

NIH <u>Forms Version H</u> (Submission due dates on/after January 25, 2023)

SF424 (R&R) Application Guide

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general-forms-h.pdf

NIH Standard Due Dates for Competing Applications http://grants.nih.gov/grants/funding/submissionschedule.htm

NIH Submission Policies http://grants.nih.gov/grants/funding/submissionpolicies.htm

NIH Table of Page Limits

http://grants.nih.gov/grants/forms page limits.htm

NIH Senior/Key Personnel Definitions http://grants.nih.gov/grants/policy/senior key personnel faqs.htm#1658

How to Submit, Track and View Your Application https://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/submit-track-view.htm

eRA Commons Helpdesk http://grants.nih.gov/support/

Please note this checklist is a tool for assisting in correctly preparing the NIH application using the SF424 (R&R) Application Guide. Remember that the specific funding opportunity announcement (FOA) instructions always supersede the Application Guide. Proposal-specific instructions can be found in the related FOA.

Beginning with receipt dates on or after January 25, 2020, the requirement for ORCID identifiers will be enforced at the time of application for individual fellowship and career development awards, including the following: F05, F30, F31, F32, F33, F37, F38, F99/K00, FI2, K01, K02, K05, K07, K08, K18, K22, K23, K24, K25, K26, K38, K43, K76, K99/R00.

The ORCID ID must be entered in the eRA Commons Personal Profile associated with the username entered in the Credential field.



All PIs must be registered in eRA Commons with PI role and have their FCOI disclosure up-to-date.
Formatting Requirements: Use an Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger.
SF424 (R&R) : Changed/Corrected applications must be submitted before the application due date. If you check the "Changed/Corrected Application' box, then "Field 4.c Previous Grants.gov Tracking ID" is required.
Title: up to 200 Characters including spaces.
Cover Letter: Optional but encouraged. (Do not use the cover letter to communicate application assignment preferences. Use the Assignment Request Form for this purpose.)
R&R Related Project/ Performance site : Indicate the Primary Site where the work will be performed and identify other locations will be performed part of the project (If the program/project is outside the US enter 00-000 for the Congressional District.)
R&R Other Project Information: If IRB/ IACUC is not pending use protocol approval date (Human Subject Assurance number and Animal Welfare Assurance number).
Project Summary/Abstract: no longer than 30 lines of text.
Narrative: no more than short 2-3 sentences.
Bibliography & References Cited
Facilities & Other Resources : Describe facilities and any useful information for space measurement and tools used for the project.
Equipment: List major items of equipment available for project and pertinent capabilities.
Other Attachment: (if applicable) Foreign Justification (begin the section with a heading indicating "Foreign Justification" and name the file "Foreign Justification".)
R&R Senior Key Persons : Need eRA Commons login username for PD/PI (The role of "Co-PD and Co-PI" are not currently used by NIH and other PHS Agencies.)
Effective on/after January 25, 2022, NIH, AHRQ, FDA, and ORD/VA required all individuals listed on the R&R Senior/Key Person Profile (Expanded) Form to have the eRA Commons username (Commons ID).
Biographical Sketch(s): Limited to 5 pages. Unless otherwise required in a specific FOA, do not include Current and Pending Support as this comes at the Just-In-Time (JIT) stage https://grants.nih.gov/grants/forms/biosketch.htm



- **A. Personal Statement** Briefly describe why you are well-suited for your role(s) in this project. 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/or your past performance in this or related fields, including ongoing and completed research projects from the past three years that you want to draw attention to (previously known as research support).
- **B. Positions, Scientific Appointments, and Honors -** List in reverse chronological order all positions and scientific appointments both domestic and foreign, including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary). High school students and undergraduates may include any previous positions. For individuals who are not currently located at the applicant organization, include the expected position at the applicant organization and the expected start date.
- **C. Contributions to Science** All senior/key persons should complete the "Contributions to Science" section except candidates for research supplements to promote diversity in health-related research who are high school students, undergraduates, and post-baccalaureates.

For the non-Fellowship Biographical Sketch, Section D. has been removed. For the Fellowship Biographical Sketch, Section D has been updated to remove 'Research Support.' As applicable, all applicants may include details on ongoing and completed research projects from the past three years that they want to draw attention to within the personal statement, Section A.

<u>DO NOT</u> use the "Current and Pending Support" attachment field for NIH or other PHS Agency submissions unless otherwise specified in the FOA.

For mentored career development award applications, you must include "Current and Pending (Other) Support" pages for each of the mentors and co-mentor(s). You do not need to include it for the candidates. The <u>NIH Other Support Format</u> has been re-organized to separate funded projects from in-kind contributions. NIH requires e-signature and date in the Other Support document to certify accuracy of the information, and each PD/PI and senior/key personnel must personally e-sign and date their respective Other Support document (via GW Adobe Sign) prior to submission.

PHS 398 R&R Related Budget/Modular Budget and Budget Justification (R&	ķR
Subaward Budget)	

- PHS 398 Modular Budget – when requesting increments (or modules) up to \$250,000 direct cost/year. (Personnel Justification Consortium Justification are



- **Mandatory**) **Additional Narrative Justification** is not needed in application for FOAs with direct cost limits that do not spread evenly across budget periods.
- **R&R Categorical Budget** when requesting \$250,001 or more direct cost/year.

Special Instructions for Applications Submitted with a Data Management and Sharing (DMS) Plan:

Data Management and Sharing Plan: As researchers develop their Data Management and Sharing Plans, make sure you do not include hypertext (e.g., hyperlinks and URLs) in the DMS Plan attachment. The NIH hyperlink policy applies to DMS Plans as well, and NIH may withdraw your application from consideration if you include them. For example, in the DMS Plan attachment you should include the name of the proposed data repository but do not provide the link or URL. For more format guidance and other details on what to include, see the <a href="https://www.writing.angle.gov/writing.gov/writing.angle.gov/writing.angle.gov/writing.angle.gov/writing.gov/writing.angle.gov/writing.gov/writi

PHS 398 R&R Related Budget: NIH recognizes that making data accessible and reusable for other researchers may incur costs. If a Data Management and Sharing Plan is required in the proposed application (see instructions for the "Other Plan(s)" attachment on the PHS 398 Research Plan Form and the PHS 398 Career Development Award Supplemental Form, as applicable), costs to support these activities, including personnel costs (e.g., personnel who will be curating data for the project) must be noted as a single line item. The line item must be titled "Data Management and Sharing Costs" (without quotation marks, but following exact phrase and spacing). The line item must only be used for Data Management and Sharing costs and cannot include or be combined with any "Other" costs. If no cost will be incurred, enter "0" in the "Funds Requested" column.

Budget Justification: Details regarding Data Management and Sharing costs must be specified in the Budget Justification attachment. The Data Management and Sharing justification must be clearly labeled as "Data Management and Sharing Justification" within the budget justification attachment. Provide a brief summary of type and amount of scientific data to be preserved and shared and the name of the established repository(ies) where they will be preserved and shared. Indicate general cost categories such as curating data and developing supporting documentation, local data management activities, preserving and sharing data through established repositories, etc., including an amount for each category and a brief explanation. Specify in the justification if no costs will be incurred for Data Management and Sharing, if applicable. The recommended length of the justification should be no more than half a page.

PHS 398 Modular Budget: Additional Narrative Justification - if a Data Management and Sharing (DMS) Plan is required in the proposed application, see instructions for the "Other Plan(s)" attachment on the PHS 398 Research Plan Form and the PHS 398 Career Development Award Supplemental Form, as applicable), the Additional Narrative Justification is required.



Research Plan:

Introduction to Application only required for Resubmission or Revision applications. Specific Aims is limited to 1 page. Research Strategy includes background & significance, research design and methods & preliminary studies/ progress. Progress Report Publication List is required for Renewal applications only.
Vertebrate Animals: if vertebrate animals are involved, attachment is required.
Multiple PD/PI Leadership Plan: must be included if more than one PI.
Consortium/Contractual Arrangements : explain programmatic, fiscal and administrative arrangements if you have consortia/contracts in your budget.
Letters of Support: consortium and consultant letters.
Resource Sharing Plan(s): Note: Effective for due dates on/after January 25, 2023, Data Management and Sharing (DMS) Plans are now included in Section 11. Other Plan(s). When applicable, plans for Genomic Data Sharing should be provided as part of the Data Management and Sharing Plan (one plan with two components). For Sharing Model Organisms, all NIH applications and proposals that will produce unique model organism research resources are expected to include a sharing plan for distributing these research resources in the application or proposal, or provide a justification for why such sharing is restricted or not possible.
Other Plan(s): Applications proposing to conduct research that will generate scientific data are subject to the NIH Data Management and Sharing Policy and must attach a Data Management and Sharing (DMS) Plan in this field. Refer to the list of NIH activity codes subject to the DMS Policy and your FOA to determine if your application is required to provide an attachment for the Data Management and Sharing (DMS) Plan. Scientific data is defined as the recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data includes any data needed to validate and replicate research findings. Scientific data does not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects such as laboratory specimens. The NIH Genomic Data Sharing Policy expects applicants seeking funding for research that generates large-scale human or non-human genomic data to provide a plan for sharing of these data as part of their DMS Plan. 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. For more on applicability of each policy, see research subject to the NIH Data Management and Sharing Policy and the research subject to the NIH Genomic Data Sharing Policy.



Authentication of Key Biological and/or Chemical Resources : required only for established key biological/chemical resources.
Appendix - see NIH guidelines for acceptable appendix materials found here: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-126.html
Assignment Request Form (optional) : use to communicate specific application assignment and review requests.
Humans Subjects and Clinical Trials : refer to NIH's Form H Application Guide: Section G. 500:

- <u>Human Specimens/or Data</u> Required for all applications.
- <u>Delayed Onset Study</u> Required only when human subjects research is anticipated within the period of award but definitive plans cannot be described in the application.
- <u>Study Record and Attachments</u> Required for any project involving Human Subjects and/or Clinical Trials.
- Human Fetal Tissue (HFT) Research For competing applications and competing revisions submitted after September 25, 2019, NIH will require applicants/contract offerors to address HFT requirements by providing a justification of the use of HFT, details regarding procurement and costs, and information about how the applicant/contract officer will use HFT. HFT is defined as research involving the study, analysis, or use of primary HFT, cells, and derivatives, and human fetal primary cell cultures obtained from elective abortions. Applications that do not address all of the required information, including the detailed (non-modular) budget as specifically instructed, will be administratively withdrawn by NIH and the application will not reviewed.

Do's & Don'ts of Hyperlinks and URLs in the NIH Grant Application https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-174.html

- Hyperlinks and URLs are only allowed when specifically noted in the funding opportunity announcement (FOA) and form field instructions. The use of hyperlinks is typically limited to citing relevant publications in biographical sketches and publication lists. It is highly unusual for a FOA to allow links in Specific Aims, Research Strategy and other page-limited attachments.
- Hyperlinks and URLs may not be used to provide information necessary to application review.
- Reviewers are instructed against viewing linked sites and are cautioned that they should not directly access a website (unless the link to the site was specifically requested in application instructions) as it could compromise their anonymity and allow for malware to be downloaded onto their computers.



 When allowed, you must hyperlink the actual URL text so it appears on the page rather than hiding the URL behind a specific word or phrase.
 Example: NIH (http://www.nih.gov/)

GW Subrecipient Commitment Form

The <u>GW Subrecipient Commitment Form</u> should be used as internal supporting documentation for proposal preparation and review, and should not be submitted to the sponsor or any Federal funding agency. Whenever GW subrecipients are identified during proposal development, use the FDP Clearinghouse website: https://fdpclearinghouse.org/organizations to confirm Participating Organizations in the FDP Expanded Clearinghouse by clicking on a Participating Organization's name to view their profile.

- The GW Subrecipient Commitment Form should be completed by Foreign/International Entities and Non-participating Organizations that do not have a profile in the FDP Expanded Clearinghouse. The completed and signed GW Subrecipient Commitment Form with attachments listed in Section F of the form should be uploaded in myResearch Attachments for internal review and proposal routing. The GW Subrecipient Commitment Form (with attachments) should be uploaded as a separate PDF for each organization.
- The GW Subrecipient Commitment Form is not required for Participating Organizations with a profile in the FDP Expanded Clearinghouse, only proposal-specific documents (such as IRB approval, statement of work, budget, etc.) are required as internal supporting documentation for proposal preparation and review.