Program Project/Center Grants (P series)

...the sum is greater than the parts

Program project/center grants are **LARGE**, **MULTI-PROJECT EFFORTS** that generally include a diverse array of research activities. NIH Institutes and Centers issue funding opportunity announcements to indicate their interest in funding this type of program.

P01 Research Program Project Grant

GENERAL FEATURES

- Supports a broadly based, multidisciplinary, often long-term research program with a specific major objective or a basic theme.
- Involves the organized efforts of relatively large groups, whose members conduct research projects designed to elucidate various aspects or components of the objective.
- In contrast to the narrow plan of a traditional research project, a program project is directed toward a range of problems having a central research focus.
- ◆ Each research project is usually under the leadership of an established investigator (Project Leader).
- 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.
- In the context of a multi-project application, synergy entails enhancement of scientific knowledge, ideas, and outcomes obtained through the cooperative interactions of the individual projects and cores.
- Meritorious projects should demonstrate an essential element of unity and interdependence, i.e., a system of research activities and projects directed toward a well-defined research program goal.
- ◆ Can provide support for certain shared basic resources, including clinical components.

DETAILS

- Support for integrated, multi-project (two or three) research projects involving a number of independent investigators who share knowledge and common resources [Note: NHLBI PO1 the proposals are 3-4 projects. Best is 3 projects.]
- May or may not involve an administrative core or shared resource core [Note: NHLBI PO1 the proposals have a small admin core, and 2-3 cores. Best 2 cores, with additional admin core.]
- Specific dollar limit unless specified in FOA
- Higher budgets may be requested for applications that include at least four projects, one of which has an Early Stage Investigator as Project Leader.
- Investigator-initiated, institute/FOA-specific instructions on multi-PI option
- Maximum five year project period
- More than one application may be submitted from an institution if each application is scientifically distinct
- NIH Institutes follow different protocols before approving a proposal for submission and it is important to be aware of the details beforehand.
 - o NHLBI after discussions with an identified PO, a letter-of-intent is submitted which then goes through the approval process
 - O NHLBI large clinical trials grants for new applicants one presents a letter of intent and then there is either a conference call or an in-person meeting you are given the choice.
 - NIAID- after discussions with the PO, if the PO and higher ups feel the project would be competitive,
 the whole team is invited to NIAID to present the project. The overall PI as well as each project PI has

to present individually to the panel that includes the PO and senior members of that division of NIAID. The presentation is followed by a Q&A session. After a couple of weeks, the team is informed whether or not they are approved to submit

COMPONENTS

Overall Program: 12 pgEach Project: 12 pg

Administrative Core: 6 pgShared Resource: 6 pg

HELPFUL LINKS

- NIDDK Collaborative Grants Comparison: The table provides a comparison of the administrative and scientific aspects of the Program Project (P01), the Multi-PI R01, and the High Impact, Interdisciplinary Science (RC2) grant mechanisms. https://www.niddk.nih.gov/research-funding/process/apply/funding-mechanisms/collaborative-grants-comparison
- Types of Grant Programs: Describes grant activity codes for R series, P series, and resource grants.
 https://grants.nih.gov/grants/funding/funding_program.htm
- ° *NIH Guide to Grants and Contracts*: Searchable list of Funding Opportunity Announcements (FOAs), can filter by activity code (e.g., P01). https://grants.nih.gov/funding/searchGuide

Active P01 FOAs (as of 3/8/2018)

<u>Center of Excellence for Research on Complementary and Integrative Health (P01 Clinical Trial Optional)</u> - PAR-18-113

Organization: NCCIH (formerly NCCAM)

Posting Date: 10-30-2017 Expiration Date: 01-08-2020

Summary: This funding opportunity announcement (FOA) encourages the submission of applications that requires multi-project, synergistic collaboration between outstanding scientists that blends multiple research approaches by multi-disciplinary research teams. This Center of Excellence for Research on Complementary and Integrative Health (CERCIH) program is designed to support three or more highly meritorious projects that can offer significant scientific advantages and "synergy" that could not be achieved by supporting the same projects as individual research grants. Each CERCIH must be focused on questions of high relevance to the mission of NCCIH.

HIV Vaccine Research and Design (HIVRAD) Program (P01 Clinical Trial Not Allowed) - PAR-18-319

Organization: NIAID
Posting Date: 10-13-2017
Expiration Date: 03-14-2020

Summary: The purpose of this Funding Opportunity Announcement (FOA) is to support multi-component, multi-disciplinary projects that address scientific questions relevant to AIDS prophylactic vaccine discovery research. Extensive modeling of vaccine concepts in non-human primates may be included.

NHLBI Program Project Applications (P01 - Clinical Trials Optional) - PAR-18-405

Organization: NHLBI
Posting Date: 10-20-2017
Expiration Date: 01-08-2021

Summary: The National Heart, Lung, and Blood Institute (NHLBI) Program Project Grant (P01) supports research related to fundamental processes and diseases of the heart, blood and lymphatic vessels, lungs, and blood, including transfusion medicine, blood resources, and sleep disorders other programs including implementation science, health disparities, and translation research that address the mission of the Institute. This FOA requires a minimum of three interrelated research projects that investigate a complex biomedical theme or research question. The projects may be supported by core units, if justified, to facilitate economy of effort, space, and equipment. The NHLBI provides support for Program Project Grants (PPGs) in the belief that collaborative research efforts can accelerate the acquisition of knowledge more effectively than a simple aggregate of research projects that have no interaction or thematic integration. NHLBI is particularly interested in encouraging new scientific directions in PPGs. Use of the P01 activity code is viewed as an opportunity to attract scientists who have not traditionally been supported by the NHLBI. Further, the PPG environment presents an opportunity for emerging scientific leaders to gain insight into how to lead a successful scientific Program, and applicants will have the opportunity to include a project led by an Early Stage Investigator (ESI). All projects in the Program must be interrelated and have objectives that address a central theme within the scientific mandate of the NHLBI.

NIA Program Project Applications (P01 Clinical Trial Optional) - PAR-18-297

Organization: NIA

Posting Date: 11-01-2017 Expiration Date: 09-10-2019

Summary: The National Institute on Aging invites the submission of investigator-initiated program project (P01) applications. The applications should address scientific areas relevant to the NIA mission. Each application submitted to this FOA must include at least three related research projects that share a common central theme, focus, and overall objective, and an administrative core to lead the project.

NIA Revision and Resubmission Program Project Applications (P01 Clinical Trial Optional) - PAR-18-030

Organization: NIA

Posting Date: 10-30-2017 Expiration Date: 09-08-2019

Summary: The National Institute on Aging invites revision applications to ongoing NIA-supported program project (P01) awards and resubmissions of unfunded program project applications (including unfunded revision requests). The applications should address scientific areas relevant to the NIA mission. Revision applications should include expansion of (an) existing, or proposal of (a) new project or projects within a program project. Revision applications may not request support beyond the end date of the parent P01 award.

NIAID Investigator Initiated Program Project Applications (P01) - PAR-16-413

Organization: NIAID
Posting Date: 08-18-2016
Expiration Date: 09-08-2019

Summary: This Funding Opportunity Announcement (FOA) invites submission of investigator-initiated Program Project (PO1) applications. The proposed programs may address scientific areas relevant to the NIAID mission including the biology, pathogenesis, and host response to microbes, including HIV; the mechanisms of normal immune system development and function; and immune dysfunction resulting in autoimmunity, immunodeficiency, allergy, asthma, and transplant rejection; and translational research to develop vaccines, therapeutics, and diagnostics to prevent and treat infectious, immune-mediated, and allergic diseases. Each PO1 application submitted to this FOA must include at least two related research projects that share a common central theme, focus, and/or overall objective.

NIDA Program Project Grant Applications (P01, Clinical Trial Optional) - PAR-18-425

Organization: NIDA
Posting Date: 11-29-2017
Expiration Date: 09-08-2019

Summary: This Funding Opportunity Announcement (FOA) announces the availability of support for collaborative research by multi-disciplinary teams which is of high priority to NIDA and leads to synergistic outcomes based on the synthesis of multiple research approaches. The NIDA Program Projects funding opportunity will support research in which the funding of three or more highly meritorious projects as a group enriches both the component projects and the overall program to offer significant scientific advantages over supporting the same projects as individual research grants (i.e., synergy). For the duration of the award, each Program must consist of a minimum of three research projects focused on issues critical to advance the mission and goals of NIDA.

Organization: NIDDK
Posting Date: 10-30-2017
Expiration Date: 05-08-2019

Summary: This Funding Opportunity Announcement (FOA) invites submission of investigator-initiated program project applications. The proposed programs should address scientific areas relevant to the NIDDK mission including diabetes, selected endocrine and metabolic diseases, obesity, digestive diseases and nutrition, and kidney, urologic and hematologic diseases, as well as new approaches to prevent, treat and cure these diseases, including clinical research. A description of NIDDK scientific program areas can be found at http://www.niddk.nih.gov/about-niddk/research-areas/pages/research-areas.aspx.

NINDS Program Project Grant (P01) - Clinical Trial Optional - PAR-18-421

Organization: NINDS
Posting Date: 11-30-2017
Expiration Date: 01-08-2021

Summary: This funding opportunity announcement (FOA) is issued by the National Institute of Neurological Disorders and Stroke to enable submission of program project grant applications that propose to conduct innovative, interactive research to answer significant scientific questions that are important for the mission of NINDS, via a synergistic collaboration between outstanding scientists who might not otherwise collaborate. The program project grant is designed to support research in which the funding of several interdependent highly meritorious projects as a group offers significant scientific advantages over support of these same projects as individual research grants.

National Cancer Institute Program Project Applications (P01 Clinical Trial Optional) - PAR-18-290

Organization: NCI

Posting Date: 10-30-2017 Expiration Date: 01-08-2020

Summary: With this Funding Opportunity Announcement (FOA), the National Cancer Institute (NCI) invites applications for investigator-initiated Program Project (PO1) applications. The proposed Program may address any of the broad areas of cancer research, including (but not limited to) cancer biology, cancer prevention, cancer diagnosis, cancer treatment, and cancer control. Basic, translational, clinical, and/or population-based studies in all of these research areas are appropriate. Each application submitted in response to this FOA must consist of at least three research projects and an Administrative Core. The projects must share a common central theme, focus, and/or overall objective.

Program Project Grant Strategies Made Ridiculously Simple

- 1. Pick your show pony: Start with about 5-6 very strong PIs and 1-2 very strong early career assistant professors. The PIs should be what I call "show ponies," that is, they are very accomplished, well-known, productive investigators who are at the top of their science. One can include 1-2 assistant professors as long as the case is made that they are being groomed for the future as a part of the P01 application. NHLBI invites 1 assistant professor to participate; but this strategy is risky. The overall PI should be well known and respected, and ideally connected at the NIH institute with a working relationship with senior branch chiefs and program officers.
- 2. **Pick a theme:** Pick the PI and show ponies first, and develop a theme that brings the strongest science together. Others suggest bringing PIs together for a common theme. The theme could be disease-focused or mechanism-focused across diseases; nonetheless, it should firmly reside within one target institute.
- 3. **Survival of the fittest:** Once the PIs are selected, initiate monthly meetings where an aims page and supporting data for each project are presented. A project presentation each month is ideal. Over time, the group must winnow the projects down to the 3-4 best. One strategy is to have 4 projects with the idea that you'll drop one later, or after the first review you drop the weakest project (this may not be allowed-key to check with PO). This process helps select the most competitive projects and also allows the group to brainstorm about themes and programmatic focus. It is helpful to include 1-2 external senior faculty who are not participating in the P01 to provide advice on the most competitive projects. Such faculty can help to diffuse the "blame" for difficult decisions. The ideal senior faculty might be a Department Chair or Division Chief with the gravitas and confidence required to make the hard political and scientific decisions.
- 4. **Take out insurance:** Develop a timeline and submit projects as independent R01s. This provides investigators with feedback about how competitive each project is and helps ensure that something comes of the group's effort. If funded, the R01s can be placed in the P01.
- 5. **Deadlines:** Communicate constantly with your PO and branch chief about status and plans and establish rigorous deadlines.
- 6. **Synergy:** Developing a P01 for submission may take 6-12 months. This allows plenty of time to maximize synergy and for PIs to begin publishing papers together. As the P01 deadline approaches, efforts should be made to publish and collaborate among the group as much as possible.
- 7. **Commit and polish:** The most important thing is to submit individual grants and push the P01 application to completion. Having drafts submitted as independent R01s provides further opportunities to polish each project. This should be like a work of art that is polished and edited well before submission.
- 8. **Sweat the small stuff:** Every piece of a program project should be perfect, from cores to each project. Each piece should have rich figures, clear themes, project interrelationships, strong science in short, the very best and polished grant ever written. A large part of a P01 is scored on the strength of the total package. All of these details are significant.

University of Pittsburgh Clinical and Translational Research Institute. Since 2006, the University of Pittsburgh Clinical and Translational Science Institute (CTSI) has been one of 60 CTSA medical research institutions working together in a national consortium to improve the way biomedical research is conducted. CTSI provides a broad range of resources and training opportunities to support researchers across the full spectrum of translational research. CTSI fosters collaboration that can influence knowledge, experiences, and perspectives and lead to revolutionary research. At the University of Pittsburgh, the focus of CTSI is to facilitate the translation of biomedical research advances into clinical and public health practice and policy. Since its inception, CTSI has impacted 4,049 unique studies in 218 University of Pittsburgh departments and divisions. Interactions with 2,225 individual investigators have resulted in 5,015 publications acknowledging CTSI, cutting edge technology and new ideas to improve health in the community. CTSI support accounts for 25% of Pitt's NIH portfolio. By bridging the gap from laboratory bench to patient bedside to community-based practice, CTSI-supported research can accomplish its end goal of improving health in the community.

The Responsible Conduct of Research (RCR) Center provides a variety of resources for researchers to enhance their knowledge and practice of research ethics. Through an innovative series of workshops, the RCR Center offers in person training in topics of interest for bench, clinical, and translational scientists. RCR instruction is delivered in a format that combines presentations by senior researchers and research ethics experts with case-based discussion of ethical dilemmas. To meet the needs of specific trainee groups, customized presentations are also available. CTSI RCR Center staff advise researchers in the design of individualized and departmental RCR training programs. Additional support is available through consultation with CTSI research facilitators and affiliated ethicists.

Biostatistics, Epidemiology and Research Design (BERD) provides services to researchers at all stages of the research process including grant application development, study design, data analysis, and data management consultation for planning and conducting clinical research. Consultation with up to ten hours of support per project is provided at no cost. All investigators are highly encouraged to take advantage of this service early and often during the development of their research projects.

The UPMC/University of Pittsburgh CTSI Research Participant Registry/Pitt+Me The CTSI Research Participant Registry, an institutional research participant registry will assist in recruiting participants. The Registry's primary objective is to identify and recruit UPMC patients of all ages from every UPMC point-of-service location (≈4,000,000 outpatient visits and >150,000 inpatient hospitalizations per year), as well as community member volunteers, who may be eligible to participate in ongoing University of Pittsburgh clinical research studies. Registry participants receive personalized mailings about studies in which they may have interest, or that they may match based upon ICD-9/10 diagnosis criteria from their medical record and/or stated preferences. In late summer 2016, the Registry was re-branded as Pitt+Me™. Pitt+Me uses enhanced study descriptions and social media to further engage the community in research. Currently the Pitt+Me Registry has more than 98,000 active participants interested in learning more about research, and we have the ability to engage in targeting recruitment efforts. For your study, we have 2,955 female participants in our Registry between the ages of 10-14 who will be 9th grade during the participant enrollment period in the first three years of your grant proposal. This should easily allow you to identify the cohort needed for your study.

The Regulatory Knowledge and Support Core (RKSC) promotes good clinical practice and facilitates regulatory compliance in clinical and translational research. RKSC works directly with researchers in collaboration with regulatory agencies to navigate all necessary regulatory pathways at any stage of their research. The CTSI Regulatory Knowledge and Support Core further assists the planning and conduct of clinical and translational research by providing Regulatory Compliance Facilitators who directly support investigators as they address compliance regulations (e.g., IRB, IND, IDE, HIPAA).

The CTSI Institutional Data and Safety Monitoring Board (IDSMB) program, offers independent DSMBs as required for the clinical portion of the grant, through the RKSC. With this provision of an Institutional Data and Safety Monitoring Board, investigators will be able to shift their focus to other areas of their research rather than, locating DSMB members, providing administrative oversight, and collecting necessary paperwork and signatures from members. This inter-CTSA program increases the scientific expertise that is available and the independence of the DSMB committees.

The Community PARTners (Partnering to Assist Research and Translation) core is focused on one of CTSI's primary functions: to engage the community at large with multidisciplinary health professionals and biomedical researchers in advancing clinical and translational research as an avenue to better health care. For clinical research to be successful, collaboration among researchers, clinicians, and the public is essential. Without active community participation, it can be difficult to meet recruitment goals for clinical trials, thereby delaying completion of studies. When new research findings are slow to enter clinical practice, which evidence suggests is often the case; the result can be lack of communication and trust between researchers and the community they aim to serve. CTSI's Community PARTners Program bridges such gaps by collaboratively engaging health care providers and researchers with the public in the enterprise of clinical and translational research. The goals of this initiative are to develop research-informed community members and health professionals as well as community-informed researchers in order to facilitate the recruitment of subjects into clinical research studies, the translation of important research findings into health care practice, and the development of research agendas that are relevant to western Pennsylvania residents.

The Research Facilitator Program is an integral part of CTSI efforts to overcome barriers to research through the provision of a single point of contact to access an extensive array of University of Pittsburgh and CTSI programs. The CTSI Research Facilitator Program employs expert Research Facilitators (RFs) to meet the individual needs of researchers in all aspects of their research. They work directly with researchers to reduce barriers to the research process, facilitate the use of available resources and identify needs for the development of new resources. Researchers are provided with personalized service, general help, education, support and guidance for any aspect of research from hypothesis to publication. To date, Research Facilitators and RKSC facilitators have interacted with 813 scientists and clinician investigators to review and assist with 842 research projects, facilitate referrals to resources and link them with potential collaborators. Research Facilitators have delivered educational programs to over 170 groups since 2007.