Research Administration Update

Wednesday, January 31, 2018

Lazare Auditorium (S1-607)
1:00 - 2:00 pm
Agenda

• OSP Updates
  – OSP Staffing
  – Indirect Waiver requests/Cost Share approvals
  – Other AOR related changes
  – Change in IDP language
  – Proposal Information Worksheet

• NIH Updates
  – NOT-OD-17-062 FORMS-E
  – NOT-OD-18-107 Enforcement of Closeout Policy

• Proposal & Progress Report Statistics
OSP Updates

Office of Sponsored Programs

TBD
Director

Janice Lagacé
Interim Director

Barrie Stone
Document Coordinator

BLACK TEAM

James LeBlanc
Sr. Sponsored Program Administrator & Team Lead

Pam Harney
Sponsored Program Administrator II

Karen Gardiner
Sponsored Program Administrator I

BLUE TEAM

Jason Brown
Sr. Sponsored Program Administrator & Team Lead

Andrea Sjostedt
Sponsored Program Administrator II

Jenna Gerrish
Sponsored Program Administrator I
OSP Updates

• Indirect Waivers & Cost Share Approvals
  – PI requests Department Chair Approval
  – Submit to Interim Director Janice Lagacé
  – OSP will consult with RAC Subcommittee Chair
    Dr. Catarina Kiefe MD, PhD

Reminder that all IDC waivers will have a direct impact on the allocation to Departments
OSP Updates

- Cayuse Proposals – Adding the AOR
OSP Updates

- Cayuse Proposals – Adding the AOR
OSP Updates

• Cayuse Proposals – Adding the AOR
OSP Updates

• Cayuse Proposals – AOR in Routing Chain

Routing & Approval

Routing Chain

Begin

☐ Pagoto, Sherry L - University of Massachusetts Medical School: Preventive & Behavioral Med.

☐ RFS, - University of Massachusetts Medical School: Office of Research

End

Lagace, Janice - University of Massachusetts Medical School: Office of Research

An AOR is on the routing chain, but has not yet approved this proposal. The proposal will not be submittable until an AOR has approved the proposal.

Routing History

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<th>person</th>
<th>type</th>
<th>date/time</th>
<th>comments</th>
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<td>LagaceJ</td>
<td></td>
<td>Modify</td>
<td>2018-01-23 09:26</td>
<td>Auto-built chain at create time from PI</td>
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OSP Updates

- PeopleSoft Proposal Routing Forms
  If PI has not been added to the system, please use:

![Proposal Routing Form]

- PI Name: Lagace, Janice E
- Department: M495000000 - Molecular Cell & Cancer Biology
- Alt. Name: eddy, jenna
- Alt. Phone: 508/341-4405
- Alt. Email: jenna.eddy@umassmed.edu
- Requested Return Date: 02/01/2018
Blue Team Administrators

• All February Blue Team RPPR’s should be routed to Jenna Gerrish.
• List Janice Lagacé as the AOR and Jason Brown as the SO.
• After 2/16/2018 contact Janice Lagacé or SPA II Andrea Sjostedt.
OSP Updates

Individual Development Plan

Revised language has been issued by the GSBS for responding to the IDP question:

**B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?**

For more information on the IDP’s, please visit the GSBS website:

https://www.umassmed.edu/research/funding/rfsform/
UMass Medical School recognizes the critical importance of preparing our graduate students and postdoctoral scholars for success within a broad spectrum of scientific careers. All graduate students in year 3 and above are required to create an annual Individual Development Plan (IDP). The curriculum for graduate students now incorporates a course in the fall of the third year called Professionalism and Research Conduct (PARC) in which career planning and development and responsible conduct of research are taught. Included in the course is creation of the students’ first IDP. Updates and re-evaluation are required and monitored by the Graduate School of Biomedical Sciences annually. All incoming postdocs receive training in how to create an IDP as part of the required onboarding course in Responsible Conduct of Research. All trainees at UMMS have the resources of the Office for Postdoctoral Scholars and the Center for Biomedical Career Development open to them. This includes one-on-one mentoring and/or problem solving, internal workshops and career exploration options, as well as a series of external speakers who discuss career choices or who present lectures and/or workshops on a wide range of skills relevant to biomedical scientists.
OSP Updates

Proposal Information Worksheet

• Suggested by the Grants Focus Group
• Work group under the direction of Rik Madison
• Assist with capturing the required information when building a proposal

https://www.umassmed.edu/research/funding/rfsform/
**Proposal Information Worksheet**

1. General Information

<table>
<thead>
<tr>
<th>Proposal Information Worksheet</th>
<th>Administrative Use:</th>
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<tbody>
<tr>
<td><strong>Principal Investigator (PD/PI) Name:</strong></td>
<td>Multi PD/PI:</td>
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<tr>
<td><strong>Other PD/PI Name(s):</strong></td>
<td>Yes</td>
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<td><strong>Outside Contact(s):</strong></td>
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<td><strong>Sponsor:</strong></td>
<td>NIH</td>
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<td><strong>Application in Response to a Specific Opportunity:</strong></td>
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<tr>
<td><strong>Title if Known:</strong></td>
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# OSP Updates

## Proposal Information Worksheet

### 2. Budget/Personnel Information

<table>
<thead>
<tr>
<th>Budget/Personnel Information</th>
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<tr>
<td><strong>Budget Type:</strong></td>
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<tr>
<td><strong>Cost Sharing Requirements (Personnel or Other):</strong></td>
</tr>
<tr>
<td>If Yes, Provide Specifics:</td>
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<tr>
<td><strong>Target Amount:</strong></td>
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<tr>
<td><strong>Item(s):</strong></td>
</tr>
</tbody>
</table>

### Other Budgetary Restrictions:

- List Personnel/Effort and who’s Key:
  1. Role: PD/PI | Effort: | Key: Yes | No | Incl on SDFI: Yes | No |
  2. Role: | Effort: | Key: Yes | No | Incl on SDFI: Yes | No |
  3. Role: | Effort: | Key: Yes | No | Incl on SDFI: Yes | No |
  4. Role: | Effort: | Key: Yes | No | Incl on SDFI: Yes | No |
  5. Role: | Effort: | Key: Yes | No | Incl on SDFI: Yes | No |
  6. Role: | Effort: | Key: Yes | No | Incl on SDFI: Yes | No |
  7. Role: | Effort: | Key: Yes | No | Incl on SDFI: Yes | No |

- Are there any Other Significant Contributors: Yes | No
  - If yes, list Name/Institution/Department:

- Are there Outgoing Sub-Recipients: Yes | No
  - If yes, List Who and Projected Amounts:

- Will project involve foreign travel and activities outside the US or partnerships with international collaborators: Yes | No
  (If Yes, Contact Travel Office for approval)
Proposal Information Worksheet - Three Areas

3. Certifications/Other

https://www.umassmed.edu/research/funding/rfsform/
# NIH Updates

## NOT-OD-17-062 Forms E

<table>
<thead>
<tr>
<th>Use FORMS-D for...</th>
<th>Use FORMS-E for...</th>
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<tr>
<td>Applications submitted for due dates on or before January 24, 2018</td>
<td>Applications submitted for due dates on or after January 25, 2018</td>
</tr>
<tr>
<td>Applications submitted under <a href="#">NIH Late Policy</a> 2-week window of consideration for intended due dates on or before January 24, 2018</td>
<td>All application types (New, Resubmission, Renewal, Revision)</td>
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<td>Applications submitted by February 7, 2018 under <a href="#">NIH Continuous Submission Policy</a> for January 7, 2018 AIDS intended due date</td>
<td>Applications submitted early for intended due dates on or after January 25, 2018</td>
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NIH Updates

NOT-OD-17-062 Forms E

Directly effects all February 5th submissions.
There are now two Parent Opportunities for R01’s & R21’s

<table>
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<th>PA-18-484</th>
<th>NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)</th>
<th>FORMS-E</th>
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<td>PA-18-345</td>
<td>NIH Research Project Grant (Parent R01 Clinical Trial Required)</td>
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– Verify that you have chosen the correct PA

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<th>NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Required)</th>
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<td>NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Not Allowed)</td>
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NOT-OD-17-062 Forms E

• The most significant change with the new FORMS-E Application Package is the addition of a new PHS Human Subjects and Clinical Trials Information form.

• This form consolidates human subjects, inclusion enrollment, and clinical trial information previously collected across multiple agency forms.

• The information is collected at the study level.

• Allows for multiple studies.
Add a record for each proposed Human Subject Study by selecting 'Add New Study' or 'Add New Delayed Onset Study' as appropriate. Delayed onset studies are those for which there is no well-defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide the study name and a justification for omission of human subjects study information.

Other Requested Information

Add Attachment | Delete Attachment

Study Record(s)

Attach human study records using unique filenames.

Add New Study | Import Study

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Is a Clinical Trial

Delayed Onset Study(s)

Add New Delayed Onset Study

<table>
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<tr>
<th>#</th>
<th>Study Title</th>
<th>Anticipated Clinical Trial?</th>
<th>Justification</th>
</tr>
</thead>
</table>
NIH Updates

NOT-OD-17-062 Forms E

Section 1 - Basic Information

1.1. * Study Title (each study title must be unique)
LEAVE Safe with DOACs

1.2. * Is this Study Exempt from Federal Regulations?
   - Yes
   - No

1.3. Exemption Number
   - 1
   - 2
   - 3
   - 4
   - 5
   - 6
   - 7
   - 8

1.4. * Clinical Trial Questionnaire
If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.
   1.4.a. Does the study involve human participants?
   - Yes
   - No
   1.4.b. Are the participants prospectively assigned to an intervention?
   - Yes
   - No
   1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?
   - Yes
   - No
   1.4.d. Is the effect that will be evaluated a health-related, biomedical, or behavioral outcome?
   - Yes
   - No

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable.

If there is not a related number, leave this field blank.
Do not enter N/A.
Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study
- Anticoagulation in VTE Patients

Add New Condition

2.2. Eligibility Criteria

Inclusion:
1. Age 18 years or older

2.3. Age Limits
- Minimum Age: 18 Years
- Maximum Age: N/A (No limit)

2.4. Inclusion of Women, Minorities, and Children
- Kapoor_AHRQ_LEAVE-Safe_InclusionWomenMinoritiesChildren_FINAL.pdf

2.5. Recruitment and Retention Plan
- Kapoor_AHRQ_LEAVE-Safe_RecruitmentRetention_FINAL.pdf

2.6. Recruitment Status: Not yet recruiting

2.7. Study Timeline
- Kapoor_AHRQ_LEAVE-Safe_StudyTimeline_FINAL.pdf

2.8. Enrollment of First Subject: 01/01/2019 Anticipated

Be careful with any text box fields and avoid the use of symbols or character such as the < and >
G.500 - PHS Human Subjects and Clinical Trials Information

The PHS Human Subjects and Clinical Trials Information form is used to collect information on human subjects research, clinical research, and/or clinical trials, including study population characteristics, protection and monitoring plans, and a protocol synopsis.

This form accommodates the full spectrum of all types of clinical trials, including, but not limited to, behavioral, exploratory/development, mechanistic, pilot/feasibility, early phase, efficacy, effectiveness, group-randomized, and others.

Read all the instructions in the Funding Opportunity Announcement (FOA) before completing this form to ensure your application meets all IC-specific criteria. If you are proposing a clinical trial, make sure your FOA accepts clinical trials (i.e., 'clinical trial required' or 'clinical trial optional').

The PHS Human Subjects and Clinical Trials Information form, together with the rest of your application, should include sufficient information for the evaluation of the project, independent of any other documents (e.g., previous application). Be specific, describe each study clearly, and avoid redundancies. Be especially careful to avoid redundancies with your research strategy.
NOT-OD-17-062 Forms E – Helpful Links and Info


Please share this link with your PI’s.
NOT-GM-18-011  MIRA R35 Letter of Support

- Letter of support from the institution's Authorized Organizational Representative (AOR) for submission of an application to PAR-17-094 "Maximizing Investigators’ Research Award (R35)"
- Upload the Letter of Support to Section 9 of the Research Plan form
- Applications that omit this letter, or that do not indicate their acceptance of the conditions of an award, will be withdrawn without review.
- Contact our office if you need an example of the format
NIH Updates

NOT-OD-18-1017   Enforcement of Closeout Policy

• NIH recipients must submit within 120 days:
  – Final Federal Financial Report (FFR)
  – Final Research Performance Progress Report (F-RPPR)
  – Final Invention Statement

• Failure to submit timely reports may cause Unilateral Closeout resulting in:
  – corrective actions
  – withholding of further awards
  – suspension or termination
The Final Research Performance Progress Report (FRPPR) is submitted through the Commons in a format similar to the annual Research Performance Progress Report (RPPR). Further guidance and screenshots can be found here: https://era.nih.gov/erahelp/commons/Commons/status/closeout/Final_RPPR.htm

Please note that Section D.1 Participants is REQUIRED for the FRPPR. Your administrator, CC’ed on this email, should be able to assist in providing you the information and assistance needed to complete this section. Unlike the Annual Progress Report (RPPR), a FRPPR cannot be accessed by a delegate or routed to a delegate for assistance.

It must be completed under your Commons Account.

Once the FRPPR is completed and no errors are found on validation it can be submitted directly to the NIH. It does not require routing to our office for review.

The Final Invention Statement is also done electronically through the Commons. There is no need to complete and submit a paper form. Please see attached guidance on submitting a Final Invention Statement through the Commons. The Final Invention statement does require verification and submission by the Office of Sponsored Programs. We will receive automatic notification directly from the Commons when your part has been completed.

The Final Federal Financial Report is uploaded and submitted by Grant Accounting. No action is required on your part.

If you have any questions, please do not hesitate to ask!
NOT-OD-18-1017  Enforcement of Closeout Policy

From: XXXXXXXX@od.nih.gov
Sent: Monday, January 29, 2018 12:36 AM
To: Research Funding <ResearchFunding@umassmed.edu>
Cc: XXXXXXXX@umassmed.edu
Subject: CONTINUING FEDERAL NON-COMPLIANCE, Closeout of Grant 5R21NS095635-02

Dear Signing Official:

This is in follow up to our letters dated 09/06/2017 and 12/30/2017 regarding the closeout documents for the above referenced grant. In accepting the grant, your institution agreed to comply with our policies, including the requirement for submitting final reports in a timely manner. Despite our efforts, the following report, identified below, are now 30 days or more past due or the report submitted was unacceptable:

Final Research Performance Progress Report (FRPPR): An FRPPR is required, per section 8.6.2 of the NIH Grants Policy Statement. NIH requires submission of the FRPPR via the eRA Commons at https://commons.cra.nih.gov/commons. Information on the FRPPR, including screenshots and an instruction guide, may be found at: http://grants.nih.gov/grants/rppr/index.htm

Final Invention Statement (HHS 568): The Final Invention Statement form is located at http://grants.nih.gov/grants/forms.htm

We are concerned that your institution has been unable to comply with the terms and conditions of the award by submitting the required closeout documents. As previously noted, failure to submit timely and accurate closeout documents may affect future funding to the organization. Additionally, without UNIV OF MASSACHUSETTS MED SCH WORCESTER's cooperation in submitting acceptable final reports, NIH may take unilateral action to close the grant as a measure of last resort, and may also take additional actions, including, but not limited to, enforcement actions that may affect future funding. Unilateral closeout is a measure of last resort.

Again, you are reminded that the immediate submission of these reports is imperative.

Please contact me if you have questions.

Sincerely,

Grants Closeout Specialist
# PROPOSAL SUBMISSIONS TO OSP

December 2016 – December 2017

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- **On Time:** Received by OSP 5 business days prior to the requested return date.
- **Late:** Received by OSP less than 5 business days prior to the requested return date.
- **After the Fact:** Received by OSP after the requested return date.
- **Expedited Request:** Received by OSP with 3 business days or less to review before requested return date.
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PROGRESS REPORT SUBMISSIONS TO OSP  
December 2016 – December 2017

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<td>22%</td>
<td>40%</td>
<td>26%</td>
<td>24%</td>
<td>9%</td>
<td>21%</td>
<td>19%</td>
</tr>
</tbody>
</table>

**On Time:** Received by OSP 5 business days prior to the requested return date.  
**Late:** Received by OSP less than 5 business days prior to the requested return date.  
**After the Fact:** Received by OSP after the requested return date.  
**Expedited Request:** Received by OSP with 3 business days or less to review before requested return date.
## PROGRESS REPORT SUBMISSIONS TO OSP
### December 2016 – December 2017

<table>
<thead>
<tr>
<th>PROGRESS REPORTS</th>
<th>2016</th>
<th>2017</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Count</td>
<td>35</td>
<td>36</td>
<td>+1</td>
</tr>
<tr>
<td>On Time</td>
<td>63%</td>
<td>56%</td>
<td>-7</td>
</tr>
<tr>
<td>Late</td>
<td>37%</td>
<td>36%</td>
<td>-1</td>
</tr>
<tr>
<td>After the fact</td>
<td>0%</td>
<td>8%</td>
<td>+8</td>
</tr>
<tr>
<td>Total</td>
<td>100%</td>
<td>100%</td>
<td>-</td>
</tr>
<tr>
<td>Expedited Request (3 days or less)</td>
<td>23%</td>
<td>19%</td>
<td>-4</td>
</tr>
</tbody>
</table>

**On Time:** Received by OSP 5 business days prior to the requested return date.  
**Late:** Received by OSP less than 5 business days prior to the requested return date.  
**After the fact:** Received by OSP after the requested return date.  
** Expedited Request:** Received by OSP with 3 business days or less to review before requested return date.
APPENDIX
<table>
<thead>
<tr>
<th>HS/CT Forms and Documents</th>
<th>Human Subjects, Exemption 4</th>
<th>Human Subjects, no Clinical Trial</th>
<th>Clinical Trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Record Form</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Study Record Form: Section 1, 2, 3</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Study Record Form: Section 4-5</td>
<td>Do not complete</td>
<td>Do not complete</td>
<td>Required</td>
</tr>
<tr>
<td>Inclusion of Women, Minorities, &amp; Children section 2.4</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Recruitment and Retention Plan section 2.5</td>
<td>Not required</td>
<td>Required if study involves human participants</td>
<td>Required</td>
</tr>
<tr>
<td>Study Timeline section 2.7</td>
<td>Not required</td>
<td>Required if study involves human participants</td>
<td>Required</td>
</tr>
<tr>
<td>Inclusion Enrollment Report</td>
<td>Not required</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Protection of Human Subjects section 3.1</td>
<td>Not required</td>
<td>Required for all non-exempt research. For exempt, provide justification for exemption.</td>
<td>Required</td>
</tr>
<tr>
<td>Single IRB section 3.2</td>
<td>Required only for Multi-site study</td>
<td>Required only for Multi-site study</td>
<td>Required only for Multi-site study</td>
</tr>
<tr>
<td>Data and Safety Monitoring Plan section 3.3</td>
<td>Optional</td>
<td>Optional</td>
<td>Required</td>
</tr>
<tr>
<td>Overall Structure of the Study Team section 3.5</td>
<td>Optional</td>
<td>Optional</td>
<td>Required</td>
</tr>
<tr>
<td>Statistical Design and Power section 4.4</td>
<td>Do not include</td>
<td>Do not include</td>
<td>Required</td>
</tr>
<tr>
<td>FDA Regulated Intervention section 4.6A</td>
<td>Do not include</td>
<td>Do not include</td>
<td>Required for FDA-regulated intervention study</td>
</tr>
<tr>
<td>Dissemination Plan section 4.7</td>
<td>Do not include</td>
<td>Do not include</td>
<td>Required</td>
</tr>
<tr>
<td>Other Requested Information</td>
<td>Do not include</td>
<td>Do not include</td>
<td>As required by the FOA</td>
</tr>
</tbody>
</table>
New NIH "FORMS-E" Grant Application Forms and Instructions Coming for Due Dates On or After January 25, 2018

Notice Number: NOT-OD-17-062

Key Dates

Release Date: April 27, 2017

Related Announcements
NOT-OD-18-004
NOT-OD-17-119
NOT-OD-17-114
NOT-OD-16-147
NOT-OD-17-043
NOT-OD-18-009

Issued by National Institutes of Health (NIH)

Purpose

This notice informs the biomedical and health services research communities of changes to grant application form and application guide instructions for due dates on or after January 25, 2018.

Focus of changes:

- Consolidation of human subjects, inclusion enrollment, and clinical trial information previously collected across multiple agency forms
- Expansion and use of discrete form fields for clinical trial information to
  - provide the level of information needed for peer review;
  - lead applicants through clinical trial information collection requirements;
  - present key information to reviewers and agency staff in a consistent format; and
  - align with ClinicalTrials.gov (where possible) and position us for future data exchange with ClinicalTrials.gov
- Incorporation of recent Grants.gov changes to R&R Budget and SBIR/STTR Information forms

These changes will be implemented with application form packages identified with a Competition ID of "FORMS-E" and associated application guide instructions. See High-level Summary of Form Changes in FORMS-E Application Packages for a full list of changes.

Effective Date

Applicants must use FORMS-E application packages for due dates on or after January 25, 2018 and must use FORMS-D application packages for due dates on or before January 24, 2018. Applications submitted using the wrong forms for their intended due date will not be reviewed.

Availability of FORMS-E Application Guides

Application guides for FORMS-E application packages will be posted to the How to Apply - Application Guide page no later than October 25, 2017.

Availability of FORMS-E Application Packages
We will begin posting new funding opportunity announcements (FOAs) with FORMS-E application packages on October 25, 2017.

- New FOAs posted before October 25, 2017 with initial due dates on or after January 25, 2018 will be posted without application forms. Application packages will be added to these FOAs by November 10, 2017.

All NIH "parent" announcements that use standard due dates will be expired and reissued with new FOA numbers, FORMS-E application packages and instructions. The FORMS-E parent announcements will be posted no later than 60 days before their standard due date. For a transition period, both FORMS-D and FORMS-E parent announcements will be active. Applicants must choose the announcement with the appropriate application package for their due date (see table below).

All active FOAs with due dates both before and after January 25, 2018 will be updated to add FORMS-E application packages between October 25, 2017 and November 25, 2017. For a transition period, both FORMS-D and FORMS-E application packages will be active. Applicants must choose the appropriate application package for their due date when presented with both FORMS-D and FORMS-E application packages on the same FOA (see table below).

<table>
<thead>
<tr>
<th>If your due date is…</th>
<th>You must use…</th>
</tr>
</thead>
<tbody>
<tr>
<td>On or before January 24, 2018, including:</td>
<td>FORMS-D application package</td>
</tr>
<tr>
<td>- Applications submitted for due dates on or before January 24, 2018</td>
<td></td>
</tr>
<tr>
<td>- Applications submitted under NIH Late Policy 2-week window of consideration for intended due dates on or before January 24, 2018</td>
<td></td>
</tr>
<tr>
<td>- Applications submitted by February 7, 2018 under NIH Continuous Submission Policy for January 7, 2018 AIDS intended due date</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>On or after January 25, 2018, including:</th>
<th>FORMS-E application package</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Applications submitted for due dates on or after January 25, 2018</td>
<td></td>
</tr>
<tr>
<td>- All application types (New, Resubmission, Renewal, Revision)</td>
<td></td>
</tr>
<tr>
<td>- Applications submitted early for intended dues dates on or after January 25, 2018</td>
<td></td>
</tr>
</tbody>
</table>

Additional guide notices for individual FOAs with unique due date considerations will be issued as needed and referenced in the Related Notices section of each FOA.

**Form Update Timing for Administrative Supplement, Successor-in-Interest (Type 6) and Change of Institution (Type 7) Parent Announcements**

Parent announcements for administrative supplements and post award administrative actions (successor-in-interest and change of institution applications) do not have set due dates and, consequently, will follow a different timeline than other parent announcements.

The FOAs in the table below will be reissued with new FOA numbers, FORMS-E application packages and instructions on January 25, 2018. Applications started on or after January 25, 2018 must use the new FOAs and FORMS-E application packages.
These FOAs will expire on February 25, 2018 giving applicants one month to complete their initiated FORMS-D applications.

<table>
<thead>
<tr>
<th>FOA#</th>
<th>FOA Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>PA-16-285</td>
<td>Change of Grantee Organization (Type 7 Parent)</td>
</tr>
<tr>
<td>PA-16-286</td>
<td>Successor-in-Interest (Type 6 Parent)</td>
</tr>
<tr>
<td>PA-16-287</td>
<td>Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Admin Supp)</td>
</tr>
<tr>
<td>PA-16-288</td>
<td>Research Supplements to Promote Diversity in Health-Related Research (Admin Supp)</td>
</tr>
<tr>
<td>PA-16-289</td>
<td>Research Supplements to Promote Re-Entry into Biomedical and Behavioral Research Careers (Admin Supp)</td>
</tr>
</tbody>
</table>

Applications Proposing Clinical Trials

As previously announced, all applications involving clinical trials must be submitted to FOAs specifically designed for clinical trials beginning with due dates on or after January 25, 2018 (NOT-OD-16-147, NOT-OD-17-043).

We will take the following steps to accommodate this new policy:

- Issue new clinical trial FOAs with clinical trial-specific review criteria, FORMS-E application packages, and FORMS-E instructions for due dates on or after January 25, 2018
- Add a new "Clinical Trials" item to the table in Section II of all FOAs (just below "Application Types Allowed") which will include one of the following statements:
  - Only accepting applications that propose clinical trial(s)
  - Only accepting applications that do **not** propose clinical trials
  - Accepting applications that either propose or do not propose clinical trial(s)
- Expire existing (FORMS-D) clinical trial FOAs by January 24, 2018

Resources:

- [High-level Summary of Form Changes in FORMS-E Application Packages](https://grants.nih.gov/grants/forms/)
- [Annotated Form Set for NIH Grant Applications](https://grants.nih.gov/grants/forms/)
- [Do I Have the Right Form Version For My Application?](https://grants.nih.gov/grants/forms/)
- [Application Forms, Form Updates, and Choosing the Correct Forms FAQs](https://grants.nih.gov/grants/forms/)

Inquiries

Please direct all inquiries to:

NIH Grants Information
Email: grantsinfo@od.nih.gov (preferred method of contact)
Telephone: 301-945-7573

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**Weekly TOC for this Announcement**

NIH Funding Opportunities and Notices

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Reminder of Required Letter of Support for PAR-17-094 "Maximizing Investigators' Research Award (R35)"

Notice Number: NOT-GM-18-011

Key Dates
Release Date: December 11, 2017

Related Announcements
PAR-17-094

Issued by
National Institute of General Medical Sciences (NIGMS)

Purpose

The purpose of this Notice is to remind applicants of the requirement for a letter of support from the institution's Authorized Organizational Representative (AOR) for submission of an application to PAR-17-094 "Maximizing Investigators’ Research Award (R35)".

Part 2. Section IV.2. PHS 398 Research Plan

Note that a letter of support is required from the institution's Authorized Organizational Representative (AOR) indicating acceptance of the conditions of the MIRA as defined in the instructions for the Letter of Support attachment on the PHS 398 Research Plan form. PD/PIs are encouraged to work with their AOR to make sure this letter is included in this section of the application. Applications that omit this letter, or that do not indicate their acceptance of the conditions of an award, will be withdrawn without review.

Inquiries

Please direct all inquiries to:

Vernon Anderson, Ph.D.
National Institute of General Medical Sciences (NIGMS)
Telephone: 301-594-3827
Email: NIGMS_EstPI_MIRA@mail.nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices
NIH Enforcement of Closeout Policies

Notice Number: NOT-OD-18-107

Key Dates
Release Date: November 30, 2017

Related Announcements
NOT-OD-17-085
NOT-OD-17-022
NOT-OD-15-136
NOT-OD-15-135
NOT-OD-15-111
NOT-OD-14-084

Issued by
National Institutes of Health (NIH)

Purpose

The purpose of this Notice is to alert the NIH extramural community that NIH is strengthening enforcement of longstanding closeout requirements, outlined in the NIH Grants Policy Statement Section 8.6, Closeout. NIH has consistently reminded recipients of their responsibility to submit timely, accurate final grant expenditure reports, and has communicated the critical need for recipients to reconcile cash transaction reports submitted to the HHS Payment Management System (PMS) with expenditure reports submitted to NIH. In order to fulfill agency requirements under the Grants Oversight and New Efficiency (GONE) Act and HHS grants policy, NIH will no longer delay the closeout of awards unless the recipient submits a prior approval request to the IC providing an acceptable written justification. Without prior approval from the awarding IC, NIH will initiate unilateral closeout for all awards that fail to meet closeout requirements within 120 days as required by the NIH Grants Policy Statement (NIH GPS) Section 8.6. See below for details.

Background

Recipient Responsibilities

The requirement for timely closeout is generally a recipient responsibility. However, NIH may initiate unilateral closeout if a recipient does not provide timely, accurate closeout reports or does not respond timely to NIH requests to reconcile discrepancies in grant records.

NIH recipients must submit a Final Federal Financial Report (FFR), Final Research Performance Progress Report (F-RPPR), and Final Invention Statement and Certification (FIS) within 120 calendar days of the end of the period of performance (project period), as required in section 8.6 of the NIH GPS. The reports become overdue the day after the 120 calendar day period ends. Cash transaction data continues to be submitted directly to and processed by PMS. It is the recipient's responsibility to reconcile reports submitted to PMS and to the NIH awarding Institute or Center.

NIH Actions

NIH is committed to addressing and reducing grant closeout delays and to enhance compliance with HHS regulations and policies, and the GONE Act. Therefore, NIH will strictly enforce its closeout policies. When recipients fail to submit timely reports, NIH will initiate unilateral closeout. It is important to note that for financial closeout, if a recipient fails to submit a final expenditure FFR, HHS policy directs NIH to close the grant using the last accepted Federal Cash Transaction Report’s cash drawdown amount. This could be considered a debt or result in disallowed costs. In addition, failure to correct recurring reporting problems may
cause NIH to take one or more actions that may include, but are not limited to, corrective actions, withholding of further awards, suspension or termination.

Inquiries

Please direct all inquiries to:

Division of Grants Policy
Office of Policy for Extramural Research Administration
Office of Extramural Research
Telephone: 301-435-0949
GrantsPolicy@od.nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices