

Research Integrity Through Research Compliance

**It's the Law and
a Matter of Public Trust**

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**MGH Office for Research Career Development
Professional Development for Researchers**



Today's Agenda

- Who Am I & Where Do I Fit In?
- What's Research Compliance?
- What's the Big Deal? Our Changing Environment
 - Recent Settlements & Public Scrutiny
- What We Can Do?

A Day in Our Lives

- Conflicts of Interest
- Gifts
- Vendor Relationships
- HIPAA
- Professional Behavior
- Grants Management
- Time & Effort
- Cost Sharing
- Cost Transfers
- Grant Preparation
- Post Award
- Subcontract
- Ts, Ks, (ABCs)

A Day in Our Lives

- IRB
- Quality Assurance
- Data Monitoring
- INDs/IDEs/HDEs
- Informed Consent
- Scientific Misconduct
- Billing
- Coding
- Contracting
- Good Clinical Practice
- Federal Wide Assurance
- AAHRPP
- IACUC
- Lab Safety
 - BPHC
 - Fire Department
 - State

What's the Big Deal?

- Investigations & Settlements
 - BIDMC – 1999 (\$920K) & 2004 (with Harvard) (\$3.3M)
 - Northwestern – 2003 (\$5.5M)
 - Johns Hopkins/Bayview Med. Ctr – 2004 (\$2.6M)
 - U. of Alabama Birmingham – 2005 (\$3.4M)
 - Mayo Foundation – 2005 (\$6.5M)
 - Weill Med. College of Cornell – 2006 (\$4.4M)
 - U. of Connecticut – 2006 (\$2.5M)
 - Yale – 2006 (ongoing)

What Happened?

- Nothing that couldn't happen anywhere else
- Good people misguided as to how to do the right thing
- Documentation, documentation, documentation

False Claims Act

Violation

- Knowingly submit
- Deliberately ignorant
- Recklessly disregard

• Penalties

- Triple Damages
- \$10,000 fine for each claim
- Disbarment
- Criminal Charges

• Qui Tam (Whistleblower) Provision

The Hook: In Every Grant Application...

- **Principal Investigator Assurance:**

I certify that the STATEMENTS HEREIN ARE TRUE, COMPLETE and ACCURATE to the best of my knowledge. I am aware that any FALSE, FICTITIOUS, OR FRAUDULENT statements or claims may subject me to CRIMINAL, CIVIL OR ADMINISTRATIVE PENALTIES. I agree to accept responsibility for the SCIENTIFIC CONDUCT of the project and to provide the required PROGRESS REPORTS if a grant is awarded as a result of this application.

The Hook: In Every Grant Application...

- Applicant Organization Certification and Acceptance:

I certify that the STATEMENTS HEREIN ARE TRUE, COMPLETE and ACCURATE to the best of my knowledge, and ACCEPT THE OBLIGATION TO COMPLY with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any FALSE, FICTITIOUS, OR FRAUDULENT STATEMENT OR CLAIMS may subject me to CRIMINAL, CIVIL, OR ADMINISTRATIVE PENALTIES.

The Hook: In Every Grant Application...

- Human Subjects
- Vertebrate Animals
- Debarment and Suspension
- Drug Free Workplace
- Lobbying
- Delinquent Federal Debt
- Handicapped individuals
- Sex Discrimination
- Age Discrimination
- Financial Conflict of Interest
- Research Misconduct
- Civil Rights
- Notice of Grant Award

Grants Management Special Considerations

- Time & Effort Reporting
 - Includes all professional effort for MGH (patient care, instruction and teaching, administration, and research)
 - Total professional effort cannot exceed 100%
 - Not based on a 40 hour work week

What You Can Do

- Know the Terms of Your Award
 - http://grants.nih.gov/grants/policy/nihgps_2003/index.htm
- Know What Activities/Changes NIH Must Pre-Approve (pg. 105 of NIH Grants Policy Statement)
 - i.e. 25% reduction in T&E
 - i.e. Transferring work off-site
- Know When Reports are Due

What You Can Do

- Help Manage the Grant Account
 - Know the NIH Cost Principles - *Every Charge Must Be:*
 - Reasonable
 - Allowable
 - Allocable
 - Conform with institutional policies
 - Reconcile account regularly, monthly ideally
 - Cost Transfers – if not completed within 90 days, make sure they comply with NIH requirements

What You Can Do

- Personnel Management
 - Conflicts of Interest
 - Time and Effort
- Laboratory Management
- Data Management – Record Retention

What We Can Do

- RAMP Initiatives
 - Organizational Improvements
 - RAMP Steering Committee
 - New Positions & Workforce Development
 - Standard Policies & Procedures
 - Systems
 - InfoEd
 - PeopleSoft
 - Research Compliance
 - Education
 - Resources

Research Compliance Program

- Part of the Partners' RAMP Initiative
- Arises from federal statutes and regulations
- Dedicated to aiding employees, investigators and the organization to do the right thing
- Helps maintain our focus in the midst of everyday pressures

Maintaining Focus

- Resources
 - Policies and Procedures
- Education and Training
- Implementation
- Follow-up
 - Assessment and Evaluation
- Adjustment and Modification

What Can We All Do

- Understand the law
- Ask Questions
- Do the Right Thing
- Document, Document, Document

Ostriches may feel safe



but, they don't live longer!

Questions?

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Final Note

MGH Compliance HelpLine

617-726-1446

PHS Compliance & Business Integrity

617-724-1177

Partners Compliance HelpLine

800-856-1983