

## INVESTIGATOR-INITIATED INTERACTIVE RESEARCH PROJECT GRANTS

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P.T.

### Keywords:

National Institute on Alcohol Abuse and Alcoholism  
National Institute on Aging  
National Institute of Allergy and Infectious Diseases  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
National Cancer Institute  
National Institute of Child Health and Human Development  
National Institute of Dental Research  
National Institute of Diabetes and Digestive and Kidney Diseases  
National Institute on Drug Abuse  
National Institute of Environmental Health Sciences  
National Library of Medicine  
National Institute of Mental Health  
National Center for Nursing Research  
National Center for Research Resources

Application Receipt Dates: February 15, June 15, October 15

### PURPOSE

Certain questions in biomedical and behavioral research require research efforts that extend beyond the level practicable in a single project or require a variety of technical approaches beyond the means of a single investigator. There may be areas of investigation that are underrepresented in individual research project (R01) and First Independent Research Support and Transition (FIRST) (R29) applications because of the lack of available collaborative effort on a local level. Further, the perceived merit of individual projects may be diminished by the lack of a comprehensive, interdisciplinary approach or by limitations in resident technical expertise.

The National Institutes of Health (NIH) has used many ways to encourage strong collaboration among research scientists. These have ranged from specific interaction of the Federal government with academia/industry through contract or cooperative agreement solicitation to Requests for Applications (RFAs) that solicit research applications involving various forms of cooperation among applicants. This Program Announcement provides for a new kind of formal interaction, based on the initiative of applicants, to enhance existing interactions with colleagues or to develop new collaborative relationships.

The Interactive Research Project Grant (IRPG) program encourages the coordinated submission of related research project grant (R01) and, to a limited extent, FIRST award (R29) applications from investigators who wish to collaborate on research, but do not require extensive shared physical resources. These applications must share a common theme and describe the objectives and scientific importance of the interchange of, e.g., ideas, data, and materials, among the collaborating investigators. A minimum of two independent investigators with related research objectives are encouraged to submit concurrent, collaborative, cross-referenced individual R01 or R29 applications. Applicants may be from one or several institutions. Applications will be reviewed independently for scientific merit. Applications judged to have significant and substantial merit will be considered for funding both as independent awards and in the context of the proposed IRPG collaboration.

#### ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign institutions, however, are not eligible for the R29 award. Applications may be submitted from one institution or may include arrangements with several institutions if appropriate. Applications from or involving minority institutions, individuals, and women are encouraged.

Applicants for IRPGs may not concurrently submit additional R01 or R29 applications (either investigator-initiated or in response to a Request for Applications) that represent significant duplication of the efforts described in the IRPG. Concurrent submission of program project (P01) or cooperative agreement (U01) applications that request support for essentially similar work is also prohibited.

## MECHANISM OF SUPPORT

Support of this program will be by the traditional research project (R01) grant and the FIRST (R29) award. The IRPG must consist of a minimum of two independent applications. An IRPG package may consist of a combination of R01s and R29s, or R01s only, but may not consist solely of R29 applications. Applications for both new (Type 1) and competing renewal (Type 2) awards may be submitted as IRPGs.

Occasionally, Institutes and Centers (ICs) within NIH may issue additional Program Announcements on topics that include the IRPG as a mechanism of response. The RFA may also be used, in limited circumstances, to solicit applications for IRPGs in a discrete scientific area. Although the level of interaction for IRPGs between or among applicants in these solicitations will conform to those outlined here for the investigator-initiated IRPG, there may be minor differences outlined in the RFA. For example, all RFA solicitations will specify a single receipt date that will be different from those listed in this announcement.

All Public Health Service (PHS) and NIH grants policies will apply to applications received in response to this announcement.

This announcement supersedes any previous announcement regarding IRPGs. Future IRPG applications must follow the instructions presented in this announcement.

## RESEARCH OBJECTIVES

The NIH encourages qualified independent investigators to develop and submit coordinated R01 and R29 applications that address any research area supported by the Institutes and Centers listed above. Applications submitted as part of an IRPG package must be tightly focused, and the interactions and benefits of the proposed linkages must be made explicit. The IRPG mechanism could be used constructively to support collaborative efforts designed to accelerate the development of fundamental knowledge and/or enhance the clinical application of that knowledge. The IRPG mechanism may fit well with clinical applications that propose limited, testable research questions or focused therapeutic and related correlative laboratory studies. However, the IRPG mechanism is not appropriate for large epidemiologic studies or for multi-institutional clinical trials using common protocols.

Historically, the NIH has relied on multi-component awards, such as program projects (P01), center grants (P30, P50), and cooperative agreements (U01) to encourage multidisciplinary

collaboration in areas requiring integration and central direction of basic and clinical research components. In general, such awards include the provision of extensive core facilities/resources and appointment of a program director to manage the overall effort.

However, for many research areas it may be appropriate to consider an intermediate level of collaboration that is beyond that practicable for single projects. For such scientifically originated collaborative efforts, the exchanges of data, materials, and ideas, rather than shared extensive physical resources or central oversight, are the primary requirement. The concept of the IRPG put forth in this announcement is meant to address and facilitate this class of research activity.

The IRPG offers a means of promoting collaborative efforts between or among projects with a common theme, while providing a record of independently acquired awards credited to each individually funded investigator and allowing retention of research autonomy by the named Principal Investigator (PI). Each grantee will have the ability to submit on his/her behalf competing supplements as appropriate to incorporate promising new directions of research as they evolve. The freedom to establish collaborations on an equal footing at separate sites (including foreign locations) and the transferability of awards made to individual investigators are other benefits.

R01 grantees (and R29 awardees) previously unable or unwilling to join in P01s may wish to participate in an IRPG. One reason given by some grantees for reluctance to participate in P01s is the potential loss of autonomy. Such concerns are not pertinent with the IRPG because each investigator retains autonomy over his/her project. At the same time, each investigator may benefit because the IRPG mechanism establishes a larger framework of reference for the proposed work and facilitates formal collaborations tailored to achieving investigator-initiated research objectives.

If there is a question about the appropriateness of a set of applications for the IRPG mechanism, applicants are encouraged to discuss the issues with NIH staff contacts listed at the end of the announcement.

## STUDY POPULATIONS

If human subjects are involved, each component application must address these issues.

## SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH policy is that applicants for NIH clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders, and conditions that disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 in the Research Plan Sections 1-4 AND summarized in Section 5, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans [including American Indians or Alaskan Natives], Asian/Pacific Islanders, African Americans, Hispanics). The rationale for studies on single minority population groups must be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders, or conditions.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the review will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in the priority score assigned to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

#### APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91). These forms are available at most institutional offices of sponsored research and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892; telephone (301) 435-0714.

Each application must be identified by checking "yes" on line 2a of the PHS 398 face page, citing this announcement, PA-93-078, and including the phrase "investigator-initiated IRPG."

All requirements with regard to type size, page limitations, appendix material, etc. must be followed or applications will be returned without review. FIRST applications (new and revised) must be accompanied by three letters of reference; FIRST applications without these letters will be considered incomplete and returned without review.

The receipt dates for IRPG applications, whether new (Type 1), competing renewal (Type 2), or revised applications, are February 15, June 15, and October 15 of each year. For each component IRPG, a signed, typewritten original, five exact single-sided copies, and five sets of appendix material must be submitted. Each application must be complete in itself, with all

necessary approvals, budgets, and signatures from the appropriate officials of the applicant institution.

All R01 or R29 applications constituting the proposed IRPG cohort must be submitted in a single package, whether or not the applications arise from the same institution. Each application within the package must be clearly identified and a cover letter must list the total number of applications submitted for the IRPG cohort, indicating the Principal Investigator of each. The various applications should not be collated into an IRPG "package." For each application, the original, five copies, and the appendix material must be packaged together and clearly identified. Failure to follow the instructions regarding submission date and packaging may lead to a delay in review.

The IRPG package must be sent or delivered to:

Division of Research Grants  
National Institutes of Health  
Westwood Building, Room 240  
Bethesda, MD 20892\*\*

Any questions regarding the format for submission of an IRPG package may be directed to the Referral Office, Division of Research Grants, Westwood Building, Room 248, telephone (301) 594-7250.

#### Special Instructions

Particular attention must be paid to completion of Section 7, Consultants and Collaborators, for each IRPG application. In addition to those collaborations that would be necessary to carry out the proposed research, whether or not the IRPG mechanism is involved, within Section 7, each application that is a component IRPG must provide an identical statement (titled "IRPG INTERACTIONS") regarding the IRPG collaboration. This section should list each application that is part of the IRPG, including title, Principal Investigator, and other participating scientists. The single Program Coordinator, responsible for coordinating the collaborative efforts among the research projects and for promoting interaction and communication among the Principal Investigators, should be identified here. This section should further discuss the intended interactions among the components of the IRPG and the perceived benefits of supporting all of the components of the IRPG as a combined effort.

Requests for limited shared resources, if any, should be included in this part of Section 7. This should include costs and full budget justification. To further clarify the utilization of shared

resources, additional succinct information is needed and it is suggested that two tables be included. Table I would be identical in all applications of the IRPG cohort; it will specify the percent utilization and dollar amount requested of each interactive resource by each IRPG in the proposed cohort. Table II will detail the distribution of effort for all of that application's personnel (professional, technical and clerical) on all shared activities and/or resources. (A sample format may be obtained from the IC contacts listed at the end of this announcement.) The utilization of these resources by each IRPG will be evaluated independently by the study section and any appropriate modifications recommended.

## REVIEW PROCEDURES

Upon receipt, applications and supporting material will be examined by the Division of Research Grants for completeness. Incomplete applications will be returned without further consideration.

Applications will be reviewed independently for scientific and technical merit by initial review groups (IRGs) according to standard NIH review procedures. Most often these reviews will be conducted in Study Sections of the Division of Research Grants. Following scientific and technical merit review, applications will receive a second level review by the appropriate national advisory council(s).

Both IRG (study section) and Institute/Center assignment will be governed by established PHS referral guidelines. Therefore, depending on the subject matter of each IRPG, it is possible that the component applications will be assigned to different study sections for initial review and to different Institutes/Centers for funding consideration. This reemphasizes the need for each application to be complete within itself and for all IRPGs to have identical statements regarding the special interactions of the IRPG.

The initial review for scientific and technical merit will focus on each application independently. Reviewers will read Section 7 and will assess the intended collaborations just as they do the proposed collaborative arrangements in any other application. As appropriate, the effectiveness and merit of the collaborations may contribute to the overall assessment of each application. In addition, budget recommendations related to the appropriateness of collaborative arrangements and core utilization will be assessed for each application.

Further consideration of these special interactions will be given by the appropriate advisory council or board and Institute/Center staff.

## AWARD CRITERIA

Applications will compete for available funds with all other applications found to have significant and substantial merit. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o The interactive nature of the program and of the component IRPGs
- o Availability of funds
- o Program balance among research areas

Each Institute/Center will have the opportunity to fund some or all of the component IRPGs assigned to it. If the components are assigned to more than one Institute/Center, co-funding may be considered. If some component IRPGs are considered not supportable, the collaborative plans may need to be changed. If an Institute/Center chooses to fund an entire IRPG package, a review of the collaborative plans in toto will be conducted by an appropriate advisory council.

## INQUIRIES

Contact any of the following individuals for further information:

Dr. Kenneth Warren  
Director, Office of Scientific Affairs  
National Institute on Alcohol Abuse and Alcoholism  
Telephone: (301) 443-4375

Dr. Miriam Kelty  
Associate Director, Extramural Affairs  
National Institute on Aging  
Telephone: (301) 496-9322

Mr. Allan Czarra  
Director, Office of Program Coordination and Operations  
National Institute of Allergy and Infectious Diseases  
Telephone: (301) 402-0160

Dr. Michael Lockshin  
Director, Extramural Program  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
Telephone: (301) 496-0802

Dr. Marvin Kalt  
Deputy Director, Division of Extramural Activities  
National Cancer Institute  
Telephone: (301) 496-4218

Ms. Hildegard Topper  
Special Assistant to the Deputy Director  
National Institute of Child Health and Human Development  
Telephone: (301) 496-0104

Dr. Norman Braveman  
Assistant Director for Program Development  
National Institute of Dental Research  
Telephone: (301) 594-7648

Dr. Walter Stolz  
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National Institute of Diabetes and Digestive and Kidney Diseases  
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Ms. Eleanor Friedenbergl  
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Dr. Thor Fjellstedt  
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National Institute of Environmental Health Sciences  
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Dr. Milton Corn  
Acting Associate Director, Division of Extramural Programs  
National Library of Medicine  
Telephone: (301) 496-4621

Dr. Anthony Pollitt  
Associate Director for Extramural Policy  
National Institute of Mental Health  
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Dr. Mary Lucas  
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National Center for Nursing Research  
Telephone: (301) 594-3290

Dr. Louise Ramm  
Director, Biological Models and Materials Research Program  
National Center for Research Resources  
Telephone: (301) 594-0630

#### AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No 93.3. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

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