Research Administration Practices (RAP) Sessions

NIH Proposal Resources and Updates

Bernadette Vallely, NIH Lead Liaison
Team Manager, Grant & Contract Administration, RAS

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Introductions

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Team Manager, Grant & Contract Administration, RAS
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.

• Notices Of Funding Opportunities (NOFOs)
  • Clinical Trails and Human Subjects
  • eRA required for all Key Personnel
  • Attachments: Format, Human Subjects form
  • Biographical Sketch / Other Support Forms
• Budget Issues
  • Salary Cap
  • Graduate Student compensation
  • DMSP costs
• Post-Submission and Closeout

Research Administration Practices (RAP) Sessions
Notice Of Funding Opportunities

Parent Announcements (For Unsolicited or Investigator-Initiated Applications)

Parent announcements are broad funding opportunity allowing applicants to submit investigator-initiated applications for specific activity codes. They are open for up to 3 years and use standard due dates.

Not all NIH Institutes and Centers participate on all parent announcements. Before submitting your application, make sure the NIH Institute or Center that might be interested in your research is listed as a participating organization in the announcement.

The following Parent Announcements are available (sorted by Activity Code):

[ Research (R) | Research Training (T) | Career Development (K) | Fellowships (F) | Admin Supplements | Post-award Administrative Action ]

Research (R) Announcements

<table>
<thead>
<tr>
<th>Activity Code(s)</th>
<th>Title</th>
<th>Announcement Number</th>
<th>Issue Organization</th>
<th>Release Date</th>
<th>Open Date</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>R01</td>
<td>NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)</td>
<td>PA-20-185</td>
<td>NIH</td>
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<tr>
<td>R01</td>
<td>Research Project Grant (Parent R01 Basic Experimental Studies with Humans Required)</td>
<td>PA-20-184</td>
<td>NIH</td>
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<td>R01</td>
<td>Research Project Grant (Parent R01 Clinical Trial Required)</td>
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<td>R03</td>
<td>NIH Small Research Grant Program (Parent R03 Clinical Trial Not Allowed)</td>
<td>PA-20-200</td>
<td>NIH</td>
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<tr>
<td>R13</td>
<td>NIH Support for Conferences and Scientific Meetings (Parent R13 Clinical Trial Not Allowed)</td>
<td>PA-24-141</td>
<td>NIH</td>
<td></td>
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<tr>
<td>R21</td>
<td>NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Not Allowed)</td>
<td>PA-20-195</td>
<td>NIH</td>
<td></td>
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</table>

Notices of funding opportunities specify allowability of clinical trials in the funding opportunity Title and Section II Award Information with the following designations*:

- **Clinical Trial Not Allowed**: Only accepts applications that do not propose clinical trial(s)
- **Clinical Trial Required**: Only accepts applications that propose clinical trial(s)
- **Clinical Trial Optional**: Accepts applications that either propose or do not propose clinical trial(s)

*dictates what needs to be included in the application in terms of Human Subjects. If a clinical trial is required human subjects must be part of the application.
Decision Tool: Am I Doing Human Subjects Research?
The questionnaire is a tool to assist you with determining whether your project involves non-exempt human subjects research, meets the criteria for exempt human subjects research, or does not involve human subjects research.

**QUESTION ONE**

Please check which best describes your research:

- For the purpose of this study, at some point there will be an intervention or interaction with subjects for the collection of specimens or biological material or data (including health or clinical data, surveys, focus groups or observation of behavior).
- This study will involve only the use of secondary analysis of biological material/tissue/specimens or data not collected specifically for this study.
- This study will involve materials/specimens or data from deceased individuals only.
- My study does not fit any of these categories.

Next
RAS: NIH Human Subjects and Clinical Trials

Human Subjects and NIH Proposals

Clinical Trial or Not?

Understanding whether a human subjects research study meets the NIH definition of a clinical trial helps you connect with the appropriate funding opportunities and complete submission forms correctly. Use NIH's Decision Tool to learn whether your study is a clinical trial.

Human Subjects and Clinical Trial Information Form

Detailed instructions for completing the Human Subjects and Clinical Trial Information Form [PDF]

Proposals with Human Subjects (non-clinical trial)

For all proposals with Human Subjects and that will not have a delayed onset, the applicant will need to include at least one New Study Record.

The New Study record is intended to capture and consolidate the details of the planned use of human subjects. Many sections will be familiar, such as the Inclusion of Women, Minorities, and Children, which was previously captured in the Research Plan form.

These proposals must complete sections through section 3.2 of the New Study form.

Proposals with Clinical Trials

Proposals that meet the NIH Definition of “Clinical Trials” (no delayed onset) must also include at least one New Study Record. In this case, Sections 1, 2, 3, 4 must be included and Section 5 may be required if specified in the solicitation.

Proposals with Delayed Onset of Human Subjects (either Clinical or not)

For Delayed Onset studies, a Delayed Onset Study Record must be uploaded listing the title of the study and the justification for the omission of the human subjects study information. Multiple delayed onset studies may be uploaded in a single record/justification attachment.

Visit the MIT COUHES website for more information.
eRA Commons ID: Required for ALL Key Persons

• eRA Commons ID must be entered in the **Credential, e.g. agency login** field for all Senior/Key Personnel, and Other Significant Contributors listed on the R&R Senior/Key Person Profile Form.

• If the **Credential, e.g. agency login** field is blank or does not contain a valid eRA Commons ID, validation has been updated to an **ERROR** (due dates on or after January 25, 2024).

• Applicants are encouraged to check eRA Commons ID roles and MIT affiliation before the due dates.

eRA Commons ID requests for MIT persons ([nih-help@mit.edu](mailto:nih-help@mit.edu))
To request an eRA Commons account for someone at MIT, please email the following information to nih-help@mit.edu:

- First Name
- Last Name
- Email address
- Does user have an existing eRA Commons Account at another organization?
- What role will they need? See the eRA Commons Roles Matrix for guidance.
Pre-Doctoral (F31) and Post-Doctoral (F32) Research Fellowships

NIH NRSA Fellowship – Proposal Preparation Checklist
Before You Begin
- READ THE FQA
- Refer to the SF424 Guidelines.
- Proposals MUST be submitted on or before 5:00pm Local Time on Deadline Date. If an NIH “standard deadline” date falls on a weekend or Federal holiday, the deadline is extended to the following business day.
- The individual Fellowship applicant for whom support is being requested is designated as the PD/PI on the application and must be registered in eRA Commons as PI. The mentor, also needs a valid eRA Commons ID listed with the role of “mentor.” Please contact nihr-help@mit.edu if an eRA Commons ID or new role are needed.

Kuali Coeus (KC)
- The mentor should be the named PI in the proposal; similar to any other fellowship. The fellow is listed as key personnel. Both need to certify.
- Delivery Info tab: On the Submission Account ID, suggest the Workspace or Assist number
- Sponsor & Program information Tab: On the Opportunity ID field – suggest adding in the NOFO

Sections of the Application
RR SF424 Cover Page – please note:
1. Ensure correct box is checked: "Application". Note: change/corrected applications are only used if the original proposal submitted errored before reaching NIH and needs to be resubmitted.
4a. Box is completed with the NIH grant number or a Resubmission I.e., CA123456
5. Applicant Information – Enter the UEI (Unique Entity Identifier) - E2NYLC1ML6V1
6. Employer Identification: 04-210-3594
8. Type of application: ensure correct box is check (either NEW or RESUBMISSION)
11. Title: No special characters should be used. Limit 200 characters including spaces and punctuation.
12. Ensure start dates are correct. Note: The start date is an estimate, typically nine months after application submission and many times follows the NIH Standard Due Dates.
13. MIT Congressional District = MA-007
16. The program is NOT covered by E.O. 12372
17. Should be AGREE

• Kuali Coeus (KC) Key Personnel:
  • Mentor = PI; Fellow = key person.
  • Both need to certify (Fellow must have MIT Kerberos and email).

• Delivery Info tab: On the Submission Account ID, suggest the Workspace or Assist number

• Sponsor & Program Information Tab:
  On the Opportunity ID field – suggest adding in the NOFO
Attachments: Format Guidelines

Be familiar with the following format guidelines:

- Citations
- Combining Information into a Single Attachment
- Electronic Signatures
- Filenames
- File Size
- Flattened PDFs
- Font
- Format Pages
- Headers and Footers
- Hypertext, Hyperlinks, and URLs
- Images
- Language & Style
- Marking Up Attachments
- Orientation
- Page Limits & Lines of Text Limits
- Paper Size and Margins
- Scanning
- Security Features
- Single vs. Multi-column Page Format
- Video

See NIH Format Attachments
 NIH has been working with the NSF and other federal agencies on the Common Forms for the Biosketch and Current and Pending (Other) Support. The Common Forms have been cleared by OSTP and OMB and are posted on the NSF website.

• NIH Estimated timeline as outlined in **NOT-OD-21-073**:
  • Common Forms (Biosketch and Current and Pending (Other) Support) Implementation: January 2025
  • SciENcv templates available: May 2025

• Until the Common Forms are fully adopted by NIH, **NIH requires applicants and recipients to use the current NIH Biosketch and Other Support formats** for applications, Just-in-Time (JIT) Reports, and Research Performance Progress Reports (RPPRs).
  • Electronic signatures and supporting documentation are required.
  • Failure to follow the appropriate formats may cause NIH to withdraw applications from or delay consideration of funding.
RAS NIH Disclosure Resources

RAS National Institutes of Health Disclosure Guidance

NIH Biosketch/Other Support/ RPPR Checklist PDF Checklist.

Effective January 25, 2022:
- Supporting documentation for outside contracts, agreements and other working arrangements with foreign entities must be submitted with Other Support. See the section on Supporting Documentation below for instructions on how to comply with these requirements at MIT.
- The new FORMS-G for Other Support has an added signature block for the PI/KP to certify the accuracy of the information submitted. Each form must be electronically signed by the PI/KP and submitted as a flattened PDF. Electronic signatures can be generated using DocuSign or Adobe Pro DC (requires external license; wet signatures and image files are not acceptable). RA Support has prepared instructions for preparing and flattening PDF attachments.

NOTE: The checklists below are intended to be used as a tool when preparing disclosure information for NIH grant proposals and awards. While we have tried to capture the essential aspects of agency guidance, it is still important to review all agency guidance, solicitation documents and relevant FAQs before final submission to NIH. Please contact your RAS administrator if you have any questions.
- NIH Grants Policy Statement
- NIH Application Guide
- NIH Other Support
- MIT NIH Checklists and Preparation Guides

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<tr>
<th>BioSketch</th>
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</thead>
<tbody>
<tr>
<td>Review NIH Biosketch Format Pages, Instructions and Samples</td>
</tr>
<tr>
<td>List in reverse chronological order the positions you’ve held that are relevant to this application, starting with your present position; also list any relevant academic and professional achievements and honors. All academic, professional or institutional appointments. Include the following:</td>
</tr>
<tr>
<td>Any titled academic, professional or institutional position regardless whether or not remuneration is received</td>
</tr>
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Budget Issues: Direct Cost Limit

• Direct Costs of $500,000 or more (excluding consortium F&A) in any one budget year – requires applicant to obtain prior approval at least six weeks in advance of submission from Scientific/ Research Contact listed in the NOFO. Refer to Section IV of the individual NOFO for detailed information.

• NIH aims to notify applicants in writing of its decision within 10-20 business days of receipt of the request letter. Should be included with Cover Letter.

• This policy applies to new, renewal (competing continuation), resubmission (amended), or revision (competing supplement) applications.

• Note: Approval given for an application is limited to the requested cycle. If the application is submitted or resubmitted during a future cycle, the PI must again request prior approval at least six weeks in advance of submission.
Salary Caps: NIH will not pay requested salary above annual salary cap. Effective January 1, 2024, the salary limitation for Executive Level II is $221,900. See NOT-OD-24-057.

Options for proposal budget if investigator’s salary is above the salary cap:

- Salary is requested is based on investigator’s MIT institutional base salary. NIH will reduce that line item to the salary cap, resulting in a reduced total award amount.
- Budget to salary cap.

PI/DLCI must fund the portion of the PI salary above the capped amount. At award stage, this is managed by Sponsored Accounting.

NOTE: In future years, if the salary cap increases, grantees may rebudget to pay investigator salaries up to the new salary cap, but NIH will not increase the total award amount.
**Salary Cap: NIH Guidance**

**Guidance on Salary Limitation for Grants and Cooperative Agreements FY 2024.**

**Example 3. Individual with a Nine-Month Appointment**

Research effort requested in application/proposal – 9 months (30% effort)

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<tr>
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<tbody>
<tr>
<td>a.</td>
<td>Individual's institutional base salary for a nine-month calendar year appointment</td>
<td>$180,000.00</td>
</tr>
<tr>
<td>b.</td>
<td>Direct salary requested</td>
<td>$54,000.00</td>
</tr>
<tr>
<td>c.</td>
<td>Fringe Benefit Requested at 25% of salary</td>
<td>$13,500.00</td>
</tr>
<tr>
<td>d.</td>
<td>SUBTOTAL</td>
<td>$67,500.00</td>
</tr>
<tr>
<td>e.</td>
<td>Requested F&amp;A (indirect) costs at 45% of subtotal</td>
<td>$30,375.00</td>
</tr>
<tr>
<td>f.</td>
<td>Total amount requested</td>
<td>$97,875.00</td>
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The salary cap for the above individual will be calculated as follows:

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<tbody>
<tr>
<td>g.</td>
<td>Salary Cap – FY 2024</td>
<td>$221,900.00</td>
</tr>
<tr>
<td>h.</td>
<td>Salary Cap – FY 2024 (9-month rate)</td>
<td>$166,425.00</td>
</tr>
<tr>
<td>i.</td>
<td>Salary Cap with Research effort (30%)</td>
<td>$49,927.50</td>
</tr>
<tr>
<td>j.</td>
<td>Fringe Benefits calculated at 25% of allowable salary</td>
<td>$12,481.88</td>
</tr>
<tr>
<td>k.</td>
<td>SUBTOTAL</td>
<td>$62,409.38</td>
</tr>
<tr>
<td>l.</td>
<td>Associated F&amp;A (indirect) costs at 45% of subtotal</td>
<td>$28,084.22</td>
</tr>
<tr>
<td>m.</td>
<td>Total amount to be awarded due to salary limitation</td>
<td>$90,493.60</td>
</tr>
</tbody>
</table>
Graduate Student Stipend and Tuition

- NIH allows budget for stipend and tuition to be no more than “0” level Post Doc (presently, $56,484, subject to change by NIH) – NIH usually updates the Post Doc levels yearly and may be found on NIH's website.

- If budget requested exceeds that amount, NIH will cut before Awarding.

- Institutions may rebudget funds to charge more than the awarded amount.
11.2.10 Supplementation of Stipends, Compensation, and Other Income.

NIH recognizes that Kirschstein-NRSA fellows (predoctoral or postdoctoral) may seek *part-time employment* incidental to their training program to offset further their expenses. Fellows and trainees may spend on average, an **additional 25% of their time** (e.g., 10 hours per week) in **part time research, teaching, or clinical employment**, so long as those activities do not interfere with, or lengthen, the duration of their NRSA training.

Compensation may *not be paid* from a research grant that supports the same research that is part of the fellow's planned training experience as approved in the Kirschstein-NRSA individual fellowship application.
Pre-Doctoral (F31) and Post-Doctoral (F32) offset stipend and tuition shortfalls at MIT

Pre-Doctoral F31 Fellow (Graduate Student)
Graduate students paid on NRSA fellowships or NIH Training Grants can hold concurrent research assistant position (25% FTE, salary and tuition)

See Section 3 Part C of Graduate Student Appointment Policies: Oct 3, 2023 for MIT policy on MIT appointments to augment fellowships.

Post-Doctoral F32 Fellow
Postdoctoral fellows can hold up to a 25% FTE concurrent postdoctoral associate position to bring their stipend up to MIT’s minimum.
Data Management Sharing Plan – MIT Resources

• National Institutes of Health (NIH) Policy for Data Management and Sharing, effective January 25, 2023: promotes the management and sharing of scientific data generated from NIH-funded or conducted research and requires data management plans within grant proposals.
  • MIT’s Key Points: NIH Data Management and Sharing Policy (PDF)
  • MIT Resources for NIH Policy for Data Management and Sharing (PDF)
Budgeting Data Management Sharing Plan

No longer requires single line item titled "Data Management and Sharing Costs" (NOT-OD-23-161).

Reasonable, allowable costs may be included in NIH budget requests when associated with:

- Curating data and developing supporting documentation
- Local data management considerations
- Preserving and sharing data through established repositories

(Note: if a DMS Plan proposes preserving and sharing scientific data for 10 years in an established repository with a deposition fee, the cost for the entire 10-year period must be paid prior to the end of the period of performance).
DMS: Budget and Budget Justification

• DMS costs must be requested in the appropriate cost category, e.g., personnel, equipment, supplies, and other expenses, following the instructions for the R&R Budget Form or PHS 398 Modular Budget Form. **Supporting details, including a breakdown of any personnel effort, must be included in the budget justification.**

• **R&R Budget Form**: Estimated DMS costs must be outlined in the *Budget Justification* attachment of the in a section clearly labeled *Data Management and Sharing Justification*. The recommended length of the justification should be no more than half a page.

• **PHS 398 Modular Budget Form**: if there is a *Data Management and Sharing Plan*, please make sure that in there is an attached “**Additional Narrative Justification**” even if there is no funds being requested, stating that or what the funds are for.
Post Submission Material / Just-In-Time

Post-Submission Material Policy
For materials submitted after the initial grant application submission but prior to initial peer review, NIH will only accept materials resulting from unforeseen administrative issues. Instructions for submission and all other materials listed in NOT-OD-19-083 as acceptable post-submission materials will continue to be accepted if submitted 30 days before the study section meeting. See Post-Submission Materials Policy for further detail.

Just-In-Time
The eRA Commons Just-in-Time link will appear on the Status screen within 24 hours after the impact score has been released. NIH issues Just-in-Time emails for all applications that receive an overall impact score of 30 or less. However, applicants should not submit any Just-in-Time information, including Other Support, until a specific request for information is received via email from the system and/or grantor agency. See NIH Just-in-Time Procedures
If Awarded

- PI or Delegate may view eRA Commons Notice of Award
- Data Management and Sharing
Progress Reports (RPPR)

Annual *Research Performance Progress Report (RPPR)* Format

- **Due Dates**
  - Non-SNAP: Approximately 60 days before the start of next budget period
  - SNAP: Approximately 45 days before start of the next budget period
  - Multi-Year Funded: on or before award anniversary date
• 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 Grants Policy Statement.

• NIH previously sent reminder emails to recipients 10, 120, and 150 days after the project period end date.

• Effective January 2024, NIH has begun sending an additional reminder closeout email notification 90 days after the project period end date.
Closeout

Closeout of an award is the process by which NIH determines that all applicable administrative actions and all required work of an award have been completed by the recipient and NIH.

NIH continues to require and enforce longstanding closeout requirements *due within 120 days* of the project period end date:

- Final Progress Report (RPPR)
- Final Federal Financial Report (FFR) (SF 425)
- Final Invention Statement and Certification (HHS 568)

• NIH will initiate unilateral closeout (including potential enforcement actions) if recipients fail to submit final reports on time.
On January 23, 2024, NIH issued NOT-OD-24-055, NIH Enforcement of Unilateral Closeout Reporting in the System for Award Management Responsibility/Qualification

• NIH is committed to addressing and reducing grant closeout delays and to enhance compliance with Federal regulations and NIH policies. Therefore, NIH will strictly enforce its closeout policies. When recipients fail to submit timely reports, NIH will initiate unilateral closeout. If a recipient does not submit all required closeout reports within a year of the period of performance end date, NIH will unilaterally close the award and report the recipient's failure to comply with the terms and conditions of award in SAM.gov. 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 per Section 8.5.2 of the NIH GPS.

Learn more: NOT-OD-24-055
Feedback

We are providing a **QR Code** for you to access a **RAS-ED feedback survey** via your phone or mobile device.

I will also provide the link [https://mit.co1.qualtrics.com/jfe/form/SV_9SmzI4oOs8Q CZdY](https://mit.co1.qualtrics.com/jfe/form/SV_9SmzI4oOs8Q CZdY) to access the form via the web and in a follow up email.