NIH Forms Version I (Due dates on or after January 25, 2025)

SF424 (R&R) Application Guide

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general-formsi.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 Senior/Key Personnel Definitions http://grants.nih.gov/grants/policy/senior_key_personnel_faqs.htm#1658

NIH Table of Page Limits

http://grants.nih.gov/grants/forms_page_limits.htm

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

eRA Commons Helpdesk <u>http://grants.nih.gov/support/</u>

Please note that this checklist is a tool for assisting in correctly preparing the NIH application using myResearch. The application instructions can be found in the specific Notice of Funding Opportunity (NOFO), previously referred to as the Funding Opportunity Announcement (FOA).

Beginning with receipt dates on or after January 25, 2020, the requirement for <u>ORCID</u> 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, F12, 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.

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All PIs must be registered in eRA Commons with PI role and have their FCOI disclosure up-todate.

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 **PHS** Assignment Request Form for this purpose. The PHS Assignment Request Form is only seen by staff in the Division of Receipt and Referral (DRR), Center for Scientific Review (CSR).

- Mentored Career Development Award (CDA) applicants must include a cover letter that contains a list of referees (including name, departmental affiliation, and institution).
- Non-mentored CDA applicants are encouraged, but not required, to include a cover letter. The cover letter should include a list of referees (including name, departmental affiliation, and institution).
- **Individual Fellowship applicants** must include a cover letter that contains a list of referees (including name, departmental affiliation, and institution).
- **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 attachment **"Foreign Justification"**.)
- R&R Senior Key Persons: All individuals listed on the R&R Senior/Key Person Profile
(Expanded) Form are required to have an eRA Commons username (Commons ID), see NIH



Notice <u>NOT-OD-24-042</u>. Note: The role of "Co-PD/Co-PI" is not used by NIH and other PHS agencies.

Biographical Sketch:

Updated April 14, 2025 NIH Common Forms Implementation is Postponed NIH is postponing the May 25, 2025 implementation for all applications. NIH applicants and recipients must continue to use the current NIH <u>Biosketch</u> format pages for applications, Just-in-Time (JIT) and RPPRs, as applicable. NIH will issue future Guide Notices outlining the new effective date and additional implementation details as they are finalized.

****Current and Pending (Other) Support****

Unless specified in the NOFO, <u>do not</u> use the "Current and Pending Support" attachment field for application submission to NIH or other PHS agencies.

For mentored career development award applications, you must include "Current and Pending Support" pages for each of the mentors and co-mentor(s). Each mentor/co-mentor "Current and Pending Support" attachment is limited to 3 pages. No Current and Pending Support is required for the candidates.

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

- R&R Categorical Budget is used when requesting \$250,001 or more direct costs/year.
- Data Management and Sharing (DMS) Costs. Single budget line-item requirement for data management and sharing costs was rescinded <u>Read full announcement on the</u> <u>NIH website here</u>. DMS costs should be placed in appropriate budget categories, such as personnel, equipment, supplies and other expenses. Details regarding Data Management and Sharing costs must be specified in the Budget Justification attachment (L), pursuant to application instructions in the <u>How to Apply – Application</u> <u>Guide, Budget/Costs FAQs</u>, and <u>Frequently Asked Questions (FAQs) Data Sharing</u>.
- **PHS 398 Modular Budget** is used when requesting increments (or modules) of \$25,000 up to \$250,000 in direct costs/year. Personnel costs are required, in addition to Consortium costs as applicable. <u>Additional Narrative Justification</u> (as applicable): Provide this attachment for any variation in the number of modules requested, and

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when the Data Management and Sharing (DMS) Plan is required in the proposed application. Prior to award, NIH may request additional budget justification in exceptional circumstances.

Research Plan:

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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 and preliminary studies/progress. **Progress Report Publication List** is required for Renewal applications only.

Vertebrate Animals: if vertebrate animals are involved, attachment is required.

Select Agent Research: include attachment if proposed activities involve the use of select agents at any time during the proposed project period, either at the applicant organization or at any performance site.

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 consortiums/contracts in your budget.

Letters of Support: consortium and consultant letters.

Resource Sharing Plan(s): Effective for due dates on or after January 25, 2023, Data Management and Sharing (DMS) Plans are now included in the section Other Plan(s).

Plans for Genomic Data Sharing should be provided as part of the Data Management and Sharing Plan as one single plan.

Plans for Sharing Model Organisms, applications where the development of model organisms is anticipated, regardless of the amount requested, include a specific plan for sharing and distributing unique model organisms or state why such sharing is restricted or not possible.

Other Plan(s): Applicants proposing to conduct research that will generate scientific data are subject to the <u>NIH Data Management and Sharing Policy</u> and must attach a Data Management and Sharing (DMS) Plan.

Effective January 25, 2025, NIH will implement an update for data management and access practices under the Genomic Data Sharing (GDS) Policy (see Guide Notices <u>NOT-OD-24-157</u> and <u>NOT-OD-25-021</u>) which will affect researchers and institutional officials who access controlled-access data repositories subject to the GDS Policy. The <u>NIH Genomic Data Sharing</u> <u>Policy</u> 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. <u>Note: 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.</u>

Refer to the complete list of NIH activity codes subject to the DMS Policy and your Funding

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Opportunity Announcement to determine if your application is required to provide an attachment for the Data Management and Sharing (DMS) Plan. For more on applicability of each policy, see <u>research subject to the NIH Data Management and Sharing Policy</u> and <u>research subject to the NIH Genomic Data Sharing Policy</u>.

For assistance with writing the NIH DMS Plan, visit the <u>OSP website on NIH Data</u> Management and Sharing Plan Policy.

Authentication of Key Biological and/or Chemical Resources: required only for established key biological/chemical resources.

Appendix: see the updated NIH Guide Notice on the Appendix Policy.

Assignment Request Form (optional): use to communicate specific application assignment and review requests.

Humans Subjects and Clinical Trials:

- <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.
- <u>Human Fetal Tissue (HFT) Research</u> 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 required information, including the detailed (non-modular) budget as specifically instructed, will be administratively withdrawn by NIH and the application will not be reviewed.

Do's & Don'ts of Hyperlinks 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 NOFO and form field instructions. The use of hyperlinks is typically limited to citing relevant publications in biosketches and publication lists. It is highly unusual for a NOFO 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 (<u>http://www.nih.gov/</u>)

Internal Subrecipient Commitment Form (as applicable) should be included for internal routing and review before submission.

- FDP Members (requires Proposal-Specific Documents Only) https://sponsoredprojects.gwu.edu/subrecipients
- Non-FDP Members or Foreign/International Entities (requires GW Subrecipient Commitment Form with attachments in section F)
- FDP Clearinghouse <u>https://fdpclearinghouse.org/organizations</u>
- GW Subrecipient Commitment Form, available using the following link: <u>https://sponsoredprojects.gwu.edu/sites/g/files/zaxdzs2401/f/downloads/Subrecipient_Com</u> <u>mitment_Form.pdf</u>