NIH Updates and OSRA Announcements

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osra.weill.cornell.edu
NIH Updates and Implementation Timeline


New Training Data Tables – December 1\textsuperscript{st}, 2015
Required for Research Performance Progress Reports (RPPRs)

Rigor and Transparency Requirements – January 25\textsuperscript{th}, 2016
Required for Competitive Grant Submissions and RPPRs

Age of Children Revised – January 25\textsuperscript{th}, 2016
Affects all applications, updated to under 18 years old

Vertebrate Animals Section – January 25\textsuperscript{th}, 2016
Required for all applications except F’s and T’s until May 25\textsuperscript{th}, 2016

Full Implementation and Integration – May 25\textsuperscript{th}, 2016
Adobe Forms D
New Training Table Formats
NIH Action To Date

• NIH release of new data tables and website http://grants.nih.gov/grants/funding/424/datatables.htm

• Introduction of xTRACT module in eRA Commons

• Set Implementation Deadlines
  • RPPRs due on or after December 1\textsuperscript{st}, 2015
  • Competitive applications due on or after May 25\textsuperscript{th}, 2016
  • Competitive applications due before May 25\textsuperscript{th}, 2016 must include prior table formats

**Always read FOA to confirm requirements**
New Training Table Formats

Major Changes

Reducing the maximum number of tables from 12 to 8
• Tables 9 – 12 are eliminated, removing or relocating information collected on Qualifications, Admissions and Completion Records, and Appointments Data

Minimizing the reporting of individual-level information
• Table 5A & 5B no longer contain prior academic degree information including institution, degree type and degree year

Extending the tracking of trainee outcomes from 10 to 15 years
• New table formats permit an evaluation of the effectiveness in achieving the training objectives for up to 15 years
NIH xTRACT System
What is xTRACT?

xTRACT is a new eRA Commons Module

• Create research training tables for progress reports and institutional training grant applications
• Populated from xTrain and manually generated tables
• Maintains data in system for reuse
• Automation of table generation to reduce workload
NIH xTRACT System
xTRACT Implementation

For NIH FY 2016, xTRACT is available on a pilot basis for:

- T32, TL1, T90/R90, and T15 training grants
- Research Performance Progress Reports due on or after December 1st, 2015
- Competitive applications due on or after May 25th, 2016

xTRACT System is not required in NIH FY 2016, NIH will accept tables completed in MS Word through September 30th, 2016
Rigor and Transparency

NIH Areas of Focus

Major Goal
• Enhance the reproducibility of research findings

Approach
• Revised instruction for preparing application Research Strategy
• Use of the new “Authentication of Key Biological and/or Chemical Resources” attachment
• Additional rigor and transparency questions for application reviewers

Focus
• The scientific premise forming the basis of the proposed research
• Rigorous experimental design for robust and unbiased results
• Consideration of relevant biological variables, and
• Authentication of key biological and/or chemical resources
Rigor and Transparency
Research Strategy

**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 are factored into research designs and analyses for studies in vertebrate animals and humans.
Rigor and Transparency

Authentication of Key Biological and/or Chemical Resources

• New application component in which PIs must briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies

• Information should focus on the authentication and/or validation of key resources to be used in the study

• Separate PDF attachment
  • Adobe Forms C – Other Attachments
  • Adobe Forms D – Specific Upload
Rigor and Transparency
RPPR and Review Focus

RPPRs:
• Progress Reports submitted on or after January 25th, 2016 must emphasize rigorous approaches taken to ensure robust and unbiased results
• The RPPR instructions will be updated by January 25th, 2016

New Reviewer Focus:
• Strong scientific premise
• Robust and unbiased approach
• Clearly address biological variables for animal and human studies
Vertebrate Animals Section

**Updated Requirements**
- Description of Procedures
- Justifications
- Minimization of Pain and Distress
- Euthanasia consistent with American Veterinary Medical Association (AVMA) Guidelines

**Significant Changes**
- A description of veterinary care is no longer required
- Justification for the number of animals has been eliminated
- A description of the method of euthanasia is required only if the method is not consistent with AVMA guidelines
NIH Updates to Come in 2016

Application Guide Updates – November 25th, 2015
PHS Assignment Request Form – May 25th, 2016
New Font Guidelines – May 25th, 2016

Additional Systems and Forms to be updated in 2016:
Inclusion Management System – Screen Updates
Statement of Appointment
Termination Notice
PHS 2590
Final Progress Report
OSRA Announcements

• Website
• Annual Compliance Checklist
• Subrecipient Monitoring
OSRA Website

News & Updates

- News & Updates
- Better Resources
- Current Information
- Navigation
- Policy and Process
- Contact Information

OSRA News & Updates

Petty Cash

Weill Cornell Medicine’s new Petty Cash process announced by Joe Schwartz at the October 12th RAPID meeting takes effect on November 1st. All Petty Cash requests on WBS accounts must be submitted to GCA_PettyCash@med.cornell.edu for review by OSRA. The full SOP is available on the OSRA Policy page.

Annual Compliance Checklist

Introducing the new Annual Compliance Checklist for grants that do not require a formal progress report. This tool represents an interim step toward eliminating the Electronic Routing Form and further streamlines workflow managing active grant awards. The form is available for download on the OSRA forms page and will be presented in detail at the November 9th RAPID meeting.

Important NIH Updates:

- Updated training and data tables and the launch of xTRACT (NOT-OD-15-007 and xTRACT) – effective 12/1/2015
- Rigor and Transparency requirements (NOT-OD-16-011 and NOT-OD-16-012) – effective 1/25/2016
- NIH Definition of a Child revised to under the age of 18 (NOT-OD-16-010) – effective 1/25/2016
- Simplification of the Vertebrate Animals Section (NOT-OD-16-006) – effective 1/25/2016
- Adobe Package D, PHS Assignment Request Form and other major initiatives (Phase II of NOT-OD-15-004) – effective 5/25/2016
OSRA requires the following annually:

Electronic Routing Form
- Serves a compliance checklist for upcoming award year
- Triggers workflow for award processing and tracking
- Obtains official approval from PI and Department

Updated compliance information as needed
- IRB approval
- IACUC approval
- Conflicts of Interest Disclosure
- Cost Sharing Form

Detailed Budget
Annual Compliance Checklist
Private/Non-Federal Sponsors

• Many private/non-federal sponsored awards have unique attributes
  • All funding and/or award years are committed up front
  • No annual progress report or progress report endorsement required

• Since there is no deliverable, OSRA typically engages department annually for ERF and budget

• Given unique process, delays occur due to conflicting priorities and system performance
Annual Compliance Checklist

New Annual Checklist Form

• Replaces ERF for awards that do not require annual signed progress report from OSRA
• Single one page PDF document requiring endorsement of Departmental Grants Coordinator and PI, no Chair approval required
• OSRA will engage department to collect form
• OSRA still requires annual budget for upload into SAP

When does OSRA still require an ERF?

• New/competitive grant submissions
• NIH progress reports
• Other progress reports that require OSRA signature
• Annual subaward amendments requiring OSRA signature
Annual Compliance Checklist

Non-Competitive Grant Award
Annual Compliance Checklist

For the upcoming budget period, please confirm the following:

- Human Subjects Use:  • Yes   • No
- Protocol Number: [ ] Approval Date: [ ]
  
- Animal Use:  • Yes   • No
- Protocol Number: [ ] Approval Date: [ ]

Conflicts of Interest Disclosure
Any personnel on this award with a potential conflict of interest must contact the Conflicts Management Office at conflicts@med.cornell.edu. Information regarding WCMC’s Conflicts Management Program can be found on the Office of Research Integrity website http://researchintegrity.well.cornell.edu/

Significant Changes/Updates
Please check all of the below that apply to inform OSRA of significant project changes which may require OSRA and/or Sponsor approval:

- Significant Rebudgeting
- Key Personnel Effort Modification
- Change in Human Subjects Use
- Change in Animal Use
- Change in Project Aims
- New Key Personnel
- New Performance Site
- Other Changes (please use text box below)

Required Signatures

<table>
<thead>
<tr>
<th>Principal Investigator:</th>
<th>Departmental Administrator:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: [ ] Signature: [ ]</td>
<td>Name: [ ] Signature: [ ]</td>
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Please complete the following page to request modification to any existing subaward agreements under this award.
Subaward Performance Monitoring
Current State

OSRA

• Performs Annual Risk Assessment
  ▪ Subrecipient audit
  ▪ Subrecipient attributes
  ▪ Sponsor and award attributes

• Amend agreements as necessary to mitigate risk factors

PI and Department

• Review and approve invoices
• Obtain scientific progress information
Subaward Performance Monitoring
Subaward Amendment Checklist

Purpose
• Allows Department to inform OSRA of amendment requirements
• Provides opportunity for Department to provide subrecipient performance feedback
• Feedback can be reviewed by OSRA to further inform risk assessment
• Can lead to additional agreement terms and conditions to mitigate risk
• Records risk monitoring efforts for potential audit

Attached to the NOA Checklist and Annual Compliance Checklist
Subaward Amendment Checklist

For non-competitive awards only

Please complete this form if this non-competitive award year requires the amendment of an existing subcontract

Name of Subrecipient Institution: ____________________________

Please check all that apply to indicate changes:

- Additional Time
  - Start Date: _______ End Date: _______

- Additional Funding
  - Direct Costs: _______ Indirect Costs: _______

- Carryover Approval
  - Direct Costs: _______ Indirect Costs: _______

Note: If providing additional funds and/or carryover approval, please submit the subrecipient budget to OSRA for inclusion in the subaward amendment

☐ Change in Subrecipient Key Personnel
☐ Significant Effort Reduction for Subrecipient Key Personnel
☐ Change in Subrecipient Scope of Work
☐ Change in Animal Use
☐ Change in Human Subjects Use

Subrecipient Performance

1. Is the Subrecipient Institution satisfactorily performing their assigned Scope of Work?  
   ☐ YES ☐ NO

2. Are the reports and deliverables satisfactory?  
   ☐ YES ☐ NO

3. Did the Subrecipient Institution invoice in a timely manner?  
   ☐ YES ☐ NO

4. Are expenses reasonable based on the technical progress of the project?  
   ☐ YES ☐ NO

Please complete this checklist for each subrecipient institution receiving an amendment under this award. If this project will require a new subaward agreement, please complete a Statement of Intent to Establish a Consortium Agreement form found on the OSRA forms page, here:  
http://osra.weill.cornell.edu/forms.html
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Updates and important announcements coming to the OSRA home page: osra.weill.cornell.edu