**NIH R01 General Guidelines**

**About**

The NIH R01 is a large funding mechanism for independent health-related research projects that focus on the missions of individual institutes within the NIH. Successful R01 proposals generally ask compelling research questions, provide strong preliminary data, articulate a well-defined approach, and give a clear demonstration of the project's significance, innovation, and feasibility. Complimentary collaborations are also strongly encouraged.

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| General Information | |
| NOFO | [PA-25-301](https://grants.nih.gov/grants/guide/pa-files/PA-25-301.html) (expires January 8, 2028) |
| Standard Due Dates | [Link to standard due dates](https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm): generally at the beginning of February, June, and October |
| Project Period | Up to 5 years |
| Budget Limit | Application budgets are not limited but need to reflect the actual needs of the proposed project. Full indirects provided. Cost sharing not required. |
| Sample Applications | [Link to sample applications](https://www.niaid.nih.gov/grants-contracts/sample-applications) |

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| Formatting Information | |
| Document | PDF only with no headers or footers. |
| Font type | Arial, Georgia, Helvetica, Palatino Linotype are recommended. |
| Font size | Minimum 11 pt. Smaller font is acceptable in figures and graphs but must be legible when viewed at 100% zoom. |
| Margins | Minimum 0.5 inches on all sides. |
| Other formatting | [Link to additional formatting instructions.](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) |

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| Required Proposal Documents | |
| Project Summary | (no more than 30 lines) Concise description of the importance, objectives, and methodology of the proposal suitable for public dissemination. |
| Project Narrative | (2-3 sentences) Description of the public health relevance of the proposal suitable for a lay audience. |
| Specific Aims | (1 page) A highly important document for all NIH proposals. Concisely state the importance, goals, and specific objectives (Aims) of the proposal. Describe expected outcomes and impact on the research field if successful. |
| Research Strategy | (12 pages) Should include the following headed sections;   1. Significance: Describe the importance of the problem being addressed, current barriers in the field, and how the proposed research addresses the problem/barriers. Describe how achievement of the proposed research will advance the research field. 2. Innovation: Depending on the nature of the proposed research, describe;    1. How the proposed research challenges existing paradigms in the field.    2. How the proposed concepts or methodologies are novel and advantageous over existing concepts or methodologies.    3. Any refinements, improvements, or new applications of existing concepts, methodologies, or instrumentation to advance an existing field. 3. Approach: This section will be the most detailed description of the proposed research strategy and methodology that will lead to successful completion of the proposed Aims. This section can be organized in different ways as preferred by the PI, but is often sectioned out by Aim with appropriate figures for easier reading. Should include the following information;    1. Preliminary Data: Successful proposals will include preliminary results that support the proposed research. Preliminary data can be included here or in the Significance section.    2. Research Plan: Detailed discussion of the proposed research plan and methods, including appropriate controls and statistical analysis.    3. Potential Problems and Alternative Strategies: Identify likely places that the proposed methods may struggle or fail. Describe alternative strategies (methods and techniques) that would be used to circumvent or overcome these problems.    4. Expected Outcomes: Describe expected results from the proposed research. Could include milestones or “go-no-go” criteria. |
| Bibliography & References Cited | (no page limit) Complete listing of the references cited in the Research Strategy. |
| Biosketches | (5 pages per person) Required for each Senior/Key Personnel (PI or Co-PIs) and Other Significant Contributors. Should review [specific biosketch formatting requirements](https://grants.nih.gov/grants/forms/biosketch.htm). Can be prepared using [SciENcv](https://www.ncbi.nlm.nih.gov/sciencv/). Should include sections for personal statement, awards and honors, and contributions to science. |
| Facilities and Other Resources | (no page limit) A detailed description of the facilities (lab, computer, animal) and resources (supplies, space, time, funding) provided by the institution that support the capability to complete the proposed research. |
| Equipment | (no page limit) Provide a list of equipment pertinent to the proposed research along with its location and capabilities. |
| Budget | Requested budgets of $250,000 or less in direct costs per year use the Modular Budget form, requesting direct funds in $25,000 increments. Budgets greater than $250,000 in direct costs per year require a detailed budget using the R&R Budget form. Budgets greater than $500,000 in direct costs per year require pre-submission approval by the NIH. Budgets should be drafted by the PI, refined and approved by ORSP, and completed in NIH ASSIST by ORSP. |
| Budget Justification | (no page limit) Detailed justification of the requested funds. |
| Data Management and Sharing Plan | Complete the [Data Management and Sharing Plan Format Page](https://grants.nih.gov/grants/forms/data-management-and-sharing-plan-format-page). Describes the type of data that will be collected and how it will be preserved, accessed, and distributed. |

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| If Applicable/Optional Proposal Documents | |
| Resource Sharing Plan | If developing any [model organisms or new research tools as defined by the NIH](https://www.niaid.nih.gov/grants-contracts/resource-sharing-plan), describe the plan for sharing these resources. |
| Vertebrate Animals | Required if working with vertebrate animals. Describe proposed procedures involving animals, including species, strains, ages, sex, and total number to be used, justifications for the use of animals versus alternative models, interventions to minimize discomfort, distress, pain and injury, and justification for euthanasia method if not consistent with the AVMA Guidelines for the Euthanasia of Animals. |
| Protection of Human Subjects | Required if working with human subjects. Complete the Study Record form in ASSIST for each proposed study involving human subjects. |
| Select Agent Research | Required if working with a [federally designated Select Agent](https://www.selectagents.gov/sat/list.htm). |
| Multi-PI Leadership Plan | Required if multiple PIs (not Co-PIs) are indicated for the proposed research. Describe the rationale for a multi-PI approach, organization structure of the leadership team, and how communication, decision making, and conflict resolution will be handled. |
| Authentication of Key Biological And/Or Chemical Resources | Required if working with key biological or chemical agents. Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. |
| Consortium | Required if issuing a subaward from the institution. Should be completed by the institution receiving the subaward. |
| Letters of Support | Optional. Can solicit letters from collaborators or institution programs supporting the proposed research. |
| Introduction to Resubmission | (1 page) Required if proposal is a resubmission. Should address reviewer concerns from original submission and specify how the proposal has been strengthened. |
| Progress Report Publication List | Required if proposal is a renewal. List the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively. List the PubMed Central ID (PMCID) for each publication that was authored by the PI arising from NIH support. |