Title: NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed)

Program Announcement (PA) Number: PAR-22-225

The purpose of Program Project (P01) grants is to support integrated, multiproject 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 individual research projects that contribute to the program objective. Each individual 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, applicants must include an Administrative Core and may propose one or more optional scientific cores if needed for the proposed research. Each core must be utilized by two or more projects within the program. For renewals and resubmissions, new cores may be proposed and/or existing cores may be augmented or dropped to support the proposed research.

Highlight Synergy

Synergy is the interaction or cooperation among different groups working on the same project. In the context of a multiproject application, synergy entails enhancement of scientific knowledge, ideas, and outcomes obtained through the cooperative interactions of the individual projects and cores. Synergy is also 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. 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 an R01, for example). Examples of synergy include, but are not limited to, sharing data, samples, reagents, pathogens, human subject population(s), technologies, research approaches, data management and analysis tools, and model organisms, which will impact the direction of science and research outcomes in the Program. To highlight Program synergy applicants may:
- Describe in the Overview section how the individual components (projects and shared 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.

The program should be cohesive with the projects and shared resource cores integrated into a common theme of the Program Project.

Applicants are referred to NIAID's Multiproject Research (P, U) Applications at https://www.niaid.nih.gov/grants-contracts/multiproject-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: *All - new, renewal, resubmission, revision*	Program Project Grants	January 11, 2023 January 11, 2024 January 10, 2025	June 08, 2023 June 11, 2024 June 11, 2025
	AIDS and AIDS-Related Applications	May 7, 2023 May 7, 2024 May 7, 2025	September 7, 2023 September 7, 2024 September 7, 2025

Applications must be submitted electronically on (by 5:00 PM 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.

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APPLICATION AND SUBMISSION INFORMATION

Overall Program Project:

Introduction (one page): An introductory page is allowed only in resubmissions to address reviewers' critiques.

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

Overall Research Strategy (12 pages): The Program Overview Section describes the significance, innovation, and approach of the overall application and should highlight the program's conceptual unity by describing the scientific problems to be addressed and laying out a broad research strategy to address them. The synergistic nature of the proposed projects and shared scientific 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. Renewal applications should contain a brief description of progress.

Bibliography and References Cited/Progress Report Publication List. 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.

External Advisory Committee (EAC). Reviewers will be instructed regarding the following information: **For new applications**, if you choose to appoint an EAC, you may provide scientific expertise and the responsibilities of the EAC members in the Program Overview Section of the application. However, you should NOT contact any individuals for the purpose of serving on the EAC, nor should you identify any such individuals in the application. However, if you have already contacted new member(s) for EAC you must provide the name(s) of the person(s).
For competing renewal applications, 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 Program Overview Section of the application. You should NOT contact any new member for your renewal application until after the peer review is completed. However, if you have already contacted new member(s) for 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-PIs are allowed for the overall program, but not for the projects or cores.

Resource Sharing Plan. (Data Sharing Plan, Sharing Model Organisms, and Genomic Data Sharing Plan). Include a data sharing plan for the overall Program Project if the overall budget requests $500,000 or more in direct costs for any year.

Guidance on developing data sharing plans:
https://grants.nih.gov/policy/sharing.htm

See NIAID's implementation of the Genomic Data Sharing Policy at
https://sharing.nih.gov/genomic-data-sharing-policy

Additional information regarding the NIH Genomic Data Sharing Policy may be found here:
https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/

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 subcontract within a subcontract.

Individual Research Projects (1, 2, 3, etc. consecutively):
Each research project should be prepared according to the standard SF424 (R&R) instructions and additional guidance provided in the NIAID guidelines (https://www.niaid.nih.gov/grants-

contracts/multiproject-research-p-u-applications). The interactions among projects and core facilities should be described within each project.

- Research Plan:
- Introduction to Resubmission (if applicable; one page)
- Specific Aims (one page)
- Research Strategy (12 pages) has three parts: significance, innovation, and approach.
- Progress Report Publication List (for Renewal Applications)
- References/Literature Cited

Individual Cores (A, B, C, etc. consecutively):
Each core should be prepared according to the SF424 (R&R) instructions and additional guidance in the NIAID guidelines (https://www.niaid.nih.gov/grants-contracts/multiproject-research-p-u-applications). Each core unit must provide essential **facilities or services** for **two or more** research projects. A multiproject application may include two types of cores: an administrative core and scientific cores.

- Core Research Plan
- Introduction to Resubmission Application (if applicable; one page)
- Core Specific Aims (one page) - summarize the resources and facilities the Core provides that are essential for two or more projects in the application
- Core Research Strategy (six pages) has three parts: significance, innovation, and approach.
- Progress Report Publication List (for Renewal Applications Only)
- 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:
  - Include any resource sharing plans that apply: data sharing, model organism, and genomic data sharing plan. For data sharing, include a plan only if the individual project or core budget requests $500,000 or more in direct costs for any year; otherwise put data sharing information under the overall program. Plans for model organism and genomic data sharing plan have no dollar limit.

Biographical Sketches five 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 four 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 four 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 :
http://grants.nih.gov/grants/forms/biosketch.htm

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.

Allowable appendix materials
- Blank informed consent/assent forms
- Blank survey/ questionnaire/ data collection forms

Consequences for submitting disallowed appendix materials
Applications will be withdrawn and not reviewed if they are submitted with appendix materials that are not specifically listed in NOT-17-098 or the FOA as allowed or required.

For more details see NIH Appendix Policy and Frequently Asked Questions:
https://grants.nih.gov/grants/policy/appendix_policy.htm

Post-Submission Materials: Post-submission materials that will be accepted are those resulting from unforeseen administrative issues and news of an article accepted for publication. The policy on post-submission application materials is not intended to correct oversights/errors discovered after submission of the application. Post-submission materials will only be accepted 30 calendar days prior to the peer review meeting and include the following:

Allowable Post-Submission Materials for All Applications
- Citations of issued patents
- Revised budget page(s) (e.g., due to new funding or institutional acquisition of equipment)
- Biographical sketches (e.g., due to the hiring, replacement, or loss of an investigator)
- Letters of support or collaboration due to the hiring, replacement or loss of an investigator
- Adjustments resulting from natural disasters (e.g., loss of an animal colony)

- Adjustments resulting from change of institution [e.g., PD/PI moves to another university]
- News of professional promotion or positive tenure decision for any PD/PI or Senior/Key Personnel
- Approval by the NIH Stem Cell Registry of a human embryonic cell line(s) after submission of the application.
- Videos, within defined limits, that demonstrate devices and experimental data with a temporal element, which refers to the need to show how something functions or occurs over time, or demonstrates movement or change. Applicants must follow the directions in NOT-OD-20-061 and NOT-OD-12-141 for submitting videos to accompany grant applications
- Other post-submission materials specified in the FOA for which the application was submitted or in a special *Guide* notice.
- **News of an article accepted for publication since submission of the application,** which must include *only*:
  - List of authors and institutional affiliations
  - Title of the article
  - Journal or citation (if available)

Copies of articles, links to articles, or any other materials related to an article accepted for publication, copies of patent applications or patents, or any other materials related to a patent application or granted patent, *will not be accepted as post-submission materials, unless specified in the Funding Opportunity Announcement (FOA) for which the application was submitted or a special Guide notice.* Note that preprints and other interim research products (NOT-OD-17-050) are not accepted as post-submission materials because they do not represent unforeseen events.

Page limit for Post-Submission Materials:
One printed page for each Project, Core and Overall Program.

For other requirements for submitting post-submission materials and more detail:
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-083.html

Other Important Information: Project and Core Leaders do not lose new/early stage investigator status.

Sending an Application to the NIH: Applicants must follow the instructions in the SF424 (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 as a whole to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved. Individual research subprojects, supporting cores (if proposed), and the Program as an integrated effort are collectively considered. The relationship and contributions of each research subproject and core to the overall theme of the Program Project are evaluated.

Reviewers will be instructed to discuss the overall program considering the 5 NIH standard review criteria and review criteria specific to the FOA 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, considering the 5 standard review criteria, and how these strengths and weaknesses relate to the overall program. Following the overall discussion, reviewers will conduct brief discussions of individual projects and cores.

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 (in PAR-22-225, Individual Projects are evaluated by the 5 standard review criteria 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: https://www.niaid.nih.gov/grants-contracts/multiproject-research-p-u-applications#Avoid%20Common%20Pitfalls

RECENT POLICY UPDATES:
Notices of NIH Policy Changes: https://grants.nih.gov/policy/notices.htm
NIH Policy & Compliance Topics: https://grants.nih.gov/policy/index.htm
    Inclusion of Individuals Across the Lifespan: https://grants.nih.gov/policy/inclusion/lifespan.htm
    Vertebrate Research Animals: https://olaw.nih.gov/
NIAID-relevant *Guide* notices, Special Announcements: https://www.niaid.nih.gov/grants-contracts/special-announcements
NOT-OD-16-010: Children defined as individuals under 18 years old.

RESOURCES:
Multiproject Research (P, U) Applications: https://www.niaid.nih.gov/grants-contracts/multiprojectresearch-p-u-applications
Portal for the ASSIST system: ASSIST
Peer Review Policies and Practices: https://grants.nih.gov/policy/peer/index.htm
Budget (Subawards): https://www.niaid.nih.gov/research/grants-subawards-consortium-agreements

Enhancing Reproducibility through Rigor and Transparency:
https://grants.nih.gov/policy/reproducibility/index.htm