NIH R01/R21 Proposal
Research Administration Services Guidance

Before You Begin

- ***READ THE PA/RFA SOLICITATION AND MAKE SURE YOU CHOSE THE RIGHT FUNDING OPPORTUNITY***. Pay attention to the "Application and Submission Information" section.
- Individual NIH PA/RFAs take precedence over NIH SF424 general guidelines; the NIH SF424 Application Guide takes precedence over this document.
- Proposals MUST be submitted via Grants.Gov or Assist 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. For RFAs with specific deadline dates the deadline is fixed and does NOT change for any reason.
- Note: Workspace is used to apply via grants.gov. ASSIST is used when applying by eRA Commons.
- NIH will only accept six new, renewal, resubmission, or revision applications from an individual Principal Investigator/Program Director or Multiple Principal Investigator for all council rounds in a calendar year. This policy applies to all activity codes except T activity codes and R13 Conference Grant Applications. It also does not apply to non- competing continuations, administrative supplements or change in institution applications. Please see NOT-OD-25-132 for details.

Set Up Notes in KC

Who needs to be added as personnel?:

All key personnel named in the project

Who needs to certify?:

MIT key personnel. The key persons at subcontractor sites, OSC, Collaborations should be named as personnel, but they do not need to certify.

Where to record specifics on the application:

- Delivery Info tab>>Submission Account ID: Add the Workspace or Assist number is in this field.
- Sponsor & Program Information Tab>>Opportunity ID: Suggest the NOFO is added to this field

Sections of the Application

[1] SF424 R&R (Cover Page)

Self-explanatory, but please note:

- ☐ Box 1. Ensure correct box is checked: "Application" or "change/corrected". Note change/corrected is used when the application is being submitted again because the first time it errored or the PD/PI wants to edit the application.
- ☐ Box 4a. Box is completed with the NIH grant number if a Resubmission or Renewal, e.g., format: CA123456
- ☐ 4.b. Agency Routing Identifier: if required by FOA, Applications in response to a NIH Notice of Special Interest require the notice number (e.g., NOT-IC-FY-XXX) to be entered into this field in order to assign and track applications and

awards for the described initiative
- ☐ Box 5: UEI is E2NYLCDML6V1
- ☐ Box 6. TIN/EIN = 042103594; can also be entered as **1042103594A1** which is the PMS identifier.
- ☐ Box 8. Type of application: ensure correct box is check.
- ☐ Box 11. Title: limit 200 characters including spaces.
  Note, "revision" application should have the same title as the currently funded grant.
- ☐ Box 12. Ensure start dates are correct.
- ☐ Box 13. MIT Congressional District = MA-007.
- ☐ Box 16. The program is NOT covered by E.O. 12372
- ☐ Box 17. Should be AGREE
- ☐ Box 21. Cover letter is attached here.

Cover letter

Usually optional; used for NIH internal purposes.

Note: Do not use to request application assignment or review, that information is conveyed by the PHS Assignment Request Form.

Cover letter and prior approval are no longer needed when budget request is $500,000 or more per year, see NOT-OD-26-019.

[2] Project/Performance Site Information(s)

- ☐ List MIT plus any other sites where science will be performed.
- ☐ If the application has subcontracts, each site should be listed.
- ☐ Need to use a 9 digit zip code for all US sites; if site outside USA use 00-000.
- ☐ Do not check the box for "I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization" unless otherwise specified by the FOA.

[3] R&R Other Project Information

1. Human Subjects-Assurance No. FWA00004881.
   a. If YES and EXEMPT: the exemption number must be included.
   b. If YES and IRB review is necessary: ensure all necessary attachments are included on the study record attachment 'PHS Human Subjects and Clinical Trials Information' (see more information below).
2. Animal Assurance No. D16-00078
   Note: For NEW applications, the IACUC review should always be 'pending'. If applicant answers "NO" to "PENDING" then an approval date must be entered. If not, the package will error.'
   ***Please note, boxes 1 and 2 should agree with the compliance tab in KC and with the certification questions for the PI.*
3. Proprietary information – see SF424 Guide for instructions. If 'YES' text must be marked
4. Environmental Impact – yes or no
5. Research at a historical place – yes or no
6. International Collaboration – if YES a foreign justification should be included in field 12. (see SF424 guidance). = Please pay careful attention to this section. The PI should disclose a foreign component if there are any letters of support from foreign collaborators. Omitting disclosure along with foreign collaboration letters has resulted in proposal withdrawal by NIH after the proposal is submitted and before it gets assigned

by the Center for Scientific Review (CSR).
7. Project **Summary** /Abstract – 30 lines max; summary of the proposed activity
8. **Narrative** - short 2-3 sentences for lay audience explaining "relevance to Public health"
9. **Bibliography and References** – List of citations from the application. No specific format style. Use of hyperlinks in this section is not allowed unless specified in the NOFO.
10. **Facilities/Resources** – Identify the facilities available to the program to demonstrate capability of research site to complete the proposal, *include all performance sites*.
11. **Equipment** – list equipment available to the program to demonstrate capability of research site, *include all performance sites*
12. Other Attachments - If required by PA/RFP solicitation. If needed, foreign justification is attached here.

[4] Research & Related Senior/Key Persons

- ☐ All Senior/Key persons, including Other Significant Contributors, MUST provide eRA Commons User ID in the "Credential" box.
- ☐ Ensure the * sections are completed (address, e-mail, phone number and use a 9 digit zip code).
- ☐ List OSCs and Consultants after other Senior/Key persons
- ☐ Biosketches required for ALL persons listed in this Senior/Key Person Profile page.

NIH adopted a new, **two-part biosketch** format to align with federal "Common Form" standards. This format requires using SciENcv to generate a combined PDF consisting of the "Biographical Sketch Common Form" and a mandatory "NIH Biographical Sketch Supplement," which must include an ORCID ID.

Do not flatten this PDF attachment. The links automatically generated in the Biographical Sketch Common Form in SciENcv are allowable to NIH.

Key Components of the New Format

The biosketch consists of two distinct parts that SciENcv merges into a single, digitally certified PDF:

1. **Biographical Sketch Common Form**:
   - **Identifying Information**: Name and ORCID iD - Senior/key personnel must have an ORCID iD linked to their eRA Commons profile.
   - **Professional Preparation**: Education and training details.
   - **Positions and Appointments**: List all professional appointments outside of MIT for the last three years. If a professional appointment concluded more than three years ago, it does not need to include, but can be add if relevant
   - List all academic or institutional appointments for the duration of one's career.
   - **Products**: Divided into two sub-sections:
     - **Closest to Project**: Up to 5 products most relevant to the current proposal.
     - **Other Significant Products**: Up to 5 other products highlighting your general expertise.
2. **NIH Biographical Sketch Supplement**:
   - **Personal Statement**: A narrative (max 3,500 characters) describing your suitability for the project. Note that you may no longer include citations here; you must refer to products in the Common Form instead.
   - **Honors**: A list limited to a maximum of 15 entries.
   - **Contributions to Science**: Up to 5 narrative entries (max 2,000 characters each). Citations are prohibited within this section; refer back to the products listed in the

Common Form.

More information can be found at NOT-OD-26-018.

[5] PHS 398 Cover Page Supplement

Section is self explanatory.

[6] PHS 398 Research Plan

Research Plan Attachments

1. Introduction – ONLY for application type = resubmission or revision. 1 page limit.
2. Specific Aims – 1 page limit.
3. Research Strategy – Limited to 12 pages for an R01; 6 pages for an R21
    a. Significance
    b. Innovation
    c. Approach

    Note: new proposals should include preliminary studies; Renewal/Revisions should include progress report.
4. Progress Report Publication List - for renewal submissions only

Other Research Plan Sections

5. Vertebrate Animals if "YES" - this section should address the following:
    - Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the "Research Strategy" section. Identify the species, strains, ages, sex, and total numbers of animals by species, to be used in the proposed work. If dogs or cats are proposed provide the source of the animals.
    - Justifications: Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g. computational, human, invertebrate, in vitro).
    - Minimization of Pain and Distress: Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain, and injury.
      For additional information, see Worksheet for Review of the Vertebrate Animal Section
6. Select Agents : See SF424 for instructions; complete if project uses hazardous biological agents or toxins.
7. Multiple PI Plan: A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts.
8. Consortium/Contractual Arrangements:
    a. For *MIT internal procedures*, a letter of intent, etc. should be included in KC.
    b. For *the NIH proposal*, this section should describe arrangement with the subawardees.
9. Letters of Support - except for MIT persons being charged to the budget include one for each person named in Senior/Key Persons to affirm their participation. If a consultant letter is included, ensure it states the rate and hours expected to dedicate to project. Letters should stipulate expectations for co-authorship and whether cell lines, samples or other resources promised in the letter are freely available to other investigators in the scientific community or will be provided to the particular investigators only.

10. Resource Sharing Plan(s) - This field is now for Sharing Model Organisms plans, if needed
11. **Other Plans**: Applicants proposing to conduct research that will generate scientific data are subject to the NIH Data Management and Sharing Policy; a plan, suggested not to exceed 2 pages, should be included. Applicants subject to both the NIH Data Management and Sharing Policy and the NIH Genomic Data Sharing Policy must attach a single Plan including elements for both policies. **This is now a required field**.
12. Authentication of Key Biological and/or Chemical Resources: Attach if applicable to the proposed science
13. Appendix – it is UNUSUAL if anything is attached in this section. Only if instructed in FOA.

[7] Budget

Two options exist:

1. PHS 398 Modular Budget – when requesting $250,000 Direct Cost or less /year
2. R&R Categorical Budget – when requesting $250,001 or more Direct Cost/year

PHS 398 Modular Budget

Funds are requested in $25,000 increments (or modules) up to $250,000 direct cost/year.
Note: the F&A costs associated with any subcontract do not factor into the $250,000 direct cost limit.
Could have up to three attachments for the budget justification:

1. Personnel Justification (mandatory)– list all personnel including name, person months devoted to project and role.
2. Consortium Justification – state dollars of subaward rounded to nearest thousand for each year, state domestic or foreign entity, list personnel including name, effort and role.
3. Additional Narrative Justification – Used to explain different numbers of modules per year or to explain anything unusual in the budget. This attachment must be included if a Data Management and Sharing Plan is included on the PHS398 Research Plan section an should state if cost for the DMSP are included in the budget.

Note: The Additional Narrative Justification is not needed in applications to FOAs with direct cost limits that do not spread evenly across budget periods (e.g., R21 FOAs that allow $275,000 in direct costs over two years).

R&R Categorical Budget:

Detailed Budget module used for budgets of greater than $250,000 TDC per year.

- Personnel should include their role and effort. In order to be considered key personnel, effort must be on the budget form + justification. (Other significant contributors do not have effort and therefore are not included in the budget section).
- The salaries of administrative and clerical personnel should normally be treated as F&A costs. Inclusion of such costs may be appropriate only if all of the following conditions are met:
    1. Administrative or clerical services are integral to a project or activity;
    2. Individuals involved can be specifically identified with the project or activity;
    3. Such costs are explicitly included in the budget or have prior written approval of the Federal awarding agency; and
    4. The costs are not also recovered as indirect costs.
- Requests for direct charging or Secretarial/Clerical Personnel (i.e., administrative and clerical staff) must be appropriately justified in the Budget Justification.
- Budgets no longer need a separate line item for **Data Management and Sharing Plan** costs. Costs to support the activities described in the DMS Plan must be requested in

the appropriate cost category(ies), e.g., personnel, equipment, supplies, and other expenses. Investigators must also include a justification of the activities proposed in the DMS Plan that will incur costs. This justification must be labeled as "Data Management and Sharing Justification" within the budget justification attachment, followed by the estimated dollar amount. The justification should include a brief summary of type and amount of scientific data to be preserved and shared, and the name of the established repository(ies) to be used. It should also indicate general cost categories (such as curating data and developing supporting documentation, local data management activities, preserving and sharing data through established repositories, etc.); each category should include an amount and a brief explanation. If no costs are anticipated for the DMSP, the justification indicates no funds are being requested.

- All budget categories should be justified.
- If there is a consortium agreement, the subaward budget needs to be completed and uploaded (See R&R 424 instruction for additional details).

Notes:

- If personnel have effort without salary, that is cost sharing.
- Be aware of the NIH salary cap in effect. For a categorical budget, can request salary in excess of the cap and NIH will reduce at award time.
- In general, modular budgets are used only for R01, R03, R15, R21, and R34 applications.
- Unless the PA/RFA requests – do NOT use Budget Section E – Participant/Trainee Support Costs.
- Graduate Students : the total compensation that will currently be funded for graduate students is the zero level post doc level (stipend + tuition) – you can ask for above this level but it may be reduced.

In accordance with the Notice: NOT-OD-02-017 entitled, "GRADUATE STUDENT COMPENSATION" published on December 10, 2001, in the NIH Guide for Grants and Contracts, total direct costs (salary, fringe benefits and tuition remission) for graduate maximum allowable amount (zero level of the Ruth L. Kirschstein National Research Service Award stipend in effect at the time of the competing award). Support recommended for future years has been adjusted accordingly, if applicable.

Information on Human Subjects

As of January 25, 2018 NIH updated their forms, and definition of clinical trial. With the new definition, some MIT applications *may* be classified as a clinical trial. PIs should contact COUHES for guidance if they are unsure if their project should be classified as a clinical trial; RAS can not make that determination. Not all human research is considered a clinical trial, but the definition is broader than in the past. This change in definition makes it critical that the PI/DLC/RAS take a moment to ensure they are using the correct funding opportunity.

In KC

- In the compliance tab – human subjects should be pending.
- What is completed on the study record is dependent on the type of study:

Human Subjects Scenarios

A. Human Subjects Research - not a clinical trial
    1. Complete sections 1 – 3.2 on form. (note, section 1.5 will be blank)
    2. Sections 3.3-3.5 are optional; but most likely left blank

3. Do not complete sections 4 or 5

B. Human Subjects Research – clinical trial
   1. In KC, within the Human Subjects noted on the compliance tab, the box for clinical trial should be checked.
   2. Complete sections 1-4 (note, section 1.5 will be blank)

C. Exempt Human Subject Research:
   1. Complete all of section 1 and section 3.1 which is a justification of the exemption. (note, section 1.5 will be blank)
   2. Note, COUHES should also approve the exemption.

D. Delayed Onset Human Subject study
   1. In KC, within the Human Subjects noted on the compliance tab, the 'delayed onset' box should be checked.
   2. Delayed onset justification is attached (not the study record as noted on scenarios A,B and C).

Human Specimens

An application may say NO to human subjects, but does include human specimens. In this case, you will see, on the Attachment Tab of KC, an upload/explanation for human specimen.

Notes

- Since you can name more than one Study Record attached, one may exempt and one may be clinical trial – make sure the correct FOA is chosen.
- If the PI has answered YES to all of the questions in section 1.4 of the Study Record – this is a clinical trial – make sure the correct FOA is chosen and the all the correct fields are completed.
- More information is available from the Annotated Form Set for NIH Grant Applications - Forms-H Series.

Helpful Websites

- SF424 Instructions
- Annotated forms
- Standard Due Dates
- Format Attachments
- NIH Policy on Use of Hyperlinks
- Parent FOAs

Additional Information for Subcontracts

NIH no longer accepts new applications that request funds for foreign components using the traditional grant subaward/consortium structure. Instead, foreign components should use the structure described in NOT-OD-25-155.

The following two paragraph statement can be provided in a document signed (electronic is OK) by the Subawardee RAS Representative in lieu of a signed PHS398. XXX's must be filled in with the Subawardee Institution name.

"In signing below and offering to participate in this research program, XXX certifies that: neither it nor their principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from receiving funds from any federal department or agency and are not delinquent on any federal debt; it is in compliance with the Drug Free Workplace Act of 1988; it is in compliance with U.S. Code, Section 1352, restrictions on the use of federal

funds for the purpose of lobbying; it is in compliance with 42 CFR part 50 (Objectively in Research) regarding financial conflict-of-interest; it has filed annually with the Office of Scientific Integrity a PHS form 6349 governing Misconduct in Science; it has filed with DHHS compliance offices certification forms governing Civil Rights (441), Handicapped Individuals (641), Sex Discrimination (639-A), and Age Discrimination (680); it is in compliance with PHS policy governing Program Income; it has established policies in compliance with 45 CFR Part 46, Subpart A (protection of human subjects); the Animal Welfare Act (PL-89-544 as amended) and the Health Research Exchange Act of 1985 (Public Law 99-158); and that it is in compliance with NIH guidelines regarding human pluripotent stem cell research, transplantation of fetal tissue, recombinant DNA and human gene transfer research, and inclusion of women, children & minorities in research.

The appropriate programmatic and administrative personnel of each institution involved in this grant application are aware of the National Institutes of Health consortium grants policies and procedures for research administration and are prepared to establish the necessary inter-institutional agreement(s) consistent with the policy."