

INVESTIGATOR-INITIATED INTERACTIVE RESEARCH PROJECT GRANTS

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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 Institute of Nursing Research
National Center for Research Resources

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

Introduction: This is to rescind NIH PA-93-078, on Investigator-Initiated Interactive Research Project Grants (Volume 22, Number 16, April 23, 1993), and replace it with the following Program Announcement.

The purpose of this revised Program Announcement is to clarify several important aspects of the Interactive Research Project Grant (IRPG) program, as originally announced in the NIH Guide for Grants and Contracts, Vol. 22, No. 16, April 23, 1993. The full text of the revised Program Announcement, which replaces and supersedes the original text, is available electronically, as

well as from the Institute or Center contacts listed under INQUIRIES. In addition, a new brochure, "Special Instructions for Preparing Applications for Investigator-Initiated Interactive Research Project Grants," is available from the Office of Grants Information, Division of Research Grants, NIH, 301/435-0714, and from the Institute or Center contacts.

The key clarifications in this revised Program Announcement are as follows:

1. The important characteristics of IRPG applications and their differences from Program Projects are explained more clearly.
2. The section on STUDY POPULATIONS has been updated to reflect the latest NIH policy required under the NIH Revitalization Act of 1993 and announced in the Federal Register of March 28, 1994 (FR 59 14508-14513), and printed in the NIH Guide for Grants and Contracts, Vol. 23, No. 23, March 18, 1994. All applications received on or after June 1, 1994 must conform to this new policy.
3. The requirements for format and layout of each application in the IRPG group have been stated more clearly.
4. The procedures for submission of applications and the receipt dates for applications, including AIDS and AIDS-related applications, have been clarified.
5. The guidelines for requesting limited shared resources for projects in the IRPG group have been clarified.
6. The special instructions for preparation of Section 7, Consultants/Collaborators, of the Research Plan have been clarified.
7. Table II, Distribution of Effort of All Personnel in the IRPG, is no longer required.
8. The process for referral of the applications and the review criteria for the collaborative arrangements have been clarified.

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 under-represented in individual research project grant (R01) and First Independent Research Support and Transition (FIRST) (R29) award 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 solicitations 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 be scientifically interrelated in some manner and must 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 and/or R29 applications. The proposed projects must not be dependent upon each other to the extent that one could not be accomplished in the absence of the other. 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 or more institutions. Applications from or involving minority institutions, minority individuals, and women are encouraged.

Applicants for IRPG awards may not concurrently submit additional R01 or R29 applications (either investigator-initiated or in response to an RFA) that represent significant duplication of the efforts described in the IRPG. Concurrent submission of program project (P01) or cooperative agreement (U01, U10, U19, etc.) applications requesting support for essentially similar work also is prohibited.

MECHANISM OF SUPPORT

Support of this program will be by the traditional research project (R01) grant and the FIRST (R29) award. The IRPG group must consist of a minimum of two independent applications. An IRPG package may consist of a combination of R01 and R29 applications, or R01 applications 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 of the NIH may issue additional Program Announcements that include IRPGs. The RFA also may be used, in limited circumstances, to solicit applications for IRPG awards 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 program announcement.

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

This revised program announcement supersedes any previous program announcements regarding IRPG awards. Future IRPG applications must follow the instructions presented in this program 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 or Centers listed above. The IRPG program 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 award may fit well with clinical applications that propose limited, testable research questions or focused therapeutic and related correlative laboratory studies.

However, the IRPG program is not appropriate for large epidemiologic studies or multi-institutional clinical trials using common protocols.

If there is a question about the appropriateness of a set of applications for the IRPG program, applicants are encouraged to discuss the issues with NIH staff contacts listed under INQUIRIES.

IRPG Characteristics

The IRPG application consists of a number of investigator-initiated projects that share an aspect of relationship of objectives. The projects may involve several institutions and may be interdisciplinary. The IRPG program is intended to promote collaborative efforts between or among projects, 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) of each project. 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, with the exception that only domestic organizations and institutions are eligible to receive FIRST (R29) awards), and the transferability of awards made to individual investigators, are other benefits. Nevertheless, each investigator may benefit, because the IRPG award establishes a larger framework of reference for the proposed work and facilitates formal collaborations tailored to achieving investigator-initiated research objectives.

Thus, the IRPG application must demonstrate a sense of collaboration toward related goals. It must describe how the participants intend to take the opportunity to participate in mutually-beneficial interactions, while maintaining the independence of their projects. The IRPG application may involve utilization of shared resources in advancing effective collaborations. It is important for each individual application comprising a portion of the overall IRPG to describe the proportion of the shared resources needed for that individual project.

Since each component R01 and R29 is an independent application, it should be prepared in the same level of detail and with the same care as a traditional R01 or R29 application. Each project also should be able to stand on its own scientifically; the projects proposed must not be dependent on each other, but should be designed so that they could be accomplished independently. For example, one project should not be completely dependent on another project for provision of a critical chemical or reagent, testing or processing of key samples, or interpretation of data.

Comparison with Program Projects

Historically, the NIH has relied on multi-component awards, such as program projects (P01), center grants (P30, P50), and cooperative agreements (U01) to encourage multi-disciplinary collaboration in areas requiring integration and coordinated 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 program announcement is meant to address and facilitate this class of research activity.

The IRPG allows interaction to be initiated among applicants, as is the case with a program project grant (P01) application, but the IRPG differs from the P01 in important ways. The IRPG group consists of investigator-initiated applications on related but independent topics, with a formalized agreement to collaborate in specific ways. The collaboration may include limited shared scientific resources. The IRPG program can be useful where interdependency among efforts is not a requirement, but where the intended collaboration would enhance goal achievement. The IRPG application must provide for interaction between or among the investigators arising from their desire to collaborate as independent investigators. The scope of research in each component of a successful IRPG group should be greater than could be achieved without the collaboration. The proposed collaborations should have a demonstrable impact on ability of the investigators to achieve the projects' goals.

In contrast, the P01 has a well-defined major objective or central theme, most commonly incorporates collaborative efforts among investigators from the same institution, may involve significant core resources, and is under the direct control of a central principal individual with authority over research direction and budget. If significant core resources beyond a limited amount are needed, applicants should consider applying for a P01.

STUDY POPULATIONS

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

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minority in Study Populations) which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990. The new policy contains some new provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513), and reprinted in the NIH Guide for Grants and Contracts, Vol. 23, No. 11, March 18, 1994. Investigators may obtain copies from these sources or from the contact person listed below. The contact person may also provide additional relevant information concerning the policy.

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 Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 435-0714.

Before preparing an IRPG application, applicants should obtain the brochure "Special Instructions for Preparing Applications for Investigator-Initiated Interactive Research Project Grants," available from the Office of Grants Information, Division of Research Grants, NIH, 301-435-0714, and from the Institute or Center contacts.

Each application must be identified by checking "YES" on line 2a of the PHS 398 face page, citing this IRPG program announcement number, and including the title: "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 will be returned without review.

IRPG applications, whether new (Type 1), competing renewal (Type 2), or revised applications, will have common receipt dates as shown in the table below. Receipt dates for AIDS and AIDS-related applications also are given. For each component IRPG application, a signed, printed 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. Each application must have its own descriptive title and a separate Principal Investigator. Since each component project of an IRPG application is an independent R01 or R29 application, the component projects should NOT be presented as subcontracts to one parent project. Each requested shared resource must be included in one of the component applications; no shared resource may be submitted separately. If the shared resource is in other than an applicant institution, the shared resource may be supported as a subcontract to one of the component institutions.

All information about the interactive nature of the projects should be included in a subsection of Section 7 of the Research Plan of each component IRPG application. Specific detailed instructions for completing all parts of Section 7 of the Research Plan, are provided in the brochure, "Special Instructions for Preparing Applications for Investigator-Initiated Interactive Research Project Grants." In addition to a description of project-specific collaborations, each component application of the IRPG Group must contain an identical subsection (entitled "IRPG INTERACTIONS") and identical information showing utilization of any requested shared resources. The IRPG INTERACTIONS subsection of Section 7 should address the intended interactions among the component projects of the IRPG group and the perceived benefits of supporting all of the components of the IRPG group as a combined effort.

Description of the shared resources that will be supported through one of the IRPG component applications, if any, should be inserted as a separate section of the application after Section 8 (Consortium/Contractual Arrangements) of the Research Plan and before Section 9 (Literature Cited). As described in detail in the instructions brochure, this should include an explicit description of the methods and procedures to be used, the services, tests, animals, facilities, etc. to be provided, and a description of the involvement and protection of human subjects or vertebrate animals, if appropriate.

Extensive shared resources, or those with large budgets, may be more appropriate for full-fledged Cores in program projects. Applicants are urged to contact the NIH staff listed under INQUIRIES to discuss the nature and extent of proposed shared resources in an IRPG group. In no case should a resource be submitted as a separate application.

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 projects comprising the IRPG application should not be collated together, as is done for a program project. For each application of the IRPG group, the original, five copies, and the appendix material must be bundled together and clearly identified.

If two or more, but not all, applications within an IRPG Group receive initial funding as an IRPG, and unfunded applications within that group are subsequently amended and submitted on later receipt dates, the awarded IRPG component(s) should be identified and may be cited in the amended applications. In such cases, those amended R01/R29 applications must make reference to being part of a partially funded IRPG. They may, however, request support to extend beyond the end date of the already awarded component R01(s), consistent with the scientific goals of the application.

Revised applications should highlight the changes made in the Research Plan in response to the previous critique, and also should indicate in Section 7 how the delay in initiating the collaboration will be addressed. This is particularly important if some projects in the IRPG group were awarded and research on those projects already has begun.

If the IRPG group is not fundable as such, any individual application within the IRPG group may be considered as a possible candidate for funding as an individual R01.

IRPG Receipt and Review Schedule

Application Receipt Date:	Feb 15	Jun 15	Oct 15
Initial Review:	Jun	Oct	Feb
Council Review:	Sep/Oct	Jan/Feb	May/Jun
Anticipated Date of Award:	Dec 1	Apr 1	Jul 1

Instructions for AIDS and AIDS-related applications

IRPG applications for AIDS-related research must be identified as such, and should be submitted in accordance with the AIDS expedited review process. The receipt and review schedule for AIDS-related IRPG applications is given below.

Application Receipt Date:	Jan 2	May 1	Sep 1
Initial Review:	Mar/Apr	Jul	Nov
Council Review:	May/Jun	Sep/Oct	Jan/Feb
Anticipated Date of Award:	Jul 1	Dec 1	Apr 1

Failure to follow the instructions regarding submission date and packaging may lead to a delay in review.

The IRPG application 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.

REVIEW CONSIDERATIONS

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.

Each application in an IRPG Group will be referred to the most appropriate Initial Review Group (IRG), according to standard NIH referral and review procedures, for scientific and technical merit review. The IRG could be either a DRG Study Section or an Institute or Center-managed review committee, depending on the referral guidelines for the particular research proposed. Since applications in the IRPG might be referred to different IRGs, the IRPG INTERACTIONS part of Section 7 must be complete so that reviewers can understand the collaborations and interactions without necessarily seeing any of the other applications in the Group. Following scientific and

technical merit review, applications that may be considered for award will receive a second level review by the appropriate national advisory council(s).

Institute or Center assignment of each component application in the IRPG also 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 NIH Institutes or Centers for funding consideration. This underscores the need for each application to be complete within itself and for all component applications to have identical subsections on IRPG INTERACTIONS in Section 7 of the Research Plan. As with any R01 or R29 application, each component of the IRPG Group must be able to stand on its own merit. Consequently, the application must be prepared with the same detail as a traditional R01 or R29 application.

The initial review for scientific and technical merit will focus on each application independently, using standard review criteria for R01 and R29 applications generally, and each application will be assigned its own priority score. In addition, the reviewers will read Section 7 and will assess the intended IRPG interactions. In an Administrative Note, the reviewers will indicate the effectiveness and feasibility of the proposed IRPG interactions and whether they enhance the prospects for reaching the stated objectives of the Group, and the extent of synergy between the various projects derived from the interactions. The appropriate national advisory council or board and the program staff in the Institute or Center to which the applications are assigned will consider these comments on the proposed collaborations in making award decisions.

The IRG will evaluate the requested Shared Resource component(s) in the application (qualifications of key personnel; adequacy of approaches, methods, and facilities; appropriateness for the IRPG Group; and utilization by component IRPGs) independently from the research project. The IRG may also make recommendations about the Shared Resource(s) or the reasonableness of the budget. These recommendations will be taken into account when funding decisions are made by the awarding Institute or Center. The actual amount of Shared Resource(s) awarded may depend on the number of component projects actually awarded.

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 or Center will have the opportunity to fund some or all of the component IRPG applications assigned to it. If the components are assigned to more than one Institute or Center, co-funding may be considered. If some component IRPG applications are considered not supportable, the collaborative plans may need to be changed. If an Institute or Center chooses to fund an entire IRPG package, a review of the collaborative plans in toto will be conducted by an appropriate advisory council. As stated above, if the IRPG group is not fundable as such, any individual application within the IRPG group may be considered as a possible candidate for funding as an individual R01 or R29.

INQUIRIES

Additional written instructions for the preparation of applications are available upon request. This document, "Special Instructions for Preparing Applications for Investigator-Initiated Interactive Research Project Grants," is available from the Office of Grants Information, Division of Research Grants, NIH, 301-435-0714. Applicants should be aware that not all Institutes or Centers are participating in this program. 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
Director, Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Telephone: (301) 594-7277

Ms. Eleanor Friedenber
Director, Office of Extramural Program Review
National Institute on Drug Abuse
Telephone: (301) 443-2755

Dr. Thor Fjellstedt
Deputy Director, Division of Extramural Research and Training
National Institute of Environmental Health Sciences
Telephone: (919) 541-0131

Dr. Milton Corn
Acting Associate Director, Division of Extramural Programs
National Library of Medicine
Telephone: (301) 496-4621

Dr. Hugh Stamper
Director, Division of Extramural Activities
National Institute of Mental Health
Telephone: (301) 443-3367

Dr. Theresa S. Radebaugh
Director, Division of Extramural Programs
National Institute of Nursing Research
Telephone: (301) 594-7590

Dr. Louise Ramm
Deputy Director
National Center for Research Resources
Telephone: (301) 496-6023

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.113, 93.114, 93.115, 93.121, 93.198, 93.306, 93.333, 93.371, 93.393, 93.394, 93.395, 93.396, 93.397, 93.847, 93.848, 93.849, 93.855, 93.856, 93.864, 93.865, 93.929, 93.866, 93.879, 93.361, 93.846, 93.242, 93.273, and 93.279. 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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