use in Research

The NIH Office of Laboratory Animal Welfare (OLAW) is still seeking input on the draft report by the 21st Century Cures Act, Section 2034(d) Working Group on Reducing Administrative Burden to Researchers for Animal Care and Use in Research.

The RFI is a coordinated effort of the Director of the National Institutes of Health, in collaboration with the Secretary of Agriculture and the Commissioner of Food and Drugs, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals.

The comment period was extended by 15 days and will now close on February 20, 2019.

- All responses to this RFI must be submitted electronically at https://grants.nih.gov/grants/rfi/rfi.cfm?ID=83

Notice of Clarification Regarding Harassment and Discrimination Protections in NIH Training Applications

All NIH training grant applications submitted on or after January 25, 2019, must include information regarding an institutions commitment to ensuring that proper policies, procedures, and oversight are in place to prevent discriminatory harassment and other discriminatory practices.

- This information is to be included in the same letter with the information about the applicant institutions commitment to the planned program. Separate letters are not required.

The signed letter should be on institutional letterhead from a President, Provost, Dean, or other key institutional leader with institution-wide responsibilities.

NIH Implementation of the Final Rule on the Federal Policy for the Protection of Human Subjects (Common Rule)

The Final Rule (45 CFR part 46) is intended to enhance protections for human research participants, facilitate valuable research, and reduce burdens for investigators, research institutions, and Institutional Review Boards (IRBs)

HHS issued a Final Rule delaying the implementation until January 21, 2019.

The following provisions will apply to studies subject to the Revised Common Rule:

- Removal of the requirement for IRBs to review grant applications related to the research
- For NIH-funded or supported clinical trials, informed consent documents must be posted on a public federal website
    - After recruitment closes, no later than 60 days after last study visit
- Changes to categories of research qualifying for exemption
- Removal of the requirement for annual review for certain categories of research.

Note: The NIH policy on the use of single IRBs in multi-site studies took effect in January 2018.

See NOT-OD-19-050

Removal of the Requirement for Institutional Review Board Review of NIH Grant Applications and Contract Proposals Related to Research

Effective January 21, 2019, NIH will no longer require IRB review of an entire grant application or contract proposal.

- Grantees and offerors will be required to certify to NIH that an IRB has reviewed and approved all NIH-supported non-exempt human subjects research (i.e., protocols) and further provide NIH with the date of final IRB approval.

The certification and IRB date requirements align with current NIH policy and Just-in-Time procedures.

- The only change to NIH policy is that IRB review is no longer required for NIH grant applications and contract proposals.

Under no circumstances may NIH-supported non-exempt human subjects research be initiated prior to meeting the requirements for conducting an IRB review of protocols as well as obtaining the date of final IRB approval.

See NOT-OD-19-055

FY 2019 Academic Research Enhancement Award (R15) Program Changes

The FY 2019 NIH Academic Research Enhancement Award (AREA) program will focus on supporting grants to undergraduate-focused institutions that do not receive substantial funding from NIH (must meet the new criteria), rather than all institutions with less than $6 million of NIH support.

- NIH will also continue to provide R15 research enhancement opportunities for health professional and graduate schools under separate announcements.

****Existing R15 FOAs referencing the ineligibility list will not be reissued.****

See NOT-OD-19-015 for additional information

Policy Reminders

FY 2019 NIH Grants Policy Statement

The updated NIHGPS was posted on October 23, 2018.

- The revised Grants Policy Statement is applicable to all NIH grants and cooperative agreements with budget periods beginning on or after October 1, 2018.

- A summary of the significant changes is available online.

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

Inclusion Policy Changes

Individuals of all ages, including children, must be included in all human subjects research conducted or supported by NIH, unless there are ethical reasons not to include them.

- Applies to all competing grant applications for due dates on or after **January 25, 2019.**

- Policy has been expanded to include individuals across the lifespan.

- Clinical research studies are expected to submit individual level data on sex/gender, race, ethnicity and age at enrollment with annual progress reports.

See NOT-OD-18-116

Prospective Basic Science Studies Involving Human Participants

Studies that meet the NIH-definition of clinical trials and the Federal definition of basic science

- Delayed enforcement of registration and reporting in ClinicalTrials.gov for prospective basic science studies involving human participants until September 24, 2019.
- FOAs specifically for prospective basic science studies involving human participants.
- Leniency for incorrect FOA submission.
- Request for Information (RFI) was published seeking input from stakeholders on how best to implement the NIH CT policy for this subset of trials.

Policy Update: Early Stage Investigator Status (ESI)

NIH considers requests for extension of the ESI period on a case by case basis.

Almost 50% of the ESI extension requests are related to childbirth, effective immediately, NIH will approve an ESI extension of one year for childbirth within the ESI period.

- PDs/PIs must provide the child's date of birth in the extension request justification on the NIH Extension portal

NIH policy on extension criteria for Early Stage Investigators (ESIs).

For additional information see NOT-OD-18-235

FCOI: Investigator Disclosures of Foreign Financial Interests

- Reminder that 42 CFR Part 50, Subpart F, Objectivity of Research, applies to each institution, domestic and foreign, that applies for or receives NIH research funding in the form of grants or cooperative agreements
- Regulation applies to:
  - Prime Recipients
  - Subrecipients
  - Domestic and Foreign
  - Each investigator who is planning to participate in, or is participating in, such research
  - *Does not apply to Phase 1 SBIR/STTR awards*
- Investigators must disclose all financial interests received from a foreign institution of higher education or the government of another country

See NOT-OD-18-160 and the FCOI Website

Bayh-Dole Act

The Bayh-Dole Act (1980) – few changes since 1980.

- Codified at 35 U.S.C. § 200;
- Implemented at 37 C.F.R. 401
- Revised April 13, 2018. NIH implementation for all subject inventions made with new NIH grant funding on or after October 1, 2018.

Applies to most federal funding agreements.

Sets forth rights and responsibilities of grantee/contactor and Government for inventions and discoveries made in whole or in part with federal funding.

For additional information see NOT-OD-18-233

Revised Process for SBIR/STTR Life Cycle Certifications

Effective January 1, 2019, NIH will require SBIR/STTR grant recipients to submit the Life Cycle Certification within the Interim and Final-RPPR.

- Reporting milestones remain unchanged.

Revised policy does not impact the SBIR Funding Agreement Certification required by all SBIR/STTR applicants for new or renewal grants that is required prior to award of a new or a competing renewal award.

For additional information see NOT-OD-19-025

Other Transaction Authority (OTA)

NIH uses OTA when it needs greater flexibility to identify and engage nontraditional research partners, or to engage traditional partners in new ways, and negotiate terms and conditions that will concentrate their efforts, spur innovation, and facilitate collaborative problem solving.

- NIH's unique activity code (OT1, OT2, OT3) to track funding linked to OTAs.
- Other Transaction Authority was recently used for the following programs:
  - Stimulating Peripheral Activity to Relieve Conditions (SPARC)
  - All of Us (AoU)
  - Human BioMolecular Atlas Program (HuBMAP)

See RFA-RM-18-001 and OTA-RM-18-012 for details.

New to Working with NIH? Consider this unique opportunity to hear from and visit with over 100 NIH experts.

Don’t Miss the NIH Regional Seminar on Program Funding & Grants Administration in Baltimore, MD

May 15-17, 2019

https://regionalseminars.od.nih.gov/baltimore2019/

Questions?