Research Administration Practices (RAP) Sessions

NIH Proposal Updates and Resources

May 15, 2020

Bernadette Valalley, Senior Contract Administrator, RAS; MIT Lead Liaison for NIH

Rosemary Hanlon, Senior Research Administration Support and Education Specialist, VPR
Agenda

RAP Sessions: Targeted skills based educational offerings open to the Research Administration community at MIT. Information gathered and shared with attendees can be taken back to their desks and applied immediately.

- Introductions
- NIH Updates on COVID-19
- Forms-F
- PHS/NIH Human Subjects Clinical Trial form
- Questions/Help
Introductions

Bernadette Vallely, Senior Contract Administrator, RAS; MIT Lead Liaison for NIH

Rosemary Hanlon, Senior Research Administration Education & Support Specialist, VPR
NIH is Open for Business

• Extramural staff are working remotely
• We continue to process applications and make awards
• We are conducting peer review meetings virtually
• We are working diligently to provide funding opportunities to support COVID-19 research
This is a rapidly evolving situation

Check Information for Applicants & Recipients (above)
COVID-19 Funding Opportunities

• Funding through competing supplements, administrative supplements, new awards
• Many Funding Opportunities Specific to COVID-19 at bottom of webpage
• About COVID-19 Funding and Funding Opportunities - Emergency or Urgent Notice of Special Interest (NOSI)
NIH Advice for Applicants & Recipients

• For general questions regarding COVID-19 flexibilities, contact NIH’s Office of Extramural Research at grantspolicy@nih.gov

• For questions specific to your NIH award, contact the grants management or program staff at the funding institute or center

Frequently Asked Questions (FAQs)
COVID-19 Flexibilities
FAQs frequently updated. Check back often!

See NOT-OD-20-086 Flexibilities Available to Applicants and Recipients of Federal Financial Assistance Affected by COVID-19

- Research Administration FAQs
- Sponsor Specific Guidance regarding how the COVID-19 response may impact proposals and awards.
- Research Continuity Guidance For Laboratories And Research Facilities
- MIT’s Response to the Challenge of COVID-19 (Coronavirus)
- Funding Opportunities Specific to COVID-19
NIH Forms-F: for due dates on or after May 25, 2020

https://www.youtube.com/watch?v=qxwua8Uy84A

– Resources –


https://grants.nih.gov/grants/guide/parent_announcements.htm

MIT RAS – NIH Updating Forms to Forms-F


Research Administration Practices (RAP) Sessions May 15, 2020
NIH Forms-F: Changes

Noted changes:

• PHS Assignment form has been updated with Forms F, please use version 3 only if using Forms F for submission.
• Note the Fetal Tissue question on the PHS 398 Cover Page Supplement

Added Human Fetal Tissue Section including question - “Does the proposed project involve human fetal tissue obtained from elective abortions?”

• If Yes, two new attachments are requested
  1. HFT Compliance Assurance
  2. HFT Sample IRB Consent Form

Note: NIH is allowing late submission for certain FOAs. If the due date is prior to May 25th, use Forms E.
NIH Fellowships and Career Development

• Career Development:
  Added new attachment titled “Description of Candidate’s Contribution to Program Goals” to the Environment and Institutional Commitment to Candidate Section

• Fellowships:
  Added new attachment titled “Description of Candidate’s Contribution to Program Goals” to the Institutional Environment and Commitment to Training Section
Choose the correct FOA in KC and Workspace

• NIH may include multiple Competition ID’s until May 25\textsuperscript{th} (Forms-E vs. Forms-F)
• Make sure you search for the newest opportunity postings
  https://grants.nih.gov/grants/guide/parent_announcements.htm

If you’ve begun working on a proposal, you can still change the FOA:
• KC: use the ‘change opportunity’ feature to search and replace
• Workspace: you can copy your current workspace to a new opportunity. It is designed to bring as much information as it can (There will be additional fields to answer & attachments to add, based on the forms.)
Fetal Tissue - Cover Page Supplement

• Even if sub, as the lead we need to provide details.
• Consult your PI & researchers before answering the Questionnaires.
• If Yes, then the Proposal Attachments are required.
Fetal Tissue – in the RR Budget

• The specific line item must be added in the RR budget.

• For KC, select the Category in order to present the Object Code.

• In Workspace, you must enter the line manually in Line 8, 9, or 10.
Assignment Request Form

• User attached in KC, use the correct version
• Clarified instruction text displayed on form
• Changed several field labels
• Removed fields
  o Do Not Assign to Awarding Components
  o Do Not Assign to Study Sections
• Added “Rationale for assignment suggestions” text box

• Workspace – download preview grant image it won’t include assignment request, cover letter or appendices – but it is included but not included with the reviewers. MIT needs everything. Upload cover letter, etc. separately in KC.
• Reworked landing page to require an answer and supporting explanation (if applicable) for the question “Does any of the proposed research in the application involve human specimens and/or data?” for all applications

• Changes in the Study Record:
  • Separated “Inclusion of Women, Minorities, and Children” attachment into two attachments – “Inclusion of Individuals Across the Lifespan” and “Inclusion of Women and Minorities”
  • Renamed “Enrollment of First Subject” field to “Enrollment of First Participant”
  • Added “Inclusion Enrollment Report Title” field to the Inclusion Enrollment Report
  • Removed “Brief Summary” attachment
  • Renamed “Narrative Study Description” attachment to “Detailed Description”
  • Added new question and checkbox – “Is this an applicable clinical trial under FDAAA?”

New RA Support Guide to this form & study record – overview of usage.
Overview of PHS HSCT submission options

This versatile form must have some data provided – but how it is added varies:

• **Biospecimen or biospecimen** data use.
  • A justification/explanation file attached.

• **Delayed onset of either Human Subjects or Clinical Trial**.
  • A justification/explanation file attached

• **Exempt Research**
  • Requires the study record – but not all sections

• **Human Subjects research**
  • study record required – sections through 1-3.2

• **Clinical Trial**
  • study record required, all sections 1 through 4
Virtual Drop-In RA Support
Monday May 18th 1:00 – 2:00 PM
Rosemary Hanlon will review the Forms-F PHS Human Subjects and Clinical Trial Info

For Zoom link see Virtual Drop-In RA Support Sessions

Guide to Forms F PHS Human Subjects Clinical Trial Info and Study Record for KC and Workspace
Proposals for sponsored projects, regardless of submission method, must have a KC proposal created and routed for internal approvals.

For Workspace and Assist: create a **KC Non-System-to-System** proposal that matches the proposal being submitted to NIH and route for internal approvals.
Workspace & KC Submission Overview

Requires Workspace Manager role
Must grant RAS Contract Administrators (AOR) participant access to view and submit.
Validates at Grants.Govs and agency

Workspace export upload to KC as Attachment

Submission

NIH
Merit Review & Processing

RAS CA / Liaison

Proposal Development

PI and Co-I certification
Subaward organization(s)
Upload workspace export as Attachment
Summary budget or Detailed Budget
Compliance / Special reviews
Route for internal approval

Workspace AOR
RAS CA / Liaison

APPROVED & SUBMITTED

KC Institute Proposal (Pending)

Research Administration Practices (RAP) Sessions May 15, 2020
Interested in Workspace?


NCURA Virtual Workshops and Webinars

Course Catalog

Details
The National Council of University Research Administrators (NCURA) is focused on advancing the profession of research administration through education, knowledge sharing, and the fostering of a collegial and respected global community. MIT is pleased to offer access to previously recorded NCURA virtual Workshops and Webinars for our research administration community.

Select webinar(s) to view from the PART I: KNOWLEDGE list below. To receive MIT Learning Center credit for completing each webinar course, select the corresponding title in the PART II: KNOWLEDGE CHECK list and complete a brief webinar quiz.

Assignments This Course Will Fulfill
NCURA Virtual Workshops and Webinars

Part I: Knowledge
Overview of the NIH grants process

Links
A. NIH Fundamentals
B. NSF Fundamentals

How Does NIH Fund Research?

- NIH provides financial support in the form of grants, cooperative agreements, contracts and other transactions to support the advancement of the NIH mission to enhance health, extend healthy lives, and reduce the burdens of illness and disability
- 24 of the 27 NIH Institutes and Centers (ICs) fund research, based on their mission and priorities, budget, and funding strategy
- In FY2017 NIH awarded 44,389 Research Grants, 3,380 Cooperative Agreements and 1,981 Research and Development Contracts

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NIH Cycles – Standard Dates by Activity Code

If the FOA says "standard dates apply", refer to grants.nih.gov » About Grants » How to Apply - Application Guide » Due Dates

Note: renewal, resubmission, revision applications may have different due dates than new.

The AIDS and AIDS-related dates apply to all activity codes.

<table>
<thead>
<tr>
<th>Activity Codes</th>
<th>Program Description</th>
<th>Cycle I Due Date</th>
<th>Cycle II Due Date</th>
<th>Cycle III Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>P Series</td>
<td>Program Project Grants and Center Grants</td>
<td>January 25</td>
<td>May 25</td>
<td>September 25</td>
</tr>
</tbody>
</table>

NOTE: Applicants should check with the relevant Institute or Center (IC), since some do not accept P series applications for all three receipt/review/award cycles.

<table>
<thead>
<tr>
<th>R18, U18 R25</th>
<th>Research Demonstration Education Projects</th>
<th>January 25</th>
<th>May 25</th>
<th>September 25</th>
</tr>
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<tr>
<th>T Series</th>
<th>Institutional National Research Service Awards Other Training Grants</th>
<th>January 25</th>
<th>May 25</th>
<th>September 25</th>
</tr>
</thead>
</table>

NOTE: Applicants should check with the relevant Institute or Center (IC), since some do not accept T series applications for all three receipt/review/award cycles. Applicants should refer to the IC Table of Contacts for information for each IC's scientific/research contact for the NRSA T32 program.

<table>
<thead>
<tr>
<th>D Series</th>
<th>Construction Grants</th>
<th>January 25</th>
<th>May 25</th>
<th>September 25</th>
</tr>
</thead>
</table>

| C06/UC6 All - new, renewal, resubmission, revision | | | | |

| G07, G08, G11, G12, G13, G20, R24, S06, S11, S21, S22, SC1, SC2, SC3, UG1, U10, U13, U24, U2C, U41, U42, U45, U54, U56 All - new, renewal, resubmission, revision | Other Activity Codes | January 25 | May 25 | September 25 |

| R01 new | Research Grants | February 5 | June 5 | October 5 |
MIT NIH Checklists and Preparation Guides

- MIT checklists for NIH Grant applications
  - R01/R21
  - K99/R00
  - K Series
- NIH Director Pioneer (DP1) & Director Innovation (DP2):
  - NIH Training Grants
  - NIH F-Series
  - (NRSA) F31 & F32
NIH Resources

• NIH Application Guides: https://grants.nih.gov/grants/how-to-apply-application-guide.html

• RAS NIH Guidance: https://ras.mit.edu/grant-and-contract-administration/sponsor-information/national-institutes-health.nih

NIH Resources: Detailed Guides for Forms F

• Research Instructions:  

• Fellowship Instructions:  

• Career Development Instructions:  

• Training Instructions:  
NIH Resources

- KC Website NIH FAQs: https://kc.mit.edu/category/faq/phs-nih
- KC Website S2S FAQs: https://kc.mit.edu/category/faq/grantsgov-s2s
Questions – Help

- RAS Contract Administrator
- RA-Help@mit.edu
- Drop-In RA Support (via Zoom)
- COUHES Office
  - couhes@mit.edu
  - 617-253-6787