Northeast Conference on College Cost Accounting (NECA)

“A Look at Compliance From Both an Institutional and Federal Point of View”

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Gary Thompson
Associate Dean for Research Compliance
Harvard Medical School
A Quick Look at NIH

Division of Grants Compliance and Oversight

- OPERA
- External and internal compliance issues
- Proactive Compliance Site Visits
Office of Management Assessment (OMA)

- Grant related allegations in FY2000 were up by 37% from FY99
- Grant-cases to Total-cases was up from 40% in FY99 (30/75) to 53% (41/78) in FY2000
- Most allegations were institutional and involved Universities
Problem Areas

- Misuse of Funds
- Unallowable Costs
- Allocation of Costs
- Accelerated Expenditures
- Cost Transfers
- Effort Reporting
- Financial Conflict of Interest
Common Contributors to Compliance Problems

- Lack of understanding of roles and responsibilities of institutional/Federal staff
- Outdated or nonexistent policies and procedures (lack of management controls)
- Inadequate staff training and education
- Inadequate systems (e.g., effort reporting, financial management, program income, other support)
NIH Proactive Compliance Site Visits

Moving from Reactive Noncompliance To Proactive Compliance
NIH PCSVs: Purpose

To assesses the level of understanding of certain Federal/NIH requirements by discussing policies, procedures, and practices at recipient institutions to ensure compliance with NIH requirements

Is institutional understanding congruent with that of NIH?
NIH PCSVs:  Goals

- Increase NIH’s level of confidence in grantees ability to effectively manage NIH sponsored project funds
- Minimize or eliminate incidents of noncompliance
- Nurture partnership relationship with biomedical research community
Subject Matter Focus

Non-Regulatory:
- Roles and Responsibilities
- Training and Education

Regulatory:
- Financial Management of Sponsored Projects
- Financial Conflict of Interest
- Invention Reporting / Bayh-Dole
- Data and Safety Monitoring
Outcome

- PCSVs 2000: A Compendium
- Available on Grants Compliance and Oversight Page

http://grants.nih.gov/grants/compliance/compliance.htm
Compliance Basics

- Institutional expectation and responsibility
- “Zero tolerance”
- \( c = t + e + o + cdrr \)
- Define R & R
- Build compliance activities into work processes and assign oversight responsibility
- Communicate, Educate, and Partner
  - Communicate, Educate, and Partner
  - Communicate, Educate, and Partner
- REDUNDANCY IN EDUCATION!
Human Subjects Protection

- Informed consent procedures may be inadequate
- Researchers may be putting patients into clinical trials when the patients should not participate in that particular research project
Human Subjects Protection

- The Institutional Review Board (IRB) may fail to properly review a research proposal, may be keeping inadequate records of its review, or holding meetings without proper attendance and/or preparation.

- Researchers are not reporting adverse affects of investigational drugs used on clinical trials to the FDA... and/or they are failing to obtain permission to commercialize a product.
Human Subjects: Possible OHRP Actions Against Institutions

☐ Restrict your “assurance” which will require increased oversight, monitoring, and reporting for particular projects

☐ Suspend an assurance for all or part of an institution, preventing some or all research on patients from continuing until corrective actions have been taken as specified by the OHRP
Possible FDA Actions Against Institutions or Individuals

- Suspending a research project or all research at an institution
- Withdrawing a researcher’s authorization to use an investigational drug, preventing the researcher from conducting any research regulated by the FDA
Animal Welfare

- Animal care practices or protections may not be adequate
- Institutional Animal Care and Use Committee (IACUC) may not be following proper procedures for approval of animal research protocols, or may be keeping inadequate records, or holding meetings without proper attendance
Possible OLAW Actions Against Institutions

- Restrict your “assurance” which will require increased oversight, monitoring, and reporting for particular projects involving laboratory animals.

- Suspend an assurance for all or part of an institution, preventing some or all research on animals from continuing until corrective actions have been taken as specified by OLAW.
Research Misconduct

- Researchers falsifying or fabricating research data in laboratory notebooks, grant applications, progress reports to NIH, publications, patent applications
- Plagiarism by researchers
HHS Office of Research Integrity (ORI)

- Reviews investigations of research misconduct conducted by the institution
- May ask for further information or further investigation
- Recommends a finding to the Office of the Assistant Secretary for Health, HHS
ORI...
Possible Actions Against Individuals

- Increased supervision
- Ineligibility to serve in any advisory role to the Department
- Debarment from eligibility for Federal funding, (i.e., the researcher cannot receive any Federal funding for a specified period)
Possible NIH Actions Based on ORI Findings

- Recover grant funds that have been awarded to a researcher who has been found to have committed research misconduct
- Require a new principal investigator or new key personnel to work on the project
Financial Mismanagement

- Researchers and/or administrative staff incorrectly reporting time and effort that researchers spend on grants
- Failing to report program income earned from projects supported with grant funds
- Researchers being paid with grant funds when they are not working on the project
Financial Mismanagement

- Research grant funds used for activities that are not part of the project
- Improper accounting of overhead costs
- Improper transfers of funds across research projects
- Failure to report financial conflicts of interest, or other research support
Grants Administration

- Lack of institutional oversight of principal investigators
- Unclear definition, understanding of roles and responsibilities of researchers and administrators
- Lack of training in and understanding of administrative/financial issues
- Failure to properly monitor and keep track of expenditures, time and effort, and other administrative/financial requirements
NIH Office of Management Assessment (OMA) and HHS Office of the Inspector General (OIG)

- Conduct investigations/reviews
- Ask for, or subpoena, information
- Conduct audits
- Interview staff
OMA and OIG Possible Actions

- Recommend action against institutions or individuals
- Recommend that current research grant funds be restricted, suspended, or terminated
- Recommend that funds previously awarded be recovered by the NIH
- Recommend that individual researchers (or even institutions) be debarred
NIH Office of Policy for Extramural Research Administration (OPERA)

- Will ask for information
- Make site visits to interview staff and determine if policies are being implemented and understood
OPERA
Possible Actions Against Institutions

☐ Recommend that NIH impose special conditions on all or some grants
☐ Designate all or part of an institution as “high risk”
☐ Require a corrective action plan to remedy identified problems in grants administration
OPERA
Possible Corrective Actions

- Establishing policies for roles and responsibilities
- Additional training and education
- Code of conduct for staff
- Increased reporting requirements
And What About Litigation?

- Any of the research problems discussed, and others, can be referred to the Department of Justice (DOJ) for legal action by the agency or by an individual at your institution (*qui tam* actions).

- The DOJ works with the Office of the General Counsel (OGC) at DHHS, and with the OIG to investigate and litigate cases
Department of Justice

- Determine if civil or criminal action is justified based on the False Claims Act (FCA) or other applicable statutes, and/or common law theories
- Seek to recover money, up to three times the amount misspent, and corrective actions
- Litigate, and, when appropriate, negotiate settlement
Qui Tam Actions

- Intervention in *Qui Tam* actions is rare
- DOJ and HHS only intervene when serious allegations are confirmed
- The Government may bring its own case under the False Claims Act
When Litigation May Be Pursued

- Significant amount of funds misspent under a single grant, or many grants
- Significant research misconduct that affects field of research or clinical research
- Significant deviation from grants administration requirements on a single grant or many grants
When a Case is Settled

☐ As part of settlement, the OIG will require, as a term of settlement, an Institutional Integrity Agreement, which requires:
  - an institutional compliance program
  - corrective actions related to financial administration
  - policy development
  - training and education
  - a code of conduct
  - additional reporting requirements

☐ OIG expects to coordinate these Institutional Integrity Agreements with any actions previously taken by OPERA or other HHS offices
Useful Websites

- HHS homepage - http://www.hhs.gov
- Office of Research Integrity - http://ori.dhhs.gov/
- Food and Drug Administration - http://oma.od.nih.gov/
Leaving NIH and Building a Compliance Program at Harvard

- Past...
- Present...
- Future...
  - Where the past intersects with the present

Lessons of the past
+ present experiences
= Future
Influencing change...

- New University President
- Harvard football team undefeated 1st time since? 1776...
- Bruins at top of their NHL division
- Celtics near top of their NBA division
- Executive Dean for Administration to BIDMC
- New England’s FIRST Super Bowl Champion
- Red Sox sold to new ownership who vow to rid Boston of the...
  - (A) Green Monster
  - (B) Big Dig
  - (C) Bambino Curse
- All-time mildest winter in the history of New England
## Compliance Program

- Do you have a compliance program at your institution?
  - To what does it aspire?

- Does it have a name?

- How do you identify with it?

- Does it resonate with faculty?

- Is there a culture of compliance at your institution... even in the absence of a compliance program?
Is there an institutional compliance position? What does it offer? What does it need?

- Challenge
- Opportunity
- Independence
- Integrity
- Placement
- Resources
- Institutional Commitment
- Culture of Success
Task Force: Major Categories of Action

- Establishment of a centralized compliance program...
- Clarification of responsibilities for administration and oversight...
- Improved coordination among offices throughout HMS, its affiliated institutions and Harvard University
- Clarification and widespread communication of HMS’s expectations for reporting and compliance
Task Force: Challenges for the Associate Dean

1. **Invent** and **shape** the position and office...
2. Help **improve** and **make standard and consistent** regulations...
3. **Detect points of weakness**... distinguish between behaviors arising from **bad motive** and behaviors caused by **inadequate knowledge or training**...
4. **Develop and provide** training *(and education)* that members value **rather than imposing more** “requirements”...
5. Take a **leadership role in training and retaining** HMS personnel...
6. **Shape and communicate** both to the internal Harvard community and to the outside world a set of standards for compliance worthy of an institution of HMS’s stature...
7. **Foster collegial and cooperative** **partnerships** with the affiliated institutions...
Task Force: Associate Dean will have responsibility for...

- **Shaping** a strategy and plan for implementation for a **fair, visible and effective compliance program**...
- Undertaking a **strategic risk assessment** of HMS compliance with Federal policies and procedures...
- Planning all aspects of **compliance training** *(and education)* programs...
Criteria for Success

“Within the next several years, the Associate Dean should have taken the lead in developing and implementing a model, active (rather than reactive) compliance program characterized by widely-used and highly-valued education and training programs, consistent and smoothly functioning monitoring and reporting systems, and “widespread recognition and acceptance of compliance as a way of life.”
Make observations... don’t jump to conclusions...

**General**

- Good people
  - Dedicated
  - Conscientious
  - Want to do the right thing
- However
  - Frustration
    - Roles and Responsibilities
    - Education and Training
    - Institutional support
- Defining quote at HMS:
  - “Hours don’t matter, results matter”!
Common Findings

Roles and Responsibilities

- Poorly defined
- Lack of clarity around individual’s R & R
- Lack of clarity around understanding other’s R & R in the administrative continuum
- Issues around “recognition” and “credit”
Establish a sound base

Roles and Responsibilities

- Develop a framework document (matrix)
- Map entire research process from cradle to grave
- Prepare two test representations of the R & R document
  1. Describe the research process and identify the roles in the process
  2. Describe the respective roles in the research process
- Clearly define all responsibilities
- Develop a web-based presentation to help describe the matrix
Common Findings

- **Training and Education**
  - Not apparent that a “core” or “central” component exists
  - Past efforts:
    - Successful; or
    - Abject failures...
  - Department/Component driven
  - Staff “too busy” to do training...
  - Faculty training and education is lacking
    - Abrogation of responsibility
Get faculty and staff more on the same page...

Training and Education

- Begin to Partner... an initial effort might include:
  - Grants Management 101 for Faculty
    - Provide a basic fundamental understanding of faculty’s responsibility as PI of a sponsored project
      - Develop “Quick Guide” Reference for Investigators
  - Lay Science 101 for Administrators
    - Provide some basic lay terminology to enhance administrators appreciation and lay understanding of the research that they facilitate through administration
      - Develop “Quick Guide” Reference for Administrators
Common Findings

- Organizational Issues...
  - Decentralized
    - Decentralization to an art-form...
    - Individual fiefdoms
    - Autonomy to an extreme
  - Academia versus Administration
    - With different reporting lines, are organizational components operating in vacuums?
  - Aren’t we really more alike than different?
    - Are there coordinated efforts toward the common good?
  - Are resources being utilized effectively?
    - Are mutual interests being underserved by splintered efforts and support?
Look at your Departments

Department Chairs

- Supportive – Skeptical
- Aware – Denial
- Carrot – Stick
- Abrogate – Enforcement
- Appreciation - Suspicious

Some DCs appear to use their DAs as deputy/assistant/associate chairs… is this as it should be?

- Does this place the interests of the Department ahead of the Institution?
Is your institution your only concern?

Example: At the HMS...

- Seventeen affiliated institutions... either hospitals or research institutions
- Institutional relationships are not always clearly understood
- Faculty appointments present interesting issues...
  
  - Professors \hspace{2cm} 664
  - Associate Professors \hspace{2cm} 1,107
  - Assistant Professors \hspace{2cm} 1,552
  - Instructors/Lecturers \hspace{2cm} 5,453
  - Training \hspace{2cm} 6,204 TOTAL 14,980

- The GOOD and the BAD reflect back on HMS
Next Steps: Building Bridges...

- Getting everyone on the same page
  - Emphasize how we are alike rather than how we are different
  - Identify the “common good” and promote it through a strong partnering effort and formulation of myriad partnerships
  - Develop strategy that best addresses the content of the document or initiative that serves as the basis for your position (e.g., “Report of the Task Force...”)
  - Consistent with the mission of your institution, identify and develop approach to meet the goals cited by your institution and that is most likely to meet the established criteria for success
The HMS Compliance Program will...

- Be a proactive **training, education and outreach** program whose institutional charge is to ensure that researchers and their laboratories involved in grants administered by HMS meet the financial, administrative, programmatic, and reporting requirements established by grant and contract sponsors;

- Develop training, education and outreach efforts that members of the research community welcome as **providing added value rather than imposing more requirements**;

- Mobilize HMS personnel to **share a common mission** of providing excellent service to the research community;

- **Establish standards** for compliance and respond rapidly and surely to questions and concerns about whether behavior of members of that **community live up to these standards**; and

- Foster **collegial and cooperative partnerships** within HMS as well as with affiliated institutions, and extend help, advice, and service on compliance policy and enforcement to the HMS affiliated hospitals and research institutions.
So, what is a Compliance Program... what is it not?

- It’s about research
- It’s a plan or system under which action may be taken toward conformity in fulfilling official requirements
- It’s intended to facilitate the pursuit of biomedical research
  - To preserve, promote, protect, and sustain the research effort and those individuals and institutions who are responsible for the conduct, administration, and reporting of sponsored research
- It’s a process where faculty and staff are educated to reduce the risks associated with non-compliance
- It’s not intended to “catch” you, but it must have that capability and enforcement authority

**IT’S ABOUT RESEARCH!**
Compliance Program at the Harvard Medical School

HMS-ASPIRE

Alliance of Stewards and Partners Interacting for Research Excellence
ASPIRE:
Career and Training Awards

- National Research Service Awards
- Research Training and Career Development Awards
ASPIRE:
Enhancing faculty and staff...

- Mock Study Section
- Scientific Peer Review
- Set-asides and Earmarks
- Sponsor Updates
ASPIRE: Helping faculty...

- Formula for Grant Success
- Improved Opportunities for Funding
- Research Emphases
ASPIRE: Institutional...

- Developing a Culture of Compliance
- GMAS: Grants Management Application Suite
- NIH Proactive Site Visit and Harvard’s A-133 Audit
ASPIRE: Partnering...

- Lay Science for Administrators
- NIH (Sponsor) Fundamentals
- Project Monitoring
- Research Administration for Faculty
ASPIRE:
Regulatory/Required/Pre-Emptive...

- Clinical Trials and DSMB’s
- Individual Conflict of Interest
  - Institutional CoI
- Intellectual Property, Invention Reporting, and Technology Transfer
- OHRP, Human Subjects, and IRBs
- OLAW and Animal Welfare
- Responsible Conduct of Research
COMPLIANCE

- There’s no need to apologize for developing and promoting a culture of compliance in your institution...

BUT

- You must be prepared to deal with the reality of demonstrating the value added, especially for faculty
And to make it work you must have…

- Unqualified institutional support at the highest level; and,

- At the core of your program:
  - Clearly defined Roles and Responsibilities; and
  - An effective and ongoing Training and Education program

- Patience and Persistence!
HMS Winter Trilogy: Our own “March Madness”...

1. Formula for Grant Success
   - Enhance your chance... March 5th

2. Scientific Peer Review
   - De-mystifying peer review... March 7th

3. Fundamentals for Principal Investigators
   - Protecting the common good as partners and stewards... March 12th
A complex organization...

- Responsibility for managing sponsored research is shared by specific individuals and selected administrative support units within both the Medical School and the University.
Responsibility for Managing Sponsored Research At HMS (ORC)
Components of a Research Compliance Program (HMS/ORC)

- Human Subject Research
- Misconduct in Science
- Radiation Safety
- DNA
- EH&S
- Biohazard/Biosafety
- Animal Subject Research
- Financial Reporting
- Cash Draw downs
- IRB's
- DSMB's
- Effort Reporting
- Tech Transfer
- Material Transfer Agreements
- Conflict Of Interest
- DNA
- Misconduct In Science
- Radiation Safety
- DNA
- EH&S
- Biohazard/Biosafety
- Animal Subject Research
- Financial Reporting
- Cash Draw downs
- IRB's
- DSMB's
- Effort Reporting
- Tech Transfer
- Material Transfer Agreements
- Conflict Of Interest
Other Compliance Areas
(?HMS/ORC?)

- Use of University Name
- HIPAA
- Internal Audit & Advisory Services
- Affiliates X17
- Grant Expense Authorization
- Race Discrimination
- Drug & Substance Abuse
- Sex Discrimination
- Property Management
- Equipment Management
- Age Discrimination
- Sexual Harassment
- Lobbying
- Other Compliance Areas (?HMS/ORC?)
Challenge and Opportunity...

- Identify the “common good”
- Develop strong partnering effort
- Proactive training, education, and outreach
- Promote, protect, and preserve research excellence
- Build alliances
Finally, can the Alliance extend beyond HMS (or your institution)?

US TOTAL (from NIH alone) – FY2000 $14.721B

- Massachusetts (No. 2 State)
  - $1.534B (10.4%)

- Boston (No. 1 City)
  - $1.078B (7.3%)
    - Cambridge (No. 15) $216M
    - Worcester (No. 46) $78M
    - Watertown (No. 89) $27M
    - Waltham (No. 98) $23M

- Boston Medical Area
  - $1.422B (9.7%)
Questions/Discussion

Gary Thompson
617-432-5588
gary_thompson@hms.harvard.edu