



School of Medicine

Grant Writing Manual
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PREFACE

We are delighted to provide the **Grant Writing Manual**, now in its 12th year of production, as a resource for School of Medicine faculty. It has been assembled over time based on the insight of senior faculty members, and with considerable effort to keep pace with changes in the funding environment.

As many of our investigators will attest, there is nothing more exciting than when years of hard work culminate in scientific discovery. Hours and hours of effort and attention have finally produced a meaningful contribution to a body of knowledge or to a therapy. And, while this scientific contribution may be singular, the process of getting there is always collaborative in nature — aided by peers in the field and trainees and students in the laboratory.

This spirit of collaboration animates the School of Medicine, and can be seen every day throughout campus in so many different forms: in the guidance offered by investigators to their trainees, or in the advice exchanged by peers across departments. Reaching these collective goals requires substantial funding, the majority of which is provided by external foundations and agencies such as the National Institutes of Health.

This **Manual** was created to support our faculty as they look to build on these partnerships and funding sources. It is intended as a valuable resource for junior investigators who seek a foundation for successful grant writing. It contains advice and guidance as you assess your specific laboratory and research goals. The **Manual** is also meant to serve senior investigators, who may be looking for a focused reference tool or an update on the latest developments in the grant application process.

Most importantly, I hope that you will consider the Office of the Executive Vice Dean and Chief Scientific Officer as a helpful internal resource as you pursue your individual and collective research goals.

Glen N. Gaulton, Ph.D.
Executive Vice Dean and Chief Scientific Officer
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INTRODUCTION

The purpose of this manual is to assist investigators in obtaining financial support for their research. The information is aimed predominantly at obtaining federal funds, but much of the information is applicable to the pursuit of any successful grant application. The manual comprises five areas: 1) a practical guide in the fundamentals of grant writing for research applications; 2) lessons learned from well-funded, experienced faculty at Penn; 3) a general survey of resources available at Penn and NIH to assist faculty in navigating the funding process; 4) budget and administrative issues facing grant writers; and 5) highlights of NIH structure and policies.

A frequent problem encountered by new investigators is their inability to obtain early and appropriate advice from experienced investigators and faculty members. A good place to start to obtain such assistance is with knowledgeable colleagues as well as division and department directors or mentors. Many Penn faculty members are also on federal agency advisory committees, and we have provided their names on pages 25-27. In addition to providing scientific advice, these individuals can also offer insight into managing the review process and even provide suggestions about the appropriate response to a notice of an unsuccessful grant application. Importantly, investigators can also access NIH Study Section type feedback on draft proposals through the Voluntary Internal Review of Grant Applications (VIRGA) program. A description of the VIRGA program appears in this manual on page 18.

Other resources that are often overlooked by new investigators are specialized services and facilities that exist in centers, institutes and research core units within the Penn community. These resources may provide important expertise ranging from statistical support to the latest biomedical technologies. These services are listed online at http://www.med.upenn.edu/rpd/core_facil.html under the title of “Directory of Research Core Facilities.”

The tension of approaching deadlines, the vast array of forms and formats, and the numerous steps involved in the grant writing process may seem daunting, but does not have to be overwhelming. Start the process early. Listen carefully to the advice of colleagues. Don't be intimidated by bureaucracy. Most of all, reach out for help. The process that begins with an interesting scientific hypothesis may ultimately lead to a funded research study.

CHAPTER I:

The Basics of Grant Writing

A. BRIEF ESSAY ON BASIC PRINCIPLES

The majority of competing applications for NIH biomedical research support now require electronic application submission. The Funding Opportunity Announcement (FOA) to which you are applying will identify whether you must submit electronically or use paper submission. Note that paper submissions require use of the PHS 398 <http://grants.nih.gov/grants/funding/phs398/phs398.html> application form, while electronic submission requires the SF424 (R&R) <http://grants.nih.gov/grants/funding/424/index.htm> application form. The PHS (Public Health Service) estimates it will take approximately "... 40 hours to complete this application for a regular research project grant." While the actual time spent typing at a keyboard may come close to the PHS estimate, the time spent in developing the grant content inclusive of experimental data and in editing the text to presentation quality amounts to much more. Estimates of the total time devoted to producing a new application may range from two to three months or longer. Revised applications and renewals usually take less time, but are still a major effort and should not be underestimated. In summary, it is certainly a good idea to start the writing process months in advance of any expected due date.

While writing the grant, a number of basic principles should be kept in mind:

1. **Establish your major point(s) succinctly and repeatedly.** No matter how much time you spend writing, the reviewer will have only a small amount of time to devote to reading and studying the grant proposal. This is dictated by the relatively large number of grants assigned to each peer review committee (upwards of 75 or more) and the number of grants assigned to each reviewer for careful review with a written critique (9 grants are not unusual). Thus, clarity of writing and organization are virtues to be cultivated.
2. **Write for Technically Diverse Reviewers.** The majority of study section members may not be sufficiently familiar with your area to understand the technical points of your arguments. In most instances, at least one of the two principal reviewers on the study section will be technically competent to understand the nuances of your work. However, most reviewers will require (and appreciate) a less technical style.
3. **Avoid Unnecessary Complexity.** Present your main supporting arguments clearly and directly. Complex arguments that are difficult to follow may serve only to antagonize a reviewer. Do as much work as you can for the reviewer by distilling arguments to their most dynamic and compelling elements.
4. **Collect and Submit Preliminary Data.** Preliminary data are considered crucial to establishing the credibility of the proposed research. It is not enough to just have a good idea. Proof must be offered that the proposed work is both sound and can be accomplished.
5. **Follow Instructions.** The instructions for proposal preparation must be read carefully and followed meticulously. Proposals can be returned, or their chances for funding damaged, for failure to observe requirements for page limits, type size, margins, etc. Since only a limited amount of reviewer time is available for each application, errors of preparation that distract the reviewer from the scientific presentation may have a serious negative effect.

At its best, grant writing is a creative process. The document is a thoughtful presentation of the ideas, as well as the data for the proposed research project. Enthusiasm for your ideas should show through. A well-prepared proposal should be capable of generating the reviewer's interest. Your goal is to position the reviewer to serve as your advocate for the proposed research. In the highly competitive situation that exists in most peer review sections, nothing less than advocacy will suffice to secure a rating high enough to assure funding for your proposal.

B. FREQUENTLY ASKED QUESTIONS

How do I start?

If you don't already have a funding source in mind, you should develop a list of key words to describe your research. Key words can serve as the basis for a database search for funding sources. You should also include your own characteristics, such as young investigator, member of an underrepresented minority group, or junior faculty. Assistance in identifying potential funding sources is available through the Office of Research Program Development; contact Stephanie Oram at 215-898-0273 oram@mail.med.upenn.edu.

Where do I get an application?

New Electronic grant applications must be submitted in response to a Funding Opportunity Announcement; a list of parent announcements to be used for unsolicited or investigator-initiated applications can be found at http://grants.nih.gov/grants/guide/parent_announcements.htm. The Business Administrator of your department or center has copies of the PHS 398 NIH application forms (to be used for paper based submissions), or you may download the 398 forms directly from the NIH website at <http://grants.nih.gov/grants/funding/phs398/phs398.html>. For other funding sources, you must contact the sponsor directly for the appropriate forms. Templates are often found on sponsor's home pages on the Internet.

Can I simply mail my application or submit it electronically to the funding source?

There is an internal review and approval process that begins in your department, center or institute and continues through the School of Medicine Office of Research Support Services to the University Office of Research Services. While all of these offices understand the pressure of deadlines of the various funding agencies, the review process requires a certain amount of time. In general, we ask you begin the internal sign-off process at least one-two weeks (five to ten working days) before your deadline. Please note that applications submitted electronically will require an allowance of time to electronically transmit the required documents.

What about the use of animals and human subjects in research?

It is also imperative to allow sufficient time for institutional review of your research protocol so that the appropriate research subject approvals are in place when your grant is reviewed by the sponsor. Certain designated NIH programs allow for animal and human subject use approvals to be submitted "just-in-time." Just-in-time procedures allow applicants to defer verification of IRB and IACUC approvals until after completion of the peer review and just prior to funding. The relevant University policies for the use of animal and/or humans in research may be accessed through the Office of Regulatory Affairs or the Office of Human Research.

Where is help available?

Although all SOM departments and centers have staff that are familiar with the grant application process and will assist you with the administrative aspects of your application, the School's Office of Research Support Services (ORSS) is dedicated to this process. In the case of multi-investigator applications, the School's Office of Research Program Development can assist you in a variety of ways to facilitate the application process. The key to accessing these services is planning. You must give all concerned enough notice of your needs so that they can set aside time to focus on your project and give your grant the attention it deserves. Chapter III provides more detailed information on sources of help.

C. NIH APPLICATION REVIEW PROCESS

Assignment of the Application for Review and Funding Consideration

Investigators sometimes ask how much of the application is read in making an assignment. The honest answer is as much of the application as needed to make the determination. Referral staff have access to the entire application, not just the title and Abstract/Description. In many cases, they concentrate on the Abstract/Description and Specific Aims in making an assignment, with attention also paid to the Significance and Research Methods sections. Requests made by investigators and the assignment of previous applications are also considered. Some applications are quite easy to assign for both review and Institute/Center consideration, while others are more difficult. Referral staff regularly discuss the assignment of applications or how to handle unusual situations. The assignment of a grant application involves a series of decisions.

· Determination of grant mechanism. There are more than 100 grant mechanisms to support research and research training, ranging from individual fellowships through very large center grants. Nearly all Institutes and Centers (ICs) use the R01 and F32; very few ICs use other mechanisms. The identification of the correct Funding Opportunity Announcement is critical for determination of the grant mechanism, particularly for electronic submissions. Mechanisms are identified in the NIH system by a letter and number code. Examples include:

F32	Individual NRSA Postdoctoral Fellowship
K08	Mentored Clinical Scientist Development Award
P01	Program Project
R01	Research Grant
R43	Small Business Innovation Research (R44 for Phase II)

More information is available at the NIH Grants Web page http://grants.nih.gov/grants/funding/funding_program.htm

· An institute or center is identified for primary assignment for funding consideration. This determination is based on the focus and mission of each of the twenty-four institutes and centers of NIH. Due to the increasingly multidisciplinary nature of scientific inquiry, the complex biological problems being addressed, and the use of many common research methodologies, the ICs share many common interests. The interests of the Institutes and Centers are described on the main [NIH Web site](#).

· Applications may receive primary and dual assignments. Dual assignments acknowledge the shared interests of ICs in a given scientific topic and make all of the appropriate ICs aware of the application. The primary assignment is reflected in the assignment number (CA for the National Cancer Institute, AG for the National Institute on Aging, etc.). When multiple dual assignments are made, a rank order (secondary, tertiary, etc.) is not established. Both the primary and dual Institute/Center have access to the application, and summary statement and council consideration is given by both the primary and dual ICs. However, a dual assignment does not necessarily increase the chance of an award. The frequency of a dual assignment leading to a change to primary and award is less than 2%.

· Finally, the grant application is assigned for review to the CSR or to one of the IC Review groups. CSR reviews most R01s, fellowships, and small business applications. IC review groups handle applications that have Institute-specific features such as program projects, training grants, career development awards, and responses to Requests for Applications.

Within an Institute/Center, a general assignment is made to that IC and the staff in the review unit decides whether the application is to be reviewed by one of their standing committees or by a Special Emphasis Panel. Within CSR, a two-stage process is employed, with initial assignment to the IRG (Integrated Review Group, a cluster of scientifically related Study Sections) level and subsequent assignment to a specific Study Section or Special Emphasis Panel. By assigning all applications to the IRG level rather than directly to an individual study section, the IRG Chief and the Scientific Review Administrators (SRAs) within the IRG have the opportunity to gain a broad perspective of the areas of science covered by their IRG and to appreciate changes in emphasis and the emergence of new areas. A number of methods are used to determine assignments within the IRG, though all involve discussions among the SRAs and the Chief. Finally, the IRGs also have the option of suggesting that the application is more appropriate for a different IRG. They may discuss this with other SRAs or IRG Chiefs or return the application to the DRR for reassignment.

The NIH no longer sends paper letters about assignments (or other aspects of the peer review process). All Principal Investigators must be registered in the eRA Commons and include their eRA Commons User Name as part of each paper or electronic application submission. Information on the assignment of grant applications is accessed through the Commons at <https://commons.era.nih.gov/commons/>.

This information has been excerpted from the NIH website:

<http://cms.csr.nih.gov/ResourcesforApplicants/Submission+And+Assignment+Process.htm>

For a more complete discussion of this subject, please refer to this web site.

D. QUICK GUIDE TO THE NIH APPLICATION REVIEW PROCESS

Your application is assigned to a review group and an NIH Institute or Center

One or more CSR Referral Officers examine your application and determine the most appropriate Integrated Review Group (IRG) to assess its scientific and technical merit. Your application is then assigned to one of the IRG's study sections. A study section typically includes 20 or more scientists from the community of productive researchers. Your application also will be assigned to the NIH Institute or Center (IC) best suited to fund your application should it have sufficient merit. (More than one IC may be assigned if appropriate.)

Referral Officers follow established guidelines that define the review boundaries of each study section. These boundaries frequently overlap, and more than one study section may have the expertise to review your application. You may request in a cover note with your application that it be assigned to a particular study section or IC. The CSR referral office seriously considers such requests.

Checking the status of your application

As soon as your application is received and assigned to a study section, notices are posted to your online NIH Commons account. Information on the Commons and how to register is available via the Commons Web page <https://commons.era.nih.gov/commons/>. You may question either your study section or IC assignment by contacting the Scientific Review Administrator (SRA) named in your notification or the CSR referral office (301-435-0715). It usually takes weeks to refer the thousands of applications submitted each round. If a notice is not posted in your Commons account within 3 weeks of the submission date, you should contact the referral office.

Reviewers are identified

Your SRA will analyze the content of your application, check for completeness, and decide which reviewers can best evaluate it. Reviewers receive a copy of your application approximately 6 weeks before their meeting. Each application is assigned to three reviewers, and at least two of them provide written critiques. These assigned reviewers lead the discussions at the meeting.

Because of the multi-month period between submission and review, applicants often wish to submit additional materials. Before you do, you should contact your SRA to see if this is possible and what kinds of limitations apply.

Before the study section meets, reviewers confidentially submit preliminary critiques and scores to CSR. Reviewers are then given a list of applications that were initially scored in the lower half. If all reviewers agree, these applications are "streamlined," which means they will not be discussed at the meeting. "Streamlining" is not equivalent to disapproval, so applicants may resubmit a better application after considering the critiques they receive.

The review meeting is convened

Study sections convene for about 2 days. One member serves as chair and conducts the meeting with the SRA. Relevant NIH extramural staff are encouraged to attend, but they may not participate in the evaluation. Assigned reviewers and discussants present their evaluations and outside opinions are read. After a general discussion, reviewers mark their priority scores privately on scoring sheets, which are later tabulated by CSR.

The results are released to you

Within a few days after the meeting, your priority score and percentile ranking is available to you via the NIH Commons. Within a month, your summary statement will be available via your NIH Commons account. It will include (1) the written critiques produced by the assigned reviewers; (2) the SRA's summary of the study section's discussion; (3) study section recommendations; and (4) administrative notes of special consideration. For new investigators submitting R01 applications, this information is posted within 10 days after the meeting.

The assigned NIH Institute or Center takes charge

After the review, an IC program officer will be your main point of contact. He or she may help interpret your review results or answer questions about the further consideration of your application. In a second level of peer review, IC Advisory Councils may consider the study section's recommendations and determine the relevance of your proposed research to IC priorities and public health needs.

Get More Information on Peer Review at CSR

Inside the NIH Grant Review Process Video:

<http://cms.csr.nih.gov/ResourcesforApplicants/PolicyProcedureReview+Guidelines/OverviewofPeerReviewProcess/InsidetheNIHGrantReviewProcessVideo.htm>

Guidelines for Study Section Chairs :

<http://cms.csr.nih.gov/PeerReviewMeetings/BestPractices/Guidelines+for+Study+Section+Chairs.htm>

How Scientists Are Selected For Study Section Service :

<http://cms.csr.nih.gov/PeerReviewMeetings/BestPractices/How+Scientists+Are+Selected+For+Study+Section+Service.htm>

Review Meeting Procedures (pdf) :

<http://cms.csr.nih.gov/NR/rdonlyres/C2A9D5DE-8773-456B-A52C-FEC4B15E22C5/11979/ReviewMeetingProcedures092106.pdf>

Resources for Applicants:

<http://cms.csr.nih.gov/ResourcesforApplicants/>

This information has been excerpted from the NIH website

<http://cms.csr.nih.gov/ResourcesforApplicants/PolicyProcedureReview+Guidelines/OverviewofPeerReviewProcess/>

For a more complete discussion of this subject, please refer to this web site.

CHAPTER II:

Lessons from the Experts

The following sections are drawn from presentations by University of Pennsylvania School of Medicine faculty at our annual grant writing symposium.

A. THE ANATOMY OF AN NIH GRANT **by Alan D. Schreiber, M.D.**

I want to review with you briefly the structure of an NIH grant, focusing on some ideas that have proved to be helpful. In the current environment it is critical to have your grant reviewed by the appropriate study section. The investigator should submit a letter, accompanying the grant, stating why you, as principal investigator, believe it should be assigned to a particular study section and institute. This can facilitate the appropriate handling of your application when it is received.

Thus, the initial section of an NIH grant application involves a cover letter and statements on personnel, budget, and your scientific environment and available resources. The cover letter, title, and abstract should be used to help direct your grant to the appropriate study section. The cover letter should be regarded as a mandatory part of the application and should state why your proposal should be reviewed by the study section you indicate.

Budget requests should be accurate and honest. Sometimes it is stated that budget estimates should be inflated, in order to anticipate a cut from the study section. Sometimes you hear that the estimates should be low, as if that would be an incentive for the study section to approve and fund your grant. Both rationales are faulty. The study section members will see through any attempt at manipulation. They are likely to view inflated or deflated figures as evidence of your poor planning, which can adversely influence their enthusiasm for your proposal.

Under “Resources,” take advantage of the strengths here at Penn. We have a rich scientific environment at the Medical Center. If another investigator on campus has particular expertise in part of your proposal, you can cite that individual as a resource. Similarly, if your work requires a particular technology or method that the Medical Center, or Penn at large, offers in the way of a core facility, cite that facility. One section of the grant manual indicates the helpful resources available at Penn.

The next part of the grant application is the Research Plan. Generally, the best way to enter material in the Specific Aims section is in outline form, e.g., Specific Aim #1, Specific Aim #2, etc. The section on Background and Significance of your proposal is generally two to three pages, and there too a concise, clearly focused discussion should be presented. In the Progress Report/Preliminary Studies section, it is best to focus on original observations coming from your laboratory, rather than observations that confirm the work of others.

The next section of the application, the largest and most important part, is the Research Design and Methods. It is important to be clear and succinct. A presentation that is readable and that flows is most likely to capture the enthusiasm of the reviewers. The reviewer most likely is reading several ROIs and is apt to be tired when he or she reads your grant. To help reviewers understand the significance of your proposal, and to help them generate enthusiasm of their own for it, make it easy for them. To this end, it is best to place the Methodology section (accompanied by appropriate detail) in the back of the Research Design and Methods section. The reviewers can turn to read it if they so choose. This enables the Research Design and Methods section to flow smoothly and to read well without technical and methodological detail.

In addition, your discussion should address potential pitfalls in your approach and potential problems in your experimental design. Under these circumstances be sure to mention alternative approaches of experimental design. Follow the outline of your specific aims. For each specific aim, present the rationale in a paragraph or two, followed by the experimental design. It is appropriate to include hypotheses and to state them clearly. It is also helpful to state hypotheses in the specific aims as well, so that the reviewers understand the ideas to be tested in both sections of the grant application. Similarly, in the Methodology section, it is best to follow the outline format presented in the Specific Aims section.

The grant length is 25 pages. The NIH intends for tables, figures, charts, and preliminary data, all material that one would have previously placed in the Appendix section, to be placed in the body of the grant. It is important to use the pages for the purpose intended, as the enthusiasm of study section members may otherwise be lessened.

It is important to use the appropriate NIH format in the grant. Do not squeeze words, reduce type size, or otherwise try to evade the established format in the interest of jamming more information in a given space. Some reviewers attend

closely to the set format, even to the point of counting lines, and they might well return your grant—causing you the unpleasant experience of missing a cycle.

Much more documentation is now required for animal studies or human studies, where appropriate, and for collaborators and consultants (a biographical sketch of each consultant associated with the grant is now required, just as one is required for each co-investigator). It is best to detail exactly what the collaborators or consultants will do. Will they be sending you reagents? If so, what reagents? For what experiments? Will they perform experiments? If so, specifically what experiments? In your laboratory or their own?

These details need not be an overwhelming concern. Nor should they prevent you from applying for more than one NIH grant for a body of work. Continuity of funding through more than one research grant is a wise route. You can obtain more than one grant for a body of work as long as you make clear that the specific aims in one grant are distinct and different from the specific aims in another grant. Point out that there is no overlap in funding and no overlap in the thematic approach.

As a corollary to the application process, it may be useful for you get to know the executive secretary of the study section reviewing your application. Know who they are, talk to them, meet them, if possible. The executive secretary will be calling you if a reviewer flags a problem in your application, and resolving it might be easier if you and the executive secretary have already established some rapport.

You will also be contacting the executive secretary when you submit supplemental material. Most executive secretaries set a specific date as to the last period when they will accept supplemental material; that is, the preliminary data you have gathered since you submitted the grant application. It's generally a good idea to send all of the supplemental material at one time, close to the due date.

New applicants often ask how much preliminary data to include. They might think that a grant is most likely to be funded if they have already done the work and accumulated the data; by the same token, they could assume that the reviewers are unlikely to fund research that has already been done. There is a fine line between giving the reviewers sufficient background information without giving away the whole story, and this is part of the art in preparing the application.

Reviewers will be interested in what was accomplished from the time of your application to the time of review; therefore be sure to mention data you are analyzing or methods being developed. Update the status of any paper that was under editorial review, and mention additional papers submitted for publication. Demonstrate to the reviewers that you have been thinking about the grant, and encourage them to think about you as a competent investigator.

Be aware of the time pressures on the reviewers. They are busy people involved in their own research. They are unlikely to be able to give additional material the same attention as the 25-page core of the grant application, especially as the additional material grows in length. Be concise. If you send a letter with your supplemental material, keep it to two or three pages only. Remember your main point, that you are stating the case for the grant. Assume that only the central core of the application will stand as the primary documentary evidence on why you should receive a grant.

B. THE IMPORTANCE OF PRELIMINARY STUDIES

by Raquel Gur, M.D., Ph.D.

The Preliminary Studies section is an important part of the application. New applicants should use this section to provide an account of work in their laboratory pertinent to the application, and any other information that will help to establish their experience and competence to pursue the proposed project. Preliminary Studies is where you convince the reviewers that you are ready to be a principal investigator (PI) on a grant and that you can assume responsibility for the science proposed. Look at this section as your chance to show that (1) you know what you are talking about and (2) you are ready for this opportunity. An intelligent summary in the Background and Significance section is not enough to convince the reviewer of your ability to conduct the research. Too often there are discrepancies between a nice review of the literature and demonstrating abilities in a specific manner within the allotted pages.

The Preliminary Studies section is best structured by providing details related to the Specific Aims. The goal is to walk the study section readers through your application, and the clearest way to do that is to structure all the Research Plan according to the Specific Aims. The application should unfold for the reader like an exciting story that is neatly packaged: Specific Aims, Background and Significance, Preliminary Studies, Research Design and Methods. The reader must clearly see in Preliminary Studies that you have data pertinent for achieving each Specific Aim.

Whether you plan a clinical or a basic study, you have to provide details that will convince the reviewer that you have done the groundwork necessary for the proposed project. Suppose, for example, that your goal in a clinical project is to examine a new innovative treatment for cardiac patients and you specify inclusion and exclusion criteria in Research Design and Methods. In the Preliminary Studies section, it is important to state whether a clinic is available. How many patients are being evaluated there? What is the distribution regarding the specific diagnosis your project examines? Who is seeing the patients? By providing these details in Preliminary Studies you demonstrate that the study is feasible and that you have established the necessary collaborations to ensure that the Specific Aims can be attained. For a basic science project, for example, if you are proposing a new, exciting and challenging procedure, you must demonstrate the steps taken to implement the procedure and the validity of the data obtained.

The Preliminary Studies section is your opportunity to convey that you have done your homework and have carefully attended to the methods you propose to apply in the project. When well written, this section provides the necessary details to assure the reviewer that you are competent to conduct the experiments. Comments such as “it is not clear how are they going to enroll these patients” or “they gloss over the difficulties in the procedures” should not arise. When well written, this section inspires trust in the ability of the PI and research team to conduct the study. Unfortunately, once concerns like that emerge, the application is unlikely to make it. By attending to specific details, maintaining the focus on the Specific Aims, the information in this section is most useful to provide evidence that the research is ready to take off.

In summary, the Preliminary Studies section is the part of the application for demonstrating what was already accomplished that puts you in a position to pursue the proposed project. The specific details must demonstrate the feasibility of the proposed research and your command as PI. You need to establish the fact that you are ready to conduct the research. How do you fit in? What have you done to merit this award? What individuals in the discipline have you spoken to? Remember that the reviewers are experts in the field. If they know of potential collaborators in your institution but your research plan fails to show that you have incorporated the wisdom of local colleagues who have published extensively in the field, you are in trouble.

C. AVOIDING THE COMMON PITFALLS OF GRANT PRESENTATION

by Ann R. Kennedy, D.Sc.

My comments are drawn from the critiques, major problems, and themes that ran through the grant reviews conducted by the NIH study section of which I was a member.

State your hypothesis. Formulate the question to be answered by the study, and make sure it is an important question to answer. You would be astounded by how many investigators propose merely to look at various phenomena in a “testing” fashion. Testing needs to be done, but by a contract organization rather than in an RO1 grant. You must demonstrate that your research is hypothesis-driven.

The subject area of your grant should be one of current interest in your field of research. The last thing you want is for a reviewer to read your grant, picture the data you’ll be obtaining, and think, “So what?” Your topic has to be important, and there has to be a major reason for studying it.

Avoid a fishing expedition. We saw many grants that did not have a hypothesis; rather, the investigator was obviously hoping that something interesting would pop up in the course of his or her investigation. That sort of approach is usually not appealing to a study section.

Describe your contingency plans. Remember the frequently heard expression of exasperation from scientists: “another hypothesis shot down by an ugly fact.” What do you do then? Many researchers do not indicate how they will deal with “negative” data. Tell the study section exactly how you will proceed if your data do not support your hypothesis. I like to think of someone putting in a grant as a captain of a ship, steering in the proper direction. You need to give the study section a feeling that, if you get one result, you will go in one direction, and if you get another, then you’ll steer in another direction. The area itself should be of interest to study; then adjustments in direction are seen as part of the natural course of events.

Fact vs. opinion. When you write the grant, clearly separate the facts in your field from the opinions or speculations. A study section member who is in the same field will be annoyed to read claims of fact when he or she is trying to elucidate the point in his or her own research.

Give a balanced view of the literature. Anticipate the counterarguments, and deal with them. It is quite common to find a grant without a balanced literature review. You might say, “Dr. X quotes papers to support his hypothesis but ignores all of the contradictory evidence.” The reader naturally concludes that Dr. X’s review of the literature is either selective or superficial. You don’t want the study section to think either of those things about you as an investigator.

Be sure your experiment will answer the hypothetical question posed. If it won’t, this is what I call a “fatal flaw.” An example of such a fatal flaw can be taken from in vitro experiments in which the investigator proposes measuring a new enzyme which will be produced by cells which have been altered by some specific treatment. If the investigator is studying differentiation, and only 10% of the cells differentiate in response to the treatment, he/she would never pick up the biochemical change because only a small fraction of the population is likely to have that alteration. As a corollary, beware of proposing experiments that simply cannot be done. Many investigators who propose experiments with normal human cells fail to account for the fact that the cells have a limited proliferative capacity in culture - they’d all be dead, and thus inappropriate for the studies proposed by the investigator. So it’s very important for you to consider the system to be used and to give preliminary data showing that you can, in fact, measure what you propose to measure.

Make sure all the facts are correct. Make sure that you have adequate statistical power. An example of a problem in this area can be taken from cancer prevention research. The Food and Drug Administration evaluates the efficacy of cancer preventive agents by looking at the effects of potential cancer preventive agents on certain markers. In one grant proposal, the marker to be studied was dysplasia in a population of patients with ulcerative colitis. If all of the ulcerative colitis patients in the population had dysplasia, the study could have been performed as proposed by the investigator. As only 10% of patients with ulcerative colitis have dysplasia, this was too low a percentage to end up with statistically significant results in the study. One way around such a problem is to limit the study only to those patients with ulcerative colitis who have evidence of dysplasia. Another way is to change the marker to one that is present in a high percentage of patients. The lesson is: look at the characteristics of the population available to you and the sorts of analyses needed to show a statistically significant effect. From my experience as a member of a study

section, I know that many grants fell on this particular—indeed, fatal—flaw, that is, proposing to do an experiment that cannot yield statistically significant effects.

Equally fatal is to send negative data to support your hypothesis. Our study section actually received negative data, sent in as preliminary studies for a proposal. Needless to say, it amused the members of the study section. No data are better than negative data.

Statisticians are essential in the design of any laboratory experiments or trials. It's much easier if you plan from the beginning to get adequate statistical power.

Ask senior investigators in your field or department to read your grant. They can help you avoid the problem just mentioned, of submitting data that will not support your proposal. They can also help with clarity. This point has been made in earlier discussions, and it is worth repeating: The pages of a grant application are restricted, but they amount to a sales pitch, an effort to persuade and enthuse the reviewers who will read it, so they should look good and read well.

One particular (often neglected, but important) detail: the references should be accurate. Grant applicants are often given priority scores in the non-fundable range because of discrepancies between what an investigator claims is in a reference/citation and what is actually in the article being cited. A friendly reader can help with consistency here.

Be flexible in the institute you intend to apply to. It is not widely known by investigators that the different institutes at NIH have different priorities for levels of funding. When I served on a study section, I saw many grants that were as appropriate for another institute—specifically, the National Institute for Environmental Health Sciences—as for the National Cancer Institute, to which the grant proposal had been assigned. The priority level assigned to the grant was within the funding lines of the former but not the latter.

Sometimes investigators themselves have the grants transferred to other institutes to gain funding. I'm personally aware of several that were funded in the same cycle just by having the investigator change the institute to which the grant was assigned. The activities of the various institutes overlap on occasion, and a priority number that falls outside the level of funding of one institute might fall within the level of another. It's worth your while to find out which institutes might be interested in your proposal.

A related possibility is having two institutes sponsor your grant. In many cases dual sponsorship will make the difference in having your grant funded. It happens all the time. An alert investigator can help the process occur. NIH personnel will help you locate an alternative institute or find dual sponsorship. Dr. Schreiber also made this point earlier in this chapter: make the appropriate contacts at NIH, both with the executive secretary in the study section of your first choice and with personnel in the specific funding programs. You should think of them as your advocates in court.

Your NIH contacts are important resources if you do become funded but the amount falls short of your request. The differential may prevent you from successfully performing what you promised. Discuss your situation with NIH personnel. Eventually you will have to prepare a progress report. You will have to account for why you failed to carry out everything you originally intended, or why you did not do it exactly as you proposed. In your progress report you will discuss the changes you were forced to make, and you'll note the conversation with the program person. That person might suggest a way to put the excised part of your proposal in another grant. You will, of course, need to demonstrate its importance to your overall project.

CHAPTER III:

Where Can I Go for Help

A. THE PENN SUPPORT STRUCTURE

It is the goal of the University and the School of Medicine to foster the pursuit of new knowledge by the faculty. Faculty often choose to use funds from a variety of external sources to support their research efforts. There are many offices designed to assist in the pursuit of external funds.

Following is a brief summary of the many offices and services offered to faculty. As you review them, we encourage you to call the individual offices for additional information. As you know, programs and policies continue to change in response to advances in science, revised government regulation and amended University policy. Each of these offices can answer questions or provide referrals.

In addition to using the following references, grant writers may also access many of these people or services electronically. The University of Pennsylvania and the School of Medicine both maintain home pages at (<http://www.upenn.edu/> and <http://www.med.upenn.edu/research/>). Faculty are encouraged to explore the Internet and the many resources it offers to researchers.

B. DIRECTORY OF RESEARCH SUPPORT OFFICES

Executive Vice Dean and Chief Scientific Officer: Glen N. Gaulton, Ph.D.

357 BRB II/III /6160

Phone: 215-898-2874 Fax: 215-573-7945

<http://www.med.upenn.edu/research/>

Other relevant senior staff:

Assistant Dean for Research & Faculty Development: Alan D. Schreiber, M.D.

705 BRB II/III /6160

Phone: 215-573-4700 Fax: 215-573-7049

Associate Dean for Clinical Research: Susan S. Ellenberg, Ph.D.

611 Blockley Hall/6021

Phone: 215-573-3903 Fax: 215 573-4865

Associate Dean for Research Program Development: Jonas Ellenberg, Ph.D.

604 Blockley Hall/6021

Phone: 215-573-3903 Fax: 215 573-4865

Associate Dean for Research at Philadelphia Veterans Administration Medical Center: Joel N. Maslow, M.D.

Phone: 215- 823-5800, ext. 2627

Office of the Executive Vice Dean and Chief Scientific Officer

Mission Statement:

The Office of the Executive Vice Dean and Chief Scientific Officer supports the research and research training missions of the School of Medicine at the University of Pennsylvania. In this regard, the office seeks to promote excellence in research and research education, and to support School of Medicine faculty in the creation and dissemination of new knowledge and the development of new therapies. The Vice Dean has operational, planning, and financial responsibility for the academic components of all research and research training activities within the School of Medicine.

Objectives:

- Advance the highest standards of excellence in research and research education
- Establish the School of Medicine as an internationally recognized leader in biomedical research
- Promote cross-departmental and School collaboration, and a culture that supports collective research excellence
- Promote targeted interdisciplinary science and education that spans basic, translational, and clinical research
- Facilitate activities and institutional relationships related to global research and trainee education
- Promote human research for the advancement of healthcare while ensuring the highest level of research participant safety
- Support graduate and postdoctoral programs to maximize recruitment and ensure high-quality training for the greatest number of outstanding trainees and postdoctoral fellows
- Build new linkages both within the University and to the private sector
- Plan and manage core facilities and animal support services to sustain the highest caliber of research

Offices reporting to the Vice Dean for Research and Research Training include: Biomedical Graduate Studies; Biomedical Postdoctoral Programs; Combined Degree and Physician Scholar Programs; Corporate Alliances; Human Research; Masters Programs; and Research Program Development.

The Art and Science of Obtaining Funding Symposium

This yearly symposium is sponsored in conjunction with the Office of Faculty Affairs and Professional Development. The symposium includes an address by a keynote speaker as well as a series of presentations by School of Medicine faculty, all focused on helping investigators improve grant competitiveness and maximize success rates.

Grant Writing Manual and Directory of Research Core Facilities

The grant writing manual (this publication) is available online at: <http://www.med.upenn.edu/rpd/documents/gwm.pdf>.

The research core directory is also available online and provides information about each core facility, including a description of services and contact information: http://www.med.upenn.edu/rpd/core_facil.html

Voluntary Intramural Review of Grant Applications (VIRGA)

The VIRGA program, coordinated through the Office of Research Program Development, helps School of Medicine investigators make their grant applications more competitive by providing an internal critique and peer review criticism of an applicant's Research Plan prior to submission to a sponsor. Participation in VIRGA is voluntary, with reviewers selected from volunteer faculty who have active grant portfolios and expertise in related disciplines. More information is available from Elizabeth Bien, Director, Research Program Development, at 215-898-0132.

Office of Research Program Development

Elizabeth Bien, Director

322 Anatomy/Chemistry Building/6061

Phone: 898-2726 Fax: 898-0993

Email: biene@mail.med.upenn.edu

<http://www.med.upenn.edu/rpd/>

The Office of Research Program Development (RPD), formerly known as Sponsored Programs Services (SPS), was established in 1993 to foster multidisciplinary biomedical and health services research at the University of Pennsylvania. In this role, RPD

- Provides funding, editorial assistance and staff support for departments and centers in the development of [multidisciplinary grant proposals](#) and Federal contracts
- Coordinates and provides funding for [multidisciplinary research retreats](#)
- Coordinates and provides administrative support for [NIH site visits](#) and teleconferences
- Provides staff support for preparation of [federal request for proposals \(RFP\) applications](#)
- Provides guidance to faculty and staff concerning proposal submission and the administration of sponsored projects
- Serves as resource for the School of Medicine regarding sponsor policies and federal regulations
- Facilitates the identification of funding sources

In addition to these functions, the Office of Research Program Development is responsible for maintaining the University of Pennsylvania School of Medicine Research website; administration of the School of Medicine's Awards of Excellence; coordination of the School's limited application process; and administrative oversight of the grant writing seminar and manual.

RPD assistance is intended to supplement, not supplant, departmental, institute and/or center resources. RPD tailors its services to the specific needs and requirements of individual departments and investigators. Information is available online at <http://www.med.upenn.edu/rpd/>. For additional information about the application process or additional information about their services, please call or send the request via e-mail.

Office of Research Support Services

Marianne Achenbach, Executive Director

270 Anatomy/Chemistry Building/6061

Phone 573-8798 Fax: 573-8802

Email: achenbac@mail.med.upenn.edu

<http://www.med.upenn.edu/orss/>

Mission Statement:

The Office of Research Support Services (ORSS) was established in February 2000 to promote the research endeavors of the School of Medicine faculty. In this role, the ORSS :

- provides assistance in developing proposals to outside funding agencies
- develops tools for standardization of budgeting
- provides oversight management of sponsored programs
- ensures compliance with sponsor and university expectations for managing sponsored program funds
- serves as a resource for the School of Medicine regarding sponsor policies and federal regulations and
- provides training in pre and post award grants management

ORSS Roles, Responsibilities and Interactions with Faculty and Research Staff

The Office of Research Support Services is the designated office for review of all sponsored research proposals and signs all necessary paperwork on behalf of the Dean. The Business Administrator of each department, center or institute should be familiar with the internal proposal review process. The staff of ORSS understands the pressure of deadlines of the various funding agencies and do their best to accommodate the timing needs of the faculty who are submitting proposals. At the same time, it is important that faculty and business administrators recognize the time needs for the review process and the volume of proposals that ORSS must review, especially just before major deadlines. The key to receiving timely service is planning. Proposals received in the last days before the deadline may be subject to delays, because of that volume. By submitting proposals at least *five to ten working days* prior to your deadline, your proposal will receive the attention and consideration it deserves.

ORSS is also responsible for developing policies and procedures for the administration of sponsored programs. Included in this manual are some of the School of Medicine policies and procedures related to sponsored programs. While the most recent versions are included here, faculty are reminded that these policies are subject to periodic revision. Please check with the School of Medicine, Office of Research Support Services to be sure that you are using the most current policies. Also refer to <http://www.med.upenn.edu/policy/res.htm> for additional policies and procedures relating to sponsored programs.

ORSS also carries out post-award monitoring for ensuring compliance with sponsor, University and School policies. The Office has developed a series of Standard Operating Procedures (SOP's) as well as a comprehensive training curriculum for departmental grant managers to help improve service quality to principal investigators and to ensure proper stewardship of our sponsored program awards. Faculty and staff may contact Marianne Achenbach (573-8798) for additional information about ORSS services.

Office of Research Services

Deborah Fisher, Director, Pre-Award Non-Financial Administration

Email: Dfisher2@pobox.upenn.edu

Franklin Building, Rm. P221

Phone: 573-6706

Alice Dunleavy, Associate Director

Email: dunleavy@pobox.upenn.edu

Phone: 573-2555 Fax: 898-9708

<http://www.upenn.edu/researchservices/>

The Office of Research Services (RS) is responsible for implementing the policies of the University and for administering research and other projects supported with funds from external organizations including the government, corporations, and foundations. In this role, RS is responsible for the review and approval of all proposals developed by the faculty requesting funds from external organizations in support of research and other projects. RS is also responsible for negotiation of grants and contracts, and has the authority to accept all such agreements on behalf of the University. RS provides oversight and guidance to faculty principal investigators, departments and schools for administration of sponsored projects to assure adherence to regulations as well as good stewardship of our sponsors' funds.

A guide for faculty and staff who conduct sponsored projects as been developed by RS. The guide, *Sponsored Projects Handbook*, contains the research policies and procedures of the University, as well as the references for further information and assistance. Every faculty and staff member who is involved in sponsored projects will find it an invaluable reference. An online version is available at <http://www.upenn.edu/researchservices/Manual.html>. Another resource produced by RS is a monthly newsletter sent to all subscribers of the Research Services list serve. Back issues of the newsletter, instructions on how to subscribe to the listserve and additional information may be found on the RS website at <http://www.upenn.edu/researchservices/newsletter.html>.

Office of Regulatory Affairs

133 S. 36th Street, Mezzanine Level

<http://www.upenn.edu/regulatoryaffairs/>

Yvonne K. Higgins, Director, Human Research Protections

Phone: 215-573-1206 Fax: 215-573-9438

Email: yhiggins@pobox.upenn.edu

Mary Jo Shepherd, Director, IACUC

Phone: 215-573-7302 Fax: 215-573-9438

Email: shephemj@pobox.upenn.edu

The Office of Regulatory Affairs (ORA) is responsible for the review and approval of all biomedical and behavioral research that involves the use of human and/or animal subjects. The ORA reports to the Vice Provost for Research and is primarily responsible for reviewing the research protocol, regardless of funding source.

Human research must be reviewed by a convened meeting of the Institutional Review Board (IRB) unless the research is determined to be exempt or is eligible for expedited review. Final review category and submission requirements will be determined by the IRB administrative staff. The work of reviewing submissions involving human subjects is divided among 8 IRBs. IRBs 1-5 & 7 review biomedical research. IRB 8 reviews behavioral and social sciences research. IRB 6 serves Pennsylvania Hospital. Each board meets once a month to review research involving human subjects.

Research involving animals is reviewed by the Institutional Animal Care and Use Committee (IACUC). The IACUC meets at least once a month. This committee is also responsible for the semi-annual inspection of all animal research facilities on campus and at the New Bolton Center in Kennett Square, and semiannual reviews of the animal care and use program as required by federal law.

Research involving the use of human and animal subjects at the University of Pennsylvania is governed by federal regulations as well as state law and institutional policies. Currently there are approximately five thousand human subject and two thousand animal subject studies active in the Regulatory Affairs office.

Information about the University of Pennsylvania's human and animal research protections programs, including information on submission and review requirements, is available online at: <http://www.upenn.edu/regulatoryaffairs>. Questions may be directed to ORA administrative staff. Contact information is available online at: <http://www.upenn.edu/regulatoryaffairs/Contact.html>. The main phone number for ORA is 215-898-2614.

Office of Human Research

Gregg J. Fromell, M.D., Executive Director

150 Anatomy-Chemistry/6061

Phone: (215)746-7400; Fax: (215)746-7373

Email: gfromell@mail.med.upenn.edu

Director, Clinical Research Operations Services: Nancy Pultorak, 746-7400, FAX: 746-7373

Email: npultora@mail.med.upenn.edu

Director, Information Systems Integration for Research: Mark Weiner, M.D., 215-898-5721

Email: mweiner@mail.med.upenn.edu

<http://www.med.upenn.edu/humanresearch>

The Office of Human Research (OHR) was established with the mission of promoting human research, with a focus on maintaining the highest level of research subject safety and research data integrity. This mission is accomplished through supporting the investigator and research team with research education and training services, the introduction of process enhancements and innovative tools services, and monitoring of human research studies. The OHR collaborates with the IRB and other oversight offices to foster continuous quality improvement and regulatory compliance in human research. The OHR supports the investigator through the process from initial scientific question through protocol creation, regulatory submission and FDA interface, study implementation, study oversight/monitoring, and ultimately study close-out. The OHR is also working to streamline the research administrative process; they have developed research cost standards and web-based budget tools, and provide patient informatics services to assist in the study recruitment process.

Center for Technology Transfer

Michael J. Cleare, Ph.D., Associate Vice Provost for Research and Executive Director, Center for Technology Transfer

3160 Chestnut Street, Suite 200
Phone: (215) 573-4500, FAX: 215-898-9519

The Center For Technology Transfer (CTT) obtains and manages patents, copyrights and trademarks for the University's academic and research enterprises. The CTT creates relationships with industry, including licensing of Intellectual Property, commercializing intellectual property resulting from the University's research and negotiating research agreements (SRA's) related to such licenses. CTT is also responsible for starting new corporate entities, to develop, protect, and transfer Penn's intellectual property.. For more information please see: <http://www.ctt.upenn.edu>.

Office for Corporate Alliances

Terry Fadem, Managing Director

267 Anatomy-Chemistry Building

Phone: 215-898-2420

Email: fadem@mail.med.upenn.edu

<http://www.med.upenn.edu/corporate/index2.htm>

The Office of Corporate Alliances (OCA) provides the link between PENN Medicine and the business and corporate communities. OCA provides access to expertise and resources that can transform basic medical science knowledge into technology that will benefit patient care. Corporate alliance development, business planning, sponsored research relationships, negotiation training, and general business advice and management are some of the support services provided by the office.

Global Health Programs

Neal Nathanson, M.D., Associate Dean

Blockley Hall, Suite 1007

Phone: 215-898-8048

Email: nathansn@mail.med.upenn.edu

<http://www.med.upenn.edu/globalhealth/index.shtml>

Global Health Programs coordinates the global activities of the School of Medicine and supports the international aspects of all research, educational, and service programs. Activities include: placement of Penn medical students in international rotations; hosting of international medical students at Penn; recruitment of postdoctoral fellows from international institutions; administration of a university-wide framework program in global health; facilitation of international research initiatives and sponsored programs undertaken by faculty of the School of Medicine; coordination of global activities with other schools of the University and the Office of the Provost; provision of information for faculty, students, and administration; and representation of the School of Medicine in interactions with international Universities.

Office of Research Compliance and Integrity (RCI)

Debbi Gilad, J.D. , Executive Director

240 John Morgan Building/6055

Phone: 215-573-8800 Fax: 215-573-0280

Email: debbig@mail.med.upenn.edu

<http://www.med.upenn.edu/penn/comply/>

The Office of Research Compliance and Integrity (RCI) was established as part of the School of Medicine's commitment to ensuring ethical and compliant conduct throughout our School. The office reports to the SOM's Vice-Dean of Administration and Finance and oversees a vigorous SOM-wide effort to promote compliance and a positive, ethical work environment for all faculty and staff.

The SOM Compliance Program provides a proactive approach built on solid organizational ethics, which ensures full compliance with all applicable policies, procedures, laws and regulations. The Executive Director's responsibilities include development, implementation and management of a program of action designed to promote ethical and compliant behavior. The program will endeavor to protect the reputations of the SOM, the University of Pennsylvania and the University of Pennsylvania Health System for integrity and ethics in our dealings with students, sponsors, patients, and other stakeholders.

A key element in the success of the program is the cultivation and nurturing of an environment committed to the principle of good stewardship and efficient utilization of resources. The office serves as a focal point for an

understanding of the SOM's total compliance responsibilities, proactively seeks to train faculty and staff, and facilitates the active solicitation and discovery of concerns followed up by an appropriate inquiry into problem areas and the timely resolution of issues.

The SOM Office of Research Compliance and Integrity also encourages the use of the University of Pennsylvania's Helpline, a confidential/anonymous organizational ethics and conduct helpline for reporting and discussing concerns about SOM activities.

University Laboratory Animal Resources (ULAR)

Diane Gaertner, D.V.M., Director

Phone: 215-898-2434, FAX: 573-9998

Email: gaertner@pobox.upenn.edu

<http://www.ular.upenn.edu/>

University Laboratory Animal Resources (ULAR) is responsible for the procurement, care and use of all University-owned animals used for teaching, research and testing as approved by the Institutional Animal Care and Use Committee (IACUC) and as mandated by federal law and regulations. To fulfill the above responsibilities, ULAR provides or has oversight for the provision of husbandry and veterinary medical care for all University-owned animals. It provides professional and technical consultation, assistance and training to administrators, researchers and their staff on the humane, proper and efficient use of animals, design of new and renovated animal housing areas, and interaction with the public on animal use in biomedical research. It procures all animals used by the University and maintains the legally required records pertaining to the procurement and use of animals.

Investigational Drug Service

Kenneth Rockwell, Pharm.D., M.S., Director

Phone: 215-349-8817, FAX: 349-5132

Email: rockwelk@mail.med.upenn.edu

http://www.itmat.upenn.edu/ids/ids_welcome.shtml

The Investigational Drug Service (IDS) is a research pharmacy charged with the management of research medications used in clinical (human) drug trials, as well as the oversight of medication use in drug trials conducted throughout the University of Pennsylvania and its affiliates. Agents overseen by the IDS include drugs, natural products, vitamins, biologic, and gene therapy agents.

Environmental Health and Radiation Safety Office (EHRS)

Matthew Finucane, Director

Phone: 215-898-6057, Fax: 215-898-0140

Email: matt@ehrs.upenn.edu

Robert D. Forrest, RSO, Associate Director

Phone: 215-898-2109, Fax: 215-898-0140

Email: rforrest@ehrs.upenn.edu

Laura H. Peller, Associate Director

Phone: 215-898-1914, Fax: 215-898-0140

Email: lpeller@ehrs.upenn.edu

The University of Pennsylvania's Office of Environmental Health and Radiation Safety (EHRS) promotes health, safety and environmental protection in teaching, research, health care, and administrative activities by providing services, advice and compliance assistance. The EHRS provides leadership in developing, implementing and supporting high quality programs that allow students, faculty and staff to protect themselves from hazards they may encounter at the University. The EHRS also provides the expertise needed to direct efforts towards compliance with health and safety laws and regulations.

The EHRS, under the auspices of the Vice Provost for Research, the Radiation Safety Committee and the University Environmental Health and Safety Committee, oversees the use of biological materials, hazardous materials and radioactive materials. For additional information please see: <http://www.ehrs.upenn.edu/>.

**C. PENN FACULTY ON NIH COMMITTEES AND PANELS
CENTER FOR SCIENTIFIC REVIEW**

- Abrams, Charles S., M.D., Division of Hematology/Oncology; Hemostasis and Thrombosis (2010)
- Ahima, Rexford S., M.D., Ph.D., Division of Endocrinology, Diabetes and Metabolism; Integrative Physiology of Obesity and Diabetes (2010)
- Axelsen, Paul H., M.D., Department of Pharmacology; Biochemistry and Biophysics of Membranes (2009)
- Bartolomei, Marisa S., Ph.D., Department of Cell and Developmental Biology; Molecular Genetics B (2008)
- Beck, Sheryl G., Ph.D., Department of Anesthesiology; Neurobiology of Motivated Behavior (2008)
- Berretini, Wade H., M.D., Ph.D., Department of Psychiatry; Molecular Neurogenetics (2008)
- Blank, Michael B., Ph.D., Department of Psychiatry; Behavioral and Social Science Approaches to Preventing HIV/AIDS (2010)
- Bhatnagar, Seema, Ph.D., Department of Anesthesiology; Neurobiology of Motivated Behavior (2008)
- Blank, Michael B., Ph.D., Department of Psychiatry; Behavioral and Social Science Approaches to Preventing HIV/AIDS (2010)
- Chacko, Samuel K., Ph.D., D.V.M., Department of Pathobiology; Urologic and Kidney Development and Genitourinary Diseases (2009)
- Chou, Margaret, M., Ph.D., Department of Cell and Developmental Biology; Membrane Biology and Protein Processing Study Section (2011)
- Clark, Christopher M., M.D., Department of Neurology, Neurological, Aging and Musculoskeletal Epidemiology (2009)
- Dancis, Andrew B., M.D., Division of Hematology/Oncology; Erythrocyte and Leukocyte Biology (2009)
- Davatzikos, Christos A., Ph.D., Department of Radiology; Biomedical Imaging Technology (2011)
- Delisser, Horace M., M.D., Department of Medicine; Lung Injury, Repair, and Remodeling (2011)
- Deutschman, Clifford S., M.D., Department of Anesthesiology and Critical Care; Surgery, Anesthesiology and Trauma (2009)
- Diehl, J. Alan, Ph.D., Department of Cancer Biology; Molecular Oncogenesis (2011)
- Dinardo, Stephen, Ph.D., Department of Cell and Developmental Biology; Cellular, Molecular and Integrative Reproduction (2009)
- Discher, Dennis E., Ph.D., Department of Chemical and Biomolecular Engineering; Erythrocyte and Leukocyte Biology (2009)
- Dominguez, Roberto, Ph.D., Department of Physiology; Macromolecular Structure and Function C (2010)
- Elliott, Dawn M., Ph.D., Department of Orthopaedic Surgery; Musculoskeletal Tissue Engineering (2008)
- Faith, Myles S., Ph.D., Department of Psychiatry; Psychosocial Risk and Disease Prevention (2009)

Flanagan-Cato, Loretta M., Ph.D., Department of Psychology; Neuroendocrinology, Neuroimmunology, and Behavior (2008)

Hahn, Stephen M., M.D., Division of Hematology/Oncology; Clinical Oncology (2011)

Haskins, Mark E., Ph.D., Department of Pathology and Medical Genetics; Gene Therapy and Inborn Errors (2008)

Ho, Wenzhe, M.D., Department of Pediatrics; Neuroaids and Other End-Organ Diseases (2009)

Hoshi, Toshinori, Ph.D., Department of Physiology; Biophysics of Neural Systems (2011)

Kaestner, Klaus H., Ph.D., Department of Genetics; Gastrointestinal Cell and Molecular Biology (2009)

Kim, Junhyong, Ph.D., Pennsylvania Genomics Institute; Genetic Variation and Evolution (2011)

Koumenis, Constantinos, Ph.D., Department of Radiation Oncology; Basic Mechanisms of Cancer Therapeutics (2010)

Litt, Brian, M.D., Department of Neurology and Bioengineering; Clinical Neuroscience and Disease (2010)

Maity, Amit, Ph.D., M.D., Department of Radiation Oncology; Radiation Therapeutics and Biology (2011)

Markman, James F., Ph.D., M.D., Department of Surgery; Transplantation, Tolerance and Tumor Immunology (2011)

Millar, Sarah E., Ph.D., Department of Dermatology, Arthritis Connective Tissue and Skin (2010)

Nusbaum, Michael P., Ph.D., Department of Neuroscience, Sensorimotor Integration (2008)

Pack, Michael A., M.D., Department of Medicine; Clinical and Integrative Gastrointestinal Pathobiology (2010)

Penning, Trevor M., Ph.D., Department of Pharmacology; Cancer Etiology (2008)

Price, R. Arlen, Ph.D., Department of Psychiatry, Clinical and Integrative Diabetes and Obesity (2008)

Robertson, Erle S., Ph.D., Department of Microbiology; Virology A (2011)

Sankar, Pamela L., Ph.D., Department of Bioethics; Ethical, Legal and Social Implications of Human Genetics (2008)

Scherer, Steven, M.D., Ph.D., Department of Neurology; Neurodifferentiation, Plasticity, and Regeneration (2008)

Schnall, Mitchell D., Ph.D., Department of Radiology; Medical Imaging (2008)

Schuster, Stephen J., M.D., Department of Medicine; Chronic Fatigue Syndrome / Fibromyalgia Syndrome (2008)

Shen, Hao, Ph.D., Department of Microbiology, Host Interactions with Bacterial Pathogens (2009)

Shore, Eileen M., Ph.D., Departments of Genetics and Orthopedic Surgery; Skeletal Biology Development and Disease (2011)

Siman, Robert, Ph.D., Department of Pharmacology; Clinical Neuroplasticity and Neurotransmitters (2008)

Song, Wencho, Ph.D., Department of Pharmacology; Innate Immunity and Inflammation (2009)

Spielman, Richard S., Ph.D., Department of Genetics, Genetics of Health and Disease (2008)

Spinner, Nancy B., Ph.D., Department of Pediatrics, Genetics of Health and Disease (2009)

Veasey, Sigrid C., M.D., Department of Medicine; Biological Rhythms and Sleep (2011)

Wasik, Mariusz A., M.D., Department of Pathology and Laboratory Medicine; Tumor Cell Biology (2011)

Weissmna, Drew, Ph.D., M.D., Department of Infectious Diseases; AIDS Immunology and Pathogenesis (2010)

Wells, Rebecca G., M.D., Department of Medicine; Hepatobiliary Pathophysiology (2009)

Wilson, James M., M.S., Division of Medical Genetics; Gene Therapy and Inborn Errors (2008)

Revised September 2007

March 15/October 31

Statement of Purpose and Guidelines

The University Research Foundation (URF) is an intramural resource to support research for faculty for a variety of purposes, including:

- Helping junior faculty undertake pilot projects that will enable them to successfully apply for extramural sources of funding, and aid in establishing their careers as independent investigators.
- Helping established faculty perform exploratory research, particularly on novel or pioneering ideas, to determine their feasibility and develop preliminary data to support extramural applications.
- Providing support in disciplines where extramural support is difficult to obtain and where significant research can be facilitated with internal funding.
- Providing limited institutional matching funds that are awarded contingent upon a successful external peer-reviewed application that requires an institutional match.

Conference Support Guidelines are at the end of this document.

Scope

Disciplines. The URF supports research in all disciplines, including international research. For purposes of review, applications are assigned to four broad disciplinary areas: Biomedical Sciences, Humanities, Natural Sciences and Engineering, and Social Science and Management; see <http://www.upenn.edu/research/ReviewPanels.htm>.

Term. Grants are given for a single year only. Applications for a renewal of a previously funded project may be submitted but usually receive low priority. Funds must be spent within 12 months of the beginning of the grant, and may not be "banked" for future use. Unexpended funds must be returned to the Foundation. If justified in writing, carryover of unexpended funds may be approved by the Vice Provost for Research. Request for carryover of unexpended funds should be made prior to the expiration of an award. No extensions will be considered if request is made after award is expired.

Budget. Applications up to \$50,000 will be entertained.

Eligibility. Eligibility is limited to University faculty, in any track, at any professorial level. Instructors and Research Associates may apply but need to establish (by letter from the Department chair) that the applicant will receive an appointment as an Assistant Professor by the time of the award.

Conference Support. Scholarly conferences of a research nature will be considered for funding at the level of up to \$3,000 per conference (See Conference Support Guidelines below).

The Application

Applications that fail to meet the guidelines will not be reviewed.

Dates. Applications are accepted twice each year, for October 31 and March 15 deadlines. If the date falls on a weekend or holiday, the deadline is the next working day. Every effort will be made to process applications and notify applicants of the outcome within 10 weeks after the deadlines.

The application. Brevity and clarity will enhance the likelihood of success. Please number all pages at the bottom right hand corner. Use one-inch margins and a 12-point font. Applications should be limited to 10 pages (applications over the page limit will not be reviewed) and must include in this order:

- A completed (with all signatures) [University Research Foundation Cover Sheet](#). The application should be classified under one of the four Statement of Purpose categories listed above.

- An abstract of no more than 200 words, written for the educated non-specialist.
- A description of no more than 5 single-spaced pages of the research proposed. Proposals must provide background, hypothesis or purpose of the research, significance of the research, methods used, work to be undertaken, and outlook for future extension of the research and its potential for external funding (see Review Process below). NOTE: an application formatted for another sponsoring agency or failing to conform to these guidelines will not be reviewed.
- A [University Research Foundation Budget Form](#), supplied here as a link, must be used justifying each item requested. Allowable items include research costs associated with supplies, salaries of non-faculty personnel and travel expenses essential to the project. Equipment costs up to 100% of the proposed budget may be eligible for funding, but such requests must be justified in the application as essential to the research. In addition, if all or most of the budget is to be used for equipment, the applicant must document that other resources are available to conduct the proposed research. Specific research objectives should be identified and described. The review will focus not on the equipment being requested but on the scientific program to which it will be applied. Equipment requests for multiple user items will enhance the likelihood of success. Faculty salaries, including summer salaries or release time, are not funded. Because it may not be possible to fund meritorious proposals fully, the budget must prioritize items in the order of their importance to the project (not simply list all items requiring support for which support is requested).
- Research support must be clearly stated, including other current funding (direct and indirect costs) with a list of titles, amounts, sources, and grant periods, expired funding for the prior three years, and pending applications (include notification of pending applications), as well as faculty research funds and funds associated with professorial Chairs. Prior grants from the University Research Foundation must be itemized, with dates, title, and amount of funding, plus a statement about whether external funding was received as a result of the URF grant. Other research support for co-investigators should be identified.
- **Regulatory issues.** If research involves human subjects, animals, biohazards, or other regulatory issues, the application should identify those concerns and provide documentation that they will be addressed. **Please note that IRB approval may be required for human subject research in all disciplines, including the sociobehavioral sciences and humanities. If IRB, IACUC or Environmental Safety review and approval is required, it may be obtained after the application has been approved, but before funds are provided or research has been initiated.** For advice please consult the [Office of Regulatory Affairs](#).
- A single page biographical sketch for the principle investigator and all co-investigators. The biographical sketches do not count against the page limit.
- Assistant Professors in all tracks (including Tenure, Clinician Educator, and Research track) are required to include a letter from their Department Chair indicating their career plans within the department, future commitment of independent space and of department or School resources, including all department funding (startup packages, etc.). In addition, the letter should establish that the applicant will be working as an independent investigator or scholar. Such additional documentation can be provided as an appendix and will not be included within the page count.
- **Conflict of interest.** The applicant should explicitly make a statement about whether or not the application involves any potential conflict of interest, and any such conflicts should be described. For instance, if the research could forward the interests of a company in which the applicant has a financial interest, this should be disclosed. [Conflict of interest documentation](#) (if required) can be provided as an appendix to the body of the application and will not be included in the page count.

<http://www.upenn.edu/researchservices/docs/findisc.doc>

- Resubmitted applications that were not funded in a previous cycle must be revised, and it would be of benefit to indicate the nature of the changes.

Submission. An original of the complete proposal with the original signatures of the PI, Chair and Dean should be submitted to the Office of the Vice Provost for Research, 118 College Hall/6303, on or before 5:00 pm on the deadline date. In addition, please send a PDF version, using the following directives:

- PDF file name must be the last name of the principal investigator

- Full proposal must be one PDF document, to include the fully signed cover sheet, budget sheet and all attachments in the exact same order as the submitted original proposal.
- Email to: vpr@pobox.upenn.edu
- Must be received on or before 5:00 pm of the deadline date.

Review Process

Applications are reviewed by one of [four review panels](#): Biomedical Sciences, Humanities, Natural Science and Engineering, and Social Science and Management. Funding is spread equitably across the major disciplines. Each application is reviewed for a variety of attributes, including

- scholarly merit, creativity and innovation
- feasibility
- significance of the research
- time-limited opportunities that require immediate funding
- prospects for future extramural funding
- matching support from other sources
- availability of alternate funding sources
- career development at early stages of career
- evidence that junior applicants will be working as independent investigators
- advancement of school or institutional objectives, such as interdisciplinary research

Certain frequently found weaknesses should be avoided, such as

- "reinventing the wheel" due to ignorance of prior published work, often in cognate fields
- a fishing expedition without a focused hypothesis
- repeated requests for research projects that are eligible for but have failed to garner external peer reviewed support

Critiques of applications will not be provided for unsuccessful applications by the VPR office. Please do not contact the faculty who volunteer their time as peer reviewers.

If awarded :

- Regulatory approvals must be obtained before funds are transferred to the department.
- The home department must have a 26-digit budget code.
- A brief (1 to 2 pages) report should be submitted to the Vice Provost Office of Research within one year of the date of the award. The report should include publications, other funding, patents or discoveries which resulted because of this award.

University Research Foundation Conference Support Guidelines

March 15/October 31

Scope

The conference support program is designed for scholarly meetings that will be convened on the Penn campus, thereby providing enrichment opportunities to interested faculty, students, and staff, most frequently in the format of a 1-2 day colloquium. The intent is to support meetings that are designed to enhance existing research and scholarly programs, particularly in disciplines where external funding is difficult to obtain. **High priority will be given to inter- or cross-disciplinary conferences that include faculty from more than one School.**

The Application

Funding will be limited to no more than \$3,000 per event, and should be dedicated to reimbursing the speakers for travel and accommodations, but not for meals and entertainment. It is expected that funding from the University Research Foundation will supplement funding from other sources and will not be the sole source of funding for the meeting. Applications must be brief, usually no more than three (3) pages, and should include,

- A completed [Conference Proposal Cover Sheet](#), with all signatures, which includes name and contact information for the applicant, who must be an appointed faculty member (tenure, research, or clinician-educator track) and the appropriate review committee must be indicated

<http://www.upenn.edu/research/ReviewPanels.htm>

- A description of the purpose of the meeting
- A proposed program agenda (appendix)
- A proposed list of presenters (appendix)
- The number of Penn students and faculty expected to attend
- An explanation of the benefit to Penn students and faculty
- An explanation of the benefit to scholarly or research programs at Penn
- Relationship of the meeting to department, institute or center programs
- The names of faculty who are organizing the meeting
- Identity and contact information for the business administrator responsible for administration of the funds
- A [University Research Foundation Budget Form](#), itemizing the types of proposed expenditures (appendix)
- Evidence of matching funding from institutional or external sources
- Evidence of institutional support in the form of no cost facilities and AV support
- A University Research Foundation Budget Form, link, itemizing the types of proposed expenditures (appendix)

Submission

An original of the complete proposal with the signed cover sheet should be submitted to the Office of the Vice Provost for Research, 118 College Hall/6303, on or before the deadline date. In addition, please send a PDF version, following these guidelines:

- PDF file name must be the last name of the principal investigator
- Full proposal should be one PDF document, to include the signed cover sheet, budget sheet and all attachments in the same order as the hard copy.
- Email to: vpr@pobox.upenn.edu

- Must be received on or before 5:00 pm of the deadline date.

Applications for the Conference Support Program are processed in the same cycles, and will be reviewed by the same committees that are used for URF research applications. Please identify which Review Committee will review your conference proposal (Biomedical Sciences, Humanities, Natural Sciences and Engineering, and Social Science and Management). <http://www.upenn.edu/research/ReviewPanels.htm>

Questions should be directed to:

Irene Soroka
215- 898-3603
vpr@pobox.upenn.edu
Vice Provost for Research
118 College Hall/6303

This information has been excerpted from the University of Pennsylvania website <http://www.upenn.edu/research/FoundationGuidelines.htm>. For a more complete discussion of the subject, please refer to this site.

CHAPTER IV:

Budget and Administrative Issues

**A. UNIVERSITY OF PENNSYLVANIA SCHOOL OF MEDICINE
POLICY CONCERNING THE PORTION OF FACULTY SALARIES TO BE
FUNDED FROM SPONSORED PROGRAMS**

**Effective 1/1/93
Revision approved 11/22/04**

Introduction

The sponsored research activities of School of Medicine (SOM) faculty are funded through various sources that include grants and contracts, gifts, endowment, clinical trials, patient care, and subvention from the School. To ensure that the salary recovery from sponsored research is commensurate with the effort expended, the SOM has developed the following policy regarding faculty salaries chargeable to sponsored programs.

Policy Statement

The following details the SOM's policy regarding the charging of salary to sponsored programs:

- Faculty are expected to develop salary support from sponsored research in an amount reflective of the total amount of time allocated to research activities.
- All grant and contract proposals submitted and awards received by SOM faculty must reflect salary support for the faculty in an amount equal to the percentage of time to be spent on the project, consistent with the policies of the sponsor.
- If the amount of a grant or contract award differs significantly from the proposal, the faculty salary support and associated percentage of time to be spent on the project may need to be adjusted. If percentage of time to be spent should remain as originally proposed, adjustments must be made within the other expense categories.
- All sponsored program University budgets must include, and all sponsored program expenditures must reflect salary support for the faculty in an amount equal to the percentage of time to be spent on the project, consistent with the amount shown in the proposal and award, and consistent with the policies of the sponsor.
- All faculty salary changes to a sponsored program University budget must be approved in advance by the appropriate Department Chair.
- Exceptions to these policies must have the written approval of the Department Chair and the Executive Vice President/Dean or his or her designated representative.

Implementation

The policy is effective January 1, 1993. Each faculty member is responsible for compliance with this policy, and each Department Chair has compliance responsibility for faculty within that department. The Executive Vice President/Dean and his or her staff will monitor compliance annually through the budget review process. Implementation of this policy will not affect the amount of EVP/Dean's subvention provided to departments. The level of EVP/Dean's subvention provided to departments is the result of many factors, only one of which is faculty support from sponsored programs. Questions regarding this policy should be directed to the Executive Director of the Office of Research Support Services.

**B. UNIVERSITY OF PENNSYLVANIA SCHOOL OF MEDICINE
POLICY CONCERNING THE DESIGNATION OF SPONSORED PROGRAM ACTIVITY**

**Effective 3/1/93
Revision approved 11/22/04**

Introduction

The sponsored program activities of the School of Medicine (SOM) are critically important to the success of the School's research mission. These activities are funded through various sources, including grants, contracts, and clinical trials. To manage the School effectively and to evaluate performance, it is essential to have accurate activity reports. To ensure that the sponsored program activity is designated to the appropriate department, the School of Medicine has developed the following policy.

Policy Statement

The following details the SOM's policy regarding the designation of sponsored program activity at the proposal and award level:

- For both external and internal reporting purposes, the department of the Principal Investigator's primary appointment will always be designated. An award may be designated to a department other than that of the Principal Investigator with approval of both affected department chairs.
- For external reporting purposes, all program project or Specialized Center of Research (SCOR) grants will be designated to the department of the program project director. For internal reporting purposes, all program projects and SCOR sub-accounts will be designated to and managed by the department of the sub-account's Principal Investigator. Only sub-accounts assigned to the director of the program project or SCOR will be designated to the department of the program project director.
- All sponsored individual (e.g., National Research Service Awards) fellowships will be designated to the primary department of the recipient's faculty mentor. All training grants will be designated to the department of the Principal Investigator.
- Any exceptions to this policy must have the written approval of the Department Chair and the Executive Vice President/Dean, or his/her designated representative.

Implementation

This policy is effective March 1, 1993. Each faculty member is responsible for compliance with this policy, and each Department Chair has compliance responsibility for faculty within that department. The Executive Vice President/Dean and his or her staff will monitor compliance through the proposal transmittal and award process. Questions regarding this policy should be directed to the Vice President and/or the Executive Director of the Office of Research Support Services.

C. OFFICE OF RESEARCH SERVICES GENERAL ADMINISTRATIVE STRUCTURE

The [Office of Research Services](#) (ORS) reports jointly to the Senior Vice President for Finance & Treasurer and the Vice Provost for Research. The ORS exists to implement the research policies of the University and to provide services to the faculty and their schools and departments in administering sponsored projects. An Executive Director who is supported by Directors, Associate Directors, Assistant Directors, Contract Administrators, Research Accountants, and other administrative staff, heads ORS. The functions of ORS include the following:

- Formulating grant and contract administration policies and procedures for approval and promulgation by the Senior Vice President for Finance and the Vice Provost for Research;
- Overseeing the negotiation, execution and administration of sponsored project grants and contracts throughout the University from inception through closeout;
- Assuring timely receipt of and proper fiscal stewardship for sponsor funds;
- Negotiating University-wide F&A costs and employee benefit rates;
- Assuring University compliance with federal requirements such as effort reporting, cost sharing and service centers;
- Maintaining liaison with sponsoring agencies concerning University organization, policies and procedures; representing the University in negotiations with sponsoring agencies to assure consistent contract and grant provisions and policies; resolving problems and settling disputes;
- In cooperation with other University offices (see below), assuring compliance with sponsor's policies, e.g., fiscal, property, intellectual property, human and animal subjects;
- In cooperation with other University offices maintaining official records concerning sponsored projects including official grant and contract files;
- Assisting faculty and department/school staff in the preparation of proposals and other administrative aspects of sponsored projects as needed; and
- Training of administrative staff in the policies, procedures and practices of the University and sponsors.

The Trustees of the University of Pennsylvania have authorized the Executive Director, Directors, Associate Directors, and Assistant Directors of ORS to sign contracts, grants and other documents related to sponsored projects. **Only these individuals are permitted to commit the University to accept a sponsored project agreement (see Sponsored Projects Policy Nos. [2102](#) and [2105](#)).** Contracts and other award documents signed only by the principal investigator are not binding on the University.

For more information: <http://www.upenn.edu/researchservices/>

D. DETERMINATION OF DEPARTMENTAL ADMINISTRATIVE COSTS

F.6.b. The following guidelines apply to the determination of departmental administrative costs as direct or F&A costs.

- In developing the departmental administration cost pool, special care should be exercised to ensure that costs incurred for the same purpose in like circumstances are treated consistently as either direct or F&A costs. For example, salaries of technical staff, laboratory supplies (e.g., chemicals), telephone toll charges, animals, animal care costs, computer costs, travel costs, and specialized shop costs shall be treated as direct costs wherever identifiable to a particular cost objective. Direct charging of these costs may be accomplished through specific identification of individual costs to benefiting cost objectives, or through recharge centers or specialized service facilities, as appropriate under the circumstances.
- The salaries of administrative and clerical staff should normally be treated as F&A costs. Direct charging of these costs may be appropriate where a major project or activity explicitly budgets for administrative or clerical services and individuals involved can be specifically identified with the project or activity. "Major project" is defined as a project that requires an extensive amount of administrative or clerical support, which is significantly greater than the routine level of such services provided by academic departments.
- Items such as office supplies, postage, local telephone costs, and memberships shall normally be treated as F&A costs.

For more information: <http://www.whitehouse.gov/omb/circulars/a021/a021.html>

CHAPTER V:

NIH Structure and Policies

A. ODDS OF BEING FUNDED BY NIH

Fiscal Year	Type of Grant	Activity	Applications	Number Awarded	Total Cost Awarded	Success Rate
2006	New	DP1	471	13	10,277,299	2.8%
		P01	214	47	79,410,465	22%
		R01	22,148	3,610	1,299,711,823	16.3%
		R03	3,206	622	48,316,742	19.4%
		R15	658	157	32,442,915	23.9%
		R21	9,934	1,533	299,243,879	15.4%
		R33	158	17	6,022,483	10.8%
		R34	334	62	13,497,524	18.6%
		R36	27	9	386,293	33.3%
		R37	2	2	705,052	100%
		R55	3	3	300,000	100%
		R56	54	54	15,722,030	100%
		U01	961	242	344,823,053	25.2%
		U19	48	17	20,380,897	35.4%
		UC7	2	2	2,000,000	100%
	Total New		38,220	6,390	2,173,240,446	16.7%
2006	Continuation	P01	188	81	140,800,052	43.1%
		R01	6,666	2,231	824,841,341	33.5%
		R03	8	1	38,103	12.5%
		R15	65	27	5,495,865	41.5%
		R33	1	1	204,091	100%
		R37	164	157	68,983,834	95.7%
		R55	1	1	100,000	100%
		R56	51	51	11,195,425	100%
		U01	175	143	119,107,030	81.7%
		U19	1	1	3,207,647	100%
	Total Continuation		7,320	2,694	1,173,973,388	36.8%
2006	Supplements	P01	22	6	1,366,369	27.3%
		R01	117	37	8,226,354	31.6%
		U01	5	0	0	0%
		U19	4	1	1,532,045	25%
	Total Supplements		148	44	11,124,768	29.7%
FY TOTAL			45,688	9,128	3,358,338,602	20%

Source: http://grants.nih.gov/grants/awards/success/Success_ByActivity.cfm

B. HEALTH RELATED FEDERAL OFFICES

Centers for Disease Control and Prevention	Director	Julie Gerberding, MD, MPH	404-639-7000	http://www.cdc.gov/
Nat'l Center on Birth Defects and Developmental Disabilities	Director	Jose Cordero, M.D.	404-498-3800	http://www.cdc.gov/ncbddd/
Nat'l Center for Environmental Health/Agency for Toxic Substance and Disease Registry	Director	Howard Frumkin, MD, PhD	404-498-0004	http://www.cdc.gov/nceh/
Nat'l Center for Chronic Disease Prevention/ Health Promotion	Director	Janet Collins, Ph.D.	770-488-5401	http://www.cdc.gov/nccdphp/
National Office of Public Health Genomics	Director	Muin Khoury, MD, PhD	770-488-8510	http://www.cdc.gov/genomics/
National Center for Health Marketing	Director	Jay M. Bernhardt, Ph.D.	404-498-0990	http://www.cdc.gov/healthmarketing/
National Center for Health Statistics	Director	Edward J. Sondik, PhD	301-458-4500	http://www.cdc.gov/nchs/
Nat'l Center for HIV, STD, and TB Prevention	Director	Kevin Fenton, MD, PhD	404-639-8000	http://www.cdc.gov/nchstp/od/nchstp.html
National Center for Infectious Disease	Director	Rima Khabbaz, MD	404-639-3967	http://www.cdc.gov/ncidod/
Nat'l Center for Injury Prevention and Control	Director	Ileana Arias, PhD	770-488-4696	http://www.cdc.gov/ncipc/
National Immunization Program	Director	Anne Schuchat, MD	404-639-8200	http://www.cdc.gov/nip/
Nat'l Institute of Occupational Safety and Health	Director	John Howard, MD, MPH, JD	202-401-6997	http://www.cdc.gov/niosh/homepage.html
National Center for Public Health Informatics	Director	Leslie Lenert, M.D., M.S	404-498-2475	http://www.cdc.gov/niosh/homepage.html
Nationall Center for Zoonotic, Vector-Borne, and Enteric Diseases	Director	Lonnie King, DVM	404-639-7380	http://www.cdc.gov/nczved/
Food & Drug Administration	Commis.	Andrew von Eschenbach , MD	301-827-2410	http://www.fda.gov/
Center for Biologics Evaluation and Research	Director	Jesse Goodman, MD, MPH	301-827-0372	http://www.fda.gov/cber/
Center for Devices & Radiological Health	Director	Daniel G. Schultz, MD.	240-276-3939	http://www.fda.gov/cdrh/
Center for Drug Evaluation and Research	Director	Steven K. Galson, MD, MPH	301-594-5400	http://www.fda.gov/cder/
Center for Food Safety and Applied Nutrition	Director	Robert E. Brackett, Ph.D.	301-436-1600	http://vm.cfsan.fda.gov/list.html
Center for Veterinary Medicine	Director	Steve Sundlof, DVM, Ph.D.	240-276-9000	http://www.fda.gov/cvm/
National Center for Toxicological Research	Director	William Slikker, Jr. Ph.D.	870-543-7516	http://www.fda.gov/nctr/
Department of Health and Human Services	Secretary	Mike Leavitt	202-690-7000	http://www.os.dhhs.gov/
Office of the Surgeon General	Acting Surgeon General	Steven K. Galson, MD, MPH	301-443-4000	http://www.surgeongeneral.gov/
National Institutes of Health	Director	Elias A. Zerhouni, MD	301-496-2433	http://www.nih.gov
Center for Scientific Review	Director	Antonio Scarpa, MD. PhD	301-435-1114	http://www.drg.nih.gov/
Fogarty International Center	Director	Roger I. Glass, MD, PhD	301-496-1415	http://www.fic.nih.gov/
National Library of Medicine	Director	Donald Lindberg, MD	301-496-6221	http://www.nlm.nih.gov/
Warren Grant Magnuson Clinical Center	Director	John I Gallin, MD	301-496-4114	http://clinicalcenter.nih.gov
National Human Genome Research Institute	Director	Francis S. Collins, MD, PhD	301-402-0911	http://www.genome.gov/

Nat'l Ctr. Complementary/Alternative Medicine	Director	Stephen Straus, MD	301-435-5042	http://nccam.nih.gov/
Nat'l Center for Minority Health/Health Disparities	Director	John Ruffin, PhD	301-402-1366	http://www.ncmhd.nih.gov/
Nat'l Center for Research Resources	Act. Dir.	Barbara M. Alving, MD	301- 496-5793	http://www.ncrr.nih.gov/
National Eye Institute	Director	Paul Sieving, MD, PhD	301-496-2234	http://www.nei.nih.gov/
National Heart, Lung and Blood Institute	Director	Elizabeth G. Nabel, MD	301-496-5166	http://www.nhlbi.nih.gov/
National Institute on Aging	Director	Richard J. Hodes, MD	301-496-9265	http://www.nia.nih.gov/
National Institute on Alcohol Abuse/ Alcoholism	Director	Ting-Kai Li, MD	301-443-3885	http://www.niaaa.nih.gov/
Nat'l Institute of Allergy and Infectious Disease	Director	Anthony Fauci, MD	301-496-2263	http://www.niaid.nih.gov/
Nat'l Inst. of Arthritis & Musculoskeletal and Skin Disease	Director	Stephen I. Katz, MD, PhD	301-496-4353	http://www.niams.nih.gov/
Nat'l Inst. of Biomedical Imaging and Bioengineering	Director	Roderic Pettigrew, PhD, MD	301-496-8859	http://www.nibib.nih.gov/
Nat'l Institute of Child Health & Human Development	Director	Duane Alexander, MD	301-496-3454	http://www.nichd.nih.gov/
Nat'l Inst. on Deafness/Communication Disorders	Director	James Battey, MD, PhD	301-402-0900	http://www.nidcd.nih.gov/
Nat'l Institute of Dental and Craniofacial Research	Director	Lawrence Tabak, DDS, PhD	301-496-3571	http://www.nidcr.nih.gov/
Nat'l Institute of Diabetes/Digestive/ Kidney Disease	Director	Griffin P. Rodgers, MD	301-496-5741	http://www.niddk.nih.gov/
National Institute on Drug Abuse	Director	Nora Volkow, MD	301-443-6480	http://www.nida.nih.gov/
National Institute of Environmental Health Sciences	Director	David A. Schwartz, M.D.	919-541-3201	http://www.niehs.nih.gov/
National Institute of General Medical Sciences	Director	Jeremy M. Berg, PhD	301- 594-2172	http://www.nigms.nih.gov/
National Institute of Mental Health	Director	Thomas Insel, MD	301-443-3673	http://www.nimh.nih.gov/
National Institute of Neurological Disorders and Stroke	Director	Story Landis, PhD	301-496-9746	http://www.ninds.nih.gov/
National Institute of Nursing Research	Director	Patricia Grady, PhD, RN	301-496-8230	http://ninr.nih.gov/ninr/
National Library of Medicine	Director	Donald Lindberg, MD	301-496-6221	http://www.nlm.nih.gov/
Warren Grant Magnuson Clinical Center	Director	John I. Gallin, MD	301-496-4114	http://clinicalcenter.nih.gov

C. ELECTRONIC SUBMISSION

Big changes are coming to grants submission at the National Institutes of Health and the Agency for Healthcare Research Quality. Both NIH and AHRQ will soon **require** all competing research grant applications to come in **electronically** via the web portal of Grants.gov on a new SF 424 Research and Related (R&R) application.

NIH is phasing in the changes by type of grant program (mechanism), beginning with the Dec. 1, 2005 submission date for small business (SBIR/STTR) applicants [see [Transition Plan](#)].

Applicants should carefully note the transition date for the grant mechanism for which they wish to apply.

- Once a grant mechanism is transitioned to the electronic mode and the grant opportunity is posted on Grants.gov, applicants will be able to download and begin working on their application package. For instance, if a grant opportunity is posted Oct. 17, applicants will be able to download and begin working on the application package on or after Oct 17. However, they cannot submit the application until the funding opportunity's open date. That grant opportunity may have an open date of Nov. 7 for a Dec. 1 submission deadline. In that case, the applicant can submit an application electronically to Grants.gov any time between the open and submission dates, i.e., any time between Nov. 7 and Dec. 1.
- An applicant must be cognizant of the fact that until a grant mechanism is transitioned, any applications submitted for that grant mechanism should be submitted on paper [PHS 398 forms](#). NIH systems will not be ready to receive those applications electronically until the transition.
- Applications for the transition submission date and thereafter must utilize the SF424(R&R) form and be submitted electronically through Grants.gov. Paper applications will not be accepted after the transition date for a grant mechanism.

As mechanisms are transitioned, Funding Opportunity Announcements (also known as Request For Applications and Program Announcements) will be issued in the [NIH Guide for Grants and Contracts](#) and posted in Grants.gov. NIH will usually post a grant opportunity for a minimum of 60 days before the submission date, just as it does today.

What does this tremendous change in grants submission mean for the applicant community? Applicants are encouraged to prepare themselves **now** to participate in electronic submission through Grants.gov [[Preparing for electronic submission](#)]. They are strongly urged to acquaint themselves with the new forms, the technology and changes in the process. They are also urged to regularly visit this website to keep pace with changes in NIH's quickly evolving electronic receipt program.

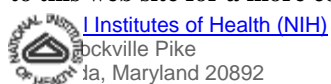
See [Electronic Receipt FAQ](#) for more details on electronic submission. To see the graphical representation of the Electronic Receipt process, [click here](#).

NIH's projected timeline for transitioning various grant mechanisms to the SF 424 (R&R) via Grants.gov to NIH is listed in the table below. (Also see [NIH Guide Notice on Initial Plans](#))

NIH Transition Plan

Type of Grant	Grant Mechanism	Target Submission Date for Non-AIDS Applications	Target Submission Date for AIDS Applications
Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR)	R41,R42 R43,R44	Dec. 1, 2005	Jan. 2, 2006
Support for Conferences & Scientific Meetings	R13 /U13	Dec. 15, 2005	Jan. 2, 2006
Research Dissertation Grant Program	R36	Feb. 17, 2006	May 1, 2006
Academic Research Enhancement Award (AREA)	R15	Feb. 25, 2006	May 1, 2006
Biomedical Research Support Shared Instrumentation Grants	S10	March 22, 2006	May 1, 2006
Interdisciplinary Research Consortium (Roadmap)	X02	April 18, 2006	May 1, 2006
Small Grant Programs	R03	June 1, 2006	Sept. 1, 2006
Exploratory/Developmental Research Grant Awards	R21		
Exploratory/Develop. Research Grant Awards/ (Phase II)	R21 /R33		
Clinical Trial Planning Grant Program	R34		
Research Demonstration and Dissemination Projects (Cooperative Agreement)	R18/U18	Oct. 1, 2006	Jan. 2, 2007
Education Projects	R25		
Research Facilities Construction Grants	C06/UC6		
NIH Director's Pioneer Award Program	DPI	Jan. 16, 2007	
Research Project Grant Program	R01	Feb. 5, 2007	May 1, 2007
Resource	G7,G8,G11,	May 25, 2007	Sept.1, 2007
Minority Biomedical Research Support Thematic Proj. Grant	G13, G20		
Research and Institutional Resources Health	S11		
Disparities Endowment Grants – Capacity Building	S21		
Research and Student Resources Health	S22		
Disparities Endowment Grants – Educ. Programs			
New transition dates for the following mechanisms will be announced soon (see NOT-OD-07-038).			
Career Development (except for K12)	K	June 12, 2007	
Fellowship	F*	Aug. 8, 2007	Sept. 1, 2007
Training	T* & D	Sept. 25, 2007	Jan. 2, 2008
Hazardous Waste Worker Health and Safety Training	U45		
Cooperative Agreement	D71/U2R		
Intl. Training Coop. Agreement/Phase 2 of FIC's	P		
D71	G12		
Centers	M01		
Resource Centers in Minority Institutes Award	S06		
General Clinical Research Center Program	SC1, SC2		
Minority Biomedical Research Support	SC3		
Individual Investigator Initiated Research for Faculty from Minority Serving Institutions	R10/U10		
Co-op. Clinical Research Grants/Co-op. Agreements	R24/U24		
Resource Related Research Projects	U01		
Research Projects (Cooperative Agreements)	U19		
Research Programs Cooperative Agreement	U54		
Specialized Center Cooperative Agreement	U56		
Exploratory Grant (Cooperative Agreements)			
Mentored Clinical Scientist Development Program Award	K12	Oct. 12, 2007	Jan. 2, 2008

This information has been excerpted from the NIH web site <http://era.nih.gov/ElectronicReceipt/index.htm>. Please refer to this web site for a more complete discussion of the subject.



D. REVISED POLICY ON THE ACCEPTANCE FOR REVIEW OF UNSOLICITED APPLICATIONS THAT REQUEST \$500,000 OR MORE IN DIRECT COSTS

Release Date: October 16, 2001

NOTICE: NOT-OD-02-004

The National Institutes of Health (NIH) is updating its policy on the acceptance of applications requesting direct costs of \$500,000 or more for any one year. Effective with the January 1, 2002 receipt dates, applicants must seek agreement to accept assignment from Institute/Center staff at least 6 weeks prior to the anticipated submission of any application requesting \$500,000 or more in direct costs for any year.

Background

The NIH supports research projects with large budgets but needs to consider such awards as early as possible in the budget and program planning process. Regardless of the merit of the application or the budget justification, unanticipated requests for unusually high amounts of direct costs are difficult for NIH to manage. It is in the best interest of all parties if applicants anticipating large direct costs contact the appropriate NIH program staff as early as possible to ensure that an Institute/Center would be willing to accept the application.

This notice clarifies and revises the policy published in the NIH Guide for Grants and Contracts on March 30, 1998.

The current policy advises an applicant planning to submit an investigator-initiated new, competing continuation, competing supplement, or any amended/revised version of the original application requesting \$500,000 or more in direct costs for any year to contact Institute or Center program staff before submitting the application. Discussions with program staff should occur as plans for the study are being developed. However, that notice does not specify a timeframe for this process.

This revised policy requires applicants to seek agreement from Institute/Center staff at least 6 weeks prior to the anticipated submission of any application requesting \$500,000 or more in direct costs for any year. If staff is contacted less than 6 weeks before submission, there may be insufficient time to make a determination about assignment prior to the intended submission date. If the requested dollars are significantly greater than \$500,000, then approval should be sought even earlier.

This policy does not apply to applications submitted in response to RFAs or in response to other Announcements that include specific budgetary limits. However, such applications must be responsive to any budgetary limits specified, or they will be returned to applicants without review.

Procedures

An applicant planning to submit a grant application with \$500,000 or more in direct costs for any year is required to contact in writing or by telephone NIH Institute or Center program staff. This contact should be made during the development process of the application but no later than 6 weeks before the anticipated submission date. If the Institute or Center is willing to accept assignment of the application for consideration of funding, the staff will notify the Center for Scientific Review before the application is submitted.

The Principal Investigator must include a cover letter with the application. That cover letter must identify the program staff member and Institute or Center that has agreed to accept assignment of the application.

An application received without indication of prior staff concurrence and identification of program staff contacted will be returned to the applicant without review. Therefore, NIH strongly encourages applicants to contact Institute or Center staff at the earliest possible time.

Inquiries

For additional information about this policy, the program staff at any Institute or Center may be contacted. Applicants who are uncertain about which Institute or Center may have the greatest interest in the research for which support is sought should contact:

Division of Receipt and Referral
Center for Scientific Review
National Institutes of Health
Telephone: (301) 435-0715
FAX: (301) 480-1987

Source: NIH Guide to Grants and Contracts, October 19, 2001.

The National Institutes of Health (NIH) is pleased to announce the publication of the revised NIH Grants Policy Statement (NIHGPS, rev. 12/03). The NIHGPS (12/03) is applicable to all NIH grants and cooperative agreements with budget periods beginning on or after December 1, 2003. This revision supersedes, in its entirety, the NIH Grants Policy Statement (03/01) as a standard term and condition of award. However, the March 2001 NIHGPS continues to be the standard term and condition for all NIH grants and cooperative agreements with budget periods that began between March 1, 2001 and November 30, 2003.

The NIHGPS provides both up-to-date policy guidance that serve as NIH standard terms and conditions of awards for grants and cooperative agreements, and extensive guidance to individuals that are interested in NIH grants.

The NIHGPS (rev. 12/03) incorporates NIH policy changes since March 2001, public policy changes, policy clarifications, as well as document enhancements. Sections of the revised policy statement have been rewritten to provide clarity; however, the overall policies in these sections have not changed. The document is available in the following electronic formats: HTML and PDF

http://grants.nih.gov/grants/policy/nihgps_2003/index.htm. Links to the 10/98 and 3/01 NIHGPS will remain the same.

NIH will publish interim grants policy changes through the issuance of NIH Guide Notices. Each change will be described, including its applicability and effective date; and the necessary language to implement it as a term or condition of award provided.

Policy changes that are implemented with the 12/03 NIHGPS include:

- Closely related work: the option for grantees to pursue prior approval to account for multiple projects under a single cost objective has been eliminated. NIH will now apply the relatedness provision of OMB Circular A-21 (C., 4., d., (3)) to all NIH recipients which states if a specific cost can not be reasonably allocated to a specific project; it can be charged to any of the benefiting projects on any reasonable basis.
- Cost transfers: policy now states that transfers of costs from one project to another or from one competitive segment to the next solely to cover cost overruns are unallowable.
- Cost overruns: included a definition to the glossary that states: "Any amount charged in excess of the Federal share of costs for the project period (competitive segment)."

Below are examples of NIH policy changes that have occurred since March 2001. Please note that the list below should not be considered all-inclusive; therefore, please refer to the NIH Guide for Grants and Contracts for details on other changes since March 2001: <http://grants.nih.gov/grants/policy/notices.htm>.

- Expanded Authorities: Application of expanded authorities as a standard term and condition to all NIH awards.

Examples of the latest changes in the application submission policies:

- NIH will continue to accept no more than two revised applications after the submission of the original application; however, the two year limitation has been eliminated;
- Resubmission of Application policy changed to allow grantees to resubmit unfunded applications as new applications in the following instances: 1) unsuccessful applications for an RFA can be resubmitted as a new investigator-initiated application; 2) previously unsuccessful investigator-initiated applications can be resubmitted in response to an RFA as a new application; and 3) unfunded applications that are reviewed for one research grant mechanism may be resubmitted for a different grant mechanism and should be prepared as a new application.
- Data Sharing: Implementation of the NIH data-sharing policy.
- Just-in-Time procedures: Expanded to include option to submit IACUC approval.
- NRSA Section Highlights: In accordance with the amendment of the Public Health Service Act, NIH renamed the National Research Service Awards to the Ruth L. Kirschstein National Research Service Awards;
- Includes the regulatory changes of NRSA part-time training;

- Audit: Threshold for A-133 audits has increased from \$300,000 to \$500,000 for fiscal years ending on or after 12/31/2003.

Public Policy Changes that are discussed in the 12/03 NIHGPS:

- Stem Cell Research
- USA PATRIOT Act
- Public Health Security and Bioterrorism Preparedness and Response Act of 2002
- HIPAA Privacy Rule

Policy Clarifications since March 2001:

- Clinical Practice Compensation (Institutional Base Salary): Compensation may be considered in the institutional base salary as long as all criteria are met: 1) clinical practice must be guaranteed by the university, 2) clinical practice must be reported on the university's appointment form and paid by the university, and 3) clinical practice effort must be included and accounted for in the university's effort reporting.
- Key Personnel: Expanded definition to describe the contribution of key personnel as "measurable" whether or not salaries are requested. Zero percent effort and "as needed" are not acceptable for individuals that the grantee identifies as key personnel.
- PI Eligibility: Elaborated on eligibility criteria for certain mechanisms/programs; no change in policy.
- A discussion on the unallowability of patent costs has been added to the NIHGPS. The policy now states that Invention, Patent, or Licensing Costs are unallowable as either direct or F&A costs because the creation of intellectual property is not a requirement of NIH grant awards. Such costs include licensing or option fees, attorney's fees for preparing or submitting patent applications, patent maintenance, or recordation of patent-related information.
- Consortium Written Agreements: Outlined that it is the responsibility of the grantees to include applicable requirements of the policy statement in their written agreements and highlighted that agreements must also include a reference to the financial conflict of interest policy, intellectual property, and data sharing requirements.
-

Document Enhancements:

- NIH Grants Policy Statement and the PHS 398 application glossaries have been merged, where appropriate.
- Other Support Policy: Previously located in the PHS 398 application has been included in the NIH Grants Policy Statement.
- Glossary included in a table format.
- Select Items of Cost section included in a table format.
- Bayh-Dole Inventions reporting requirements are now included in a table format.
- Cross Referencing Roles with eRA: NIH Grants Policy Statement role titles have been cross-referenced with the NIH eRA role titles, e.g., authorized organizational official (also known as the signing official).
- Abbreviations and acronyms: are used throughout the policy statement without parenthetical; therefore, readers should refer to the master list to identify unfamiliar terms abbreviations and/or acronyms.
- Index included.

Additional Inquiries

Additional questions about the NIHGPS may be directed to the NIH Division of Grants Policy at (301) 435-0949 or the Grants Management Specialist that is identified on the NIH Notice of Grant Award.

The full publication can be found on-line at:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-009.html>

MEMORANDUM

TO: Grant Manual Users
FROM: Alan Schreiber, M.D.
DATE: November 28, 2007
SUBJECT: Comments

As you use this manual, please take a moment to give us your comments and suggestions about its content. In our effort to give you the most useful information in a readable format, we need your help to point out what’s missing or what could be improved. Please circle your responses.

Format: The manual is well-organized and easy to use.

strongly agree agree neutral disagree strongly disagree

If you disagree or strongly disagree, please suggest where we could improve: _____

Content: I refer to the manual frequently.

strongly agree agree neutral disagree strongly disagree

The most/least helpful sections of the manual are:

(Please use an X to identify the most helpful and an O to identify the least helpful sections.)

- The Basics of Grant Writing _____
- Lessons from the Experts _____
- Where Can I Go for Help? _____
- Budget and Administrative Issues _____
- Clinical and Health Care Research _____
- NIH Structure and Policies _____

Use the back to provide additional comments. Thank you for your time and consideration. We will use your suggestion to improve the next edition. Please return the completed form and comments to:

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