

National Institutes of Health (NIH)

R01 Research Project

Template and Instructions

Template begins on page 10

This document contains information from the NIH document “Details of Application Changes for Research Grants and Cooperative Agreements (for due dates on or after January 25, 2010)” as well as general formatting guidelines. Principal investigators should refer to the SF 424, PHS 398 and funding notices (e.g., requests for applications, requests for proposals, funding opportunity announcements) and other official NIH documents when preparing their applications.

Important Information to Know When Using this Document

For Current and Specific information for R01s and other Unsolicited or Investigator-Initiated Applications, see

http://grants.nih.gov/grants/guide/parent_announcements.htm

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Table of New Page Limits

All applications for NIH funding must be self-contained within specified page limits.

Observe the page number limits provided in the table below, unless the Funding Opportunity Announcement (FOA) specifies otherwise. Page limits for activity codes not listed below should follow the page limits specified in the FOA.

SECTION OF APPLICATION Also refer to the relevant section of the application instructions and the FOA.	PAGE LIMITS *
Introduction to Revision or Resubmission Applications	1 page
Introduction to Revision or Resubmission Applications For each project and core of multi-component applications	1 page
Specific Aims	1 page
Research Strategy (Item 5.5.3 of Research Plan) For Activity Codes R03, R13/U13, R21, R36, R41, R43, Fellowships (F), SC2, SC3	6 pages
Research Strategy (Item 5.5.3 of Research Plan) For R01, single project U01, R10, R15, R18, U18, R21/R33, R24, R33, R34, U34, R42, R44, DP3, G08, G11, UH2, UH3, SC1, X01	12 pages
Research Strategy (Item 5.5.3 of Research Plan) For all other Activity Codes, including Cs, Ps, Ss, Ts, Us, etc.	follow FOA instructions *
Biosketch (per person) For all Activity Codes except DP1 and DP2	4 pages
Biosketch (per person) For DP1 and DP2	2 pages
Appendix	No page limits, but content limitations. See relevant section of instructions and FOA

- FOA instructions always supersede these instructions.

Formatting and Scoring Guidelines

Please refer to the following links for helpful information about writing, reviewing and scoring R01 applications (http://grants.nih.gov/grants/peer/reviewer_guidelines.htm):

Original Notice from the NIH on Enhancing Peer Review

<http://grants.nih.gov/grants/guide/notice-files/not-od-09-025.html>

R01 Guide for Reviewers

http://grants.nih.gov/grants/peer/r_awards/R01_Guide_for_reviewers.pdf

Template of Summary Statement

[RPG/R01/R03/R15/R21 Review Critique Template](#)

Example of Review Critique

[RPG Review Critique Example](#)

Scoring Key

<http://enhancing-peer-review.nih.gov/scoring&reviewchanges.html>

Restructured Application Forms and Instructions for Submitting for FY2011 Funding

(NOT-OD-09-149)

<http://grants.nih.gov/grants/guide/notice-files/not-od-09-149.html>

Other Helpful Resources

NIH Glossary& Acronym List

<http://grants.nih.gov/Grants/glossary.htm>

Standard Due Dates for Competing Applications

<http://grants.nih.gov/grants/funding/submissionschedule.htm>

Writing the Application

General Formatting Guidelines

(SF424 R&R)

Font

Use an Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger. (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.)

Type density, including characters and spaces, must be no more than 15 characters per inch.

Type may be no more than six lines per inch.

Paper Size and Page Margins

Use *standard paper size* (8 ½" x 11).

Use at least one-half inch margins (top, bottom, left, and right) for all pages. No information should appear in the margins, including the PI's name and page numbers.

Page Formatting

Since a number of reviewers will be reviewing applications as an electronic document and not a paper version, applicants are strongly encouraged to use only a standard, single-column format for the text. Avoid using a two-column format since it can cause difficulties when reviewing the document electronically.

Do not include any information in a header or footer of the attachments. A header will be system-generated that references the name of the PD/PI. Page numbers for the footer will be system-generated in the complete application, with all pages sequentially numbered.

URLs

Unless otherwise specified in the FOA, Internet website addresses (URLs) may not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites.

Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes

You may use a smaller type size but it must be in a black font color, readily legible, and follow the font typeface requirement. Color can be used in figures; however, all text must be in a black font color, clear and legible.

Grantsmanship

Use English and avoid jargon.

If terms are not universally known, spell out the term the first time it is used and note the appropriate abbreviation in parentheses. The abbreviation may be used thereafter.

Tips on Good Presentation

Presented by
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Office of Extramural Research

- Develop a logical outline with good use of transition phrases (“First....” “Second....”, “Finally....”; “As indicated earlier....”; “As explained earlier....”; “To achieve this goal....”; “Previous studies have shown...”)
- Use section headings to help reviewers “find things”
- Use major and minor section headings. Reviewers should understand your work simply by reading only the headings.
- Write clearly and concisely
- Make it easy for reviewers. Don't make them work hard.

Biosketch Instructions

For a PDF sample of the new biosketch format, go to
http://enhancing-peer-review.nih.gov/training_communication.html

NOTE: The Biographical Sketch may not exceed four pages. Follow the formats and instructions on the attached sample.

A. Personal Statement

Briefly describe why your experience and qualifications make you particularly well-suited for your role (e.g., PD/PI, mentor, participating faculty) in the project that is the subject of the application.

B. Positions and Honors

List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

C. Selected Peer-reviewed Publications

NIH encourages applicants to limit the list of selected peer-reviewed publications or manuscripts in press to no more than 15. Do not include manuscripts submitted or in preparation. The individual may choose to include selected publications based on recency, importance to the field, and/or relevance to the proposed research. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm. Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PMCID numbers along with the full reference (note that copies of publicly available publications are not accepted as appendix material.)

D. Research Support

List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). *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.

R01 Review Criteria

Overall Impact: Assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five core review criteria (as applicable for the project proposed). (Scored 1 [Exceptional]-9 [Poor])

Core Criteria (Score 1 [Exceptional]-9 [Poor])

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)

Are the Project Directors/Principal Investigators, collaborators, and other researchers well suited to the project? If the investigators are "Early Stage Investigators" or "New Investigators," do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-Project Directors/Principal Investigators, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

R01 Template

How to Use the Template: Fill in the blank areas beneath each question, criterion and suggestion and delete the template text, leaving the bold-faced headings. This template is to serve as a guideline only and should be modified as needed based on the specific research project and NIH funding notice (e.g., funding opportunity announcement, request for application or request for proposal). Though this template reflects the general formatting guidelines on page 6, please ensure that you have correctly formatted your own application before submitting it.

The template is formatted in 11-point Arial font

Template Begins on Next Page

Specific Aims (1-Page Limit)

NIH Instructions: State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

*****Begin Specific Aims Template Below*****

Specific Aims

- What is your project about? State your goal/objective/outcome.
- Why is it important? State the significance and overall impact.
 - Medical significance
 - Long-terms goal/objective of the project
- What is known? Provide background related to your research question.
 - This could include data from your lab as part of this background
- What is unknown? What do you hope to accomplish?
- Why is the gap in this knowledge a problem and how do you propose to address it?
 - Rationale of this study – why are you doing THIS project
 - What have you accomplished to date that suggests this approach? (Preliminary Data)
- What is your hypothesis (hypotheses)?
 - Objective of this application
- Explain how you will address your hypothesis (hypotheses) using your **Specific Aims**. (Suggested transition sentence to this section: “We proposed to address this (these) hypothesis (hypotheses) using the following specific aims:”). You may also list a hypothesis for each aim here.
 - Address “why” questions rather than “what”: no “demonstrate” or “describe” words should lead the aims, which should be very succinct and include expected outcomes
 - If you can briefly include an indication of the expected outcome/significance here, do so
 - KEEP THE AIMS SHORT – a full paragraph/aim is too much
- Summary paragraph: what you propose to do,
 - Why it is relevant/SIGNIFICANT to medical science and the field
 - Why your research team is the best team for the project
 - INNOVATION
 - Other salient features (e.g., multidisciplinary investigative team, outstanding clinical and/or laboratory environments)

*****End Specific Aims Template*****

Research Strategy (12-Page Limit)

Organize the Research Strategy in the specified order using the instructions provided below. Start each section with the appropriate section headings: (a) Significance, (b) Innovation, (c) Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References cited section of the application.

*****Begin Research Strategy Template Below*****

(a) Significance

Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.

Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.

Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

(b) Innovation

Explain how the application challenges and seeks to shift current research or clinical practice paradigms.

Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s).

Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions.

(c) Approach (Include Preliminary Studies in this section)

Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. *Tip:* make it clear what tasks are related to each specific aim. Unless addressed separately in Item 5.5.15, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.

Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.

If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work.

Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of Select Agents should appear in Sections 19 and 21.

*****End Research Strategy Template*****