

NIH Update

SRA International North Carolina Chapter
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NATIONAL INSTITUTE OF MENTAL HEALTH



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](#).



National Institutes of Health

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
Predocctoral	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

FY 2019 NIH Grants Policy Statement

The updated NIHGPS has been posted!

- 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.

Simplified Acquisition and Micro-purchase Thresholds

- On June 20, 2018, the Office of Management and Budget (OMB) issued a [memorandum](#) raising the threshold for
 - **micro-purchases to \$10,000, and**
 - **simplified acquisitions to \$250,000**
- Applies to all recipients of federal financial assistance
- The memo also implements an approval process for certain institutions that wish to request micro-purchase thresholds higher than \$10,000.
- NIH has updated its policy to reflect the new thresholds.
- This change is effective immediately

See [NOT-OD-18-129](#)

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](#)

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

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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.



See [NOT-OD-19-056](#) for additional information

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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.

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.

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.
- New FOAs specifically for prospective basic science studies involving human participants.
- Leniency for incorrect FOA submission.
- Request for Information was issued, and NIH is reviewing the comments received. Requested input from stakeholders on how best to implement the NIH CT policy for this subset of trials.



Documentation of Personnel Expenses

NIH has clarified the applicability and flexibility of the requirements for documentation of personnel expenses for its grants and cooperative agreement recipients.

- Charges to Federal awards for salaries and wages must be based on records that accurately reflect the work performed.
- Budget estimates alone do not qualify as support for charges, but may be used for interim accounting purposes.
- Records may reflect categories of activities expressed as a percentage distribution of total activities.
- When recording salaries and wages charged to Federal awards for Institutes of Higher Education, a precise assessment of factors that contribute to costs is not always feasible, nor is it expected.



Integrity in Peer Review

Maintaining integrity in the peer review process is essential.

Officials at applicant organizations, PIs, and other individuals named in applications or proposals should:

- Not contact reviewers on the study section evaluating their application.
- Not send information or data directly to a reviewer on the study section evaluating his/her application.
- Should immediately contact the SRO if contacted

Each peer reviewer must read the [NIH Confidentiality and Non-Disclosure Rules](#), and certify that he or she fully understands and will comply with the confidential nature of the review process.

If NIH determines that a situation involves a breach of integrity, NIH may take action including

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).

Updates to NIH Policy on ESI Application Status

NIH will automatically update the ESI status of an application within eRA Commons as follows:

- If a PD/PI updates his/her degree or residency information after submission of an R01 or R01-equivalent application, or if an investigator requests and/or receives an extension of ESI status after submitting an R01 or R01-equivalent application, the application will be reviewed with the designation assigned at the time of submission.
 - Within eRA Commons, the status of the pending application will be updated after release of the Summary Statement to acknowledge ESI-application eligibility.
- If an ESI-eligible application is awarded and the same PD/PI has an R01 or R01-equivalent application pending review, the pending application will be reviewed as an ESI-eligible application.
 - However, the status of the pending application will be updated after release of the Summary Statement to acknowledge the application is no longer ESI-eligible.

The goal of this change is to minimize the need for manual change requests by applicants after submission of an application, while still allowing consideration of ESI status at the time of a funding decision.

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

Revised Guidance on Protecting Life in Global Health Assistance

- Revised guidance extends the applicability of the PLGHA policy to foreign NGO subrecipients of U.S. state or local governmental entities, including state universities, (U.S public institutions).
 - Therefore, all foreign NGOs (e.g. foreign private institutions) directly supported by or subrecipients of U.S. public or private NGOs that receive U.S. global health assistance; specifically, PEPFAR, are subject to implementation and enforcement of PLGHA.
- U.S. based public and private universities are prohibited from issuing a sub-award to a foreign NGO unless that foreign NGO agrees to abide by the terms of the PLGHA policy.
 - For purposes of the policy, a foreign NGO is a for-profit or not-for-profit nongovernmental organization not organized under the laws of the United States, any U.S. State or Territory, the District of Columbia, or the Commonwealth of Puerto Rico.

See [NOT-OD-19-079](#) and the [NIH Protecting Life in Global Health Assistance Website](#)



Upcoming Change in Federal-wide Unique Entity Identifier Requirements

- Federal-wide transition from the DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) to a new Government-owned unique entity identifier (UEI).
 - Effective December 2020, the system for Award Management (SAM) will become the central repository for the new SAM Managed Identifier (SAMMI) that will be incorporated into an institution's SAM registration.
- The transition from DUNS to SAMMI is ongoing, and GSA will provide details to agencies related to the full implementation by December 2020.
- NIH will provide updates and guidance to recipients on changes to policies and procedures as additional information becomes available.

See [NOT-OD-19-098](#)



Small Business Organization Information Pulled from SAM Record Rather than Grant Application Form

- NIH will use the Small Business Organization (SBO) Type information provided in the System for Award Management (SAM) entity record to identify a small business organization as Women Owned or Socially and Economically Disadvantaged at time of application submission
- Resulting Changes:
 - The DUNS provided on the SF424 R&R form will be used to look-up the SAM information.
 - The SF424 R&R data entry screen in ASSIST no longer allows small business organizations to use the SBO Type check boxes.
 - SBO Type information submitted using other submission methods will not be retained.

See [NOT-OD-19-088](#)

Clarification: Fixed Amount Award Definition and Implementation For Clinical Trials

NIH is acknowledging that no changes have been made to our current capitation funding model and recipients can continue to distribute capitation funding consistent with their current institutional policies.

- Recipient have questioned whether they are required to use fixed amount subawards to distribute capitation funds.

Fixed Amount Subaward:

- The total value of the award is negotiated upfront.
- Requires the pass-through entity to know both the unit price and the total number of units that will be provided.

Fixed-rate agreement:

- While there is a negotiated cost per unit, e.g. per patient cost in a clinical trial (or participant in a non-Clinical Trial Human Subjects Study) the total amount of the award may be unknown when the agreement is created.
- Agreement is based on a "fixed rate" as opposed to a "fixed amount" as defined by [45 CFR 75.201](#).
- Prior approval is not required to enter into this type of agreement provided there are no other factors that would require NIH prior approval consistent with NIHGPS, section [8.1.1.4](#)

Update to the NIH/AHRQ/NIOSH Policy on Post-Submission Materials

Applicability: Applications submitted for due dates on or after May 25, 2019

What Will Change

For applications for Training Grant (T series) applications submitted for due dates on or after May 25, 2019, a list of publications up to three pages in length will be accepted as post-submission materials.

- This replaces the former one-page limit for the post-submission publication list.

Clarifications

This Notice also provides the following clarifications:

- Preprints and Other Interim Research Products ([NOT-OD-17-050](#)) are not accepted as post-submission materials because they do not represent unforeseen events.
- Missing or corrected materials cannot be submitted after the application due date unless submission of that material is specifically listed in this Notice (below) as allowable post-submission material(s).
- Materials resulting from change of institution, or change of PD/PI, that occurs between application submission and peer review must be sent to the SRO managing the review with a cc: to the Division of Receipt and Referral (csrdrr@mail.nih.gov); after review materials should be sent to the Grants Management Specialist listed in eRA Commons for that application



Special Initiatives to Keep on the Radar:

- [NOT-OD-19-059](#) - Request for Information (RFI): Soliciting Additional Input to the NIH 2018 Tribal Consultation on the Opioid Crisis in Indian Country
- [NOT-OD-19-070](#) - Notice of Availability of Funds for Revision Applications for Research Centers with a Focus in Chronic Disease and the Reduction of Health Disparities (P50, P30, U54)
- [NOT-OD-19-071](#) - Notice of Availability of Competitive Supplements/Revisions for the INCLUDE (Investigation of Co-occurring Conditions across the Lifespan to Understand Down syndromE) Project (Competitive Supplement/Revision Clinical Trial Optional)



Electronic Submission & eRA Commons

RPPR -Institutional Delegations and Decimal in Effort Reporting

**Institutional delegations for Interim and Final RPPRs
now align with delegations for annual RPPRs**

- PD/PI may delegate initiation to a program assistant
- SO may delegate authority to PD/PI to submit an RPPR*

**Data fields for effort reporting will be modified to enable use of
decimals rather than a whole number.**

*if consistent with institutional policy

See [NOT-OD-18-202](#) for additional information

Advance Notice of Transition to the xTRACT System for Preparing Research Training Data Tables

NIH anticipates mandating that required training data tables submitted with applications and progress reports for the following activity codes be created via the xTRACT system:

- T32
- TL1
- T90/R90
- T15

In late FY 2019, NIH will provide further guidance about the implementation of this expected requirement. At this time, applicants who have not yet taken advantage of the xTRACT system to create training data tables are encouraged to begin exploring its functionality and may wish to start by using the system to create Data Table 8, to accompany an RPPR.

Automated Post Award Changes

Recipients of NIH awards can submit the following prior approval requests electronically through eRA Commons:

- **Prior Approval Request for Change of PD/PI**
- **Prior Approval Request for No Cost Extension (NCE)**
- **Prior Approval Request for Carryover**

Tips for e-Submission Success

Register Early!

- Required registrations
 - System for Award Management (SAM)
 - Grants.gov
 - eRA Commons
 - DUNS
 - SBA (for small business applicants only)
- **Submit early**, and correct any errors before due date
- View your application in Commons
 - If you can't **VIEW** it, NIH can't **REVIEW** it!



Policy Reminders



Timely Progress Reports

- **Annual Progress Reports = RPPR Format**
- **Due Dates**
 - Non-SNAP: Approximately 60 days before the start of next budget period
 - SNAP: Approximately 45 days before start of the next budget period
 - Multi-Year Funded: on or before anniversary date

Searchable list to determine which progress reports are due:

<https://public.era.nih.gov/chl/public/search/progressReportByIpf.era>

Timely Financial Reporting

Federal Financial Report (FFR) (SF-425) Expenditure Data

Annual (Non-SNAP Awards)

- FFR submitted no later than 90 days after the end of the calendar quarter in which the budget period ended

Final (SNAP and Non-SNAP Awards)

- FFR submitted within 120 days following the end of the project period

Invention Reporting

- NIH recipients must file the HHS 568 at the conclusion of an NIH award
- All subject inventions reported on the HHS 568 must be reported in iEdison.
- Failure to report all inventions may result in your organization's loss of rights in the invention or other actions as appropriate.

Closeout Enforcement

NIH is strengthening enforcement of longstanding closeout requirements.

- Recipients must submit timely, accurate closeout reports
- Reports are LATE after 120 calendar days
 - NIH may allow late submission with prior approval (i.e., acceptable written justification)
 - Cash transaction data is submitted directly to PMS
 - Recipient responsibility to reconcile FFR and FCTR data

When recipients fail to submit timely reports NIH will initiate unilateral closeout.

- When no FFR is submitted, HHS policy directs NIH to close the grant using the last accepted FCTR
- This could be considered a debt or result in disallowed costs

Educational Outreach



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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/>

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OLAW Educational Outreach



OLAW free quarterly webinars series:

<http://grants.nih.gov/grants/olaw/e-seminars.htm>

- Recordings of past webinars:
http://grants.nih.gov/grants/olaw/educational_resources.htm

Disaster planning resources:

http://grants.nih.gov/grants/olaw/disaster_planning.htm

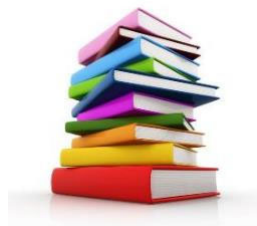
- Disaster planning webinar & FAQs



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Helpful NIH Resources



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RPPR Resources

RPPR Webpage: <http://grants.nih.gov/grants/rppr/>

Includes links to:

- RPPR Guide
- RPPR Guide Notices
- Frequently Asked Questions
- Training
- Contacts



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The screenshot shows the NIH Grants & Funding website page for "Clinical Trial Requirements for Grants and Contracts". The page features a navigation bar with tabs for HOME, ABOUT GRANTS, FUNDING, POLICY & COMPLIANCE (selected), NEWS & EVENTS, and ABOUT OER. A search bar is located in the top right corner. The main content area includes a sidebar with "Policy & Compliance" and "Clinical Trial Requirements" sections. The main heading is "Clinical Trial Requirements for Grants and Contracts". Below the heading, there is a paragraph explaining that NIH is launching a series of initiatives to enhance the accountability and transparency of clinical research. A "NIH Definition of a Clinical Trial" section follows, defining a clinical trial as a research study in which one or more human subjects are prospectively assigned to one or more interventions. A diagram titled "Wide Range" shows "NIH Clinical Trials" branching into five categories: Mechanistic, Exploratory/Development, Pilot/Feasibility, Other Interventions, and Behavioral. A call-to-action box states "Your human subjects study may meet the NIH definition of a clinical trial." and includes a "FIND OUT HERE" button. The "On This Page:" section lists various links such as "Why Changes to Clinical Trial Policies?", "Good Clinical Practice Training", and "Clinical Trial-Specific Review Criteria". A "Related Resources" sidebar on the right lists "FAQs", "Training Resources", and "Important Terms". The footer includes the NIH logo, the text "National Institutes of Health", the URL <https://grants.nih.gov/policy/clinical-trials.htm>, and the page number "40".

Frequently Asked Questions

FAQs –searchable websites for:

- Application/progress report preparation, funding initiatives, policies, human subjects, sIRB, clinical trials, animals, disaster response, PMS Subaccounts, Core Facilities, FCOI, etc....

Summary of Helpful NIH Web Pages

Office of Extramural Research (OER) Web Page:

<http://grants.nih.gov/grants/oer.htm>

NIH Grants Policy Statement (Rev. 10/18):

<http://grants.nih.gov/grants/policy/nihqps/>

NIH Extramural Nexus – newsletter for the extramural community:

<http://nexus.od.nih.gov/all/nexus-by-date/>

Grant Application Basics:

http://grants.nih.gov/grants/grant_basics.htm

eRA Training: Video Tutorials

http://era.nih.gov/era_training/era_videos.cfm

Summary of Helpful NIH Web Pages

How to Apply - Application Guide:

<http://grants.nih.gov/grants/how-to-apply-application-guide.htm>

Annotated SF424 (R&R) Application Forms (General and Small Business and Multi-project):

<https://grants.nih.gov/grants/how-to-apply-application-guide/resources/annotated-form-sets.htm>

How we check for application completeness:

<https://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/how-we-check-for-completeness.htm>

Self Help Resources page:

<http://grants.nih.gov/support/index.html>

Summary of Helpful NIH Web Pages

eRA Commons Web pages:

<http://era.nih.gov/>

eRA Commons User Guides:

http://era.nih.gov/commons/user_guide.cfm

Intellectual Property Policy:

<http://grants.nih.gov/grants/intell-property.htm>

Research Portfolio Online Reporting Tools (RePORT):

<http://report.nih.gov>

RePORT Expenditures & Results (RePORTER):

<http://projectreporter.nih.gov/reporter.cfm>

NIH OER Listservs

NIH Guide for Grants and Contracts:

Official publication for NIH Grant Policies, Guidelines & Funding Opportunities

<http://grants.nih.gov/grants/guide/listserv.htm>

Office for Human Research Protections (OHRP):

<http://www.hhs.gov/ohrp>

Office of Laboratory Animal Welfare (OLAW):

<http://grants.nih.gov/grants/olaw/references/list.htm>

eSubmission:

Separate listservs available for scientists and administrators

<http://grants.nih.gov/grants/ElectronicReceipt/listserv.htm>

Grants Information: Who to Contact?

General Application Questions:

- E-Mail: GrantsInfo@nih.gov
- Phone: 301-945-7573

Grants.gov Customer Support:

- E-Mail: support@grants.gov
- Webpage: <http://grants.gov/>
- Phone: 1-800-518-4726

eRA Commons Helpdesk:

- Web: <https://grants.nih.gov/support/index.html>
- Toll-free: 1-866-504-9552
- Phone: 301-402-7469
- Hours: Mon-Fri, 7a.m. to 8 p.m. Eastern Time

Grants Policy: Who to Contact?

Division of Grants Policy:

- E-Mail: GrantsPolicy@mail.nih.gov
- Phone: 301-435-0949

Division of Grants Compliance & Oversight:

- E-Mail: GrantsCompliance@mail.nih.gov
- Phone: 301-435-0949

Division of Extramural Inventions and Technology Resources:

- E-Mail: Inventions@nih.gov
- Phone: 301-435-1986



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TOP 10 NIH List for Research Administrators In-the-Know

10. Check out IC-specific programs, policies and procedures (xxxx.nih.gov....e.g., nimh.nih.gov)
9. Subscribe to and review weekly the NIH Guide to Grants and Contracts (find everything at <https://grants.nih.gov/searchguide/>)
8. Carefully read the Funding Opportunity Announcement (aka FOA)
7. Follow application directions (refer to <https://www.nih.gov/grants-funding>)
6. Show PI's how to access info via eRA.



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TOP 10 NIH List for Research Administrators In-the-Know

5. **Read each NoA carefully...especially Section IV**
4. **Ask the Grants Specialist questions when the NoA doesn't jive with what you expect**
3. **Ask the PI questions when it seems like things have changed**
2. **Explain the "why's" to your investigators using the NIH Grants Policy Statement**
1. **Stuff happens: don't be afraid to contact the awarding IC**



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Questions?



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