Topics

1. Rigor and Transparency in Research
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3. Vertebrate Animals
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Vertebrate Animals

For due dates on or after January 25, 2016

Removing redundancy with Institutional Animal Care and Use Committee review

Changesinclude:

- 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

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.

NIH Common Data Elements

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

URLfor 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 –

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.

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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

DahmsClinical 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.