

## **National Cancer Institute Program Project (P01) Information**

*\*The purpose of this document is to highlight important components and requirements of [PAR-23-059](#). Please read this announcement in its entirety before preparing an application.*

Standard due dates of January 25<sup>th</sup>, May 25<sup>th</sup> and September 25<sup>th</sup>

Through this Funding Opportunity Announcement (FOA), the National Cancer Institute (NCI) invites grant applications for investigator-initiated Program Projects (P01) in any area of cancer research. P01 grants support integrated, multi-project research programs involving a number of independent investigators who share knowledge and common resources while working towards a unifying overall scientific goal. The NCI provides support for Program Projects in the belief that a collaborative research effort can accelerate the acquisition of knowledge more effectively than a simple aggregate of research projects that have no interaction or thematic integration. Therefore, every P01 Program Project proposed should have a well-defined unifying research theme.

Each Program Project application must include at least three projects and an Administrative Core. The individual projects may represent several disciplines and/or address several discrete research aspects pertinent to one or more disciplines. However, all the projects must be relevant to the common unifying central theme or focus, and the overall objective of the entire Program. Each individual project should reflect a self-standing scientifically meritorious research effort. 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 will offer a distinct advantage over pursuing the individual projects separately.

### **General required components:**

Overall: Required; should include:

- A. Program Background and Statement of Objectives: Present the background, rationale and hypotheses of the central scientific theme, including overall significance, innovation, approaches, and preliminary studies, remembering that specifics for each project will be discussed in depth in the individual projects.
- B. Integration and Coordination of the Program Project: Explain how the proposed projects and shared resource cores (if proposed) will be integrated, coordinated and will work together to address the overall goals and aims of the Program more effectively than if the projects were done independently. Clearly describe which components will be interacting with each other, and the advantages or value added that may be realized by conducting the research as a Program Project rather than through separate research efforts. Specific examples of inter-project collaborations should be given, if possible. Explain how information, reagents, personnel, equipment, etc., will be shared between the proposed projects and shared resource cores to create synergy within the Program.

Research Projects: Minimum of 3, maximum of 5; The projects must share a common central theme, focus, and/or overall objective.

Administrative Core: Max of 1; This core will provide the organizational and administrative management of the Program, plans for monitoring of progress, and plans for effective coordination and communication within the Program.

Shared Resources/Cores: (Optional) Max of 5; Applicants may propose one or more Shared Resource Cores if needed for the proposed research. Each Shared Resource Core must provide support and enhance the productivity, cost-effectiveness, and/or research outcome of at least two of the proposed research projects. New cores may be proposed and/or existing institutional cores may be augmented to support the proposed research.

**Requests of \$500,000 or more for direct costs in any year:**

Applicants requesting \$500,000 or more in direct costs in any year (excluding consortium F&A) must contact a Scientific/ Research Contact at least six weeks before submitting the application and follow the Policy on the Acceptance for Review of Unsolicited Applications that Request \$500,000 or More in Direct Costs as described in the SF424 (R&R) Application Guide.

**PI Eligibility**

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

Always check the FOA for the eligibility requirements as these can vary between FOAs.

**Additional Review Criteria**

**Overall**

Significance: Does the Program Project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed Program rigorous? If the aims of the Program 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?

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 Program Project? Have investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed Program? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the projects are in the early stages of development, will the strategy establish feasibility and will

particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

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?

Program Integration: Reviewers will assign an adjectival rating to this section of the Overall based on the following:

- How well coordinated are the proposed projects and shared resource cores (if proposed)? How much more effectively will they work together to address the overall goals and aims of the Program than if the projects were to be conducted independently?
- What is the likelihood that the Program Project will exert a greater sustained, powerful influence on the research field(s) involved, than if the components were to be completed individually?
- Are there specific examples of inter-project collaborations and information regarding how reagents, personnel, equipment, etc., will be shared between the proposed projects and shared resource cores and to what extent will they create synergy within the Program Project?

### **Research Projects**

Significance: Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed program rigorous? 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 PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, 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-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation: Does the project 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 strategies, methodologies, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed program? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? 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? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

**Admin Core:**

*Reviewers will assign a merit descriptor rather than numeric scores; individual criterion scores are not provided:*

- How appropriate are the plans for organizational and administrative management, including scientific and fiscal management, for the proposed Program?
- How adequate are the plans for coordination and communication to accomplish the objectives of the overall Program?
- How sound are the methods planned to monitor progress in the projects, and how effectively are the core resources being utilized?
- If an external or internal advisory board is proposed, how adequate are the expected areas of expertise of the members, or if already convened, are the expertise areas adequate for the listed members? How appropriate are the roles and responsibilities of advisory group members?
- Are the qualifications, experience, and commitment of the Core Leader adequate?
- Is there a clearly described chain of responsibility for decision making, and a succession plan should the need arise?

**Shared Resource Core(s)**

*Resource Cores will receive merit descriptors rather than numeric scores; individual criterion scores are not provided:*

- Is the proposed Shared Resource Core well matched to the needs of the overall Program? Does it provide essential facilities or services for two or more research projects?
- What is the overall quality of the proposed Core services? Are adequate quality control processes proposed for the facilities or services provided by the Shared Resource Cores (including procedures, techniques, and quality control)? What are the criteria for prioritization and usage of Core products and/or services?
- Are the qualifications, experience, and commitment of the Shared Resource Core Director and other key personnel adequate and appropriate for providing the proposed facilities or services?
- Will the proposed shared resource Core(s) provide cost effective services to the Program? Are there adequate plans to augment and/or complement an existing shared resource supported by an NCI Cancer Center Support grant (P30), if applicable?
- Is the environment for the shared resource Core adequate to support the Program as proposed? If the Core is at a different geographic location than the projects it serves, are the plans for data/sample transfer and communication clearly described and appropriate?