Office of the Vice President for Research

Research Administration Practices (RAP) Sessions

NIH Proposal Resources and Updates

Bernadette Vallely, *NIH Lead Liaison*

Team Manager, Grant & Contract Administration, RAS

April 18, 2024

Introductions

Bernadette Vallely

NIH Lead Liaison

Team Manager, Grant & Contract Administration, RAS

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.

- 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

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

Activity Code(s)	Title	Announcement Number	Issuing Organization	Release Date	Open Date	Expiration Date
R01	NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)	PA-20-185	NIH			
R01	Research Project Grant (Parent R01 Basic Experimental Studies with Humans Required)	PA-20-184	NIH			
R01	Research Project Grant (Parent R01 Clinical Trial Required)	PA-20-183	NIH			
R03	NIH Small Research Grant Program (Parent R03 Clinical Trial Not Allowed)	PA-20-200	NIH	05-07-	05-16-	05-08-
R13	NIH Support for Conferences and Scientific Meetings (Parent R13 Clinical Trial Not Allowed)	PA-24-141	NIH			
R21	NIH Exploratory/Developmental Research Grant Program (Parent R21	PA-20-195	NIH			

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

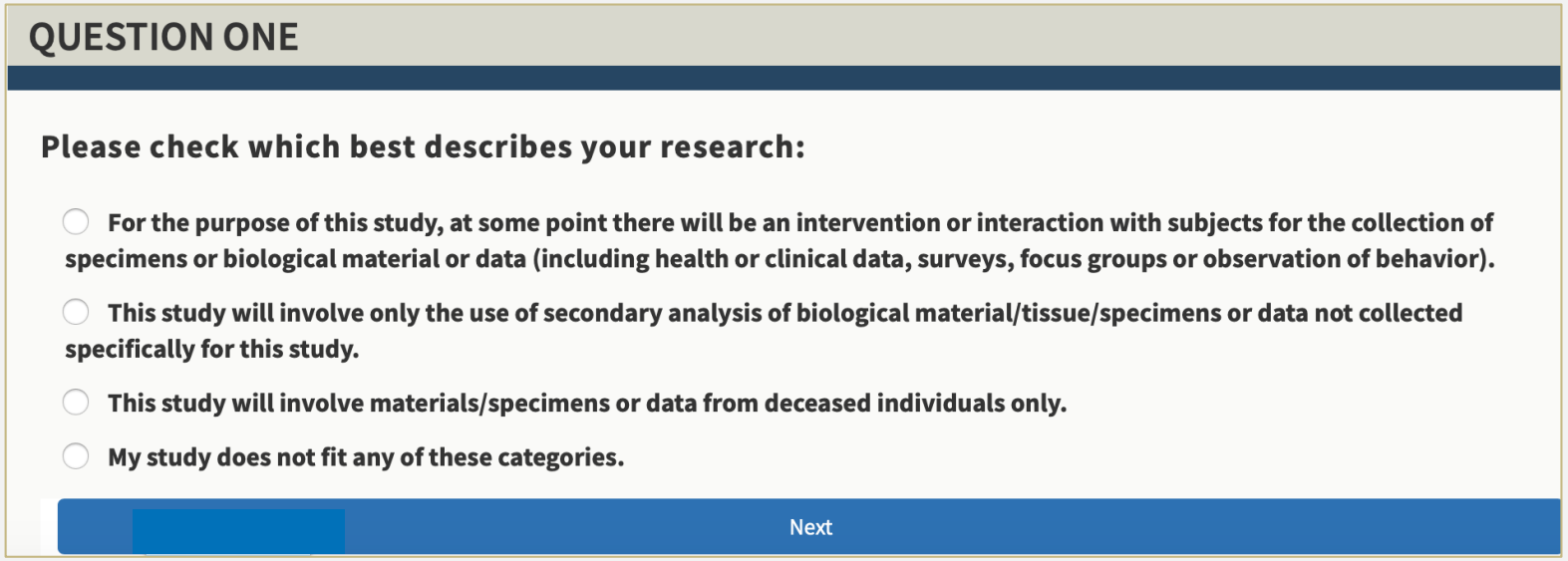
Clinical Trial Not Allowed	Only accepts applications that do not propose clinical trial(s)
Clinical Trial Required	Only accepts applications that propose clinical trial(s)
Clinical Trial Optional	Accepts applications that either propose or do not propose clinical trial(s)

***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.

NIH Human Subjects Research

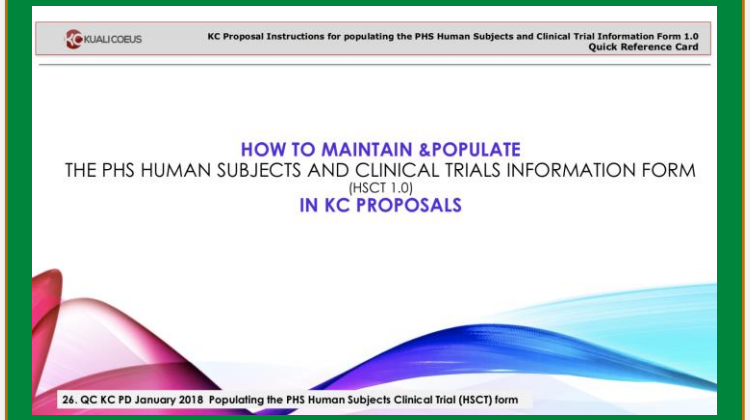
Decision Tool: Am I Doing Human Subjects Research?

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.



KC.MIT.EDU >> Quick Cards

Populating the PHS Human Subjects and Clinical Trial Information (HSCT) form in KC



See COUHES couhes.mit.edu for information on Exempt Human Subjects Research and IRB Review policies

RAS: NIH Human Subjects and Clinical Trials

Home / Grant and Contract Administration / Sponsor Information / NIH / NIH Checklists and Preparation Guides

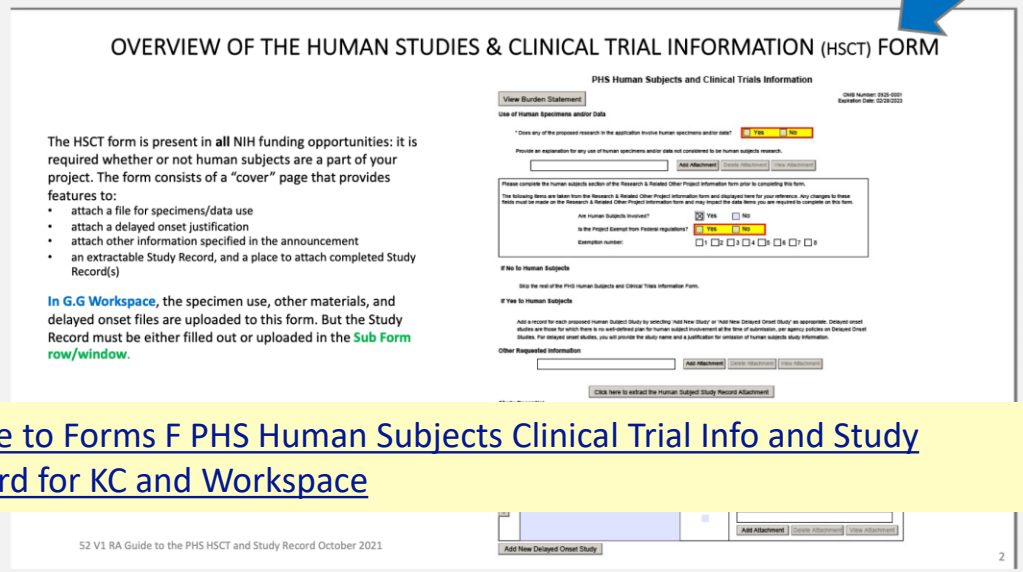
NIH Checklists and Preparation Guides

When preparing an NIH application, proposers should review the specific solicitation and the NIH SF424 Application Guide [website].

See Human Subjects and NIH Proposals if your proposal involves Human Subjects.

RAS Checklists and Preparation Guides for NIH Grant Applications

- RAS NIH R01/R21 Proposal Checklist [PDF] – Updated September 2020
- RAS NIH K99/R00 Proposal Checklist [PDF] – Updated February 2024



OVERVIEW OF THE HUMAN STUDIES & CLINICAL TRIAL INFORMATION (HSCT) FORM

The HSCT form is present in **all** NIH funding opportunities: it is required whether or not human subjects are a part of your project. The form consists of a "cover" page that provides features to:

- attach a file for specimens/data use
- attach a delayed onset justification
- attach other information specified in the announcement
- an extractable Study Record, and a place to attach completed Study Record(s)

In G.G Workspace, the specimen use, other materials, and delayed onset files are uploaded to this form. But the Study Record must be either filled out or uploaded in the **Sub Form row/window**.

PHS Human Subjects and Clinical Trials Information

52 V1 RA Guide to the PHS HSCT and Study Record October 2021

[Guide to Forms F PHS Human Subjects Clinical Trial Info and Study Record for KC and Workspace]

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.

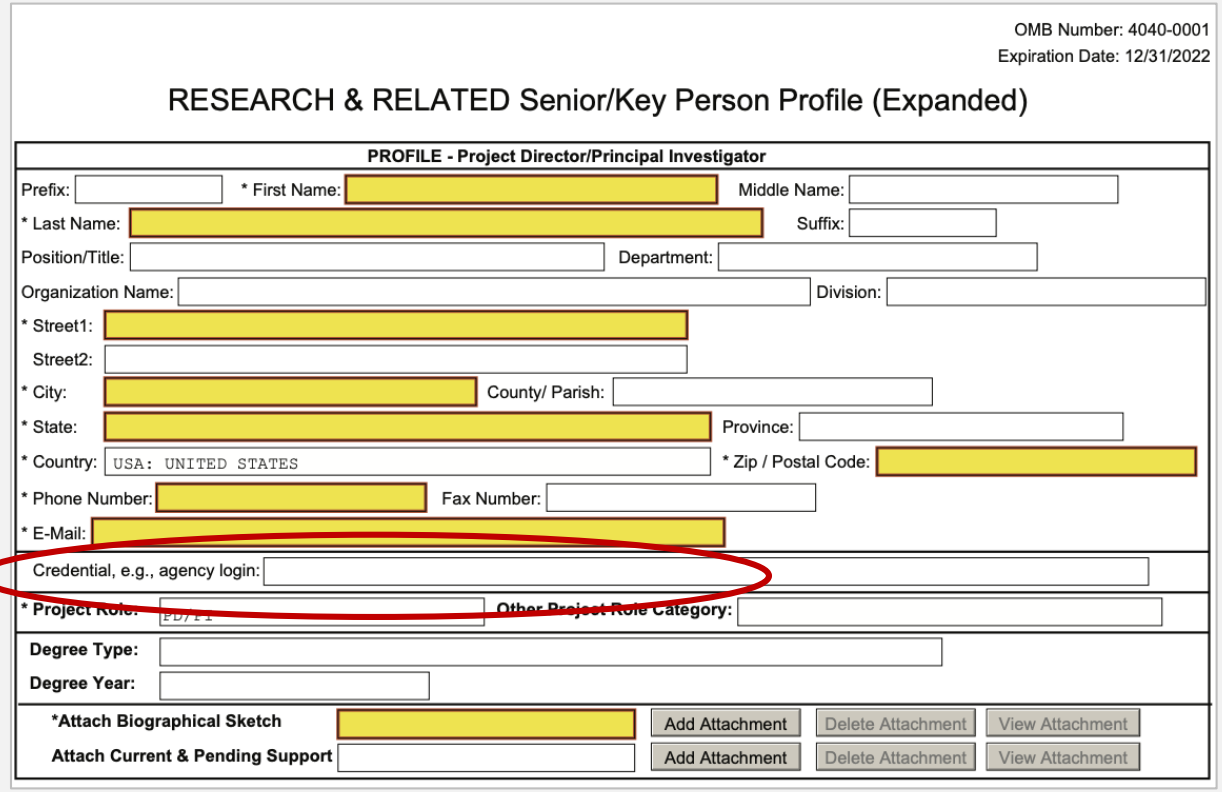
Visit the MIT COUHES website for more information.

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)

eRA Commons ID



OMB Number: 4040-0001
Expiration Date: 12/31/2022

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: * First Name: Middle Name:
* Last Name: Suffix:
Position/Title: Department:
Organization Name: Division:
* Street1:
Street2:
* City: County/ Parish:
* State: Province:
* Country: USA: UNITED STATES * Zip / Postal Code:
* Phone Number: Fax Number:
* E-Mail:
Credential, e.g., agency login:
* Project Role: PD/PI Other Project Role Category:
Degree Type:
Degree Year:
*Attach Biographical Sketch Add Attachment Delete Attachment View Attachment
Attach Current & Pending Support Add Attachment Delete Attachment View Attachment

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

Office of the Vice President for Research
Research Administration Services

NIH NRSA Fellowship – Proposal Preparation Checklist

Before You Begin

- ***READ THE FOA***.
- ***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 NIH-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 **if a Resubmission** i.e., CA123456

5. Applicant Information – Enter the UEI (Unique Entity Identifier) - E2NYLCDML6V1

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

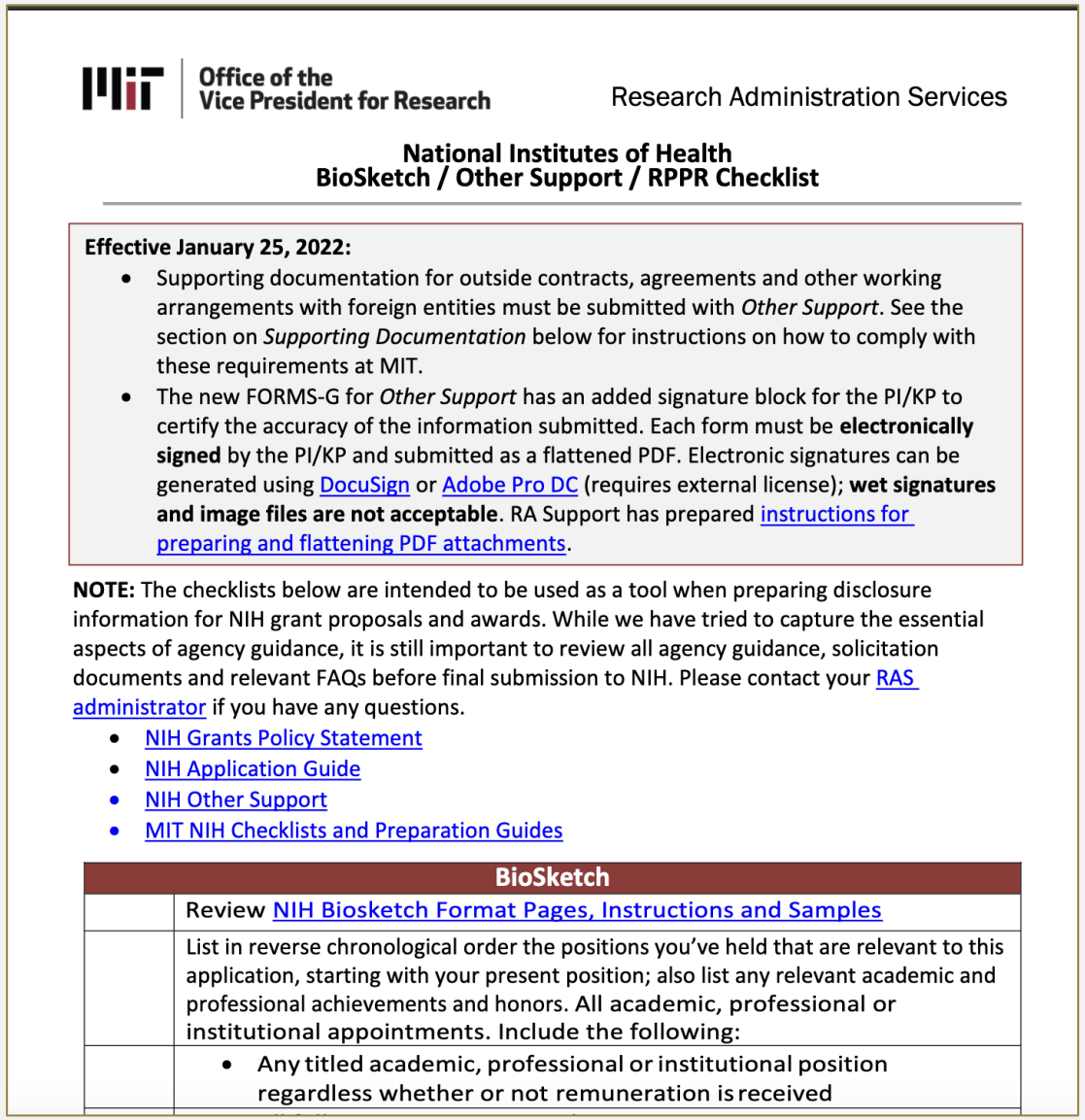
See NIH Format Attachments

Biosketch & Other Support Common Forms: Timeline

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 new forms 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



Office of the Vice President for Research | Research Administration Services

National Institutes of Health
BioSketch / Other Support / RPPR 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

BioSketch	
	Review NIH Biosketch Format Pages, Instructions and Samples
	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:
	• Any titled academic, professional or institutional position regardless whether or not remuneration is received

RAS National Institutes of Health Disclosure Guidance

NIH Biosketch/Other Support/ RPPR Checklist PDF Checklist.

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.**

Budget Issues – Salary Cap

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)

a.	Individual's institutional base salary for a nine-month calendar year appointment	$	180,000.00	(IBS x (9/12))
b.	Direct salary requested	$	54,000.00	*(a x .30)*
c.	Fringe Benefit Requested at 25% of salary	$	13,500.00	*(b x .25)*
d.	SUBTOTAL	$	67,500.00	*(b + c)*
e.	Requested F&A (indirect) costs at 45% of subtotal	$	30,375.00	*(d x .45)*
f.	Total amount requested	$	97,875.00	*(d + e)*

The salary cap for the above individual will be calculated as follows:

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

Budget - Graduate Student compensation
Research Assistants on grants and cooperative agreements

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 on NIH's web site
- If budget requested exceeds that amount, NIH will cut before Awarding.
- Institutions may rebudget funds to charge more than the awarded amount.

Pre-Doctoral (F31) and Post-Doctoral (F32) Fellows offset stipend and tuition shortfalls

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

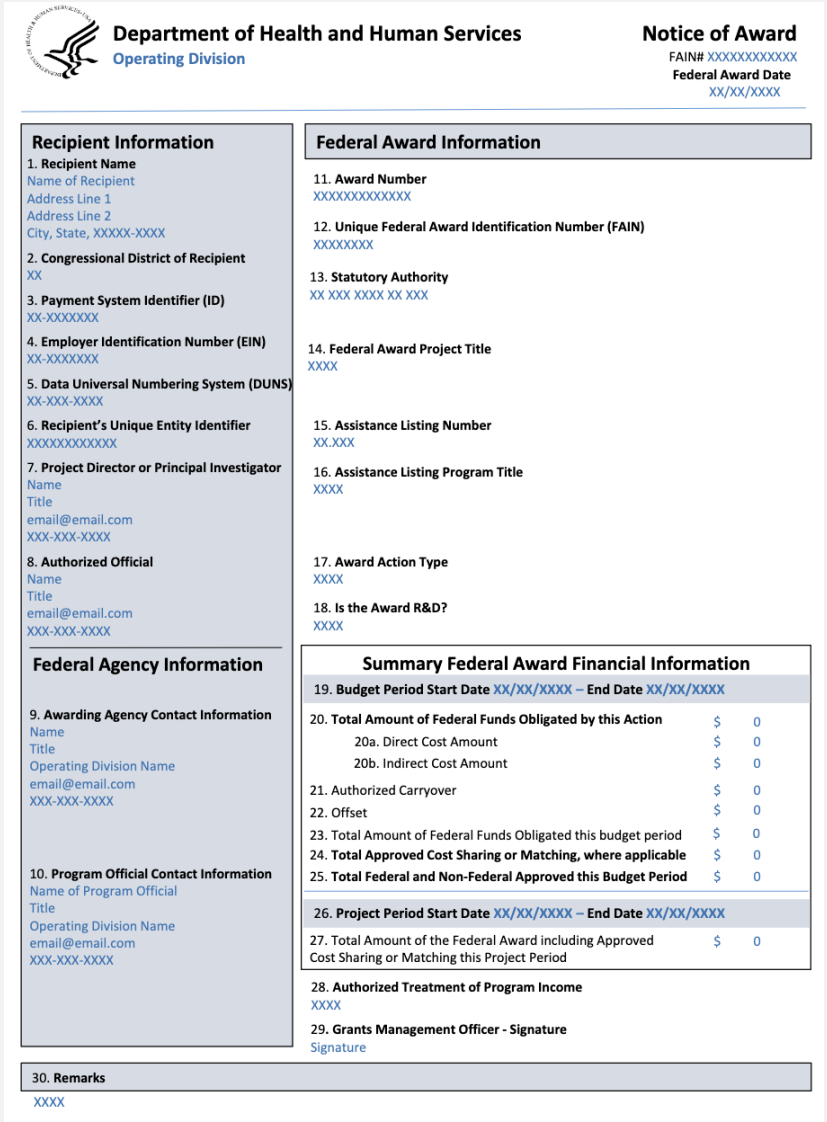
Post-Submission Material Policy

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



Department of Health and Human Services
Operating Division

Notice of Award
FAIN# XXXXXXXXXXX
Federal Award Date
XX/XX/XXXX

Recipient Information

1. **Recipient Name**
Name of Recipient
Address Line 1
Address Line 2
City, State, XXXXX-XXXX

2. **Congressional District of Recipient**
XX

3. **Payment System Identifier (ID)**
XX-XXXXXXX

4. **Employer Identification Number (EIN)**
XX-XXXXXXX

5. **Data Universal Numbering System (DUNS)**
XX-XXX-XXXX

6. **Recipient's Unique Entity Identifier**
XXXXXXXXXXX

7. **Project Director or Principal Investigator**
Name
Title
email@email.com
XXX-XXX-XXXX

8. **Authorized Official**
Name
Title
email@email.com
XXX-XXX-XXXX

Federal Agency Information

9. **Awarding Agency Contact Information**
Name
Title
Operating Division Name
email@email.com
XXX-XXX-XXXX

10. **Program Official Contact Information**
Name of Program Official
Title
Operating Division Name
email@email.com
XXX-XXX-XXXX

Federal Award Information

11. **Award Number**
XXXXXXXXXXXX

12. **Unique Federal Award Identification Number (FAIN)**
XXXXXXXX

13. **Statutory Authority**
XX XXX XXXX XX XXX

14. **Federal Award Project Title**
XXXX

15. **Assistance Listing Number**
XX.XXX

16. **Assistance Listing Program Title**
XXXX

17. **Award Action Type**
XXXX

18. **Is the Award R&D?**
XXXX

Summary Federal Award Financial Information

19. **Budget Period Start Date** XX/XX/XXXX – **End Date** XX/XX/XXXX

20. **Total Amount of Federal Funds Obligated by this Action**	$	0
20a. Direct Cost Amount	$	0
20b. Indirect Cost Amount	$	0
21. Authorized Carryover	$	0
22. Offset	$	0
23. Total Amount of Federal Funds Obligated this budget period	$	0
24. **Total Approved Cost Sharing or Matching, where applicable**	$	0
25. **Total Federal and Non-Federal Approved this Budget Period**	$	0

26. **Project Period Start Date** XX/XX/XXXX – **End Date** XX/XX/XXXX

27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$	0

28. **Authorized Treatment of Program Income**
XXXX

29. **Grants Management Officer - Signature**
Signature

30. **Remarks**
XXXX

- 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

Closeout Notification

- 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.

Unilateral Closeout Reporting

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_9SmzI4oOs8QCZdY to access the form via the web and in a follow up email.