

Current Issues at NIH

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National Institutes of Health

NIH FY 2015 Budget

NIH Fiscal Policy for Grant Awards – FY 2015

[NOT-OD-15-050](#)

NIH awarding ICs have posted their fiscal policies consistent with overall NIH goals and available FY 2015 funds.

<http://grants.nih.gov/grants/financial/index.htm#strategies>



FY2015 Legislative Mandates

This notice provides information on the statutory provisions that limit the use of funds on NIH grant, cooperative agreement, and contract awards for FY2015.

- See [NOT-OD-15-054](#) for details.



FY 2015 Fiscal Policy – Salaries and New Investigators

Salary Cap -

- Limited to Executive Level II – set at \$183,300, effective January 11, 2015.
 - See [NOT-OD-15-049](#)

New Investigators -

- Support on R01 equivalent awards will continue at rates comparable to established investigators.
- Additional information at [NOT-OD-09-013](#) and http://grants.nih.gov/grants/new_investigators/index.htm



FY 2015 Fiscal Policy - NRSA

NRSA Awards -

- Stipends increased for undergraduate, graduate students and postdoctorals
- No changes in tuition, fees, and training related expenses

See [NOT-OD-15-048](#) for details.



Policy Updates



Publication Reporting Instructions for RPPRs and Renewal Applications

In order to reduce the burden of unnecessary reporting, NIH has clarified that trainee, scholar, and participant publications must be reported in section C.1 of the RPPR if:

- the publication was accepted for publication or published during the reporting period; and
- the publication resulted from work conducted while the individual was supported by the award (i.e., receiving a stipend or salary from the award).

Publications resulting from work conducted while not actively supported by the institutional training, career development, or related award should not be reported in section C.1.

See [NOT-OD-15-091](#) for details



Delays in Grant Application Submission due to Severe Weather and Natural Disasters

NIH will consider accepting late applications, on a case-by-case basis, under the following circumstances:

- Applications must be submitted as soon as possible after the applicant organization/institution re-opens, not to exceed the number of days the applicant organization was officially closed.
- A cover letter must be submitted with the application, with enough detail about the delay so that NIH staff can make a determination whether circumstances justify accepting the application late.

See [NOT-OD-15-108](#) for additional information.



Enhancing Reproducibility Through Rigor and Transparency, Consideration of Sex as a Biological Variable in NIH-Funded Research

NIH plans to clarify and revise application instructions and review criteria to:

- enhance reproducibility of research findings through increased scientific rigor and transparency
- clarify NIH's expectation that scientists will account for the possible role of sex as a biological variable in vertebrate animal and human studies

Updates pending OMB approval will take effect for applications submitted for the January 25, 2016, due date and beyond. [See NOT-OD-15-102, NOT-OD-15-103, and http://grants.nih.gov/reproducibility/index.htm.](#)



Research Training Data Table Formats

NIH anticipates adopting new research training data table formats in FY 2016 for use with:

- Institutional training grant applications and;
- Research Performance Progress Reports (RPPRs)

NIH anticipates releasing the new training table formats by the end of September 2015, for inclusion in RPPRs submitted December 1, 2015, or later and applications submitted for the May 25, 2016, due date and after.

See [NOT-OD-15-112](#) for more details.



Deadline for Final Reports Required for Grant Closeout

Projects ending on or after October 1, 2014, recipients must submit the following documents within 120 calendar days of the end of the period of performance;

- Final Federal Financial Report (FFR)
- Final Progress Report (FPR)
- Final Invention Statement and Certification (FIS)

For any grants with a period of performance (project period) end date prior to October 1, 2014, the reporting deadline will be 90 days from the project period end date.

See [NOT-OD-15-111](#) for more additional details.



Fed-wide Streamlining Efforts



Research Performance Progress Report (Reminder)

As of October 17, 2014, NIH requires grantees to submit all type 5 progress reports using the RPPR module in eRA Commons.

Annual progress reports submitted in any format other than the RPPR will not be processed by the NIH and will require resubmission through the RPPR.

More at [NOT-OD-15-014](#)



RPPR RESOURCES

- **RPPR Webpage:** <http://grants.nih.gov/grants/rppr/>
 - Includes links to
 - RPPR Application Guide
 - RPPR Guide Notices
 - Frequently Asked Questions
 - Training
 - Contacts



Policy Reminders



Revised NIH Definition of “Clinical Trial”

NIH has revised its definition of “clinical trial” for the following reasons:

- To make the distinction between clinical trials and clinical research studies clearer, and
- To enhance the precision of the information NIH collects, tracks, and reports on clinical trials

The revised definition applies to competing grant applications that were submitted to NIH for the January 25, 2015 due date and subsequent due dates.

See [NOT-OD-15-015](#) for details

Proposed Clinicaltrials.gov Requirements

HHS issued a Notice of Proposed Rulemaking regarding the submission of registration and summary results information, including adverse event information, for specified "applicable clinical trials" to ClinicalTrials.gov. See [NOT-OD-15-018](#) for details.

NIH is drafting policy to promote broad and responsible dissemination of information on clinical trials funded by the NIH through registration and submission of summary results information to ClinicalTrials.gov. See [NOT-OD-15-019](#) for more information.



Upcoming Changes: NIH Implementation of Dual Use Research of Concern (DURC)

Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern issued on September 24, 2014

- Applies to all New and Renewal awards issued on applications submitted on or after January 25, 2015, and to all non-competing continuation awards issued on or after January 25, 2015.
- Institutions have until September 24, 2015 to establish the necessary infrastructure to come into full compliance with this policy.

See [NOT-OD-15-017](#) for more information.



NIH Requirement for Federal Recognition of Same-Sex Spouses/Marriages by Grant and Research and Development Contract Recipients

In light of the *United States v. Windsor* (June 26, 2013) ruling, all NIH grant programs and research and development (R&D) contract programs now interpret the terms “spouse” and “marriage” to include same-sex spouses/marriages.

Under this policy, a same-sex relationship between two individuals is recognized as a marriage if:

- (1) the state or other jurisdiction, whether foreign or domestic, where the couple was married recognizes the marriage under its laws or;
- (2) the state or other jurisdiction where the couple currently resides recognizes the relationship as a legally valid marriage.

See [NOT-OD-15-051](#) for more information.



NIH/AHRQ Policy for Application Submission

Reminder that the basic requirements for allowable applications have not changed with the updated NIH/AHRQ policy on application submission.

Investigators now may submit a New Application, following an unsuccessful application, without concern for scientific overlap with previously reviewed applications.

A New Application that does not conform to the rules for a New Application will not be reviewed and will not be considered for funding.

More at [NOT-OD-15-059](https://www.fda.gov/oc/ohrt/NOT-OD-15-059)



Expanding Support of Unicode Character Set

In May 2014, NIH and AHRQ databases were updated to support the collection of data using the full Unicode character set.

However, at that time Grants.gov was unable to support the expanded character set.

- Consequently, applicants could use the Unicode characters in their PDF attachments, but still could not use Greek and other special Unicode characters in the free-text form fields of their applications.

As of February 17, 2015, Grants.gov forms and systems will also support Unicode characters.

See [NOT-OD-15-058](#) for more information.



SBIR/STTR Due Dates are Changing

NIH's standard due dates for SBIR and STTR programs are changing in response to small business community feedback, congressional mandates, and recommendations from the NIH Scientific Management Review Board to decrease delays between submission and award funding.

There will not be an August 5, 2015, due date. Subsequent standard due dates will be September 5, January 5, and April 5.

See [NOT-OD-15-038](#) for additional information.



Uniform Guidance: NIH Grants Policy Statement

- **As a result of the publication of HHS' interim final rule, and in addition to NIH's Interim Grant General Conditions document, NIH has made the necessary changes to the NIH Grants Policy Statement on March 31, 2015 in order to reflect NIH's implementation of the regulations.**
- **In addition to removing all of the references to the previous OMB Circulars and HHS regulations located at 45 CFR parts 74 and 92, the following are some of the NIH GPS Chapters that have been revised in order to comply with 45 CFR part 75:**
 - **NIH GPS Chapter 1.1 – Definitions and Terms**
 - **NIH GPS Chapter 2.3 – Application Information and Processes**
 - **NIH GPS Chapter 5 – Notice of Award (NoA)**
 - **NIH GPS Chapter 6 – Payment**
 - **NIH GPS Chapter 7 – Cost Considerations**
 - **NIH GPS Chapter 8 – Administrative Requirements**



Uniform Guidance: NIH Policy Clarifications

NIH continues to provide F&A costs without the need for a negotiated rate under the following classes of awards:

- Research Training and Education Grants (e.g., R25), and K Awards
 - F&A cost under Kirschstein-NRSA institutional research training grants and K awards will be budgeted and reimbursed at a rate of 8 percent of modified total direct costs, exclusive of tuition and fees, health insurance (when awarded as part of tuition and fees), expenditures for equipment, and consortiums in excess of \$25,000.
- Grants to Foreign Organizations and International Organizations
 - F&A costs under grants to foreign and international organizations will be funded at a rate of 8 percent of total direct costs, less only equipment.



New Biographical Sketch

NIH and AHRQ encourage applicants to use the newly published biosketch format for all grant and cooperative agreement applications submitted for due dates on or after January 25, 2015, and will require use of the new format for applications submitted for due dates on or after May 25, 2015.

The revised forms and instructions are now available and adjustments have been made to improve their usability. The following are some of the features of the new format;

- Extends the page limit from four to five pages
- Investigators can outline the central findings of prior work and the influence of those findings on the investigator's field work
- Investigators involved in Team Science are provided the opportunity to describe their specific role(s) in the work

See [NOT-OD-15-085](#) for additional information



Individual Development Plans (IDPs)

IDPs not required, grantees are encouraged to develop as part of training program

As of October 1, 2014, grantees are required to report on the use of IDPs with RPPR submissions

- Grantees must include a report on the use of IDPs in Accomplishments, Question B.4 for all grad students & postdocs reported in Section D. List of Participants.

Do not include the actual IDP; instead report whether or not IDPs are used to help manage the training for these individuals

See [NOT-OD-14-113](#) for details.



Genomic Data Sharing Policy

Reminder that the NIH Genomic Data Sharing Policy became effective with NIH grant applications submitted for January 25, 2015, due dates and thereafter.

The new GDS Policy promotes sharing of large scale genomic data generated by NIH research.

- Includes human, non-human, and model organism data

See [NOT-OD-15-027](#) for reminder.



Progress Reports

- Failure to submit complete and timely progress reports may affect future funding to the organization
- Non-SNAP annual progress reports are due the 1st of the month preceding the month in which the budget period ends (electronic submission RPPR only as of 10/17/2014)
- SNAP progress reports are due the 15th of the month preceding the month in which the budget ends
- Multi-year funded progress reports due on the anniversary of the budget/project period start date of the award (electronic submission RPPR only)
- Searchable list to determine which progress reports are due:
<https://public.era.nih.gov/chl/public/search/progressReportByIpf.era>



Closeout Final Reports

- Failure to submit timely reports may affect future funding to the organization.
- Documents are due within 120 calendar days of the period of performance end date:
 - Final Federal Financial Report (FFR) SF-425 Expenditure Data (submitted through eRA Commons);
 - Final Inventions Statement & Certification;
 - Final Progress Report.
- Final FFRs must be submitted electronically through the eRA Commons
 - Grantees are strongly encouraged to submit other closeout reports through the Commons



Requirements and Compliance Assistance for OHRP and OLAW



News from the Office for Human Research Protections

- 2015 Update to the International Compilation of Human Research Standards
- Now Available at <http://www.hhs.gov/ohrp/international/index.html>

More at:
<http://www.hhs.gov/ohrp/newsroom/index.html>



Update to the PHS Policy

- **Policy on Shared Animal Welfare Concerns**
 - [NOT-OD-15-028](#) Explains how self-reports of serious animal welfare concerns involving USDA-regulated species are shared with Animal Care.
- **Guidance on Significant Changes to Ongoing Animal Activities**
 - [NOT-OD-14-126](#) Provides guidance on what is considered a significant change to an ongoing animal activity that requires IACUC review.
- **Change in Criteria for Renewal of Domestic Animal Welfare Assurances**
 - [NOT-OD-14-099](#) As of December 1, 2014, OLAW will not renew a Domestic Assurance if an institution does not have current PHS funding.



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 & FAQ

- **What Investigators Need to Know About the Use of Animals**

- *ILAR Journal*, Vol. 54(3)

- http://grants.nih.gov/grants/olaw/references/ilar_2014_54.pdf



OLAW-supported Workshops & Conferences

- **IACUC 101 Series Workshops**
 - September 3-4 – Honolulu, HI
- **SCAW Workshops & Conferences**
 - September 18 – New York, NY
 - October 8 – Chicago, IL
 - December 7-8 – San Antonio, TX
- **USDA AWIC Workshops**
 - October 28-29 – Beltsville, MD

<http://grants.nih.gov/grants/olaw/workshop.htm>



Electronic Post Award Administration



Electronic Submission Post-award Pilots

Administrative Supplements

- Optional Grants.gov and Commons submissions
- Details at [NOT-OD-12-024](#) and [PA-14-077](#)

Change of Grantee Institution

- Optional Grants.gov submission
- Details at [NOT OD-12-134](#) and [PA-14-078](#)



Electronic Submission Post-award Pilots

Change in Grantee Status (Successor in Interest)

- Optional Grants.gov submission
- Details at [NOT OD-12-133](#) and [PA-14-079](#)

Relinquishing Statements

- Available to all grants
- Details at [NOT OD-12-132](#)



Public Access Compliance

NIH will delay award if publications arising from it are not in compliance

Electronically associated on RPPRs

See Notice [NOT-OD-13-042](#)



My NCBI

My NCBI ensures compliance with [NIH Public Access Policy](#)

- On-line portal linked to Commons account
- Maintains list of all authored papers



My Bibliography

Tool in My NCBI

- My Bibliography is a reference tool that helps save citations from PubMed
- Or manually enter citations using templates

Facilitates grantee reporting

- quickly provides public access compliance status of each publication arising from the award in an easy to understand format;

See

<http://www.ncbi.nlm.nih.gov/books/NBK53595/>



SciENCeV

- Uses My NCBI to create a professional profile
Enables researchers to assemble information needed for NIH biosketch
- Integrates with eRA Commons and PubMed data.
- Permits users to link data to ORCID ID
- Tutorial available.

NOT-OD-13-114



Update on Electronic Submission & eRA Commons



Tips for E-submission Success

- **Check the application for common errors before submitting**
 - http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm
- **Correct any errors before the application due date**
 - If errors are found, a changed/corrected application must be submitted before the due date
- **Submit early!**
 - Think days, not hours or minutes before deadline



Tips for E-submission Success

- **View your application in Commons**

- Verify that the error-free application is viewable in the eRA Commons and correctly reflects the intended submission

- **If you can't VIEW it, NIH can't REVIEW it!**



Helpful NIH Resources



eRA Video Tutorials

• The following four tutorials have been added to the eRA Tutorials page

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

- Accessing the Notice of Award (SO & PD/PI)
- Accessing Just In Time (SO & PD/PI)
- No Cost Extension (SO Only)
- Change of Institution (SO & PD/PI)

Frequently Asked Questions

- **FAQs –searchable websites for:**
 - Application/progress report preparation, funding initiatives, policies, human subjects, animals, disaster response, PMS Subaccounts, Core Facilities, etc...
 - http://grants.nih.gov/grants/frequent_questions.htm

Search NIH Funding

- **Research Portfolio Online Reporting Tools (RePORT)**

<http://report.nih.gov>

- Access to reports, data and analysis of NIH research activities
- Quick links to “Frequently Requested Reports,” FAQs.

- **RePORT EXPENDITURES & RESULTS (RePORTER)**

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

- Search information from NIH project databases and funding records, PubMed abstracts and full-text articles, and invention reporting (iEdison, Interagency Edison);

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. 3/15)
<http://grants.nih.gov/grants/policy/nihgps/>
- NIH Extramural Nexus – newsletter for the extramural community
<http://nexus.od.nih.gov/all/nexus-by-date/>
- Rock Talk
<http://nexus.od.nih.gov/all/rock-talk/>
- Grant Application Basics
http://grants.nih.gov/grants/grant_basics.htm



Summary of Helpful NIH Web Pages

- **Applying Electronically**

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

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

<http://grants.nih.gov/grants/ElectronicReceipt/communication.htm#forms>

- **Ten Checks to Help Avoid Common Application Errors**

http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm#10checks

- **Do I have the right electronic forms for my NIH application?**

http://grants.nih.gov/grants/ElectronicReceipt/files/right_forms.pdf



Summary of Helpful NIH Web Pages

- **NIH Extramural Response to Natural Disasters**
http://grants.nih.gov/grants/natural_disasters.htm
- **eRA Commons Web pages**
<http://era.nih.gov/>
- **eRA Commons User Guides**
http://era.nih.gov/commons/user_guide.cfm
- **Updated (2-5-2015) Commons User Guide**
http://era.nih.gov/Docs/COM_UGV2630.pdf
- **Self Help Resources page:**
<http://grants.nih.gov/support/index.html>
- **Intellectual Property Policy**
<http://grants.nih.gov/grants/intell-property.htm>



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):**
 - [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: 301-435-0714

•Grants.gov Customer Support:

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

•eRA Commons Helpdesk:

- Web: <http://era.nih.gov/help/>
- Toll-free: 1-866-504-9552
- Phone: 301-402-7469
- Hours: Mon-Fri, 7a.m. to 8 p.m. Eastern Time



Grants Information: Who to Contact (cont'd)

- **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

