NIH R01 Guide

This NIH R01 guide is intended as a general resource. This guide does not override the specific guidance provided by mentors, program officers, or your home department.

Applicants are advised to use the LATEST funding announcement. To verify, check the "Release/Posted Date" within the "Key Dates" section of the Requests for Application/ Parent Announcement (RFA/PA). .

Please note that particular Funding Opportunity Announcement (FOAs) may include specific guidelines regarding content, format, or length. These guidelines may deviate from the general instructions presented on the NIH website and in the SF424 (R&R). In such cases, the instructions provided in individual FOAs should be given priority. Please ensure to familiarize yourself with the current R&R forms package (SF424 R&R).

Contents

Links to NIH Research Project Grant (R01) Parent Announcements

- Clinical Trial Not Allowed: PA-20-185
    - Clinical Trial definition: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
- Clinical Trial Required: PA-20-183
    - Clinical Trial definition: A research study in which human subject(s) are prospectively assigned to interventions (which may include placebo or other control) to evaluate the health-related biomedical or behavioral outcomes of those interventions.
- Basic Experimental Studies with Humans Required: PA-20-184
    - Basic experimental studies involving humans (BESH) definition: A research study meeting both the definition of basic research and the NIH definition of a clinical trial. BESH are subject to NIH clinical trial policies such as registration and results reporting. All BESH meet the NIH definition of a clinical trial; however, not all clinical trials are BESH.

Standard due dates

Check the funding announcement to see if standard due dates apply (dates may vary).

	R01 Standard Due Dates	Scientific Merit Review Dates	Advisory Council Review Dates	Earliest Project Start Date
Cycle 1	February 5	Jun-Jul	Aug or Oct	Sept or Dec
Cycle 2	June 5	Oct-Nov	Jan	April
Cycle 3	October 5	Feb-Mar	May	July

Check the announcement to see if single or multiple Principal Investigators (PIs) are allowed. For applications designating multiple PDs/PIs, **a Multiple PD/PI Leadership Plan** must be included. For more information about Multiple PD/PIs, please see http://grants.nih.gov/grants/multi_pi/faq.htm. For an example, please see https://grants.nih.gov/grants/multi_pi/sample_leadership_plans.pdf

Purpose

The Research Project (R01) grant is awarded to support a discrete, specified, circumscribed project performed by the named investigator(s) in an area representing the investigator's specific interest and competencies. The project must be based on the NIH's mission.

Budget Information

Applicants may request up to five years of funding aligned with the project's needs and timeline. The scope and duration of each grant may differ. Please note that specific FOAs may impose budget constraints. Please carefully review any budgetary limits outlined in Part 2, Section 2, titled "Award Budget" of the FOA.

Applicants seeking more than $500,000 in direct costs annually (excluding consortium Facilities and Administrative costs- F&A) are required to communicate with NIH program staff at least six weeks prior to application submission. Additionally, they must adhere to the guidelines outlined in the 'Policy on the Consideration of Unsolicited Applications Requesting $500,000 or More in Direct Costs,' as outlined in the SF 424 (R&R) Application Guide and the NIH Grants Policy Statement. Specific FOAs may also necessitate additional budget-related information and instructions, which can be found in the 'Application and Submission Information' section of the respective FOA.

Budget Resources:

- UF Division of Sponsored Programs Budget Guidelines
- UF Fringe Rates
- Budget-JustficationJustification-Template_NIH-Detailed
- Budget-JustficationJustification-Template_NIH-Modular

Sections of application

Title

Limited to **200 characters** (including spaces and punctuation marks).

Project Summary (Abstract)

- No longer than **30 lines of text**.
- Succinct and accurate description of the proposed work that can stand on its own (separate from the application). Should be informative to other persons working in the same or related fields and understandable to a scientifically literate reader. Avoid both

descriptions of past accomplishments and first person.

- State the application's broad, long-term objectives and specific aims, referring to the health relatedness of the project (i.e., relevance to the mission of the agency). Describe the research design and methods for achieving the stated goals. The project summary must reflect the key focus of the proposed project so that the application can be appropriately categorized. Do not include proprietary, confidential information or trade secrets in the project summary. If the application is funded, the project summary will be entered into an NIH database and made publicly available on the NIH Research Portfolio Online Reporting Tool (RePORT). Note that the "Project Summary/Abstract" attachment is not same as the "Research Strategy" attachment.

Project Narrative

- No more than **3 sentences**.
- Describe the **relevance to public health**: how, in the short or long term, the research would contribute to fundamental knowledge about the nature and behavior of living systems and/or the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. If the application is funded, this public health relevance statement will be combined with the project summary (above) and become public information.

Biographical Sketch

NOTE: The summary below covers applications with due dates before January 31, 2026. For applications due on or after May 2023, please see the updated instructions on the NIH's website. **Use the blank format on the Biographical Sketch Format Page to prepare this section:** https://grants.nih.gov/grants/forms/biosketch-blank-format-rev-10-2021.docx

- Each biosketch is limited to **5 pages**, including the table at the top of the first page.
- **Education:** begin with baccalaureate information.
- **"Personal Statement:"** Briefly describe why your experience and qualifications make you particularly **well-suited for your role** on this project.
    - You may cite up to **four** publications or research products. You may cite interim research products, which have specific citation requirements. See related Frequently Asked Questions for more information. (NOT including publications that have been submitted or are in preparation).
    - **Ongoing and recently completed projects**: List *selected* ongoing and completed (during the *last three years*) research projects (Federal or non-Federal support). Begin with the projects that are *most relevant* to the research proposed in this application. Briefly indicate the overall goals of the projects and your overall responsibilities. *Do not include number of person months or direct costs.*

- If you are citing NIH-funded studies in your publications section of your biosketch, and if these publications fall under the NIH Public Access Policy, provide the Pubmed Central reference number or **PMCID** (e.g., PMCID234567).
- Place all Positions, Scientific Appointments, and Honors in reverse chronological order (Current at the top).
- You may provide a URL to a full list of your published work in the **Contributions to Science**. URL must be to a .gov website. NIH recommends using My Bibliography. Providing a URL to a list of published work is not required. More information on how to obtain your myNCBI link can be found here: https://www.era.nih.gov/erahelp/Commons/Commons/myncbi.htm

Specific Aims

- **1-page limit**. The Specific Aims do NOT count toward your Research Strategy, which has a 12- page limit.
- **Concisely** state the goals of the proposed research.
- Summarize the expected outcomes, including **impact** of research on fields involved.
- **Succinctly** list objectives of proposed research (e.g., to test a hypothesis, create a novel design, solve a specific problem, etc.).

Research Strategy

This section includes three headings: Significance, Innovation, and Approach.

Cannot exceed **12 pages** (this limit is for R01s. Page limits for other grant types will vary. Please see the NIH Table of Page Limits for other grant mechanisms).

Significance

- Elaborate on the significance of the issue or the significant obstacle hindering progress in the field that your project aims to address.
- Outline how the project you're proposing will enhance scientific understanding, technical competence, and/or clinical practices across one or more expansive domains.
- Detail how the principles, techniques, technologies, therapies, services, or preventive measures central to this field will undergo transformation upon successful attainment of the proposed objectives.

Innovation

- Clarify how the application confronts and aims to reshape existing paradigms within research or clinical practice.
- Outline any original theoretical ideas, methods, techniques, tools, or interventions to be

created or employed, highlighting their advantages compared to existing counterparts.
- Elaborate on any enhancements, advancements, or novel applications of theoretical concepts, methods, tools, or interventions.

Approach

- Incorporate Preliminary Studies/Progress Report within the "Approach" Section.
- Elaborate on the comprehensive plan, methodology, and analytical approaches that will be used to achieve the specific project goals. Include details on data collection, analysis, interpretation, and any applicable plans for sharing resources.
- Explore potential challenges, alternative tactics, and measurable milestones expected in the pursuit of project objectives.
- If the project is in its early developmental phases, outline a strategy for establishing feasibility and managing any high-risk components inherent in the proposed work.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.

Other Sections

Facilities and Other Resources: PIs must identify facilities used, their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe how the scientific environment in which the research will be conducted contributes to the probability of success.

- For Early Stage Investigators, describe **institutional investment** in the success of the investigator. See NIH's Early Stage Investigator Policies.
- For boilerplate text please see:
  - Facilities and Resources Boilerplate
  - UFHCC Common Equipment

Bibliography/References Cited: this section does **not** count toward your page limit.

Inclusion Enrollment Report:

- **Who must complete the Inclusion Enrollment Report(s):** An Inclusion Enrollment Report is required for all human subjects studies unless, on Question 1.3 "Exemption Number," you selected only Exemption 4 and no other exemptions.

- **Using the Inclusion Enrollment Report:** Each proposed study, unless it falls under Exemption 4, must contain at least one Inclusion Enrollment Report (IER). However, more than one IER per study is allowed. Once you have added an IER for a given study, you may edit, remove, or view it.

  Note: You can add a maximum of 20 IERs per Study Record. These can be a combination of planned and cumulative reports

Human Subjects Sections

Protection of Human Subjects

For Human Subjects Research Claiming Exemptions:

- If you claim that your human subjects research falls under any exemptions, justify and explain why the research meets the criteria for the exemption(s) that you have claimed. Do not merely repeat the criteria or definitions themselves.

For Studies that involve Non-Exempt Human Subjects Research:

- For any proposed non-exempt study involving human subjects, NIH requires a Protection of Human Subjects attachment that is commensurate with the risks of the study, its size, and its complexity. Organize your attachment into four sections, following the headings and specified order below, and discuss each of the points listed below. Start each section with the appropriate section heading – "Risks to Human Subjects," "Adequacy of Protection Against Risks," "Potential Benefits of the Proposed Research to Research Participants and Others," and "Importance of the Knowledge to be Gained." Also include any additional information requested in the FOA.

Inclusion of Women and Minorities

Address the following points:

- Describe the planned distribution of subjects by sex/gender, race, and ethnicity.

- Describe the rationale for the selection of sex/gender, racial, and ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.

- Describe proposed outreach programs for recruiting sex/gender, racial, and ethnic group

members.

- Inclusion and Excluded Groups: Provide a reason for limiting inclusion of any group by sex/gender, race, and/or ethnicity. In general, the cost of recruiting certain groups and/or geographic location alone are not acceptable reasons for exclusion of particular groups. See the "Inclusion of Women and Minorities as Participants in Research Involving Human Subjects - Policy Implementation Page" for more information.

Inclusion of Individuals Across the Lifespan

For the purposes of the "Inclusion of Individuals Across the Lifespan," exclusion of any specific age or age range group (e.g., children or older adults) should be justified in this section.

In addition, address the following points:

- NIH-defined clinical research expects the inclusion of individuals of all ages unless there are scientific or ethical reasons not to include them. Discuss whether individuals will be excluded based on age and provide a rationale for the minimum and maximum age of study participants, if applicable. Additionally, if individuals will be excluded based on age, provide a scientific or ethical rationale for their exclusion. See the NIH Policy and Guidelines on the "Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects" for additional information about circumstances that may justify the exclusion of individuals based on age.

- Include a description of the investigative team's expertise for working with individuals of the ages included, the appropriateness of the available facilities to accommodate individuals in the included age range, and how the age distribution of participants will contribute to a meaningful analysis relative to the purpose of the study.

Study Timeline

- Provide a description or diagram describing the study timeline. The timeline should be general (e.g., "one year after notice of award"), and should not include specific dates.

Targeted/Planned Enrollment Table

- All studies must enter planned enrollment counts unless your proposed study will use only an existing dataset or resource. Planned enrollment generally means that individuals will be recruited into the study and/or that individuals have already been recruited and continue to be part of the study.

For more information about what is considered an existing dataset or resource for inclusion policy, see the NIH FAQs on Inclusion on the Basis of Sex/Gender and Race/Ethnicity.

Vertebrate Animals

- You must provide a Vertebrate Animals Setion (VAS) if your work involves the use of live vertebrate animals, including generating custom antibodies and obtaining tissue from live vertebrate animals.

Select Agent Research.

- A full discussion on the use of Select Agents should appear in this section. PIs must describe the biocontainment resources available at all performance sites.

Multiple PD/PI Leadership Plan (if applicable)

- The multi-PD/PI option presents an important opportunity for investigators seeking support for projects or activities that require a team science approach. This option is targeted specifically to those projects that do not fit the single-PD/PI model, and therefore it is intended to supplement and not replace the traditional single PD/PI model. The overarching goal is to maximize the potential of team science efforts and be responsive to the challenges and opportunities of the 21st century.

Consortium/Contractual Arrangements (if applicable):

- An applicant/recipient under consortium agreements in which the recipient collaborates with one or more other organizations in carrying out the grant-supported research. The recipient, as the direct and primary recipient of NIH grant funds, is accountable to NIH for the performance of the project, the appropriate expenditure of grant funds by all parties, applicable reporting requirements, and all other obligations of the recipient as specified in the NIHGPS. In addition, the terms and conditions flow down to subrecipients in accordance with 2 CFR Part 200.101(b)(2) and 45 CFR Part 75.101

Template: Consortium-Contractual-Arrangements

Letters of Support

- Your application should include letters of support from your institution, key personnel, collaborators, and other significant contributors. Relevant letters of support will assure your peer reviewers that your collaborations and institutional commitments are on the right track.

What to Include:
The letter text should demonstrate the commitment of your institution and contributors. Summarize the agreements you have in place to support your project.

Familiarize yourself with the recommendations given in the SF 424 "Letters of Support" instructions. In multi-component applications, you may include letters of support in the overall component, other components, or both unless stated otherwise in the notice of funding opportunity (NOFO). You may also be instructed to begin the Letters of Support attachment with a table of letter authors, their institutions, and the type of each letter (e.g., institutional commitment).

Resource Sharing Plan(s)

Your application may need to include a plan for sharing model organisms, final research data, or genomic data. If any of these requirements apply to your research, write your plan or plans as a single attachment. All plans go in the Resource Sharing Plan attachment to the PHS 398 Research Plan form. They do not count toward the Research Strategy page limit.

To find out what to do, read the information below, which summarizes the main points from NIH Sharing Policies and Related Guidance on NIH-Funded Research Resources.

Data Management Sharing Plan:

Effective Jan. 25, 2023, NIH will issue a new Data Management and Sharing (DMS) policy to encourage the sharing of scientific data. View the key differences between the 2003 Data Sharing Policy and the NEW Data Management and Sharing (DMS) Policy.

NIH defines scientific data 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 do 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 (e.g., laboratory specimens).

Resources

Formatting

Citations

- Use your preferred citation format .
  - No required specific citation format.
  - The use of "et al." in place of listing all authors of a publication is acceptable practice.
  - Most style guides include format guidance for citations and all formats are acceptable.
  - SciENcv, a tool to prepare biosketches for NIH and other agencies, uses a standard format used by the National Library of Medicine (see Citing Medicine). If your organization does not already have a standard, consider this one.
- Remember to comply with our public access policy by including the PMC reference number (PMCID) when citing applicable papers that you author or that arise from your NIH-funded research.

Combining Information into a Single Attachment

- Ensure all information is directly visible in your PDF.
  - If you need to combine information from different sources into a single document prior to uploading, do not use “bundling” or “portfolio” features which combine multiple documents into a single file by providing links to the individual files.

Electronic Signatures

- Electronic signatures on PDF attachments within your application are not allowed (unflattened signatures are not allowed).
- To adhere to policies requiring electronic signatures on PDF attachments (e.g., electronically-signed other support format pages), you can electronically sign the document and then “flatten” the PDF.
- Documents with signatures (e.g., letters of support) can be printed, signed, scanned and attached in PDF format.

Filenames

- Save all document attachments with descriptive filenames of 50 characters or less (including spaces).
- Use unique filenames for all attachments in an application (or within a component of a multi-project application).

- Use any of the following characters: A-Z, a-z, 0-9, underscore, hyphen, space, period, parenthesis, curly braces, square brackets, tilde, exclamation point, comma, semi-colon, apostrophe, at sign, number sign, dollar sign, percent sign, plus sign, and equal sign.
- If including spaces, use one space (not two or more) between words or characters and do not begin the filename with a space or include a space immediately before the .pdf extension.
- Avoid the use of ampersand (&) since it requires special formatting (i.e., &amp).

File Size

- Ensure file size is greater than 0 bytes - we cannot accept a 0 byte attachment.
- Keep attachment file size to 100 MB or less.

Flattened PDFs

A PDF that has fillable fields, electronic signatures, text boxes or images inserted, becomes layered with each of these elements representing a layer. The existence of these layers interferes with the handling of the documents in eRA systems. Consequently, PDF documents included in applications, progress reports, and other information collected in eRA Commons must be flattened. A flattened PDF is simply one in which all the layers are merged together into a single flat layer.

Many simple PDFs are already flattened - all the information is contained in a single layer. Uploading a PDF that isn't flattened may result in an eRA Commons error message. You will need to replace your PDF with a flattened version to complete the submission process.

There are a number of methods to flatten a PDF, the easiest of which is to print it as a PDF. For Adobe Acrobat, follow these illustrated instructions. For other software, check your program's documentation.

Font (size, color, type density) and Line Spacing

Adherence to font size, type density, line spacing, and text color requirements is necessary to ensure readability and fairness. Although font requirements apply to all attachments, they are most important and most heavily scrutinized in attachments with page limits.

Text in your attachments must follow these minimum requirements:

- **Font size**: Must be 11 points or larger. Smaller text in figures, graphs, diagrams and charts is acceptable, as long as it is legible when the page is viewed at 100%.
    - Some PDF conversion software reduces font size. It is important to confirm that the final PDF document complies with the font requirements.
- **Type density**: Must be no more than 15 characters per linear inch (including characters and spaces).

- **Line spacing**: Must be no more than six lines per vertical inch.
- **Text color**: No restriction. Though not required, black or other high-contrast text colors are recommended since they print well and are legible to the largest audience.

We recommended the following fonts, although other fonts (both serif and non-serif) are acceptable if they meet the above requirements.

- Arial
- Georgia
- Helvetica
- Palatino Linotype

Legibility is of paramount importance. Applications that include PDF attachments that do not conform to the minimum requirements listed above may be withdrawn from consideration.

Headers and Footers

- Do not include headers or footers in your attachments. We add headers, footers, page numbers, bookmarks, and a table of contents when we assemble your grant application upon submission.
- Headings (e.g., Significance, Innovation) within the text of your attachments improve readability and are highly encouraged.
    - Some funding opportunities and form instructions provide guidance on organizing the content of attachments including specific headings that must be included.

Hypertext, Hyperlinks, and URLs

- Hyperlinks and URLs are only allowed when specifically noted in funding opportunities and/or form field instructions. It is highly unusual for a funding opportunity 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. Applications must be self-contained and reflect the information available at time of review.
- Reviewers are not obligated to view 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.
- 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 (hypertext).

  Examples:
    - NIH (http://www.nih.gov/)

- http://www.nih.gov/

- **Note:** *During initial implementation of the new Data Management and Sharing Policy, NIH will provide leniency and will not withdraw applications that include hypertext in the DMS Plan. Leniency will remain in place throughout the Federal Demonstration Partnership DMS Pilot that is testing alternate DMS templates and will be reevaluated in FY24.*

Images

- Digital images of material such as electron micrographs or gels must only be included within the page limits of the Research Strategy. The maximum size of images to be included should be approximately 1200 x 1500 pixels using 256 colors. Figures must be readable as printed on an 8.5" x 11" page at normal (100%) scale.
- Investigators must use image compression such as JPEG or PNG.

Language & Style

- Use English. (See 45 CFR § 75.111 - English language)
- Avoid jargon.
- Spell out acronyms the first time they are used in each application section/attachment and note the appropriate abbreviation in parentheses. The abbreviation may be used in the section/attachment thereafter.

Marking up Attachments

Do not mark-up your PDF documents with comments, sticky notes, or other features that are added on top of your PDF document content. This information may not be retained in your final application image.

Orientation

Both portrait and landscape attachments are accepted. However, keep in mind that landscape can be difficult to read online and may require reviewers and staff to scroll to see all available text.

Page Limits & Lines of Text Limits

Adhere to the page limits defined in the Table of Page Limits or within the text of the funding opportunity or NIH Guide notice (including Notices of Special Interest).

- Page limits defined in a funding opportunity should be followed when different than those found in the Table of Page Limits. Page limits defined in a related NIH Guide notice should be followed if different than either the Table of Page Limits or the funding opportunity.
- If no page limit for an attachment is listed in either the Table of Page Limits, Section IV of the funding opportunity under Page Limitations, or in a related NIH Guide notice you can assume the attachment does not have a limit.
- Some page limits apply to multiple attachments that when combined must stay within a designated limit. You may want to prepare your information in a single document to ensure you are within the page limit and later break-up the information into the various separate attachments. Our systems will accommodate a certain amount of white space resulting from splitting the information into the separate attachments when verifying compliance with a limit.

We systematically check many page limit requirements and provide error or warning messages to minimize incomplete or non-compliant applications. These systematic checks may not address all page limit requirements for a specific opportunity and do not replace the checks done by staff after submission. You must comply with all documented page limits and should not rely solely on system validations.

Page limits are strictly enforced to include all text included on the page including any headers. Limits measured in lines of text are not systematically enforced. In the case of the Project Summary/Abstract and Narrative attachments on the R&R Other Project Information form, we only systematically enforce egregious issues – text exceeds one page) and our manual checks would not remove an application from consideration if only the header information put the content over the specified line limit.

When preparing an administrative supplement application, follow the Table of Page Limits using the activity code of the parent award and any additional limits specified in the funding opportunity or a related notice.

Do not use the appendix or other sections of your application to circumvent page limits (NOT-OD-11-080).

Paper Size and Margins

- Use paper (page) size no larger than *standard letter paper size (8 ½" x 11")*.
- Provide at least one-half inch margins (*½"*) - top, bottom, left, and right - for all pages. No applicant-supplied information can appear in the margins.

Scanning

Avoid scanning text documents to produce the required PDFs. It is best to produce documents using your word-processing software and then convert the documents to PDF. Scanning paper documents may hamper automated processing of your application for agency analysis and reporting.

We recognize that sometimes scanning is necessary, especially when including letters of support or other signed documents on business letterhead.

Security Features

Our systems must be able to open and edit your attached documents in order to generate your assembled application image for agency processing and funding consideration.

Disable all security features in your PDF documents. Do not encrypt or password protect your documents. Using these features to protect your documents also prevents us from opening and processing them.

Single vs. Multi-column Page Format

A single-column page format easily adapts to various screen sizes and is highly encouraged.

Multi-column formats, especially for information spanning multiple pages, can be problematic for online review.

Video

Videos cannot be imbedded in an application, but they are accepted under limited circumstances as post-submission material. See NOT-OD-12-141 and NOT-OD-20-061.

When allowed, the application must be structured at the time of submission to indicate that a video will be submitted post-submission.

- The cover letter submitted with the application must include information about the intent to submit a video; if this is not done, a video will not be accepted.
- Key images, “stills,” and a brief description of each video must be included within the page limits of the research strategy. Sufficient descriptive information must be provided within the

research strategy to understand the information presented in the video, as not all reviewers may be able to access the video, depending on technological constraints.