Current Issues at NIH

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National Institutes of Health

NIH FY 2016 Budget News

NIH is currently funded under the Consolidated Appropriations Act, 2016 (Public Law 114-113) signed by President Obama on December 18, 2015.

NIHs FY 2016 budget amount is $32.3 billion which represents a $2 billion increase over FY 2015.

NIH awarding ICs fiscal policies are posted on their respective websites. These policies are consistent with NIHs overall spending goals for FY2016.

See NOT-OD-16-046 for details.

FY 2016 Fiscal Policy – Salaries and New Investigators

Salary Cap

- Limited to Executive Level II – increased from $183,300 to $185,100, effective January 10, 2016.

See NOT-OD-16-059 for details.

New Investigators

- Support on R01 equivalent awards will continue at rates comparable to established investigators.

- Additional information can be found at: http://grants.nih.gov/grants/new_investigators/index.htm

FY 2016 Fiscal Policy - Ruth L. Kirschstein National Research Service Awards (NRSA)

Stipends increased for undergraduate, graduate students and post-doctoral recipients at a rate of approximately 2 percent.

Training related expenses (TRE) and Institutional Allowances (IA) have increased for post-doctoral recipients by $1,000.

- TRE on Institutional Training Grants:
  - *Postdoctoral Trainees:* $8,850

- IA for Individual Fellows:
  - Non-Federal Public, Private, and Non-Profit Institutions
    - *Postdoctoral Fellows:* $8,850

  - Federal and For-Profit Institutions
    - *Postdoctoral Fellows:* $7,750

No changes in tuition, fees, and TRE / IA for undergraduate and graduate students.

See NOT-OD-16-062 for details.

Precision Medicine Initiative (PMI)

The PMI will enable a new era of medicine through research, technology and policies that empower patients, researchers, and providers to work together to develop individualized care

A major piece of the Precision Medicine Initiative is the development of a research cohort that will engage a million or more Americans who volunteer to contribute their health data over many years to improve health outcomes, fuel the development of new treatments for disease, and catalyze a new era of data-based and more precise, individualized preventive care and medical treatment.

Enrollment in the Cohort will begin in 2016 and anyone living in the United States will be able to participate

$200 million was allocated to NIH for the PMI in FY16

- $130 million to build a national, large-scale cohort (research participant group) of one million or more U.S. participants
- $70 million to NCI to lead efforts in cancer genomics

NIH made its first PMI awards in FY 2016, some under OT authority

National Cancer Moonshot Initiative

The National Cancer Moonshot Initiative was established to accelerate cancer research, to make more therapies available to more patients, and to improve our ability to prevent cancer and detect it an early stage

Community input is critical to the success of the National Cancer Moonshot Initiative, and NIH is asking the community to submit their scientific ideas or suggestion for addressing cancer research challenges to cancerreseaarch@nih.gov (closes July 1)

The NCI Blue Ribbon Panel of experts will use the information submitted to help shape discussions on the cancer research priorities to be supported.

The FY2017 President's budge request includes $680 million of additional funding for NCI to support the this national cancer research initiative and a $260.5 million increase in NCI funding in its FY2016 appropriation

POLICY UPDATES

Research Terms and Conditions

The purpose of the activity was to develop a revised set of Research Terms and Conditions (RTC) as they apply to research and research-related grants made by the participating agencies to institutions of higher education and non-profit organizations.

The RTC document was published in the Federal Register on October 14, 2015. The public had a 60-day comment period, which ended December 14, 2015.

- Feedback received from the RTC/FDP subcommittee in December 2015.

Next Steps:

- Review of all comments by NIH/NSF with participating agencies and submit recommendations to RBM for consideration.
- Consideration of all public comments by RBM
- Clearance of finalized document by RBM
- Implementation targeted for FY 17

To view the draft Research Terms and Conditions, see: http://www.nsf.gov/awards/managing/rtc.jsp.

Grants Oversight and New Efficiency (GONE) Act

Enacted January 28, 2016

Key Provisions:

- HHS Secretary designated as lead because about 80% of all federal grants are provided through HHS and Treasury payment systems
- Report due to HHS Secretary and Congress NLT 12/31/17 that:
    - Lists each Federal grant award held by such agency;
    - Provides the total number of Federal grant awards, including the number of grants—
        - by time period of expiration;
        - with zero dollar balances; and
        - with undisbursed balances;
    - For an agency with Federal grant awards, describes the challenges leading to delays in grant closeout; and
    - For the 30 oldest Federal grant awards of an agency, explains why each Federal grant award has not been closed out.

Key Point of Analysis – Grants 2+ years past project end date, including all extensions, not yet closed

NIH awaiting specific guidance and requirements for implementation from HHS.

Streamlining the eRA Commons Registration Process

NIH has streamlined the registration requirements in and effort to reduce the administrative burden (i.e., time between registration submission and NIH's final determination) for organizations that present unique and complex situations (i.e., Foundations that represent already existing recipient organizations, and newly formed consortiums where the consortium members are already individually recognized as NIH recipient organizations).

Applicants are urged to consider the following eligibility considerations to make a preliminary assessment of organizational eligibility prior to initiating the eRA Commons registration process.

Eligibility Assessment:

- What is the nature of the research and business that your organization performs and how does that fit within the NIH mission?
- Is your organization professionally responsible for the research?
- How many people are in your organization?
- Are the researchers employed by your organization?
- Where physically is the proposed research to be conducted?
- Can you identify a Funding Opportunity Announcement that you would apply for?
- Has your organization applied to and/or been directly funded by any Federal agency?

Keep in mind that NIH makes the final determination of eligibility to register within the eRA Commons System.

Requirements for the Appropriate Signatures on NIH Forms and Official Documentation

Effective June 1, 2016, NIH will no longer accept forms or other documentation bearing generic departmental signatures or their electronic equivalent (e.g., Department of Sponsored Research).

All forms and documentation submitted to the NIH must reflect the name of the individual, electronic or otherwise, with the appropriate institutional authority to submit such information (i.e., Authorized Organizational Official (AOR), Signing Official (SO), Business Official (BO), Principal Investigator (PD/PI)).

Impact of Grant Application Form Update (Forms-D) on Late and Continuous Submission Applications

Due to the content and policy changes implemented in FORMS-D application packages, NIH is making a clean transition from FORMS-C to FORMS-D to ensure applications reviewed together follow the same instructions.

If you are eligible for submission under our late, continuous submission, and system issue policies, please pay special attention to the cutover dates to the new forms and use the forms and instructions for the intended due date found on the funding opportunity announcement (FOA).

FOAs that close early will be configured to allow submissions for 14 days after the close date to accommodate late, continuous submission and system issue policies.

Note: The continuous submission policy only applies to R01, R21 and R34 activities that follow the standard submission schedule. The dates specified for these three activities are the intended due dates for continuous submission applications.

Impact of Grant Application Form Update (Forms-D) on Late and Continuous Submission Applications Con't

If applying to a FOA with an intended due date before May 25, 2016, be sure to use the FOA with the FORMS-C application package .

If applying to an intended due date on or after May 25, 2016, be sure to use an FOA with a FORMS-D application package.

NIH will reissue all Parent announcements, as well as all fellowship, and individual career development FOAs to ensure that the correct forms package is available.

If your intended due date is the May 7, 2016, AIDS due date, you must complete your submission using a FORMS-C application package by May 23, 2016. NOTE: This is an earlier cutoff date for continuous submission applications than is typical – plan accordingly.

See NOT-OD-16-064 for details.

Updated Forms (Forms-D) for Administrative Supplement, Successor-in-Interest and Change of Institution Opportunities

FORMS-D Transition Plan for Administrative Supplement, Successor-in-Interest (Type 6) and Change of Institution (Type 7) Announcements without Specific Due Dates

- On May 25, 2016 NIH will reissue Administrative Supplement, Successor-in-Interest (Type 6) and Change of Institution (Type 7) Announcements that do not have specific due dates with new funding opportunity announcement (FOA) numbers and FORMS-D application packages. Applications started on or after May 25, 2016 must use the new FOAs and FORMS-D.

FORMS-D Transition Plan for Administrative Supplement FOAs with Specific Due Dates

- On May 25, 2016 NIH will close FORMS-C and add FORMS-D application packages to administrative supplement FOAs with specific due dates.

The current FORMS-C FOA's and application packages will close on May 25, 2016. Although recipients **will not** have the ability to start new applications, you will have 30 days after the close date to submit any in-progress applications and complete the submission process. FORM-C submissions will not be accepted after June 24, 2016.

Restructured and Streamlined Application Guides and Supplemental Instructions

NIH has updated the application guide and supplemental instructions for use with grant application due dates on or after May 25, 2016. In addition to incorporating policy changes, the updated (FORMS-D) application guide has been restructured and streamlined based on helpful feedback received from the NIH Request for Information issued last summer.

Key changes:

- Created a new How to Apply - Application Guide webpage that will serve as your new central resource for competing application submission information.
- Took a new approach to the format of the general application instructions
- Provided new, filtered views of the application instructions specific to research, career development, training, fellowship, multi-project, and small business applications.
- Provided in PDF format only
- Posted a chart that shows which application instructions to follow for each activity code.
- Edited and formatted content to eliminate duplicative information, and to improve clarity and scanability.
- Provided automatic redirects from old to new URLs to minimize impact of change in approach.
- Provided access to format pages, including biosketch and data table documents, under the form at attachment link on the How to Apply - Application Guide webpage as well as on the NIH forms page.

**Updates to form instructions are listed at: http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general/g.120-significant-changes.htm. **

See NOT-OD-16-084 for details.

Changes to Policies, Instructions and Forms for 2016 Grant Applications

NIH has updated application forms in response to policy changes that require additional data collection. We have received approval from the Office of Management and Budget to make the needed updates. System support and guidance for these updates are in place and effective as of March 25, 2016.

The changes focus on the following areas:

- Rigor and transparency in research
- Vertebrate animals
- Inclusion reporting
- Data safety monitoring
- Research training and training tables
- PHS Awarding Component and Peer Review Requests
- Assignment request form
- Font requirements
- Biosketch clarifications

See NOT-OD-16-004 for details.

Simplification of the Vertebrate Animal Section of NIH Grant Applications and Contract Proposals

Updated VAS and Application Review Requirements

If live vertebrate animals are to be used, federal policy requires applicants to address the following criteria:

- Description of Procedures
- Justifications
- Minimization of Pain and Distress
- Euthanasia

Implementation

These requirements, as applicable, are effective for all grant applications except Fellowship (F series) and Training (T series) grants for due dates on or after January 25, 2016, and are effective for all applications for due dates on or after May 25, 2016.

See NOT-OD-16-006 for details.

New NIH Research Training Table Formats for 2016 and the Newly Released xTRACT System

In conjunction with the development of xTRACT, and the implementation of related recommendations from the Working Group, NIH has revised existing research training data tables to:

- Reduce the number of tables from 12 to 8
- Minimize the reporting of individual-level information
- Extend the tracking of trainee outcomes from 10 to 15 years

Implementation

For applications submitted for due dates prior to May 25, 2016, applicants are advised to continue to use previously issued training data table formats.

New training data table formats must be used for RPPRs that were due on or after December 1, 2015, and applications submitted for due dates on or after May 25, 2016. Applicants may create tables for their applications and RPPRs either by using fillable tables in MS Word or via the xTRACT system.

See NOT-OD-16-007 for more details.

Changes to Post-Award Forms and Instructions

NIH has implemented new policies that require additional data collection and updates to some of our post-award forms. Approval has been received from the Office of Management and Budget to make the needed form updates and these updates are expected to be in place by March 25, 2016.

The following newly revised forms and instructions have been posted on the NIH Forms & Applications Page.

- PHS Research Performance Progress Report (RPPR)
- Statement of Appointment
- NRSA Termination Notice
- Noncompeting Continuation Progress Report
- Final Progress Report Instructions

See NOT-OD-16-005 for details.

NIH Research Performance Progress Reports (RPPR) Updated to Address Rigor and Transparency

NIH has changed the PHS RPPR instructions for all annual non-competing (Type 5) awards that support research activities.

These RPPR updates for rigor and transparency include:

- clarifying long-standing expectations to ensure that NIH is funding the best and most rigorous science,
- highlighting the need for awardees to describe details that may have been previously overlooked,
- preparing non-competing renewals for the next competitive renewal, and
- will help NIH implement and evaluate the policy for both current and new awards.

The RPPR instructions was updated to include the necessary changes within Section B – Accomplishments (i.e., post- award RPPR instructions are updated separately from NIH pre-award application instructions).

See NOT-OD-16-031 for details.

Reporting Instructions for Publications Supported by Shared Resources in RPPR and Renewal Applications

The NIH public access policy requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to PubMed Central immediately upon acceptance for publication.

If an NIH award's only contribution to a publication is a shared resource, awardees should not list the publication in section C.1 of an RPPR or in the progress report publication list of a Renewal application.

Awardees are not required to track or report publications arising from the resources they share. Instead:

- Awardees submitting an RPPR can opt to list and/or summarize these publications in section B.2. Section B.2 requests a description of accomplishments and other achievements. Publications listed and/or summarized in this section will not count against the section's two-page limit.
- Awardees submitting a Renewal application can opt to list and/or summarize these publications in the appropriate sharing plan (Data Sharing Plan, Genomic Data Sharing Plan, Model Organism Sharing Plan Resource Sharing Plan, etc.).

Awardees should only use a list or summary to highlight how shared resources lead to noteworthy impact(s). Neither a list nor summary is required. If awardees provide a list, it does not have to be complete.

See NOT-OD-16-079 for details.

Clarifications and Consolidated Biosketch Instructions and Format Pages

The biosketch instructions and format pages have been updated and should be used for application due dates on or after May 25, 2016.

Updates to the biosketch instructions will include:

- A consolidated biosketch format and instructions for research, institutional research training, institutional career development, research education, fellowship, and dissertation awards, as well as diversity supplements.

Clarified instructions:

- Indicate that a URL for a publication list is optional and, if provided, must be to a government website (.gov) like My Bibliography.
- Allow publications (peer-reviewed and non-peer-reviewed) and research products to be cited in both the personal statement and the contributions to science sections
- State that graphics, figures and tables are not allowed.
- Remove the requirement that the past 3 years of research support are listed in order of relevance.
- Option to add other names used to author research products in section A.
- Research products can include conference proceedings such as meeting abstracts, posters, or other presentations.
- Research products that are under development, such as manuscripts that have not yet been accepted for publication, can be mentioned in the narrative sections. However, they cannot be cited as one of their citations.

See NOT-OD-16-080 for details.

Final Research Performance Progress Reports (FRPPR)

- The format will be the same as the current interim/annual RPPR
- Will replace the final progress report requirement for closeout
- New requirement – Outcomes section will be publicly available, allowing recipients the opportunity to provide the general public with a concise summary of the cumulative outcome or findings of the project (analogous to the Project Summary/Abstract section of the competing application).
- Target date for NIHs implementation is October 2016

NIH Policy on Informed Consent for Human Fetal Tissue Research

- NIH-funded research involving human fetal tissue must be conducted in compliance with all applicable federal, state, and local laws and regulations.
- NIH expects informed consent to have been obtained from the donor for any NIH-funded research using human fetal tissue.
- The policy applies to all NIH-funded competing grant awards, non-competing grant awards, and R&D contracts issued after February 11, 2016 and are included in the terms and conditions of grant and cooperative agreement awards as well as contracts issued for research involving human fetal tissue.

For more details see Guide Notice NIH-NOT-OD-15-143 and NOT-OD-16-033.

Draft NIH Policy on the Use of a Single Institutional Review Board (sIRB) for Multi-Site Research

- NIH's proposed a policy that NIH funded institution will be expected to use a single IRB of record for domestic sites of multi-site studies funded by NIH whether supported through grants or contracts (as well as the NIH intramural program).
- The goal of the proposed policy is to enhance and streamline the process of IRB review and reduce administrative burden so that research can proceed efficiently without compromising ethical principles and protections
- Compliance with this Policy will be a term and condition in the Notice of Award and a contract requirement in the Contract Award. Some exceptions will be permitted on a case-by-case basis.
- Public comments received on the draft policy have been reviewed and analyzed. NIH anticipates finalizing the policy late spring/early summer 2016.

See NOT-OD-15-026 for details.

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules to Streamline Review Process for Human Gene Transfer Protocols

Effective April 27, 2016, the National Institutes of Health (NIH) has revised the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) to incorporate the recommendations of the Institute of Medicine (IOM) regarding the review of human gene transfer protocols.

Following the solicitation of public comment on its original proposal, the NIH has amended the NIH Guidelines in the following areas:

(A) the criteria for selecting protocols for in-depth review and public discussion by the NIH Recombinant DNA Advisory Committee (RAC),

(B) the process by which human gene transfer protocols are reviewed and registered with the NIH, and

(C) the streamlining of the NIH protocol submission requirements under Appendix M-I-A of the NIH Guidelines

See NOT-OD-16-076 for details.

Clarification: New Salary and Research Cost Allowances for K08 and K23 Career Development Awards

Effective February 12, 2016, for new (Type 1) and continuation (Type 5 applications) K08 and K23 applications submitted for FY 17 funding, several NIH Institutes and Centers (ICs) will increase the K awardee's salary support to a base level of $100,000 for the requested 9 person months (equivalent to 75%) of full-time professional effort devoted to research and career development.

This increase is intended to offset only that portion of the salary that is devoted to research and career development.

ICs may, at their discretion, annually increase their salary and research cost contributions for their K08 and K23 awards.

Applicants and awardees are encouraged to consult each funding opportunity announcement and contact the appropriate IC staff to determine the salary and research cost contributions for their K08 and K23 applications or awards.

See NOT-OD-16-054 for details.

Individual Mentored Career Development Awards: eRA Commons Usernames Now Required for Primary Mentors

NIH requires that an eRA Commons username be included for the primary Mentor identified in the Individual Mentored Career Development applications and awards.

Applications submitted on and after June 12, 2016, must properly identify the primary Mentor on the following Individual Mentored Career Development applications: K00 (prior to transition), K01, K07 (mentored), K08, K22 (mentored), K23, K25, K43, K76, K99. Failure to identify the primary Mentor will result in a warning for applications submitted electronically.

The primary Mentor's eRA Commons username must be reported on the R&R Senior/Key Person Profile (Expanded) form of the Career Development application, as follows:

- List the primary Mentor under the Profile for Senior/Key Person 1.
- Insert "Other" or "Other Professional" in the Project Role field, and enter "Mentor" in the Other Project Role Category field.
- Provide a valid eRA Commons username in the Credential field. If the primary mentor does not have an eRA Commons account, one with any role (e.g., Project Personnel, Scientist) can be created.

Including eRA Commons usernames for individuals designated as Co-Mentors on these applications remains optional.

See NOT-OD-16-082 for details.

Financial Conflict of Interest (FCOI)

NIH has clarified certain Investigator FCOI disclosure requirements in the Frequently Asked Questions (FAQs):

- **Disclosure of Reimbursed or Sponsored travel**
  - FAQ E.34. clarifies that a recipient's FCOI policy may establish a threshold for Investigator disclosure of sponsored travel.

- **Disclosure of Significant Financial Interests at the time of application**
  - FAQ E.35. clarifies that if the recipient has a process in place to ensure that a current disclosure is already on file, there is no need to collect Investigator disclosures each time an application is submitted.

See FAQs at http://grants.nih.gov/grants/policy/coi/coi_faqs.htm.

POLICY REMINDERS

Reminder: OMB Federal Awardee Performance and Integrity Information System (FAPIIS) Requirement

FAPIIS - a system to capture past performance and integrity and business ethics information related to recipients of Federal contracts, grants and cooperative agreements.

- HHS issued technical amendments to 45 CFR Part 75 on 1/20/2016
- NIH implemented the FAPIIS requirements on 2/16/2016.
- NIH extramural staff are required to consider information in FAPIIS prior to award.
- NIH officials are required to enter certain information related to grantee performance into FAPIIS
- Recipients with a cumulative total of greater than $10M in active Federal awards are required to enter information about criminal, civil and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period and make semiannual reports.
- Public website for FAPIIS: https://www.fapiis.gov/fapiis/index.action

See NOT-OD-16-067 for details.

Reminder
PMS Subaccounts – Timeline and Requirements

- There are no changes to the due dates, submission, or review of progress reports for domestic awards for FY 2016.

- NIH will continue to award type 4s to transition funding to subaccounts

- Subaccount Transitional Federal Financial Reports (FFRs)
  - Due no later than 90 days after the end of the calendar quarter in which the budget period ended
  - Non-SNAP awards - Equivalent to annual FFR
  - SNAP awards – report expenditure data that covers the project period from the original start date of the competitive segment through the new project period end date.
  - May include unliquidated obligations

September 30, 2016 – All awards transitioned to subaccounts

Reminder Grant Closeout (Unilateral Closeout)

Unilateral Closeout is the closeout of an award without the receipt of acceptable reports from the recipient.

- Unilateral closeout is an important action of last resort after discussions between the grantee and the government are unable to remedy the situation.
- HHS policy requires NIH to unilaterally close awards if the following reports are not submitted and accepted by the NIH within the required timeframes (120 days after the end of the period of performance).
    - Final Progress Report (FPR)
    - Final Invention Statement and Certification (FIS)
    - Final Federal Financial Report (FFR) – must ensure that there are no discrepancies between the final FFR expenditure data (in eRA Commons) and the FCTR in the PMS.

Reminder
Timely Progress Reports

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

- Non-SNAP annual progress reports are due the 1st of the month preceding the month in which the budget period ends
- SNAP progress reports are due the 15th of the month preceding the month in which the budget period 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

Reminder
Timely Financial Reporting

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

- Annual (Non-SNAP Awards)
  - FFR submitted for each budget period no later than 90 days after the end of the calendar quarter (CQ) in which the budget period ended.
  - Budget period ends 1/31/2016 – FFR due 6/30/16
    - 90 days after the end of the CQ of 3/31/16

- Final (SNAP and Non-SNAP Awards)
  - FFR submitted within 120 days following the end of the project period

Reminder
Publication Reporting Instructions for RPPRs and Renewal Applications

In order to reduce the burden of unnecessary reporting, NIH 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.

Reminder that awardees are responsible for public access compliance of all publications listed in section C.1 of an RPPR or a progress report publication list of a Renewal.

Failure to comply with reporting requirements may cause an award to become noncompliant. Noncompliant awards may have funding delayed until all publications are compliant.

See NOT-OD-15-091 for details.

Reminder
Biographical Sketch

NIH, requires the use of the new format for all applications.

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

- Extended 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 have been provided the opportunity to describe their specific role(s) in the work

See NOT-OD-15-085 for details.

Reminder
All Subject Inventions Must be Reported on the HHS 568 - Final Invention Statement and Certification and In iEdison

All recipient institutions (including but not limited to Universities, Non-Profit entities, and For-Profit entities) must file the HHS 568 at the conclusion of a NIH grant or contract.

All subject inventions that were made under an applicable funding agreement and reported on the HHS 568 must be reported in iEdison.

Failure to report (on the HHS 568 AND in iEdison) all inventions funded in whole or in part by NIH as required by your funding agreement's terms and conditions, the NIH Grants Policy Statement, and the Bayh-Dole Act may result in your organization's loss of rights in the invention or other actions as appropriate.

See NOT-OD-16-066 for additional information and resources.

Reminder
iEdison Reporting Requirements and Compliance Messages

Recipients must report inventions electronically through iEdison.

iEdison no longer permits a user to waive title to an invention or patent until all outstanding compliance issues and notification messages are resolved.

Examples of Compliance Notification Messages and actions that grantees Must take to resolve these messages:

Notification Message	Actions Necessary to Resolve Messages
No written description of this invention (Disclosure) has been uploaded into iEdison.	Upload an acceptable Invention Disclosure (see the Bayh-Dole Act).
A Government Support Clause (GSC) is missing (or not accepted) for a non-provisional patent filing.	Upload a GSC. Preferably the entire patent application as submitted to the USPTO.
The submitted Confirmatory License (CL) is missing (or not accepted) for a non-provisional patent filing.	Upload a CL. iEdison will generate the CL for you.
Title to this invention has been elected. After title has been elected, a Utilization Report must be submitted annually . . .	Upload a Utilization report for each fiscal year indicated in the "Fiscal Year" column of the Notification Search Results.

See NOT-OD-15-119 for more details.
Questions? Call 301-435-1986 or email: inventions@nih.gov

Reminder
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 and NOT-OD-16-061 for additional information.

OLAW EDUCATIONAL OUTREACH

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

OLAW-supported Workshops, Conferences and Educational Outreach

IACUC 101 Series Workshops

- June 1-2, 2016 – Dallas, TX
- August 3-4, 2016 – Sioux Fall, SD

SCAW Workshops & Conferences

- September 16, 2016 – New York, NY
- October 7, 2016 – Los Angeles, CA
- December 5-6, 2016 – San Antonio, TX

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

ELECTRONIC SUBMISSION & ERA COMMONS

Application Submission System & Interface for Submission Tracking (ASSIST)

ASSIST (optional) is now available for:

- all single and multi-project, competing grant applications;
- single-project administrative supplements;
- single-project, post-award successor-in-interest (type 6) requests; and
- single-project, post-award change of institution (type 7) requests.

Funding opportunity announcements posted in the NIH Guide for Grants & Contracts that allow ASSIST as an option contain an "Apply Online Using ASSIST" button in addition to the "Apply Using Downloadable Forms" button.

See NOT-OD-16-042 for details.

Tips for eSubmission Success

Register Early!

- Registration with both Grants.gov (organizations only) and eRA Commons (organizations & PD/PIs); must be completed before the submission deadline

- Allow at least 6 weeks to complete new registrations (Foreign organizations at least 8 weeks)

- System for Award Management (SAM) information must be updated at least every 12 months to remain active:
    - https://www.sam.gov/portal/public/SAM

Tips for eSubmission 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 eSubmission 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

NIH Regionals 2016

The NIH is pleased to announce that registration is now open for two NIH Regional Seminars focused on Program Funding and Grants Administration in 2016.

Spring Session:

Baltimore, Maryland: (Additional Registration, Agenda, and Hotel information available)
Wednesday, May 11, Optional Pre-Seminar Workshops
Thursday-Friday, May 12-13: 2-Day Seminar
Venue: Renaissance Baltimore Harborplace Hotel

Fall Session:

Chicago, Illinois: (Additional Registration, Agenda, and Hotel information available)
Wednesday, October 26: Optional Pre-Seminar Workshops
Thursday-Friday, October 27-28: 2-Day Seminar
Venue: Palmer House Hilton Hotel

See NOT-OD-16-065 for details.

RPPR Resources

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

Includes links to:

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

Frequently Asked Questions

FAQs –searchable websites for:

Application/progress report preparation, funding initiatives, policies, human subjects, animals, disaster response, PMS Subaccounts, Core Facilities, FCOI, etc…

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

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. 11/15):
http://grants.nih.gov/grants/policy/nihgps/

NIH Extramural Nexus – newsletter for the extramural community:
http://nexus.od.nih.gov/all/nexus-by-date/

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

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

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: 301-435-0714

Grants.gov Customer Support:

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

eRA Service Desk (formerly 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 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

QUESTIONS ?