

## **NIAID Investigator-Initiated Program Project Applications (P01, Clinical Trial Not Allowed)**

### **Current Program Announcement (PA) Number: [PAR-22-225](#)**

The purpose of Program Project (P01) grants is to support integrated, multi-component research programs that have a well-defined, central research focus or objective. The P01 is a confederation of interrelated research projects, each capable of standing on its own scientific merit but complementing one another. The P01 application must include a minimum of two related, synergistic research projects that share a common central theme, focus, and/or overall objective. Each research project should reflect a distinct, separate, scientifically meritorious research effort led by an independent investigator, the Project Leader. In addition, the individual projects should be clearly interrelated and synergistic so that the research ideas, efforts, and outcomes of the program as a whole offer a distinct advantage over pursuing the individual projects separately.

In addition to individual research projects, the P01 application must include an administrative core. The P01 application may include one or more scientific/resource cores, if needed for the proposed research. Each scientific/resource core must be utilized by two or more projects within the program. For renewals and resubmissions, new scientific/resource cores may be proposed and/or existing cores may be augmented or dropped to support the proposed research.

### **Highlight Synergy**

In the context of a multi-component application, synergy entails enhancement of scientific knowledge, ideas, and outcomes obtained through the cooperative interactions of the individual projects and cores. Synergy is defined as the sharing of data generated by the individual projects and cores that will inform the other project(s) such that the research is enhanced through this additional knowledge and/or the direction of science and research outcomes are changed. Describing synergy involves explaining how the proposed merger of complementary skills, perspectives, and resources has the potential to produce outcomes greater than would otherwise be achieved. For example, describe how and why the outcomes resulting from conducting the proposed research as a Program will exceed the outcomes from conducting separate research activities as a single project application (as an R01, for example). Resources and tools that can help facilitate synergy include, but are not limited to sharing research data, samples, reagents, pathogens, human subject cohort(s), technologies, research approaches, data management/analytical tools, and model organisms. The program should be cohesive with the projects and shared scientific/resource cores integrated into a common theme of the Program Project. To highlight Program synergy applicants may:

- Describe in the Overview section how the individual components (projects and resource cores) will be coordinated and work together to address the overall goals and aims of the program.
- Include a schematic overview of the interactions/collaborations among the components (projects and cores).
- Address synergistic activities in the Research Plan, and if possible, in the Specific Aims of each component.
- Indicate collaborations among members and relevant publications co-authored by members of the program.

Applicants are referred to NIAID's [Multi-component Research \(P, U\) Applications](#) for additional guidance on NIAID P01s.

**Application Due Date(s):**

Activity Code	Program Description	Cycle I Due Date	Cycle II Due Date
P Series: <i>All - new, renewal, resubmission, revision</i>	Program Project Grants	January 11, 2024 January 10, 2025	June 11, 2024 June 11, 2025
	AIDS and AIDS-Related Applications	May 7, 2024 May 7, 2025	September 7, 2024 September 7, 2025

Applications must be submitted electronically on (by 5:00 p.m. local time of applicant organization) or before the dates described above. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

**APPLICATION AND SUBMISSION INFORMATION**

**Overall Program Project:**

**Introduction to Application (1 page; Resubmission applications only):** For a Resubmission application, an Introduction to Application page is **required in the Overall component** to address the comments from the previous scientific review group.

**Specific Aims (1 page):** List the goals of the research & summarize expected outcomes.

**Overall Research Strategy (12 pages):** The Overall program section describes the significance and approach of the Program Project and should highlight the program's conceptual unity, innovation, and synergy. It should include a description of the major research objectives and strategic plan, detailing how the proposed projects and shared scientific/resource cores (if proposed) will be coordinated and work together to address the overall goals and aims of the program more effectively than if the projects were conducted independently. The synergistic nature of the proposed projects and shared scientific/resource cores (if proposed) at the overall program level should be described and include the placement/contribution of each project and core in the overall scheme. A description of how the program as a whole will benefit from any unique cohorts and samples, collaborations, or resources should be included, as well as a summary of any special features in the environment and/or resources that make the overall program strong or unique. **Renewal applications should contain a brief description of progress made in the last funding period.**

**Bibliography and References Cited/Progress Report Publication List.** When citing articles that fall under the Public Access Policy, which were authored or co-authored by the applicants 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.

**External Advisory Committee (EAC).** Reviewers will be instructed regarding the following information:

**For new applications**, if you choose to appoint an EAC (optional), the application must describe the expertise and responsibilities of the potential External Advisory Committee members in the Overall section. New applicants that include an optional EAC should NOT contact, recruit, or name potential members in the application. However, if you have already contacted new member(s) for the EAC, you must provide the name(s) of the person(s).

**For competing renewal applications**, you must provide the names of current and former EAC members (since they can't serve as reviewers for your application) as well as a description of their expertise and responsibilities in the Overall section of the application. You should NOT contact, recruit, or name any new members for your renewal application until after the peer review is completed. However, if you have already contacted new member(s) for the EAC, you must provide the name(s) of the person(s).

**Multiple PI Leadership Plan (if applicable).** If the multiple Program Directors/Principal Investigators (PDs/PIs) option is used, the Multiple PD/PI Leadership Plan must be included but **does not count against the 12-page limit. Multiple-PDs/PIs are allowed for the overall program, but not for the projects or cores.** NIAID does not support multiple Project/Core Leaders for individual Projects and Cores within a multi-component application.

**Resource Sharing Plan.** Guidance on [Writing a Data Management and Sharing Plan](#). Refer to NIAID's [Data Policy and Guidance](#) on the [Genomic Data Sharing Policy](#).

**Budget.** Subaward actions and expenditures must conform to all terms and conditions of a grant award. Subaward organizations cannot form their own subaward agreements with other organizations and may receive funds only from the grantee. Therefore, **do not include a subaward within a subaward.**

**Research Projects** (1, 2, 3, etc. consecutively):

Each research project should be prepared according to the standard [SF 424 \(R&R\) Application Guide](#) instructions and additional guidance provided in the [NIAID Guidelines](#). The interactions among projects and cores should be described within each project.

- Research Plan
- Introduction to Application (**Resubmission applications only; 1 page allowed for each research project**)
- Specific Aims (**1 page**) - Concisely and realistically describe the hypothesis or hypotheses to be tested. In addition, state the individual project's relationship to the Program's goals and how it is synergistic to other projects and relevant cores.
- Research Strategy (**12 pages**) has three parts: significance, innovation, and approach.
- Progress Report Publication List (**required only for Renewal applications**)
- References/Literature Cited

**Scientific/Resource Cores** (A, B, C, etc. consecutively):

Each core should be prepared according to the [SF 424 \(R&R\) Application Guide](#) instructions and additional guidance provided in the [NIAID Guidelines](#). **Each core must provide essential facilities or services for two or more research projects.** A multi-component application must include an administrative core and may include one or more scientific/resource cores.

- Core Research Plan
- Introduction to Application (**Resubmission applications only; 1 page allowed for each core**)
- Core Specific Aims (**1 page**) - State the core's relationship to the proposed Program's goals and how it is related to the individual Research Projects and other Cores in the application. Summarize the **resources, services, and facilities** the core provides that are essential for two or more projects in the application.
- Core Research Strategy (**6 pages**) has three parts: significance, innovation, and approach. **Please note that scientific/resource cores perform services and tasks, not research activities.** Research activities should only be conducted in the research projects.
- Progress Report Publication List (**required only for Renewal Applications**)
- References/Literature Cited

**Sections in individual projects and in individual cores**

- Protection of Human Subjects - Only include information that is relevant to protection of human subjects. Reviewers will be instructed to not consider any irrelevant information in this section.
- Vertebrate Animals - Only include information that is relevant to vertebrate animals (address the required points).
- Select Agent Research
- Consortium/Contractual Arrangements
- Letters of Support
- Resource Sharing Plan: Please comply with the instructions for the Resource Sharing Plan as provided in the [SF 424 \(R&R\) Application Guide](#).

**Biographical Sketches 5 pages total each:** Compile all biographical sketches after the Overall Budget. Each Senior/Key Person, including the PD/PI, is allowed one biosketch for the entire application. Do not repeat biographical sketches in the individual research projects or cores. Include:

- Personal statement: In this section, you may cite up to 4 publications or research products that highlight your experience and qualifications for this project. Use of hyperlinks and URLs to cite these items is not allowed in this section. Please note that Section D has been removed. Instead, 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).
- Positions, Scientific Appointments and Honors
- Contributions to Science: Description of up to five most significant contributions to science. For each contribution, you may cite up to 4 peer-reviewed publications or non-publication research products. You may provide a hyperlinked URL of full

list of published work as found in publicly available digital database (e.g., SciENcv, My Bibliography).

For more details, see [Biosketch Format Pages, Instructions, and Samples](#).

**Appendix:** Appendices are stored separately in the eRA Grant Folder (not as part of the application image) and are accessible to peer reviewers. **Do not use the Appendix to circumvent the page limitations for the Research Plan. Excess information in the Appendix won't be considered for the review. Applications will be withdrawn as noncompliant and not reviewed if they are submitted with appendix materials that are not specifically listed in [NOT-17-098](#) or the *notice of funding opportunity* (NOFO) as allowed or required.**

**Allowable appendix materials**

- Blank informed consent/assent forms
- Blank survey/ questionnaire/ data collection forms

For more details, refer to NIH's [Appendix Policy Frequently Asked Questions](#).

**Post-Submission Materials:** Post-submission materials will only be accepted 30 calendar days prior to the peer review meeting. See [NOT-OD-19-083](#) for allowable materials. For multi-component applications, a set of post-submission materials is allowed for each project or core.

**Other Important Information:** Project and Core Leaders do not lose new/early-stage investigator status if award is made.

**Sending an Application to the NIH:** Applicants must follow the instructions in the [SF 424 \(R&R\) Application Guide](#) except where instructed to do otherwise.

## **APPLICATION REVIEW INFORMATION**

Reviewers will provide a single overall impact/priority score for the Program Project application as a whole to reflect their assessment of the likelihood for the program to exert a sustained, powerful influence on the research field(s) involved. Projects/cores and the Program as an integrated effort are collectively considered. The relationship and contributions of each project and core to the overall theme of the Program Project are evaluated.

The focus of the review is on the scientific merit of the overall program. Reviewers are instructed to discuss the Overall Program considering the 5 NIH standard review criteria and review criteria specific to the NOFO with emphasis on interaction, collaboration, common programmatic theme(s), and synergy. During the overall discussion, reviewers will discuss the strengths and weaknesses of the projects and cores and how these strengths and weaknesses relate to the overall program and its chance for success. Following the overall discussion, reviewers will conduct brief discussions of individual projects and cores to identify any additional score-driving strengths or weaknesses that were not discussed during the critique of the overall program. Projects and cores only receive overall impact scores.

Please read the [Section V. Application Review Information in the PAR-22-225 NOFO](#). The criteria specified in the NOFO are what the reviewers use to guide them in their evaluations.

### **Score Summary**

- Overall Impact Score for the Entire Program (1-9)
- Overall Impact Score for the Individual Projects and Cores (1-9) in Summary Statement
- Criterion Scores for the Overall Program (1-9) in Summary Statement. Individual Projects and Cores are evaluated by their review criteria specified in the NOFO, but do not receive Criterion Scores.

### **PITFALLS**

- Overambitious aims.
- Poorly described Administrative Core.
- Core does not support at least two projects.
- Lack of detail and preliminary data in new scientific cores.
- Poorly described logistics for applications involving multiple institutions (insufficient communication, poorly described plans for shipping specimens, animals, etc.).
- Lack of description of synergy in each component of the application.
- Lack of support letters for reagents/resources/collaborations.
- Plus [these common pitfalls](#)

### **RECENT POLICY UPDATES:**

[Notices of NIH Policy Changes](#)

[NIH Policy & Compliance Topics](#)

[Inclusion Across the Lifespan](#)

[Vertebrate Animal Research](#)

[NIAID-relevant Guide notices, Special Announcements](#)

[NOT-OD-16-010: Children defined as individuals under 18 years old](#)

[NOT-OD-24-061: Guidance on Marking Changes in Resubmission Applications](#)

### **RESOURCES:**

[Multiproject Research \(P, U\) Applications](#)

Portal for the ASSIST system: [ASSIST](#)

[Peer Review Policies and Practices](#)

[Budget \(Subawards\)](#)

[Enhancing Reproducibility through Rigor and Transparency](#)