

Research Administration
The Year in Review

NCURA Region I
RADG
December 10, 2008
Boston, MA

Panelists

Audit

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Conflict of Interest & GWAS

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NIH Public Access Policy

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Audits: Current Developments & Issues For Research Organizations



RADG Meeting December 10, 2008

Mark Daniel,

Vice President, Research Administration & Finance

Dana Farber Cancer Institute



The Current Audit Environment

- The current situation was summed up well earlier this year by COGR: “The consensus is that we are part of a difficult and unrelenting audit environment”
- “SOX Effect”
 - Filtering into higher-ed and research industry
 - Lower materiality thresholds, less tolerance for errors
- Bottom Line: *We Are Working in the Federally Funded Research Business*



OMB Circular A-133

- OMB Circular A-133 Audits of States, Local Governments and Non-Profit Organizations
- Single Audit Concept vs. Individual Agency Audits
- Issued in 1990 and first reports covered two fiscal years.
- Has been revised since then
- Annual (grantee fiscal year) audit of the organization's compliance with applicable federal regulations.
- Threshold Requirement



SAS 112

- 2007- Implementation of SAS 112: “Communicating Internal Control Related Matters Identified in an Audit”
 - Covers reporting periods ending after 12/06
- What does this mean to you?
 - The bar has been lowered as to what constitutes reporting of internal control matters (deficiencies)-may mean more findings in areas that would not have qualified as a finding in the past.
 - More findings could even lead to a change from “low risk” to “high risk” for a grantee



The A-133 Compliance Supplement

- Since 1996 OMB has also produced the “*Circular A-133 Compliance Supplement*” An important guidance tool for A-133 auditors. Periodically updated.
- For example: a recent (2008) revision that could impact research organizations is in the area of guidance for auditing subrecipient monitoring
 - “the auditor should assess whether the pass-through entity made the proper classification between subrecipients and vendors...”



Examples of Key Items Mentioned in The *Compliance Supplement*

- Allowable Activities and Costs
 - Does the record show that the org. spent grant \$s in an appropriate, allowable, allocable, (to the federal award charged) and reasonable way?
- Compensation and Related Fringe Benefits
 - “employee compensation and related benefits ... comprise a significant portion of total costs ...the auditor should give particular attention to...and be familiar with the payroll distribution methods “ and the means of verification
 - Test that pay rates conform with established policy consistently applied to both federal and non-federal activities



The Government Audits the Auditors

- June 2007- The President's Council on Integrity and Efficiency (PCIE) and the Executive Council on Integrity and Efficiency (ECIE) released their report to determine the quality of Single Audit Program including A-133
- This included a quality review of over 200 A-133 Audits including many from Universities
- This review was driven in part by a concern over lack of findings and questions on the reliability of the process



The Government Audits the Auditors

- Two Groups:
 - Large Entities Spending > \$50M
 - Approx 36% were either of limited reliability or unacceptable
 - Smaller Entities Spending \$500K to \$50M
 - Approx 52% were limited or unacceptable
- What does this mean to you?
 - Additional pressure on audit firms to be more rigorous and comprehensive? More scrutiny on grantees ...



The Government Audits It's Own Research Agencies

- IGs have also conducted audits of federal research agencies
 - For example: DHHS IG Report on the NIH Monitoring of Research Project Grants
 - “Late progress reports...”
 - “Late close-outs...”
 - “Deficiencies exist in financial oversight or RPGs...”
 - What does this mean to you as a grantee?



In Addition to the “Usual Suspects”- Some Newer Ones ...

- Subrecipient Monitoring
- P-cards with Grants
- System Audits and Controls
 - Do the right people have the right level of access to PeopleSoft or other core systems? Who controls and maintains?
- COI, Pub Med, Progress Reporting
- In addition to the A-133, Federal agency reviews are increasing. May review individual award(s) or systems and controls.
- Reports are shared



Final Thoughts

- Make sure you have or are followed through on prior year ***mgt. responses and corrective action plans*** – make sure you did what you said you were going to do and it's documented. This is being monitored more closely and it will be harder in the future to get a “pass”.
- More critical than ever to take advantage of your Internal Audit function...use it as a resource to support your research compliance- proactive approach

Director
Research and Information Systems

STEPHEN DOWDY

Grants.gov

- Grants.gov BLOG
 - <http://grants-gov.blogspot.com>
 - PMO updates
 - System Status
- RSS Feeds (new ops)
 - Eliminate e-mails

Transition to Adobe

- November 30, 2008 – last day for agencies to post PureEdge
- January 31, 2009 – last closing date for PureEdge
 - Most receipts after Jan 1 need Adobe
 - NSF, NIH, DOA, DOE
- February 20, 2009 – grace period ends for PureEdge

FFATA

- Andrea - LOL
- “Pilot” or “Proof of concept”
- OMB takes the “black” mark
- Obama

Future

- We must have 10^6 - 10^7
- Cloud Computing
- Concentration on data
 - No more forms
- Funding
- S2S

- YOUR VOICE



2008 in Review:
PHS COI Requirements and
GWAS

NCURA Region 1

RADG

December 10, 2008

Mary Mitchell

Overview of Federal Agency COI Requirements

- PHS and NSF are the only federal agencies with final COI regulations.
- PHS regulation is available at:
http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm
- NSF policy is available at
http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510
- Federal agencies without final regulations may elect to include COI or contractor code of business ethics and conduct requirements in grant agreements or contracts through inclusion of FAR or agency-specific clauses.
- The FY 2009 Department of Defense (DOD) Authorization Act includes a new conflict of interest requirement that is applicable to contracts and subcontracts in excess of \$500,000 whose work is considered “inherently governmental functions.”

Basic PHS COI Requirements

- Requires each grantee establish a policy that includes
 - Investigator disclosure of financial interests for determination of whether a conflict exists and how it should be managed, reduced, or eliminated.
- Defines “research,” “significant financial interest,” and “investigator.”
- Specifies
 - When disclosure forms should be collected: time of application
 - When disclosure forms should be updated: annually or when a financial interest changes or new reportable interests are obtained) and
 - When conflicts should be reported: prior to expenditure of funds or no later than 60 days after identification of change or new significant financial interest.)
 - To whom they should be reported: Institute/Center providing funding.
- Applies to all award types (e.g., RO1, R21, K08, etc.) with the exception of Phase I Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) program applications or awards.

PHS Institutional Responsibilities

- Develop & maintain written policy
- Designate Institutional Official
- Require disclosure “by the time an application is submitted”
- Certify COI policy & procedure at time of application.
- Annual or other updating of disclosures during award
- Report conflict & management plan to PHS prior to expenditure of funds
- Require compliance by subcontractors.
- Maintain records 3-years post final FSR filing

PHS Definition of Investigator

- **Investigator** – Principal Investigator (PI) and any other person who is responsible for the design, conduct, or reporting of research funded by PHS or proposed for such funding.
- The term “Investigator” includes the Investigator’s spouse and dependent children.
- An *Investigator* is not just the Principal Investigator or Senior/Key Personnel conducting the PHS-sponsored research.
- Institutions should consider an individual’s role, rather than title, and their degree of independence when applying the definition.

PHS Definition of Significant Financial Interest

- **Significant Financial Interest:** “Anything of monetary value, including but not limited to salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g, patents, copyrights and royalties from such rights.)”
- **Excludes**
 - Salary/royalty/other payment from applicant
 - Income from seminars, lectures, teaching, or advisory committee service for public or nonprofit institutions
 - Equity not exceeding \$10,000
 - Salary, royalty or other payments in next 12 months not exceeding \$10,000

PHS Reporting Requirements

- **At the time of application:** Investigators must submit known significant financial interests to the institution.
- **Prior to the expenditure of funds:** The institution must report a financial conflict of interest to the NIH and assure that it has been managed, reduced, or eliminated.
- **COI identified after the initial report:** The institution must report within 60 days of identification and assure that it has been managed, reduced, or eliminated.

PHS COI Reporting

- All COI reports should include the following information:
 - Grant number;
 - Name of Principal Investigator (PI) or contact PI if multiple PI award;
 - Name of Investigator with the COI; and
 - Distinguish which method was used to protect the research from bias (e.g., managed, reduced, or eliminated).

PHS COI Subrecipient Requirements

- Prime has the option of requiring
 - Subrecipient Investigators to comply with the its institutional policy OR
 - Provide assurances to the grantee institution that it will comply with the PHS regulation through own institutional policy

Make sure you include COI language in your subagreements.

Remember: Grantee institution is required to report subs COI conflicts.

NIH 2008-09 COI Activities

- Engaged in system-wide review of COI policies, procedures, and guidance
- Developed eRA Commons FCOI module/reporting tool for grantees
- Updated FAQs and a Web-based tutorial
 - For grants, cooperative agreements, and contracts
- Developed Web based reporting and tracking tool for NIH staff
- New FCOI mailbox (FCOICompliance@mail.nih.gov)
- NIH Guide Notices and reminders to grantee community.
- Routine follow-up for add'l information when grantees report conflicts.
- COI site visits contemplated in 2009.
- As requested by Congress, NIH is developing an Advanced Notice of Proposed Rule Making to gather public comment on possible revisions to the COI regulation.

COI 2009 New Year's Resolutions

- Sample files to determine compliance with PHS disclosure and reporting requirements.
- Make sure collection of disclosure forms is consistent with the definition of “investigator.”
- Educate Investigators and Administrators.
- Review policy and procedures.
- Consider updating disclosure form.
- Review process for reviewing disclosures and determining whether a COI exists
- Review current conflict management plans, follow-up and monitor.
- If institution requires multiple disclosures for different purposes, consider establishing COI data warehouse.

NIH Resource: Expanded COI FAQs

- For all NIH-supported Institutions
- Categorized for ease of reference:
 - General Questions
 - Institution-Specific Questions
 - Investigator-Specific Questions
- Web Postings and Resources at:
 - <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-063.html> and
 - <http://grants.nih.gov/grants/policy/coifaq.htm>

NIH Resource: Web-based Tutorial on COI

- Reviews requirements of and responsibilities for compliance with Federal FCOI regulations
- Designed for use by:
 - **Institutional officials** responsible for managing NIH-funded grants, cooperative agreements and/or contracts
 - **Individuals** who are responsible for the design, conduct or reporting of NIH-supported research.
- Includes quizzes to test understanding

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-106.html>

Conflict of Interest

Discussion

And now for something
completely different...

GWAS:

Genome Wide Association Studies

*Caution: This presentation is a
work-in-progress*

What are GWAS?

- “Any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits, or the presence or absence of a disease or condition.”

To whom does it apply

- Investigators who receive NIH funding for GWAS in response to **competing** applications submitted with 1/25/08 deadline & beyond.
- Any grant mechanism with a GWAS component
 - Research project grants (Rs)
 - Program projects (Ps) and SCOREs (Ss)
 - Cooperative agreements (Us)
 - Individual career awards (Ks)

To whom does it NOT apply

- Institutional training grants (T32s)
- K-12 career development awards.
- Individual fellowships
- Resource grants and contracts (Ss)
- Facilities or coordinating centers funded through related activities to provide genotyping or other core services in support of GWAS
- Linkage studies

Application Submission

- Attach a cover letter indicating application contains a GWAS component.
- Include a data sharing plan as part of Section K of the research plan.

What the policy includes

- Creates a centralized registry at the National Center for Biotechnology Information (NCBI) in the National Library of Medicine for holding GWAS data.
- Expects NIH-funded PIs to submit data to the NIH Registry along with
 - Copy of the protocol
 - Questionnaires
 - Study Manuals
 - Variable measures
 - Other supporting documentation.

What the policy includes continued....

- Allows for data deposits and withdrawals.
- All data deposited available to the public.
- Submitting PI responsible for all data regardless of source.
- IRB responsible for reviewing consent forms to ascertain sharing of data is consistent with consent.
- IRB responsible for reviewing and verifying prior to submission that
 - Data submission is consistent w/initial consent.
 - PI's de-identification method consistent w/ NIH standards
 - Risks to individuals, families & groups or populations have been considered.
 - Data have been collected consistent with 45 CFR 46.

What the policy includes continued...

- Institutional Official must certify
 - Data submission is consistent with all applicable laws, regulations and institutional policies
 - Research uses/exclusions have been delineated in the consent form.
 - The identify of the individuals will never be disclosed

What the policy includes continued...

- Investigator request data must submit a formal request to a Data Use Committee (DUC) with a Data Use Certification signed by Institutional Official that local PI seeking data will
 - Only use for approved research
 - Protect data confidentiality
 - Follow data security protections.
 - Follow all applicable laws, regs and institutional policies.
 - Not attempt to identify anyone.
 - Not sell data elements.
 - Not share w/anyone not listed on request.
 - Agree to posting of research summary within GWAS repository.
 - Agree to report GWAS policy violations in real time.
 - Provide annual data use progress reports to repository.

GWAS 2009 New Year's Resolutions

- Develop data sharing plan language for PI's to include in grant applications.
- Educate PI's to GWAS requirements.
- Make sure IRB has developed criteria to determine adequacy of initial informed consent.
- Develop an IO certification process.

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NIH Public Access Policy Overview & Update



NCURA RADG 12/10/08



NIH Public Access Policy

- A requirement established to make published research funded by NIH freely accessible to all, in order to advance science and improve human health.
- Effective Date: April 7, 2008

Who does the policy apply to?



- The policy applies to an investigator whose peer-reviewed article is based on work that is:
 1. Directly funded by an NIH grant or cooperative agreement active in FY 2008 (10-01-07) or beyond
 2. Directly funded by a contract signed on or after April 7, 2008



3 Compliance Requirements

- Protect the Copyright
- Submit the article - via the NIH Manuscript Submission system (<http://www.nihms.nih.gov/>), upon acceptance for publication (or insure that the journal will submit for the PI).
- Cite the article - As of May 25, 2008, include the *PubMed Central reference number* (PMCID) associated with the article

Recent Developments – Policy status



- On Sept. 10, Rep. John Conyers, D-Mich., introduced H.R. 6845, [The Fair Copyright in Research Works Act](#), which would put the NIH's public access policy on hold. NIH has said it was acting in compliance with a federal mandate to deposit publications from funded research into its PMC database. Conyers said the bill "would restore intellectual property protections for scientists, researchers, and publishers until a more thorough analysis of the access issues and a determination of an appropriate policy can be performed." NIH is against the bill.



HB 6845

- Proposes to change copyright law to make such policies as Public Access illegal
- Would forbid federal agencies, including NIH, from seeking any rights to the research that they fund or including such language in terms and conditions
- According to LibraryJournal.com, the bill seems to show an interest in keeping up the status quo of the publishing industry. Former NIH director Elias Zerhouni explained that the Public Access Policy is "to maximize the return on investment for the public, which funds the research, and for the scientific community."



Public Access Policy Impact on Scientific Journals

- According to 2003 data, NLM estimates that on an annual basis, publications resulting from NIH-funded research represent approx. 10% of the articles in nearly 5,000 journals indexed by PubMed.
- For only 1% of these journals do NIH-funded articles account for more than half of the total published articles.
- NIH provides funding through both direct and indirect costs for publication/subscription expenses



Recent Developments – PHS Follow-up on Grantee Compliance

- Grantees demonstrate compliance by including the PMC reference number when submitting an application which references articles covered under the policy
- NIH has begun notifying PIs and Program Officials via email about articles which appear to fall under the policy but lack a demonstration of compliance by including a PMC citation



Notification E-mail (sample)

- Dear Principal Investigator,

Your recent progress report/competing continuation submission identified papers that have resulted from your NIH award. It appears that the following papers have not yet been submitted for upload to PubMed Central and may be out of compliance with the NIH Public Access Policy:

XXXX, Dddd, XXXX, Cccc. Tre hgfrs Aivpte Prwkz fo glkmn. J Immunol. 2008 Aug 15; 181(4): 2277-84.



Notification E-mail (con't)

- You do not need to resubmit your progress report. Simply ensure the following:
 - 1) If the manuscript(s) were accepted for publication on or after April 7, 2008, please enter these documents into PubMed Central as soon as possible. Information on how to submit manuscripts can be found at http://publicaccess.nih.gov/submit_process.htm
 - 2) Reply to all on to this email with confirmation that your manuscript(s) are in compliance with the NIH Public Access Policy. You can confirm compliance by including the PubMed Central reference number