NIH R01/R21
PREPARE/REVIEW/SUBMISSION CHECKLIST

The information below is provided as a tool to supplement the NIH SF424 instructions dated 3/25/2016 and is not intended be used as the only review instrument. Please consult the NIH SF424 guide and any Program-Specific Solicitation and pay close attention to the Application and Submission Information section before you complete the proposal. Application Guide takes precedence over this document. For applications submitted after May 25th, 2016 please use Forms Version D found at: http://grants.nih.gov/grants/How-to-Apply-Application-Guide.htm In addition, significant changes for Form D can be found at the end of this checklist.

Notes

Format Specifications:
Applicants must observe the page numbers given in the detailed table of page limits at http://grants.nih.gov/grants/forms_page_limits.htm unless the FOA specifies otherwise. All tables, graphs, figures, diagrams, and charts must be included within the Research Strategy page limit. If PAs or RFAs contain specific page limits, those instructions always supersede the instructions in this application guide. Be sure to download and install compatible version of the Adobe Reader check here.

File Names: Save all files with descriptive file names of 50 characters or less. Do not use the ampersand (&) character in file names. Use one space, (not two or more) between words or characters. Just like letters, a space counts as one character.

Fonts/Margins: Margins ½ inch all around and limited to 8 ½ x 11 paper size; Black font no smaller than 11 pt. FONT: Arial, Helvetica, Palatino Linotype, or Georgia typeface and 15 characters/inch; 6 lines/inch. (A symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.) You may use a smaller type size for Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes but it must be in a black font, readily legible, and follow the font typeface requirement. Color can be used only in figures; No information should appear in the margins, including the PI’s name and page numbers.

This notice informs the community of support for the full Unicode character set (including Greek and other special characters) in the free-text form fields (e.g., project title) of cooperative agreement and grant applications submitted through Grants.gov to the NIH and AHRQ after February 17, 2015. - See more at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-058.html#sthash.V9tBuzln.dpuf

SF424 R&R Cover Page -Self-explanatory, however please note:

Box 1. Ensure Correct box is checked: “Application or “Change/corrected:

Box 4a. Box is completed with the NIH grant number if a Resubmission or Renewal, i.e., CA123456

Box 6. TIN/EIN = 1042104690A1

Box 8. Type of application: ensure correct box is check. Select one: New; Resubmission; Continuation; Revision-used for competing revisions and non-competing administrative supplements.

Box 11. Title: ensure no special characters are used, only letters, digits and underscore.

(Limit 200 characters including spaces between words and punctuation; otherwise it will truncate)

Box 12. Ensure start dates are correct http://grants.nih.gov/grants/funding/submissionschedule.htm

Box 13. MBL Congressional District: MA-009

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 and used for NIH internal purposes to request Institute or Study
<table>
<thead>
<tr>
<th>Section</th>
<th>assignment. May be required if direct cost budget exceeds $500,000 in any one year, refer to the <a href="https://example.com">program announcement. Addressed to the Division of Receipt and Referral.</a> Applicants are encouraged to include a cover letter with the competing application. See guide for specific format. (See SF424 R &amp; R Guide for suggested cover letter format.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ <strong>Project/Performance Site Information(s):</strong></td>
<td>List MBL plus any other sites where science will be performed. If the application has subcontracts, each site should be listed.</td>
</tr>
</tbody>
</table>
| ☐ **R&R Other Project Information:** | Human Subjects - Enter Assurance No. if applicable  
  - If YES and EXEMPT: the exemption number must be included.  
  - If YES and IRB review is necessary: ensure all necessary attachments are included on the PHS398 Research Plan page or the package will **error** (see below).  
  Animal Assurance **No. A3070-01**  
  **Note:** if applicant answers “NO” to “PENDING” for animal or human approval then an approval date must be entered. If not, the package will **error**.  
  Proprietary information – see SF424 Guide for instructions. Text must be marked.  
  International Collaboration – Check if yes. |
| ☐ **Project Summary /Abstract:** | 30 lines max; summary of the proposed activity. |
| ☐ **Project Narrative:** | Short 2-3 sentences for lay audience explaining “relevance to Public health” |
| ☐ **Bibliography and References cited:** | List all authors – “et al” not allowed |
| ☐ **Facilities/Resources:** | Identify the facilities available to the program to demonstrate capability of research site to complete the proposal, include all performance sites. |
| ☐ **Equipment:** | List equipment available to the program to demonstrate capability of research site, include all performance sites |
| ☐ **Other Attachments:** | If required by PA/RFP solicitation |
| ☐ **Research & Related Senior/Key Persons Biosketches** *(New Format required for proposals submitted after 5/25/2015):* | Those with PD/PI role MUST provide eRA Commons User ID in the “Credential” box (for other roles this is not mandatory).  
  Ensure the * sections are completed (address, e-mail, phone number).  
  List OSCs and Consultants after other Senior/Key persons  
  Biosketches required for ALL persons listed in this Senior/Key Person Profile page.  
  **Note:** 5 pages max. for each bio and includes *(see NIH guides for required format and content)*:  
  **A. Personal Statement** – Brief description of experience and qualifications for the role in project. The relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C. Also, you may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project.  
  **B. Positions and Honors**- chronological list of previous positions, concluding with current position.  
  **C. Contribution to Science**- Briefly discuss up to five most significant contributions to science. For |
each, include historical background, the central findings, the influence of the findings on the progress of science, or the application of findings to health or technology, and the PI’s specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can list audio/video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software/netware that are relevant to the described contribution. Each description of contribution should be no longer than 1/2 page incl. figures and citations. Provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography.

**D. Research Support** – list ongoing then completed research projects for the past 3 years. Begin with the projects that are most relevant to the research proposed in the application. Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical sketch. Do not include number of person months or direct costs. Please find sample at the following link: [Sample Biosketch Form C](#).

*Unless the PA/RFA requires, do not provide “Current & Pending Support” at proposal time.*

- **PHS 398 Cover Page Supplement:**
  Section is self-explanatory.

- **PHS 398 Research Plan:**
  Research Plan Attachments:
  - **Introduction:** *(Separate Upload)*
    Use ONLY for Resubmission or Revision
    Limited to ONE PAGE unless specified otherwise in PA/RFA.
  - **Specific Aims** *(Separate Upload)*
    Limited to one page
  - **Research Strategy** *(Separate Upload)*
    Limited to 12 pages for an R01; 6 pages for an R21
    - **Significance** *(added criteria -see SF424 Guide)*
    - **Innovation**
    - **Approach** *(added criteria -see SF424 Guide)*
  
  See Instruction Guide for details on sections.

  **Note:** new proposals should include preliminary studies; Renewal/Revisions should include progress report. *(Added criteria for clinical research-see SF424 Guide)*

  1. **Progress Report Publication List** - for renewal submissions only

- **Human Subjects Section:**
  *Human Subjects - if “YES” include the following 3 attachments. Refer to the SF424 for further instructions.*
  - Protection of human subjects
  - Inclusion of women & minorities
  - Inclusion of children

- **Other Research Plan Sections:**
  *Vertebrate Animals if “YES” - this section should address the 4 points:*
  1. **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.
  2. **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. So and so...
3. **Minimization of Pain and Distress**: Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain, and injury.

4. **Euthanasia**: State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

   - Failure to address the four points above will result in the application being designated as incomplete and it will not be considered. More information can be found at:

   - Select Agents - See SF424 for instructions; should be completed if project uses hazardous biological agents or toxins.
   - 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.

**Consortium/Contractual Arrangements**:

   - For MBL internal procedures; for Contractors - a letter of intent is required; for Subcontracts – a completed Subrecipient Commitment Form is required. For the NIH proposal, this section should describe arrangement with the subawardees.
   - Letters of Support - Except for MBL 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.
   - Resource Sharing Plan - Data Sharing required for proposals greater than $500,000 TDC per year and some PA/RFAs. Model Organisms Plan required wherever they might be developed.

**Appendix** – note NIH limits in SF424 on numbers and types of publications that can be included.

### 4.6 Selecting Budget: (Two options exist)

Applicants should refer to the instructions in their specific Funding Opportunity Announcement FOA and should carefully read the application guide for detailed instructions. As a general rule, if an application meets the modular limit of $250K in direct costs for all budget periods, the applicant must submit a modular budget. Similarly, if an application exceeds $250K in direct cost for any budget period, the detailed R&R Budget form must be used. Foreign applicants must use the R&R Budget form. The applicant should complete the budget component appropriate to their situation.

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

   **Notes**:

   - If personnel have effort without salary, that is cost sharing and not allowed.
   - 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 time of award: [https://grants.nih.gov/grants/policy/salcap_summary.htm](https://grants.nih.gov/grants/policy/salcap_summary.htm)
   - In general modular budgets are used only for RO1, RO3, R15, R21 and R34 applications.
   - All budget categories should be justified in R & R Budget; Personnel in Modular Budget.
   - Unless the PA/RFA requests-do NOT use Budget Section E-Participant/Trainee Support Costs
   - Foreign institutions and international organizations may request funds for limited F&A costs
(8 % of modified total direct costs less equipment) to support the costs of compliance with DHHS and NIH including, but not limited to, protection of human subjects, animal welfare, invention reporting, financial conflict of interest and research misconduct.

4.7 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.
- PI’s MUST show effort and salary otherwise, proposals will error.
- All budget categories should be justified.
- If there is a consortium agreement, the subaward budget needs to be completed and uploaded.
- Travel: In the budget justification section, include the purpose, destination, dates of travel (if known), and number of individuals for each trip. If the dates of travel are not known, specify estimated length of trip (e.g., 3 days).
- Supplies: List total funds requested for materials and supplies. In the budget justification, indicate general categories such as glassware, chemicals, animal costs, including an amount for each category. Categories less than $1,000 are not required to be itemized.

5.4 PHS 398 Modular Budget:
Funds are requested in $25,000 increments (for modules) up to $250,000 direct cost/year. (Note AHRQ does not accept modular budgets.) Could have up to three attachments for the budget justification:
- Personnel Justification (mandatory)– list all personnel including name, person months devoted to project and role. No individual salary information should be provided. 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;
  4. The costs are not also recovered as indirect costs.
- For all individuals classified as secretarial/clerical, in addition to the name, percent effort and role, provide a justification documenting how they meet all four conditions. NIH ICs may request additional information for these positions in order to assess allowability.
- Consortium Justification – state dollars of subaward rounded to nearest thousand for each year, state domestic or foreign entity, and list personnel including name, effort and role.
- Additional Narrative Justification – usually only to explain different numbers of modules per year. Can be used to explain anything unusual in the budget.

Note: R21 applications cannot request more than $275,000 direct cost over the two years of the project. Most times the modules requested will differ between the two years so an ‘additional narrative’ section is required to explain reason for the difference in modules requested.
Additional Attachments:

**Authentication of Key Biological and/or Chemical Resources:** Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies.

a. Key biological and/or chemical resources may or may not be generated with NIH funds and: 1) may differ from laboratory to laboratory or over time; 2) may have qualities and/or qualifications that could influence the research data; and 3) are integral to the proposed research. These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics.

b. Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals.

Reviewers will assess the information provided in this Section. Any reviewer questions associated with key biological and/or chemical resource authentication will need to be addressed prior to award.

Save this information in a single file named “Authentication of Key Resources Plan,” and attach it as Item 12, Other Attachments, on the Other Project Information form. Information in this section must focus only on authentication and/or validation of key resources to be used in the study; all other methods and preliminary data must be included within the page limits of the research strategy. Applications identified as non-compliant with this limitation will be withdrawn from the review process (see NOT-OD-15-095 and NOT-OD-16-011).

**Helpful Websites:**


Deadline dates:

[http://grants.nih.gov/grants/funding/submissionschedule.htm](http://grants.nih.gov/grants/funding/submissionschedule.htm)

Avoid common errors and warnings:


**List of Common Errors**

1. Federal Identifier if application is a resubmission OR renewal
2. Employer ID # is 1042104690A1 for NIH….different from other organizations
3. Type of Application #8 on Cover – “Renewal” if application is competing continuation
4. Vertebrate Animal Research Plan (#8 of “PHS 398 Research Plan) must include all 5 points listed in 424 Directions
5. Resource Sharing Plan (# 13 of “PHS 398 Research Plan) must be included with almost every application
6. Include Progress Report in Research Strategy if application is a renewal (competing continuation)
7. Inventions/Patents must be marked (Cover Page Supplement #6) if application is a competing continuation
8. Letter of institutional commitment from Director of MBL required for R25
9. Budget pages – Must list calendar months for PI and all staff listed in Personnel
11. Senior Key Personnel page – double check agency logins for MBL and external key people (OSP)
12. Senior Key Personnel page – Course Faculty should be “Other Sig. Contributors”, not “Key”. List as “Other” in Project Role and “Other Sig. Contributor” in Other Project Role Category
13. Attachments should not contain special characters….letters, numbers, and underscore is ok. Check your attachment file names. Attachments must follow the proper naming convention: 50 characters or less, no special characters (-, *, %, /, #, ") to include periods and accent marks (should be avoided within the application attachment form fields as well). Usage of accent marks should be avoided within the application attachment form fields as well.
The NIH periodically updates grant application forms in order to remain current with the most recent form sets available through Grants.gov and approved by the Office of Management and Budget. NIH and other agencies serviced by NIH’s electronic Research Administration (eRA) use the ‘Competition ID’ field of Grants.gov application packages for quick and easy identification of the forms being used for a particular Funding Opportunity Announcement or individual application package.

Changes to PHS forms included in ‘FORMS-D’ application packages are as follows:

**PHS 398 Career Development Award Supplemental Form**
- New “Candidate Information and Goals for Career Development” attachment (combines “Candidate’s Background”, “Career Goals and Objectives”, and “Candidate’s Plan for Career Development/Training Activities during Award Period” attachments into a single attachment)
- New “Data Safety Monitoring Plan” attachment
- New “Authentication of Key Biological and/or Chemical Resources” attachment
- Updated Citizenship selections
- Reorganization of attachments
- Field order and label changes
- Added/updated burden statement and form expiration date
- Updated form instructions

**PHS 398 Cover Page Supplement**
- New Vertebrate Animals section added. New questions: Are animals euthanized?
  - If Yes, is method consistent with AVMA Guidelines?
  - If No to AVMA guidelines, describe method/provide scientific justification
- Ability to add Program Income information for 10 budget periods (previously 5)
- Field order and label changes
- Added/updated burden statement and form expiration date
- Updated form instructions

**PHS 398 Modular Budget**
- Indirect (F&A) Costs section changed to dynamically add indirect costs rather than providing static fields for four entries
- Minor label changes
- Added/updated burden statement and form expiration date
- Updated form instructions

**PHS 398 Research Plan**
- New “Data Safety Monitoring Plan” attachment
- New “Authentication of Key Biological and/or Chemical Resources” attachment
- Minor format and label changes
- Added/updated burden statement and form expiration date
- Updated form instructions

**PHS 398 Research Training program Plan**
- Removed “Background” and “Recruitment Plan to Enhance Diversity” attachments (information previously included in these attachments moved to existing “Program Plan” attachment)
- New “Plan for the Instruction in Methods for Enhancing Reproducibility” attachment
- New Data safety Monitoring Plan attachment
- Format and label changes including categorizing attachments into sections
- Added/updated burden statement and form expiration date
- Updated form instructions

Forms Update FAQ’s: [http://grants.nih.gov/grants/forms_updates_faq.htm](http://grants.nih.gov/grants/forms_updates_faq.htm)
PHS 398 Training Budget
- Minor label changes
- Added/updated burden statement and form expiration date
- Updated form instructions

PHS 398 Training Subaward Budget Attachment(s) Form
- Streamlined instruction text
- Added/updated burden statement and form expiration date
- Updated form instructions

PHS Assignment Request Form
- New, optional form
- Used to provide structured information to NIH referral staff regarding: funding component assignment preference, study section preference, individuals who should not review your application due to conflicts, and scientific areas of expertise needed to review your application
- Complements existing “Cover Letter Attachment” on SF424 (R&R) form
- Added/updated burden statement and form expiration date
- Updated form instructions

PHS Fellowship Supplemental Form
- New “Applicant’s Background and Goals for Fellowship Training” attachment (Combines “Doctoral Dissertation and Other Research Experience”, “Goals for Training and Career”, and “Activities Planned Under Award” attachments into a single attachment)
- New “Letters of Support from Collaborators, Contributors, and Consultants” attachment
- New “Description of Institutional Environment and Commitment to Training” attachment
- New “Data Safety Monitoring Plan” attachment
- New “Authentication of Key Biological and/or Chemical Resources” attachment
- New Vertebrate Animals questions added: New questions
  Are animals euthanized? Yes/No
  If Yes, is method consistent with AVMA guidelines?
  If No to AVMA guidelines, describe method/provide scientific justification
- Updated list of values for the “Field of Training for Current Proposal” field; changed from 4-digit codes to 3-digit codes
- Updated Citizenship selections
- Reorganization of attachments
- Format and label changes
- Added/updated burden statement and form expiration date
- Updated form instructions

PHS Inclusion Enrollment Report
- Combines Planned Enrollment Report and Cumulative Inclusion Enrollment Report forms into a single form
Questions used to identify type of report:
- Delayed onset study? Yes/No
- Enrollment Type? Planned/Cumulative (Actual)
- Using an Existing Dataset or Resource? Yes/No
- Enrollment Location? Domestic/Foreign
- Clinical Trial? Yes/No
- NIH-Defined Phase II Clinical Trial? Yes/No
  • Added/updated burden statement and form expiration date
  • Updated form instructions