NIH Updates and Changes for 2016

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Rigor and Transparency in Research

For due dates on or after January 25, 2016 for Research Grants

To enhance reproducibility of research findings through increased scientific rigor and transparency.

- Updates to research strategy instructions
  - **Significance**
    Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.
  - **Approach**
    Describe the experimental design and methods proposed and how they will achieve robust and unbiased results.
  - Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans.
- Reviewers will consider additional rigor and transparency questions when reviewing applications.

See NOT-OD-16-011 and NOT-OD-16-012.

May 25, 2016, applies to Fellowship and Training grant applications.

Definition of Child

For due dates on or after January 25, 2016

- Redefining the age of a child for the purposes of NIH's inclusion policy to individuals under 18 years old instead of under 21 years old.
- Note: This change does not apply to AHRQ applications.

See NOT-OD-16-010.

Vertebrate Animals

For due dates on or after January 25, 2016

Removing redundancy with Institutional Animal Care and Use Committee review

Changes include:

- Updated guidance on criteria to be addressed (description of procedures; justifications; minimization of pain and distress; and euthanasia)
- A description of veterinary care is no longer required
- Justification for the number of animals has been eliminated
- A description and justification of the method of euthanasia is required only if the method is not consistent with AVMA Guidelines for the Euthanasia of Animals

See NOT-OD-16-006.

Inclusion Enrollment Form

For due dates on or after May 25, 2016.

- Adding an optional PHS Inclusion Enrollment Report form.
- The new form, with additional study descriptors, will replace the current Planned Enrollment Report and Cumulative Inclusion Enrollment Report form.
- More details about these updated forms will be released this spring.

Data Safety Monitoring Plans

For due dates on or after May 25, 2016.

- Required for Clinical Trials.
- Use of a separate attachment will emphasize its importance and facilitate systematic enforcement of its presence.

(Previously part of human subjects protection narrative.)

Assignment Request Form

For due dates on or after May 25, 2016.

- Adding an optional Assignment Request Form
- Will provide a consistent way to collect application referral information, including:
  - Awarding component (NIH institute) assignment preference
  - Study Section preference
  - List of potential reviewers in conflict, and why
  - List of scientific expertise needed to review the application

See NOT-OD-16-008.

New Font Guidelines

For due dates on or after May 25, 2016.

- Providing additional flexibility regarding the fonts allowed in PDF attachments included in grant applications.
- Text in PDF attachments must follow these minimum requirements:
  - Font size: must be 11 points or larger
  - Smaller text in figures, graphs, diagrams and charts is ok as long as it is legible.
  - Type density: must be no more than 15 characters per linear inch (including characters and spaces)
  - Line spacing: must be no more than six lines per vertical inch
  - Text Color: must be black (color text in figures, graphs, diagrams, charts, tables, footnotes and headings is acceptable as long as it is legible)
- Some PDF converters may reduce font size. The final PDF document must comply with the font requirements.
- The following fonts are recommended:
  - Arial, Garamond, Georgia, Helvetica, Palatino Linotype, Times New Roman, Verdana
- Legibility is of paramount importance. Applications that include PDF attachments that do not conform to the minimum requirements listed above may be withdrawn from consideration.

See NOT-OD-16-009.

Review Appendix Policy

NIH is currently reevaluating and a policy change will be issued this spring.

The current policy:

- Not to be used to circumvent page limits
- Materials Allowed in the Appendix
  - Up to 3 of the following types of publications
    - Manuscripts and/or abstracts accepted for publication but not yet published.
    - Published manuscripts and/or abstracts **only** when a free, online, publicly available journal link is not available.
  - Patents materials directly relevant to the project.
  - Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents as necessary.

Review NIH Resubmit Policy

Following an unfunded resubmission, applicants may submit the same idea as a new application for the next appropriate due date.

- NIH will not assess the similarity of the science in the new application to any previously reviewed submission when accepting an application for review.
- Applies to all NIH Funding Opportunity Announcements (FOAs) that allow resubmissions.

NOT-OD-14-074, for application due dates after April 16, 2014.

The NIH will not accept duplicate or highly overlapping applications under review at the same time. NIH will not review:

- a new application that is submitted before issuance of the summary statement from the review of an overlapping new or resubmission application.
- a resubmission application that is submitted before issuance of the summary statement from the review of the previous new application.

NOT-OD-09-100

NIH Common Data Elements

- NIH encourages the use of common data elements (CDEs) in clinical research, patient registries, and other human subject research.
- Improves data quality and opportunities for comparison and combination of data from multiple studies and with electronic health records.
- NINR Common Data Elements
  - Symptom Science
  - Pain, Fatigue, Sleep, Affective-mood, Affective-anxiety, Affecitve-well being, Cognitive, Demographics

Application Compliance

- “To be fair to all concerned NIH needs to consistently apply standards for application compliance.”
- NIH may withdraw any application during the receipt, referral and review process that is not compliant.
- Examples:
  - Biosketch does not conform to the required format
  - Including inappropriate materials
  - Application submitted as new but containing elements of a resubmission or renewal application.

See NOT-OD-15-095

New NIH Attachment – Authentication of Key Biological and/or Chemical Resources

For due dates on or after January 25, 2016.

- Part of the NIH Rigor and Transparency Initiative
- Required PDF attachment related to the authentication of key biological and/or chemical resources.
- Briefly describe methods to ensure the identity and validity of these resources.
- Key resources may or may not be generated with NIH funds and:
  1) may differ from laboratory to laboratory or over time
  2) may have qualities and/or qualifications that could influence the research data
  3) integral to the proposed research.
- Example: cell lines, specialty chemicals, antibodies, and other biologics.
- Do not include standard laboratory reagents - buffers and other common biologicals or chemicals.
- Information in this section must focus only on authentication and/or validation of key resources to be used in the study; all other methods and preliminary data must be included within the research strategy.
- Applications identified as non-compliant with this limitation will be withdrawn from the review process (see NOT-OD-15-095).

May 25, 2016, applies to Fellowship and Training grants.

Research Performance Progress Reports- Rigor and Transparency

For due dates on and after January 25, 2016.

- RPPR will be expected to emphasize rigorous approaches taken to ensure robust and unbiased results.
- For any NIH grant that funds research or training in research.
- Reporting on rigor in RPPR will help NIH:
  - Implement and evaluate the policy for both current and new awards.
  - Prepare non-competing renewals for the next competitive renewal.

See NOT-OD-16-011

NIH Biosketch Clarifications

- URL for a publication list is optional and, if provided, must be to a government website (.gov) like **My Bibliography**
- Allowing publications (peer-reviewed and non-peer-reviewed) and research products to be cited in both the personal statement and the contributions to science sections
- Graphics, figures and tables are not allowed
- Section A: Personal statement – describe your role and qualifications. Include up to 4 publications.
- Section C: Describe up to 5 contributions to science. Each contribution can have up to 4 publications.

See NOT-OD-16-004

Grant Application Due Dates and Late Applications

- **Applications are on time** if an **error free** application is successfully submitted to Grants.gov by 5 p.m. local time on the due date.
- When due dates fall on a weekend or Federal holiday, they are extended to the next business day.
- New Investigators (not previously RO1 funded) have a next cycle resubmission option, an extra month to submit

  - only applies to R01 for the standard due dates (NOT-OD-11-057).

- **Late applications** are accepted if:
  - A system issue with grants.gov (or Assist) that does not allow you to submit on time
    - CFRS will contact the appropriate system support to document and confirm your issues and work with the eRA Help Desk to resolve the problem.
    - Application submitted after the deadline must include a cover letter documenting the confirmed system issues, Help Desk ticket numbers, and the action(s) taken to resolve the issue(s).
- In rare cases, late applications will be accepted within 1-2 weeks of due date.
  - Late submission is not granted in advance
  - NIH will consider acceptance on a case-by-case basis
  - Submit an explanatory letter (emergency, death in immediate family, large scale natural disaster)

See NOT-OD-11-035

Clinical Trials.gov Requirement

- Added text to clarify that results reporting is still required after the period of performance has ended.
- Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) requires Applicable Clinical Trials to be registered within 21 days of enrollment of the first participant.
- The International Committee of Medical Journal Editors and other journals require registration of clinical trials prior to enrollment of the first participant.
- Reporting information is submitted as four separate modules:
  - Participant Flow, Baseline Characteristics, Outcome Measures and Statistical Analyses, and Adverse Events

NIH Changes to Post Award Policies

- November 2015, NIH issued a new Grants Policy Statement

http://grants.nih.gov/grants/policy/nihgps/index.htm

- Major Changes include:
  - Able to reduce effort during a no cost extension without NIH prior approval
  - Clarified policies for the inclusion of women and children. Strong justification must be provided for applications proposing to study only one sex.
  - Any change in research procedures that result in an increased human subject risk requires NIH prior approval.
  - Invention disclosures and related reports must be submitted electronically through iEdison.gov

Material Transfer Agreement (MTA)

- Agreement between CWRU and a third party, and managed by CWRU Tech Transfer Office
  - Outlines the rights and responsibilities of the parties
  - Who has rights for further distribution of the materials
  - Ability to publish results
  - Send the completed MTA form and a brief narrative of your research protocol to Tech Transfer
- Andrew Jarrell, Licensing Associate, Techology Transfer Office (368-1401)
  - Will facilitate the process between you and the contractual entity
  - Can take 2-3 weeks
  - Complete at the same time as IRB
  - You will receive a final Uniform Biological Material Transfer Agreement (UBMTA)

    For your regulatory binder and a copy to IRB

Dahms Clinical Research Unit

- Previous services such as blood draws, sample processing and storage were funded by the CTSA
- Recent funding reduction has led to increase in cost of services
- Contact the DCRU asap to get a price quote for your study.

Any Questions?