



SPN Cancer Health Disparities Summit

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Grants Administration Branch

National Cancer Institute



GRANTS ADMINISTRATION BRANCH, NCI

- *The Grants Administration Branch (GAB) is responsible for monitoring NCI's grants process to ensure that all required business management actions are performed by the grantee and the Federal Government in a timely manner, both prior to and after award.*



GAB

- *GAB serves as the focal point for all business-related activities associated with the negotiation, award and administration of grants and cooperative agreements supported by the NCI.*
- *In FY 2003 GAB will award a projected \$3.1 billion in grants and cooperative agreements.*



GAB

- *In FY 2003 GAB staff will process over 11,000 grant actions and 7,500 initial grants .*
- *A typical portfolio for an NCI grants management specialist is greater than 180 grants involving more than 340 grant actions totaling more than \$83 million.*



GRANTS ADMINISTRATION

NEWS TO USE



New NIH Policy on Data Sharing

- *Investigators submitting a research application requesting \$500,000 or more direct costs in any single year must include a plan for sharing final research data for research purposes, or state why data sharing is not possible.*
- *Receipt dates on or after October 1, 2003.*
- *See NIH Guide Notice 02/26/2003*
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>



New NIH Policy on Data Sharing

Final Research Data: Factual material commonly accepted in the scientific community as necessary to document, support and validate research findings



New NIH Policy on Data Sharing

Why? To expedite the translation of research results into knowledge, products, and procedures

Expectation? Data should be made as widely and freely available as possible while safeguarding the privacy of participants, and the confidentiality and proprietary nature of the data



New NIH Policy on Data Sharing

Cost: Applicants may request funds for data sharing and archiving in their grant applications.

Timing: NIH expects the release and sharing of data no later than the acceptance for publication of the main findings from the data set.

Privacy: Prior to sharing, data should be redacted to strip all identifiers that could be used to identify participants.



HIPAA

*Health Insurance Portability and
Accountability Act of 1996 (HIPAA)*

Effective April 14, 2003



A Researcher Must Comply with the Privacy Rule if He/She is ...

A “covered entity,” which includes:

- *A health care provider who transmits protected health information (PHI) electronically for any one of eight covered transactions, potentially including researchers who are employed by a covered entity*
- *A set of decision tools answering “Am I a Covered Entity?” may be found at <http://www.hhs.gov/ocr>*



The Privacy Rule applies to one type of information

Protected Health Information (PHI)

- *Health information + Identifier = PHI*
- *Transmitted or maintained in any form*
- *Decedents' information included*
- *Does not include de-identified health information or biological tissue*



Privacy Rights Affecting Research

The Privacy Rule generally entitles individuals to:

- *Access to their health records*
- *Receive an accounting of disclosures*
- *Revoke an authorization*



New Concepts Introduced by the Privacy Rule

- *An individual's written authorization is required for PHI use or disclosure unless waived or excepted*
- *Must be for a specific research study – **blanket authorization not permitted***
- *Authorization waivers can be granted by IRBs or Privacy Boards*
- *Decedent's information is protected but authorization is not required*
- *Accounting and reporting*

Additional Information on HIPAA

- *The Office of Civil Rights website
<http://www.hhs.gov/ocr/hipaa/>*
- *NIH Guide Notice published on February 5, 2003:
Impact of the HIPAA Privacy Rule On NIH Processes
Involving the Review, Funding, and Progress
Monitoring of Grants, Cooperative Agreements And
Research Contracts.
<http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>*



Loan Repayment Program

- *Provides for the repayment of the educational loan debt of qualified health professionals pursuing careers in:*
 - *clinical*
 - *pediatric*
 - *contraception and infertility*
 - *health disparities research*
- *Covers up to \$35,000/year (principal & interest), plus Federal taxes*
- *Payments are contracts (not grants) and disbursed directly to the financial institution holding the education loan*
- *Eligibility no longer limited to NIH grantees*

Loan Repayment Program website: <http://www.lrp.nih.gov/>

Listserv for information on next application cycle. <http://www.lrp.nih.gov>



Non-Competing Continuation Grant Progress Report

*Last pre-printed “hard copy” Face Pages mailed in
June 2002 for November 2002 start dates*

*Beginning with December 2002 start dates, grantees
use the following website to identify progress report
due dates: http://era.nih.gov/userreports/pr_due.cfm*

NIH Guide Notice: August 13, 2002

<http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-066.html>



PHS 398 and 2590 - Requirements for Reporting Race and Ethnicity

- *Investigators must follow OMB standards for collecting data on race and ethnicity of research participants*
- *Requires asking subjects minimum of 2 questions:*
- *Ethnicity (Hispanic or non-Hispanic)*
- *Race with option to select more than one*

Change in Policy on Resubmission of Applications

Effective for submissions submitted on or after May 10, 2003:



Unfunded applications for an RFA should be resubmitted as NEW investigator initiated applications



Previously unfunded investigator-initiated applications subsequently submitted in response to an RFA should be prepared as NEW applications.



Unfunded applications reviewed for one research grant mechanism submitted for a different grant mechanism should be prepared as NEW applications.

- *NIH Guide Notice January 16, 2003:*

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-019.html>



Important Reminder On Certificates Of Confidentiality

- *Certificates are issued by NIH to protect identifiable research information from forced disclosure*
- *They constitute an important tool to protect the privacy of research study participants*
- *Information is available at the Certificate Kiosk
NIH Guide March 15, 2002 ,
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-037.html>*



Financial Conflict of Interest

- *Notify awarding component Chief GMO.*
 - *Assure that the conflicting interest is being managed, reduced, or eliminated.*
- *Provide additional information if requested.*
- *Should be addressed in consortium agreements.*



New Publication: Financial Conflict of Interest Policy Analysis

- *NIH reviewed a sample of financial COI policies from 300 institutions*
- *Resulting analysis organized into three sections*
 - 📖 *Findings*
 - 📖 *Helpful Suggestions and Areas of Concern*
 - 📖 *Other Issues to Consider*
- *NIH published document as an educational tool to promote awareness of and compliance with Federal financial conflict of interest regulations.*
http://grants1.nih.gov/grants/policy/coi/nih_review.htm



IMPORTANT REMINDERS

- NIH requires complete and up-to-date other support information before an award can be made
- Grantees must report changes in other support as part of the annual progress report
- NIH policy requires a countersignature from an authorized official of the grantee institution on all information submitted to NIH.



IMPORTANT REMINDERS

- *Certification of IRB approval is needed for each application – including applications for pilot projects*
- *GMO prior approval is required for rebudgeting funds restricted by term of award.*
- *The Grants Management Specialist should be copied on all correspondence requesting NCI prior approval. Only the GMO has the authority to grant prior approval when needed.*
- *GAB Website: <http://www3.cancer.gov/admin/gab/index.htm>*

The National Cancer Institute Presents...

**Everything You Wanted
to Know About the
NCI
GRANTS
PROCESS...**

**But...
Were Afraid
to Ask**

Grants Administration Branch