

# NIH Extramural Nexus

WHERE GRANTS POLICY, PROGRAM COORDINATION, COMPLIANCE AND ELECTRONIC RESEARCH ADMINISTRATION CONVERGE

September 2006

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## NEWS FROM THE DIRECTOR OF OER: Fostering New Investigators is a Community Effort



Dear Extramural Community:

I am writing today to highlight both my concern for the ability of newly-trained investigators to become independent investigators and to reiterate NIH's deep commitment to do all that we can to help them. The biomedical research enterprise cannot continue its remarkable record of discoveries and productivity without a continuous stream of dynamic new investigators.

A 1998 report from the National Academy of Sciences, titled [Trends in the Early Careers of Life Scientists](#), documented the increasing age at which scientists become Principal Investigators on NIH research grants. These trends have continued (Figure 1) along with the age at which new faculty members are hired in medical schools (Figure 2). Because most universities permit only faculty members to apply for grants, the relationship between hiring trends at universities and the age at which new faculty apply for grants is almost certainly causal. The influence of NIH policies on the increasing age of faculty is harder to explain. The Trends report suggests longer periods of training account for these observations, but the rationale for extended training periods is not clear. At least in my view, these changes reflect complex demographic, cultural and economic factors that remain to be identified.

Figure 1



Figure 2



(Click on thumbnails for larger version)

Regardless of the cause, the aging of the workforce is a reason for concern. New investigators bring fresh ideas and technologies to biomedical research, and they pioneer new areas of investigation. Replenishment of the ranks of independent, NIH-funded researchers is essential to the health and vitality of our research mission. Our interest in this area is understandably deep and longstanding.

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[Overweight in Early Childhood Increases Chances for Obesity at Age 12](#)

[NIEHS Awards \\$3.6 Million to Outstanding New Environmental Scientists](#)

[New Method of Gene Therapy Alters Immune Cells for Treatment of Advanced Melanoma; Technique Also May Apply to Other Common Cancers](#)

[Advanced HIV Drug Approved for Resistant Infections](#)

[Test Enables Quick Diagnosis of Flu Strains](#)

Over the years, NIH has created multiple programs to assist new investigators in obtaining independent research funding. The overall number of new investigators on research grants (R01, R29, R37 awards) has in fact increased from 1,421 to 1,561 between 1995 and 2005. In spite of our efforts, however, new investigators have remained between 24 and 26 percent of Principal Investigators on competing R01 equivalent awards for more than a decade. Additional information and data are available at the [Resources for New Investigators Web page](#).

We continue to provide investigators advantages and opportunities in the following ways:

- ◆ **Peer Review and Award:** Currently, we encourage new investigators to self-identify by checking a box on the face page of their applications. New investigators so identified are given special consideration at peer review and at the time of funding. Peer reviewers are instructed to focus more on the proposed approach than on the track record and to expect less preliminary information than would be provided by an established investigator. At the time of award, NIH Institutes and Centers give new investigators special consideration when selecting applications for funding and some [provide longer periods of support](#). The Center for Scientific Review also is conducting a [pilot](#) that will allow new investigators to revise a grant application that missed the funding cut-off and to submit that revision for the next review cycle. The findings from this pilot will become available during fiscal year 2007.
- ◆ **Pathway to Independence Awards:** NIH Director Dr. Elias Zerhouni recently announced the development of a new award that bridges research dependence to research independence (see the [April 2006 NIH Extramural Nexus](#)). The Pathway to Independence Award includes a one- to two-year mentored phase to complete the period of postdoctoral training, followed by an independent phase of three to four years that will allow the recipient to find a tenure-track or equivalent position and build a record of independent support. The NIH expects to make between 150 and 200 Pathway awards each year as a means of fostering the early independence of new investigators. Nearly 400 applications were received on the first receipt date and some are being considered for award this fiscal year. More information on this program is available at the [New Investigators Web site](#).

The NIH remains committed to identifying and attracting new independent biomedical researchers and will continue to look for additional ways to support new investigators. However, the NIH cannot do it alone. Institutions—our partners in this venture—must continue to look for opportunities to reduce the duration of graduate and postdoctoral training as well as find new ways to permit young scientists to apply for research funding. Certainly, we all need to be more creative in our recognition of the extraordinary achievements of young scientists, even before they are appointed to the faculty.

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## INSTITUTE AND CENTER NEWS LINKS

[NHGRI Newsroom](#)

[NCRR Reporter](#)

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It will take the combined efforts of NIH staff, working with our extramural partners, to foster innovation at all levels of the research enterprise. I welcome any new ideas you might have. Please feel free to send them by email to [DDER@mail.nih.gov](mailto:DDER@mail.nih.gov).

— *Norka Ruiz Bravo, Ph.D.* - Director, OER and NIH Deputy Director for Extramural Research

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## COMMENTS WANTED!

The following are published or forthcoming Requests for Information for which the NIH seeks public comment and input: Roadmap Initiatives; Application Appendices and Application Research Plan; and a proposal for a Genetic Repository.

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### NIH Roadmap for Medical Research: NIH to Request Public Comment on Roadmap Initiative Ideas

## » Announcements

### NIH GRANTS INFORMATION OFFICE TO ATTEND 2007 SCIENTIFIC MEETINGS

Representatives of the NIH Grants Information Office will be on hand at [several 2007 scientific meetings](#) to discuss NIH extramural research, funding opportunities, research training programs and the electronic application submission process. Be sure to visit their booth!

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### NIH ELECTRONIC SUBMISSION WORKSHOP AT THE SOCIETY FOR NEUROSCIENCE ANNUAL MEETING, OCTOBER 14-18 IN ATLANTA, GA

As part of the outreach



The [July 2006 NIH Extramural Nexus](#) featured the new process for idea solicitation and initiative selection for the [NIH Roadmap for Medical Research](#) now managed under the auspices of the [Office of Portfolio Analysis and Strategic Initiatives](#) (OPASI).

The first part of the process has begun. Several meetings have taken place to help senior NIH leadership identify crosscutting needs and challenges in biomedical research that meet the criteria for Roadmap initiatives. NIH Institutes, Centers and Offices also have been nominating ideas for Roadmap initiatives this summer. Idea descriptions from both activities will be posted for public comment and input this fall when the NIH launches a Web-based Request for Information (RFI) soliciting a broad range of input and ideas from both science and lay communities. The RFI will be released **mid-October 2006** in the [NIH Guide for Grants and Contracts](#), providing an opportunity for respondents to comment on the ideas already suggested and/or submit new ideas.

Information from this idea nomination process will be posted on the OPASI Web site as it becomes available. Please direct your questions or comments to [askopasi@od.nih.gov](mailto:askopasi@od.nih.gov).

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### Streamlining the Grant Application and Review Process: NIH Seeks

and education program supporting the transition of R01 Research Project Grant applications to electronic submission, staff from NIH Institutes, Centers and the Office of Extramural Research will present a series of [four workshops](#) at the [annual meeting of the Society for Neuroscience](#), October 14–18, in Atlanta, GA. Each workshop will include an overview of electronic grant application submission, a question and answer session, and breakout sessions to facilitate focused discussions of the electronic submission process.

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**PLAN AHEAD!  
UPCOMING OLAW  
EDUCATIONAL  
OPPORTUNITIES**

The Office of Laboratory Animal Welfare (OLAW)-sponsored Institutional Animal Use and Care Committees (IACUC) 101 Series schedule for the remainder of 2006 and for 2007 now is [posted](#).

The December Scientists Center for Animal Welfare (SCAW) Winter Conference in San Antonio has been [announced](#), as are upcoming [SCAW IACUC advanced workshops](#).

Complete details are available on the [OLAW Web site](#).

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## Comment on the Use of Appendix Material and the Optimal Length of the Research Plan Section

In an effort to facilitate and streamline the grant application and review processes, the NIH is considering changes to the inclusion of application appendix materials and to the length of the Research Plan section of the Research Project Grant R01 grant application.

The goal of changing the guidelines for grant application appendix materials is to encourage applicants to be as concise as possible while including the information needed for expert scientific review.

Reducing the current 25-page limit for the Research Plan section of the R01 grant application could allow applicants to focus less on experimental detail and more on key ideas and the significance of proposed projects. It also might facilitate the review process and make it easier to recruit qualified reviewers.

A Request for Information (RFI) was published in the [Federal Register](#), and a similar [Guide notice](#) was published seeking input from applicants, reviewers and other members of the research community regarding the utility of appendix materials in the grants submission, review and management process. All comments due by Thursday, September 14, 2006.

The NIH will seek public comment on the optimal length of the Research Plan. Look for an announcement in the [NIH Guide for Grants and Contracts](#) later this month.

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## NIH Announces Request for Input on Proposed Repository for Genetic Information



The [May 2006 NIH Extramural Nexus](#) highlighted the [NIH's Notice to Applicants for NIH Genome-Wide Association Studies \(GWAS\)](#). Recently, the NIH has issued requests for public comments on a proposed policy in the form of a [Request for Information](#) and a [Federal Register notice](#). The policy, when finalized, is designed to accelerate the research community's access to genetic data resulting from NIH-funded GWAS. Genome-based research eventually will enable medical science to develop highly effective diagnostic tools, better understand the health needs of people based on their individual genetic make-ups, and design new and highly effective treatments for disease.

The proposed GWAS policy covers protections for human subjects, submission of data to a centralized NIH data repository, data access for secondary analyses, publication of findings, and intellectual property issues.

## » Guide Notices

[Delays in Grant Application Submission due to Hurricane Ernesto](#)

[Announcing 2007 NIH Regional Seminars in Program Funding and Grants Administration](#)

[Request for Information \(RFI\): Proposed Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies \(GWAS\)](#)

[NIH Announces Requirement for Detailed \(Non-Modular\) Budget Submissions for All Competing Grant Applications from Foreign \(Non-U.S.\) Institutions](#)

[Revision: Notice of New NIH Policy for Funding of Tuition, Fees, and Health Insurance on Ruth L. Kirschstein National Research Service Awards](#)

[Request for Information \(RFI\): Proposed Change in Grant Appendix Materials](#)

[SF424 Research & Related Senior/Key Person Profile Form Issue—Workaround for](#)

The proposed policy describes the expectation that investigators funded by the NIH for GWAS submit genotypic and phenotypic data to a centralized NIH data repository in a form that will protect the privacy of research participants. The draft policy also outlines the process by which investigators can access GWAS data from the repository, proposes a period of publication exclusivity for investigators who submit the data, and asks that recipients of GWAS data acknowledge the submitting investigator in any published works.

To facilitate research progress, NIH would encourage obtaining a patent for downstream discoveries that would be necessary to develop products to meet public health needs, while discouraging obtaining a patent for early, pre-competitive information that may impede future research.

The NIH hopes to achieve several important goals, including:

- ◆ **Improve Health:** Genome-based research eventually will enable medical science to develop highly effective diagnostic tools, better understand the health needs of people based on their individual genetic make-ups, and design new and highly effective treatments for disease.
- ◆ **Maximize Public Investment:** Centralized access to and broad sharing of genetic information, for appropriate research purposes, maximizes the public's investment in genetic research.
- ◆ **Protect Human Subjects:** Developing a policy that allows for sufficient protections for the privacy and confidentiality of research participants.

The NIH believes that various and complex interests related to the submission of, and access to, GWAS data must be discussed with the public. Wide and rapid access to GWAS data may have implications for participants in studies (and their families and communities), investigators, institutions and industry. Some of the issues on which public consultation will be solicited include:

- ◆ Protections to minimize risks to research participants
- ◆ Creation of a central GWAS data repository at the NIH
- ◆ Expectations for sharing GWAS data
- ◆ Approach to scientific publication
- ◆ Approach to intellectual property

The NIH is soliciting comments on the proposed policy through the [GWAS Policy Web site](#). Comments also can be submitted via email to [gwas@nih.gov](mailto:gwas@nih.gov). A town hall meeting also is planned for early December 2006.

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[Adding More Than Eight Senior/Key Persons](#)

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[Information & Resources](#)

**NEW FUNDING OPPORTUNITIES A CLICK AWAY**

The NIH maintains an up-to-date list of new and active funding opportunities, including [Requests for Applications \(RFA\)](#) and [Program Announcements \(PAs\)](#). Presented in table format, site visitors can sort these lists by Announcement Number, Issuing Institute or Center, Release Date, Opening Date, Expiration Date, Activity Code or Title. RFAs and PAs are linked directly to the formal announcement and where applicable, related announcements. Book marking in your Internet browser the Active RFA and PA sites is your fastest way to NIH research opportunities.

**NIH KIDS' PAGE PROVIDES FAMILY-FRIENDLY LEARNING FOR ALL**

**PARTICIPATION IN NIH PUBLIC ACCESS**



The [NIH Public Access Policy](#) requests that investigators funded by NIH submit an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication to the NIH [National Library of Medicine's \(NLM\) PubMed Central \(PMC\)](#). Public Access was created to achieve three goals:

- ◆ **Archive:** A central collection of NIH-funded research publications preserves vital published research findings for years to come.
- ◆ **Advance Science:** The repository is an information resource for scientists to mine more easily medical research publications and for NIH to manage better its entire research investment.
- ◆ **Access:** Provide patients, families, health professionals, scientists, teachers, and others electronic access to research publications resulting from NIH-funded research.

Inclusion of articles in PMC increases exposure for NIH authors—PMC is used by several million people per month. Further, content in PMC is not just free and full text, but is fully integrated with other [NLM databases](#), such as PubChem and GenBank. Records in these databases are linked and accessible to articles in PMC, and vice versa.

To achieve this interconnectivity, authors must submit manuscripts to PMC through the [Manuscript Submission System](#), which converts word- processing files and portable document format (PDF) files into an archival format that can be integrated into the NLM family of databases. This conversion process, known as *tagging*, requires author verification to ensure the integrity of the article in a process similar to reviewing galley proofs.

NIH has been involved in extensive discussions with a variety of publishers to simplify compliance for authors. Three models of journal/author effort have emerged:

**Models of Publisher Facilitation of Public Access**

	<b>No Author Action Required</b>	<b>Authors Approve Article Tagging</b>	<b>Authors Submit and Approve Articles Directly</b>
<b>Journal Contribution</b>	Journal submits tagged content to NIH	Journal submits author manuscript or copy-edited PDFs to NIH	None
<b>Examples</b>	<a href="#">PMC journals, PMC (NIH Portfolio) journals</a>	Elsevier journals	Most journals

PMC journals (journals that deposit material in PMC on a routine basis and generally make all their published articles available through PMC) submit tagged, copy-edited

The [National Institute of Environmental Health Sciences \(NIEHS\) Kids' Page](#) is full of resources including information about the environment, environmental health science education and other environmental health topics. From games and quizzes to stories and jokes, the Kids' Page provides practical, fun and interesting facts available in an easy-to-read and understand format. Children are never too young to begin appreciating the marvels of science. Families are encouraged to visit the NIEHS Kids' Page today. Let the learning begin.

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» **Feedback**

**COMMUNICATE WITH THE NIH EXTRAMURAL NEXUS—WE WANT TO HEAR FROM YOU**

[Feedback \(to the Editor\)](#) from recipients and subscribers of the *NIH Extramural Nexus* is vital. Your comments, questions, and suggestions for topics will enable *Nexus* editorial staff to deliver appropriate content to the extramural

versions of all their articles to PubMed Central. PMC (NIH Portfolio) journals are similar to PMC journals, but deposit only articles funded by NIH. Both sets of journals eliminate the need for authors to take any action to comply with the Public Access Policy.

Under the Public Access Policy, NIH investigators are free to publish in any journal they choose. We encourage authors to read their copy transfer agreements carefully and ensure that they do not waive their right to submit articles to PubMed Central. Journals often indicate their level of facilitation of Public Access in these agreements. The [Public Access Frequently Asked Questions Web page](#) provides [sample language](#) for amending transfer agreements.

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## RESEARCH TRAINING GRANT AND FELLOWSHIP NEWS: New NIH Tuition/Fees and Health Insurance Policy Q&As



In August, NIH announced a [new policy for tuition, fees and health insurance costs](#) on Ruth L. Kirschstein National Research Service Awards (NRSA) Institutional Training Grants and Individual Fellowships. A [revised notice](#) corrected minor errors and clarified some questions raised by the community in response to the

original notice. The Office of Extramural Research (OER) has since developed a set of [Questions and Answers](#) that provide further clarification. Note that these are a subset of the larger body of training-related Q&As on the OER NIH [Research Training and Research Career Opportunities Web page](#).

Changes also are in progress to the PHS398, PHS2590, PHS 416-1 and PHS416-9 forms and instructions to bring them into compliance with the announced policy changes. Check the NIH Web site for [updated versions of these application forms](#). Older Program Announcements (PAs) and Requests for Applications (RFAs) may continue to refer to the older policies. Be sure to check the [NRSA Policy Issues Web page](#) for updates before submitting any applications in response to any Kirschstein-NRSA training-related program announcement.

Key policy changes that were announced:

- ◆ The formula for calculating awards was changed from \$3,000 plus 60 percent of the amount requested over \$3,000 to a straight 60 percent of the requested amount. Note that institutions should request their full tuition/fees. NIH will apply the relevant formula.
- ◆ Health insurance costs are no longer considered in the category of Tuition/Fees/Health Insurance and so are not subject to the above formula. Rather, these costs have been shifted to the Training Related Expenses Category (training grants) or the Institutional Allowance Category (individual fellowships).
- ◆ Training-Related Expenses (training grants) or Institutional Allowance

community.

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(fellowships) have been adjusted to include NIH contributions toward health insurance for NRSA mechanisms and for both predoctoral and postdoctoral levels of training.

Many of the questions from the community have dealt with the phase-in of these changes. Different policies will apply to different grants based on the Fiscal Year (FY) (October 1–September 30) of the most recent competing award. The Q&A site includes a table illustrating how this will work. This table shows:

- ◆ **Competing Awards issued in FY05 or earlier:** Nothing is changed for any years. Current and recommended budgets will not be adjusted. The awards will continue to be administered under the policy in effect at the time of the last award.
- ◆ **Competing Awards issued in FY06:** FY06 awards will not be adjusted. FY07 Non-Competing Continuation years will be adjusted to the new policy levels and future Non-Competing Continuation years will be shown at the adjusted level. Note this adjustment will be made by NIH staff and will be based on the tuition/fees requested in the FY06 Competing Application.
- ◆ **Competing Applications submitted for FY07:** should use the New Policy to make their budget requests. FY06 stipend levels should be used until FY07 stipend levels are announced, but the new policy for tuition/fees and training-related expenses (including health insurance) should be used.

For answers on how the new policies affect any specific grant award, contact the NIH program and grants management staff members whose names were listed in the most recent Notice of Award that you received. Also available are general listings of NIH Institute and Center [Chief Grants Managements Officers](#) and [Training Contacts](#).

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### **ELECTRONIC SUBMISSION NEWS: Mark Your Calendars, We've Come a Long Way! "Lessons Learned—Preparing for Electronic Grant Applications"**



To prepare the applicant community for the upcoming transition of NIH Research Project Grant Program R01s to electronic submission in February 2007, NIH will hold a training event on December 5, 2006, geared toward extramural grant applicants. With a year of electronic submission under our belt, our focus will be on lessons learned and sharing our advice on best practices for submitting applications online.

As a bonus, we will host "hands-on" computer labs giving applicants the opportunity to practice the submission process with eSubmission experts. The training event will take



place on Tuesday, December 5 (labs will be offered on Tuesday and Wednesday), at the Natcher Conference Center (Building 45), Main Auditorium, NIH Main Campus.

A [preliminary agenda is available](#). Additional details and registration are coming soon! Subscribe to the [Listserv for updates on the Electronic Submission Program](#) to be notified when registration becomes available.

Complete information about the electronic grant application submission is available at the [Electronic Submission Web site](#).

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## MODULAR MYTHS YOU CAN MUSE

**MYTH #1:** Although the grantee institution is submitting an application using the modular format, consortium participants must provide detailed budgets.

**FACT #1:** Detailed budgets for consortia are not required by the NIH; however, applicant institutions must be able to reasonably estimate the total (direct, facilities and administrative) cost of the consortium arrangement to the nearest \$1,000. Therefore, applicant institutions may request from consortium participants information necessary for making this estimate, but should only provide the following for each Consortium in the application:

- ◆ Estimate of total costs (direct plus facilities and administrative) rounded to the nearest \$1,000
- ◆ For each key individual/organization listed, the role and percent effort
- ◆ Whether each collaborating institution is foreign or domestic

**MYTH #2:** When calculating the \$250,000 direct-cost level for modular grant applications, all consortium costs (direct and indirect) should be included.

**FACT #2:** In calculating the \$250,000 direct-cost level, the applicant should not include the facilities and administrative (F&A) costs associated with any consortium/contractual arrangements. Those costs may be requested above the normal \$250,000 direct cost limit. Fields are provided to separately capture consortium F&A costs for each budget year. See *NIH Guide* notice [NOT-OD-05-004](#).

**MYTH #3:** When transferring a grant, a detailed budget must be submitted from the new institution even though the original application was awarded in the modular format.

**FACT #3:** If the original award used the modular format, then the application from the new institution should use the application instructions and forms for a modular grant.

**MYTH #4:** The modular format is applicable to Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) applications.

**FACT #4:** Although the modular format was previously available to SBIR/STTR applicants, the modular format was excluded from SBIR/STTRs beginning with the 2005 Omnibus Solicitation (see the [2006 Solicitation](#)). Therefore, all **competing SBIR and STTR applications must be submitted with a detailed, categorical budget.**

You can find more interesting facts at the newly revised [Modular Research Grant Application Frequently Asked Questions \(FAQ\) Web page](#). In addition, check out the [NIH Modular Research Grant Applications Grant Web site](#), which has a new look with updated links, data charts on IC modular funding trends, evaluative information and more.

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### **THE NEXUS FILES: Advice From NIH “Insiders” That Can Make a Difference in the Grants Process**



**Referral Refresher.** Who or what determines which study section reviews your grant application and the Institute or Center (IC) that will consider funding? In part, you do! During the referral process, the NIH reviews the content of the sections of the Research Plan (especially the Specific Aims and Background/Significance) to determine the study section selected to review your application. In

addition, a cover letter is a valuable tool to provide requests for assignment (Review Group and/or IC), identify other applications if the submission is part of a collaborative group, and identify any conflicts. Word to the wise: DO NOT use the cover letter to identify favored reviewers, convey scientific content or as a substitute for the Introduction. Consult your application guide/instructions for further guidance.

**The \$500K Delay!** Any investigator-initiated application requesting exactly \$500,000 or more in direct costs for any year of the project must seek agreement from IC staff at least six weeks prior to the anticipated submission date. It does not include indirect costs associated with any subcontracts. Without NIH prior approval, an application may be returned to the applicant without review. This policy does not apply to Requests for Applications (RFAs) or responses to other announcements that include specific budgetary limits. See *NIH Guide* notice: [NOT-OD-02-004](#).

**What’s Your Type?** Just a reminder: font typefaces for grant applications are restricted to Arial, Helvetica™, Palatino™, Linotype, or Georgia®. The “Insider” recommends Georgia font for grantees who like the look of Times New Roman. The font size should be 11 points or larger and applies to all text portions, including the Biosketch, Literature Cited, etc. It also applies to all text sections of paper submissions and all portable document format (PDF) files for electronic submissions. You can use a smaller font size for the following (ensuring that it is readily legible and follows the font typeface requirement): figures, graphs, diagrams, charts, tables, figure legends, and footnotes. The “Insider” suggests that you follow the Golden Rule and submit an application that you would find easy to read if you were in the reviewer’s chair.

**Moving Day?** If you're a Principal Investigator planning to transfer from your current institution, don't wait until the last minute to make arrangements for transferring your grant. Start early and begin communication with both your institution's research administration offices and the assigned grants management specialist in your awarding NIH IC as soon as possible. The transfer process at NIH requires prior approval and takes time to process. You can find more information in the [NIH Grants Policy Statement \(12/03\)](#) at [Part II: Terms and Conditions of NIH Grant Awards - Subpart A: General -- File 4 of 5 \("Change of Grantee Institution"\)](#).

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