



Conducting a Research Risk Assessment

*Health Care Compliance Association
Post-Conference Workshop*

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Your Presenters

HuronLifeSciences



Jodi S. Ogden, MBA, CRA

Executive Director

Sponsored Projects Administration, Office of Sponsored Projects
UTHealth | The University of Texas Health Science Center at Houston

O: 713 500 3968

Jodi.Ogden@uth.tmc.edu



Matthew Lester, MBA, MHA

Managing Director

Higher Education and Life Sciences Advisory Practice

O: 267-872-7021

mlester@huronconsultinggroup.com

Objectives

What is a risk and what does it mean to address it?

What are the major risks with research?

What are the benefits of a risk assessment?

What are the elements of a risk assessment?

How to conduct a risk assessment?

What is Risk?

Risk:

- A factor, thing, element or course involving uncertain dangers.
- Observable events or conditions that may occur and, if they do occur, would have a harmful effect.



How do you define RISK?

What is Risk?

Impact – The measurable or definable component of risk with specific observable terms (i.e. financial, legal, reputational, etc.)

Probability - The potential of a particular risk resulting in harm or an adverse outcome

Risk Tolerance – The amount/type of risk the organization is willing accept.

- *What factors play into an organization's risk tolerance?*

What is Risk?

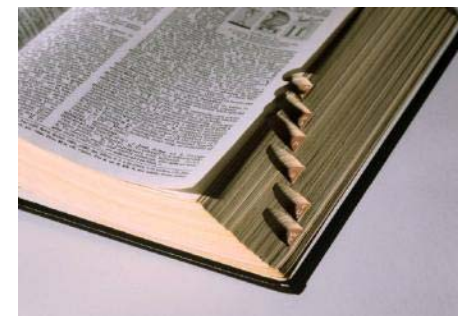
Total Risk – The risk of an event occurring without consideration for internal controls

Manageable Risk – The risk that can be mitigated through internal controls

- Not static
- Based on a multitude of factors

Remaining Risk – The risk that remains after considering current controls

- Not static
- Based on a multitude of factors



What is Risk?

Identification:

- The act of designating or identifying risk

Sources of information include:

- Audits (internal and external)
- Literature (conferences, publications, etc)
- Government workplans
- Regulatory actions / settlements
- Peer activities and risk mitigation strategies
- Insider perspectives - Impressions of individuals engaged in the process

Assessment:

- The act of judging or evaluating a situation or event.

Risk Assessment...

- *...is the identification, measurement and prioritization of likely relevant events or risks that may have a material consequence on an organization's ability to achieve its objectives*
- Process by which risks are identified, evaluated and prioritized

Risk Assessment is not...

Auditing

- Formalized, independent and objective review of a process, program or system

Monitoring

- Day-to-day review of the process, program or review.
- Quality assurance, “spot checks,” continuous quality improvement, lean manufacturing, etc.

Internal Controls

- Internal reviews, sign-offs, checks and approvals designed to ensure processes and procedures are followed

Exercise #1

Risk Assessment Tool from UTHHealth

Overview of Key Research Risk Areas

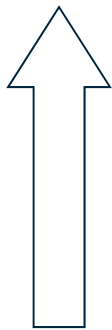
Cartoons aren't necessarily far from reality...



We must maintain our sense of humor!

Trends in Funding and Compliance

Trends related to research compliance include:



- Volume of activity
- Complexity
- Scrutiny
- Demand for accountability
- Large investments in facilities



- Pressure to maintain/reduce administrative cost



- NOW: Significant spike in funding due to ARRA replaced several years of stable / downward funding; in 2010 budget returned to pre-ARRA trend of flat or limited growth

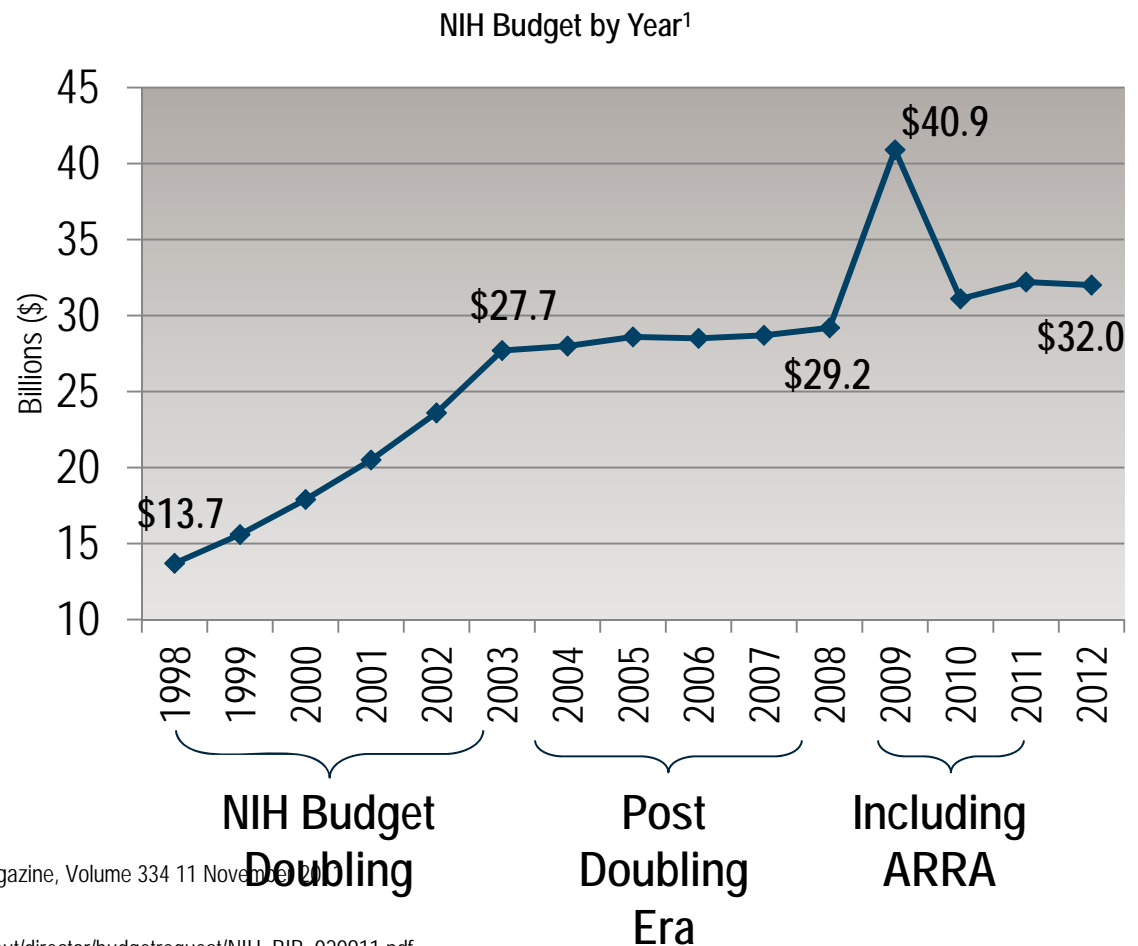
Image source: http://inapcache.boston.com/universal/site_graphics/blogs/bigpicture/ngipc_11_19/n02_sean-heavey.jpg

Industry Overview

Trends in funding and compliance

NIH budgets doubled in the period from 1998 to 2003 and growth has remained relatively flat thereafter.¹

- Recovery Act funds temporarily boosted the agency's flat budget growth.
- "In real terms, the agency's buying power is now at a 2002 level."²
- The 2013 budget is expected to be approximately \$30.9 billion, according to President Obama's proposal released in early 2012.³



1. The American Association for the Advancement of Science (AAAS)

2. Kaiser, Jocelyn, "Darwinism vs. Social Engineering at NIH." Science Magazine, Volume 334 11 November 2009

3. <http://www.hhs.gov/budget/budget-brief-fy2013.pdf>

Note: The 2012 data represents the requested budget, http://www.nih.gov/about/director/budgetrequest/NIH_BIB_020911.pdf

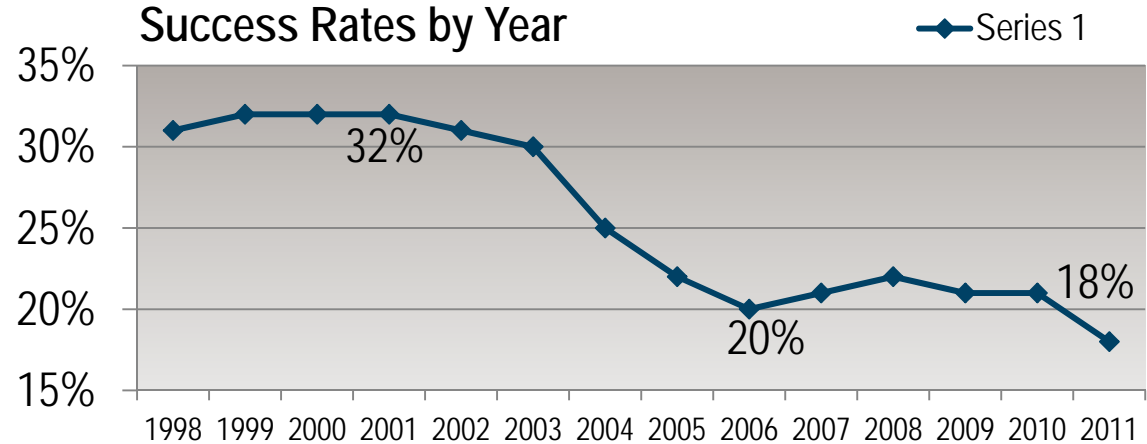
Industry Overview

Trends in funding and compliance

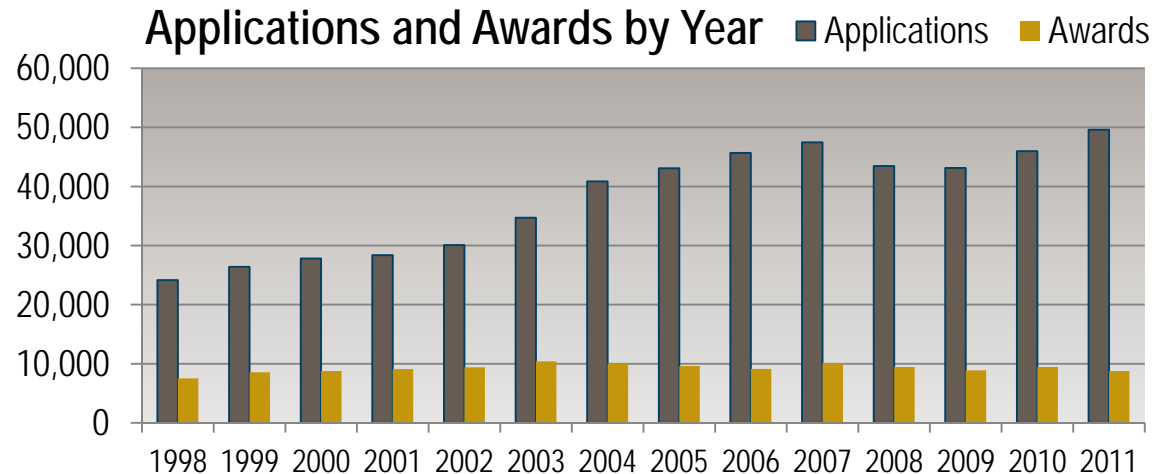
Despite flat pre-ARRA budgetary growth, demand for research funding is at an all time high

- The overall success rate for grants dropped to an all-time low 18% in 2011.
- The success rate for new NIH awards was 15.2% in 2011.
- 24,151 grant applications were submitted in 1998 versus submissions of 49,592 in 2011.

Success Rates by Year



Applications and Awards by Year



Sources: NIH Office of Extramural Research "Ways of Managing NIH Resources" October 2011; NIH Website: "Research Project Success Rates by Type and Activity for 2011"
http://www.report.nih.gov/award/success/Success_ByActivity.cfm

Introduction to Research Compliance

Achieving compliance in research is challenging

- Requires careful review, periodic assessment and diligent effort
- Research represents an area that is often targeted as high risk at many organizations.

Many health care systems and hospitals have active research programs

- Risks can change as research changes
- Ever increasing focus on translational research and new ways of advancing science
- They may not be as involved as they would like or should be.

Research compliance is a specialty as the risks in this space are considerable.

Overview of Research Compliance Environment

Complexity is found in research and fiscal areas and in the diversity of constituents:

Research & Fiscal Areas

- ◆ Clinical trials
- ◆ Genomics
- ◆ Stem cell research
- ◆ Technology transfer
- ◆ Faculty/Physician-owned start-ups
- ◆ Financial conflict of interest
- ◆ International collaborations
- ◆ Interdisciplinary Research
- ◆ Subcontracts
- ◆ Human subject protections
- ◆ Grants.gov
- ◆ Cost accounting standards, OMB circular A-21
- ◆ HIPAA / HITECH
- ◆ Clinicaltrials.gov

Constituents

- ◆ Principal investigators (“PIs”) and research teams
- ◆ Board members
- ◆ Students, residents, fellows, etc.
- ◆ Tax payers
- ◆ Federal agencies
- ◆ Commercial sponsors
- ◆ Donors and investors
- ◆ Foundations
- ◆ Human subjects
- ◆ Suppliers and procurement specialists
- ◆ Advocacy groups
- ◆ Internal administrators

Trends in Funding and Compliance

Increased complexity in fiscal management

Increased focus on accountability

- Concerns over effectiveness of A-133 audits
- Increased number of proactive compliance site visits
- ARRA reporting and oversight compliance

Institutions experiencing rapid growth often lag in the development of an appropriate infrastructure to support the research growth, particularly during a period when budgets are being cut considerably

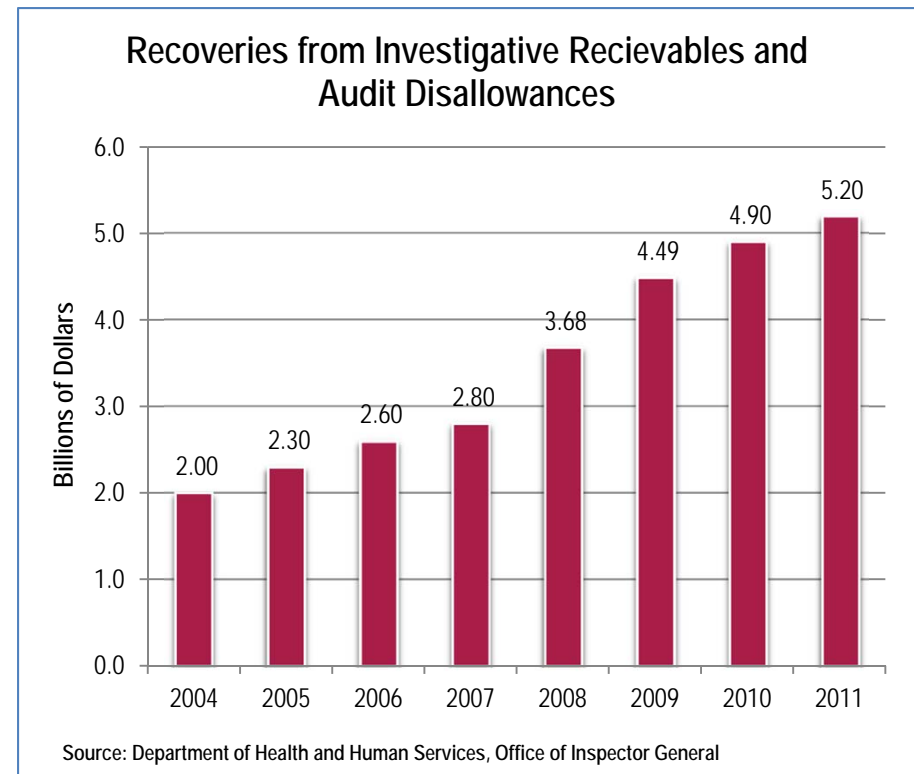
Regulatory Climate

For FY 2010, DHHS Office of Inspector General (OIG) reported financial penalties totaling:

- \$1.1 billion in audit receivables
- \$3.8 billion in investigative receivables (includes \$576.9m in non-HHS investigative receivables resulting from OIG work)

For FY 2011:

- \$627.8 million in audit receivables
- \$4.6 billion in investigative receivables (includes \$952M in non-HHS investigative receivables resulting from OIG work)
- Identified ~\$19.8 billion in savings
- Exclusions of 2,662 individuals and entities
- 723 criminal actions
- 382 civil actions



Sources: <http://oig.hhs.gov/reports-and-publications/semiannual/index.asp> and http://oig.hhs.gov/publications/semiannual_archive.asp

Regulatory Climate

Summary of DHHS OIG Workplan

NIH Focus Areas	06	07	08	09	10	11	12
Extra Service Compensation Payments Made by Education Institutions						X	X
Recharge Centers at Colleges and Universities						X	X
Colleges' and Universities Compliance with Cost Principles			X	X	X	X	X
Use of Data and Safety Monitoring Boards in Clinical Trials				X	X	X	X
University Administrative and Clerical Salaries	X	X	X				
Level of Commitment	X	X					
Conflicts of Interest			X		X		
NIH Monitoring of Extramural Conflicts of Interest	X	X		X			
Cost Transfers	X	X					
Cost Sharing Claimed by Universities							X
Subrecipient Costs and Monitoring	X						
Monitoring of NIH Research Grants		X	X				
National Institute of Environmental Health Science's Grant Process				X	X	X	
Safeguard Over Controlled Substances		X	X				

Regulatory Climate

Summary of DHHS OIG Workplan

NIH Focus Areas	06	07	08	09	10	11	12
National Institute of Allergy and Infectious Diseases' Oversight of Project Bioshield Grants						X	
Superfund Financial Activities for Previous Year	X	X	X	X	X	X	X
National Center for Research Resources' Oversight of Clinical and Translational Science Awards				X	X	X	X
Compensation of Graduate Students Involved in NIH-Funded Research		X					
National Institutes of Health's Implementation of Select Agent Regulations			X	X			
Informed Consent and Privacy Protection Procedures for NIH Grantees Conducting Genetic Research							X
Inappropriate Salary Draws From Multiple Universities							X
Awardee Eligibility for Small Business Innovation Research Awards							X

FY 2012 Challenges

Challenges related to research at universities for FY 2012 include:

NIH salary cap at \$179,700, down \$20,000 from last years level

- Increased financial pressure on universities to cover salaries of faculty members who perform NIH Research

Ensure proper stewardship of grant Funds

- Focus on preventing research misconduct, misuse of funds and/or embezzlement
- Ensuring ARRA funds are not subject to fraud, waste, or abuse

Improving Grant Administration

- Oversight of awardee's financial accountability and compliance with federal requirements

Offices of Inspectors General (OIG) Oversight Approach

OIG Oversight Approach

Current Activity

- To ensure that accountability requirements are being met, the cognizant OIG's of the 30 federal agencies distributing ARRA funds continually review their agencies' management of ARRA funds.
- As of February 28, 2011, the OIG's, along with the Recovery Accountability and Transparency Board (the RATB) had received 5,994 complaints of wrong-doing with ARRA funds^[4]:
 - 1,214 have resulted in active investigations;
 - 284 cases were closed without action.
- In addition, the OIG's have completed over 1,000 reviews of activity involving ARRA funds, with many of these reviews resulting in recommendations on how to improve use of the funds.

4. <http://www.recovery.gov/Accountability/Pages/investigations.aspx>

OIG Oversight Approach Objectives

- The RATB received approximately \$84 million in funding and will oversee the audit activities of the OIG with respect to ARRA funds.
- The goal of the OIG and the RATB with respect to oversight of ARRA funds is both:
 1. Transparency; and
 2. Prevention and detection of fraud, waste, and mismanagement.
- The cognizant OIG's for the Department of Health and Human Services (DHHS) and National Science Foundation (NSF) are taking different approaches in their oversight.

OIG Oversight Approach

NSF

- NSF has indicated its approach will be proactive and carried out in three phases:
 - **Phase I** is an inward review of NSF's monitoring and controls.
 - **Phase II** is both an inward and outward review. NSF has been conducting Capacity/Capability Reviews looking at:
 - Internal controls and system capabilities to support new funds and new reporting requirements;
 - Burn rate on ARRA funds (goal is to stimulate spending in the first 12 months);
 - "Jobs Supported" that are reported by recipients.
 - **Phase III** is an outward review of ARRA recipients and will be in the form of traditional audits.
 - Expect significant audit activity 2011

OIG Oversight Approach

DHHS

- DHHS is employing a risk-based approach to oversight of ARRA funds.
 - Like NSF it is reviewing internal controls and assessing the likelihood and magnitude of identified vulnerabilities.
 - Unlike NSF it will not be doing “Capacity Reviews.”
 - Expect most ARRA audit activity in 2011; ~40 institutions to be selected.
- The DHHS approach will be carried out in four phases:
 - **Phase I** is an inward review of the DHHS awarding agency (NIH, CDC, etc.).
 - **Phase II** involves looking at anecdotal causes of inaccurate data, including those recipients who did not complete the reporting.
 - **Phase III** will continue the inward review as well as analyze the effectiveness of the Phase II review.
 - **Phase IV** will examine the accuracy of the data reported at the recipient level. It will focus on factors such as the amount of the award, award dates, instances where the expenditures reported are greater than the amount awarded, inconsistent spending patterns, and unreasonably high numbers of reported jobs.

Food and Drug Administration (FDA) Oversight Approach

Food and Drug Administration

- Focus on efficient, aggressive enforcement for noncompliance in areas of greatest impact to public health
- Protocols and inclusion / exclusion criteria are becoming more complex
- Insufficient training, excessive delegation by PIs and inadequate sponsor oversight of CROs is leading to increased non compliance
- Political pressure on the FDA
- The result: Increase in enforcement actions (i.e. warning letters)

Food and Drug Administration

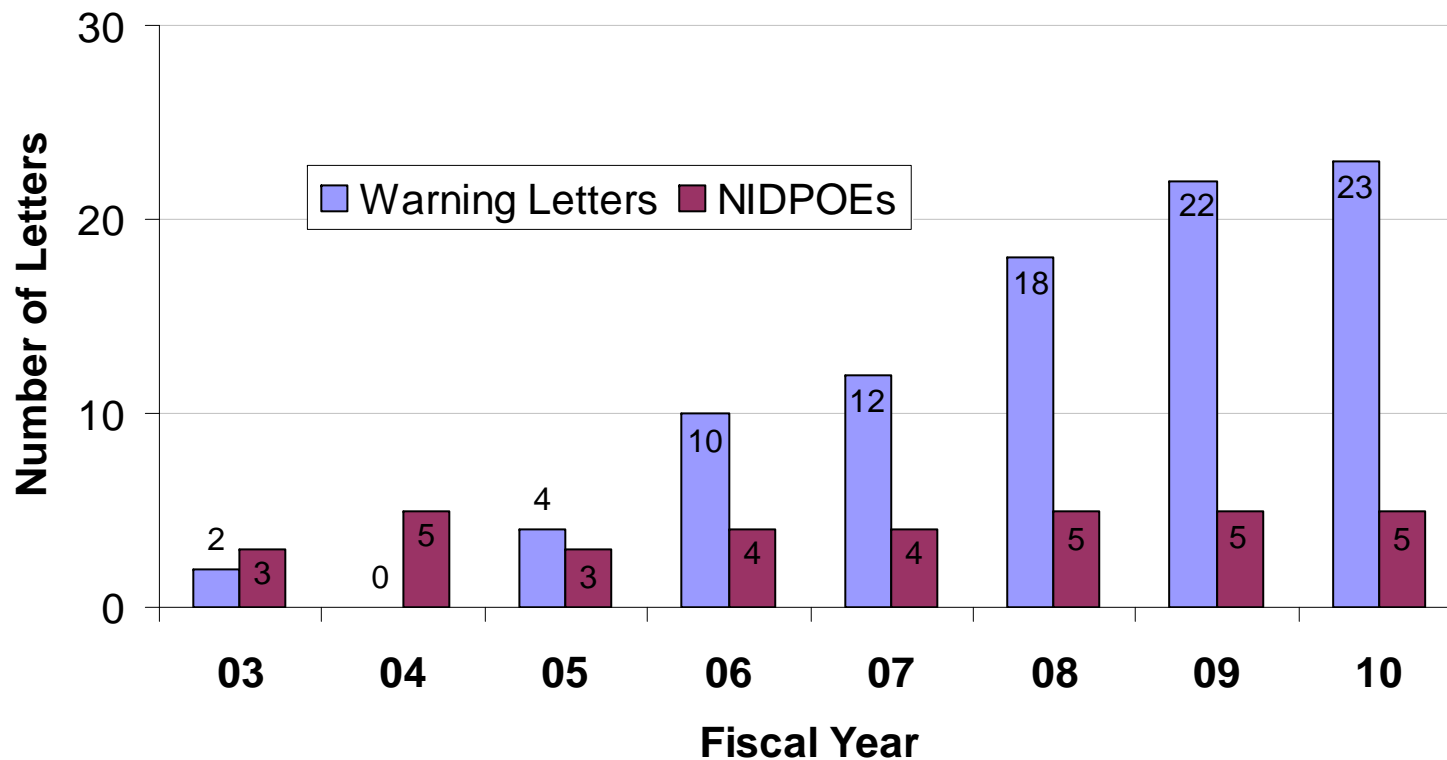
The following slides on the Food and Drug Administration were presented by Leslie K. Ball, MD and Karena Cooper, JD, MSW from the Division of Scientific Investigations, Office of Compliance, CDER, FDA.

Presentation: "Center for Drug Evaluation and Research (CDER) Bioresearch Monitoring (BIMO) Inspections and Warning Letters." Association of Clinical Research Professionals Global Conference 2011

The slides are presented herein with their permission.

Food and Drug Administration

Warning/NIDPOE* Letters: Total GCP/GLP/BE**
(CDER, FY 2003-2010)



*Notice of Initiation of Disqualifications Proceedings and Opportunity to Explain

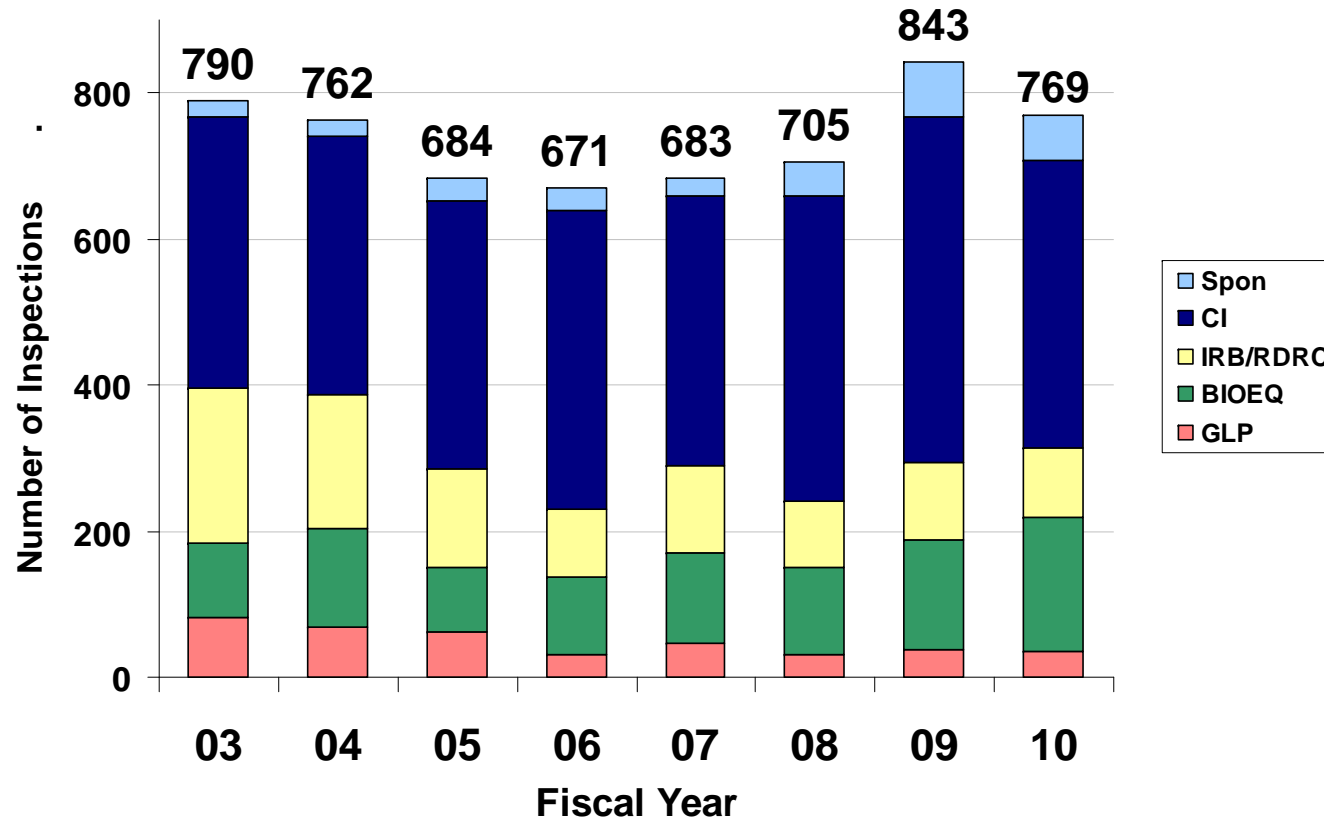
**Based on letter issue date

Preliminary data; FY10 subject to change [1/21/2011]

SOURCE: Ball and Cooper Presentation. ACRP 2011

Food and Drug Administration

Bioresearch Monitoring Program Inspections* (CDER, FY 2003-2010)



*Based on inspection start date
Preliminary data; FY10 subject to change [1/21/2011]
IRB/RDRC include some CBER/CDRH related Inspections
SOURCE: Ball and Cooper Presentation. ACRP 2011

What Triggers a GCP Inspection?

New Drug Application (Data Validation)

- ~70% of clinical investigator inspections are associated with NDA/BLA
- May include be linked with a sponsor/CRO inspection

Complaint ("For cause" inspection)

- ~30% of clinical investigator inspections follow a complaint
- Complaints come from any source

Surveillance inspections

- Institutional Review Boards
- GLP facilities

Food and Drug Administration

Complaint (“For Cause”) Inspections

Credible allegation involving significant risk to

- Subject rights and/or safety, e.g.
- Patient death or significant injury
- Inadequate subject protection
- Examples: Inadequate supervision of study staff, unqualified study personnel, inadequate or inappropriate informed consent; delayed or inappropriate IRB approval

Data quality or integrity – For example:

- Falsification of data
- Unrealistic data
- Rejection by the sponsor of investigator data
- Under-reporting or delay in submission of adverse events
- Inadequate monitoring of clinical investigations
- Significant financial interest in the product by the investigator

Food and Drug Administration

Complaint (“For Cause”) Inspections

Clinical Investigator Inspections: What does the FDA look for during the inspection?

The FDA Inspection (Audit) compares

- Source Document Medical Record Data

VS

- Case Report Forms

VS

- Data Listing Submitted to NDA

Clinical Investigator Inspections: What does the FDA look for during the inspection?

Verify Primary Efficacy and Safety Data

- Source of subjects; Did subjects exist?
- Did they have the disease under study?
- Did they meet inclusion/exclusion criteria?
- IRB Review Obtained? Consent obtained?
- Adherence to protocol?
- Verify primary efficacy measure
- Adverse events?
- Safety data: Labs, EKG etc.
- Drug Accountability? Blinding of data?

Food and Drug Administration

How can sites ensure high quality data and subject safety?

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Build quality into the conduct of the study

- Create systems that limit opportunity for errors
- Simplify protocol and outcomes assessments
- Standardize systems and formats where possible, use validated instruments/definitions
- Keep protocol amendments to a minimum and check CRFs and consent forms against each change
- Insist on training and then test it, do beta tests/dry runs
- Have a disaster plan, e.g. back ups if key study staff leave or site experiences flood or disaster

Food and Drug Administration

How can sites ensure high quality data and subject safety?

HuronLifeSciences

- Select qualified staff and ensure adequate training and supervision
- Ensure staff are not performing tasks they are not qualified to do (e.g. assessing eligibility, performing physical exams, assessing AEs)
- Ensure oversight of sub-investigators and study staff

Food and Drug Administration

How can sites ensure high quality data and subject safety?

- Fully understand scope of responsibilities
 - Ensure protocol is consistent with best interests of patients and allows adequate monitoring for subject safety
 - Assess ability to comply with protocol visits; laboratory testing; electronic systems for data capture, archiving and transmission to sponsor; maintaining records, drug accountability, inspections by FDA
- Implement system to detect and correct errors in real time
 - Pay attention to monitoring queries and respond promptly
 - Evaluate need for system wide corrections
 - Audit trail of changes should make clear what was changed, who changed it, and why it was changed.

Research Audits and Cases

Recent Research Audits

With Audits Aplenty, Institutions Should Prepare, Examine Findings , Report on Research Compliance May 2011

Ohio State University	<p>NSF's OIG recently completed an audit of \$17.5 million in costs claimed and \$5 million in cost sharing as part of \$160 million in NSF awards during the period from Nov. 1, 2003, to Sept. 30, 2009.</p> <ul style="list-style-type: none">• Five significant compliance and internal control deficiencies in OSU's financial management that contributed to the questioned costs and could impact current and future NSF awards.”• “Specifically, \$1,736,068 million (10%) of the \$17.5 million in total claimed NSF-funded costs were questioned primarily due to;<ul style="list-style-type: none">• unsupported subawardee costs participant support costs and failure to incur budgeted participant support costs of \$1,142,684;• an inadequate effort reporting system prior to 2006 resulting in \$437,735 of unsupported payroll, fringe benefit and indirect costs;• unallowable lab animal and unapproved capital purchases totaling \$44,355;• questioned cost share short fall of \$58,900.
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Recent Research Audits

With Audits Aplenty, Institutions Should Prepare, Examine Findings , Report on Research Compliance May 2011

William Marsh Rice University	<p>NSF OIG reviewed costs claimed from Oct. 1, 2004, to Sept. 30, 2009. Costs claimed were \$13.8 million and \$4 million in cost sharing for four NSF awards.</p> <ul style="list-style-type: none">• No costs were questioned. However, the auditors concluded that there were “two compliance and internal control deficiencies in Rice University’s financial and award management practice that could impact current and future NSF awards.”• Failed to adequately monitor subaward costs, by failing to “document the results of its risk assessments on potential subawardees at the pre-subaward stage,• Lacked a formal process that would provide risk assessments on subawardees on an on-going basis at the post-subaward stage and no rationale was documented to support the level of monitoring activities• Six patent applications resulted from one of the four reviewed awards, but Rice failed to list NSF on one provisional patent application and reported one application 104 days late to NSF, violations of NSF requirements and the Bayh-Dole Act
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Recent Research Audits

With Audits Aplenty, Institutions Should Prepare, Examine Findings , Report on Research Compliance May 2011

University of Alaska- Anchorage	<p>NSF auditors reviewed quarterly reports for December 2009 and March 2010</p> <ul style="list-style-type: none">• Failed to have processes in place for “(i) performing a comprehensive data quality review of Recovery Act data to preclude clerical and/or posting errors, (ii) reporting Recovery Act vendor jobs, and (iii) checking the debarment and suspension status of vendors.”• Three of eight reported data elements were incorrect — jobs, expenditures and vendor payments.• “the university had not established adequate processes to accurately report the number of jobs, expenditures, and vendor payments” and did not have a process in place to assess whether a subrecipient had ever been debarred or was facing such action.
Virginia University Research Corporation	<p>NSF’s OIG reviewed December 2009 and March 2010 quarterly Recovery Act data</p> <ul style="list-style-type: none">• “data quality review process did not preclude clerical posting and other human-related type errors” and Recovery Act “vendor jobs reporting was limited only to vendor payments greater than \$25,000.”• “four of the eight” Recovery Act data elements reviewed were incorrectly reported. Improvements were needed to ensure that the number of jobs, expenditures, funds received/invoiced, and subawards were accurately and completely reported.

Recent Research Audits

OIG Audits Seek Repayment From SUNY, Report on Research Compliance Oct 2011

<p>Research Foundation of the State University of New York</p>	<p>Following an audit by the HHS OIG that found unallowable costs among claimed reimbursements for expenditures for 70 "sponsored agreements with [HHS] component agencies," the Research Foundation of the State University of New York agreed to refund \$48,651.</p> <ul style="list-style-type: none">• The audit covered administrative, clerical, and extra service compensation expenditures claimed for reimbursement from July 1, 2008, through June 30, 2009.• During this time, the foundation "claimed reimbursement for \$7,668,380 of expenditures." While it "generally claimed federal reimbursement for administrative, clerical, and extra service compensation expenditures in accordance with federal regulations," there were problems.• "Of the 322 expenditures that we reviewed, 275 complied with federal regulations, but 47 expenditures totaling \$82,922 did not," the audit said. After further documentation from the foundation, OIG reduced the amount to \$48,651. <p>The largest category of unallowable transactions was "expenditures [that] did not solely benefit sponsored agreement" (\$59,504), followed by "extra service performed on duties not related to sponsored agreement" (\$10,331). The repayment amount reflects \$36,416 in direct costs and \$12,235 in related facilities and administrative costs.</p>
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Scientific Misconduct Cases

- The University of Connecticut Health Center, "UConn Seeks Dismissal, Retraction After Finding of Research Misconduct Against Longtime Researcher" Jan 2012
- State University of New York-Upstate, Journal Pulls Paper After SUNY Misconduct Investigation Jan 2012
- Brown University, "After On-Site Evaluation, OHRP Requests Corrective Action Plan From Brown University" Jan 2012
- State University of New York, Upstate Medical University and University of Kansas, "ORI Finds Three, Including a Supervisor, Guilty of Research Misconduct" Jan 2012
- University of Virginia Medical Center, "ORI Finds Research Misconduct Stemming From Five Publications Containing Plagiarized Text" Nov 2011
- University of Michigan Medical School and Duke University, "*ORI Issues Pair of Misconduct Findings*" Oct 2011
- University of Pittsburgh, "*ORI Issues Misconduct Finding*" Oct 2011

Recent Research Audits

In descending order by date of news article

Institution	Headline	Source	Date	Executive Summary
Creighton University	<i>Falsehoods Told to IRB, NIH Result in Misconduct Finding, Five-Year Debarment</i>	Report on Research Compliance	Feb 9, 2012	Calleen Zach, former Creighton University research assistant and database manager, engaged in research misconduct in a project funded by NIH. Zach provided falsified subject enrollment numbers in a request for a no-cost extension, an application for additional funding, and in reports to Creighton University's institutional review board in 2008 and 2009. Additionally, Zach engaged in intentionally deceptive behavior, forgery of petty cash receipts, and theft of NIH research grant funds. Zach has been sanctioned with a five-year debarment beginning Jan. 23. She also will not be eligible for any contracting or subcontracting with any agency of the US government and cannot serve as an advisor in any capacity for the Public Health Service.
The Pennsylvania State University	<i>Former Penn State Professor Charged in \$3 Million Federal Research Grant Fraud</i>	DOJ – Middle District of Pennsylvania	Jan 31, 2012	The United States Attorney's Office for the Middle District of Pennsylvania on January 31 announced that a felony indictment has been issued against Craig Grimes, charging him with "wire fraud, false statements, and money laundering." During the time period alleged in the indictment, Grimes was a Professor of Material Science and Engineering at The Pennsylvania State University. According to the US Attorney some of the charges involve defrauding the National Institutes of Health of federal grant monies that were intended to go to Hershey Medical Center to conduct clinical research. Other charges involved NSF and Department of Energy grants. Chemical and Engineering News (C&EN) reported, "Penn State fired Grimes on Dec. 31, 2010 and the university reimbursed NSF for Grimes' misused funds..."

Recent Research Audits

In descending order by date of news article

Institution	Headline	Source	Date	Executive Summary
Wayne State University	<i>HHS OIG Finds Recovery Act Fund Costs at Two Institutions Were Allowable</i>	Report on Research Compliance	Mar 15, 2012	Grant costs claimed by Wayne State University were found by the HHS Office of Inspector General to be "allowable under the terms of the grant and applicable federal regulations," according to one of two audits that were recently posted on the OIG website. Wayne State received \$434,811 from NIH for comparative effectiveness research, beginning in September 2009; as of June 30, 2011, Wayne State had claimed \$324,372, of which \$228,041 was direct costs and \$96,331 was indirect costs. "We reviewed \$39,530 of the direct costs claimed by the grantee as of June 30, 2011," the audit states, and concluded all amounts were allowable.
John Hopkins University	<i>Johns Hopkins Disputes Finding of 'Significant Deficiency' in Audit by NSF OIG</i>	Report on Research Compliance	Feb 16, 2012	John Hopkins University (JHU) was audited by a firm under contract to NSF's Office of Inspector General to review costs related to JHU's Engineering Research Center for Computer-Integrated Surgical Systems and Technology. The audit covered costs from September 1, 1998 to March 31, 2010, totaling \$32,845,250. The audit questioned just \$169,532 in NSF funded costs, but concluded that "JHU did not adequately monitor subgrantee costs, which included 10 subgrantees amounting to over \$8.22 million in claimed costs." The auditors also identified some deficiencies in internal control over financial reporting that they considered to be significant deficiency in internal control over financial reporting. JHU did not agree with the findings of the audit and cited overall compliance with applicable federal regulations.

Recent Research Audits

In descending order by date of news article

Institution	Headline	Source	Date	Executive Summary
US Antarctic Program & Georgia College	<i>NSF OIG Semiannual Report to Congress Reveals University-Based Cases</i>	Report on Research Compliance	Dec 1, 2011	The National Science Foundation's (NSF) Office of Inspector General issued its semiannual report to Congress covering the period ending September 30, 2011. The report stated that the agency "closed 50 investigations, had 5 research misconduct cases result in findings by NSF, and recovered \$12,903,449 for the government. In addition, 11 audit reports and reviews were issued which identified \$201,756 in questioned costs and nearly \$76 million in funds put to better use." Some other report highlights were the investigation of overcharges by the contractor that provides support for the US Antarctic Program led to the recovery of \$11.4 million in wrongful contract charges. Also an investigation involving a PI at a Georgia college who submitted false claims to NSF and NASA grants over five year period led to a settlement agreement requiring the college to reimburse the federal government \$1.2 million and agree to a five-year compliance plan. The college did not renew the PI's employment contract.

Recent Research Audits

In descending order by date of news article

Institution	Headline	Source	Date	Executive Summary
State University of New York	<i>OIG Audits Seek Repayment From SUNY, Find Violation at NIH</i>	Report on Research Compliance	Oct 26, 2011	Following an audit by the HHS OIG that found unallowable costs among claimed reimbursements for expenditures for 70 "sponsored agreements with [HHS] component agencies," the Research Foundation of the State University of New York agreed to refund \$48,651. "Our audit covered administrative, clerical, and extra service compensation expenditures claimed for reimbursement from July 1, 2008, through June 30, 2009," the audit stated. During this time, the foundation "claimed reimbursement for \$7,668,380 of expenditures." While it "generally claimed federal reimbursement for administrative, clerical, and extra service compensation expenditures in accordance with federal regulations," there were problems. "Of the 322 expenditures that we reviewed, 275 complied with federal regulations, but 47 expenditures totaling \$82,922 did not," the audit said. After further documentation from the foundation, OIG reduced the amount to \$48,651.
National Institute of Child Health and Human Development	<i>OIG Audits Seek Repayment From SUNY, Find Violation at NIH</i>	Report on Research Compliance	Oct 26, 2011	OIG said NIH's National Institute of Child Health and Human Development "did not comply with the time and amount requirements" of a \$164.7 million contract with Westat Inc. and should deobligate funds from fiscal 2003 to 2007 and return some \$66.5 million to the U.S. Treasury. OIG said NICHD erred by initially appropriating "only \$31.0 million of the \$164.7 million contract with fiscal year 2003 obligations." NICHD was required to record the full amount of the contract using fiscal year 2003 appropriated funds." It added that a violation of the Antideficiency Act had occurred due to the obligation issues. NIH disagreed that any funds should be returned. Contrary to OIG's position, NIH said the contract, which ended in 2008, was severable. It acknowledged there was a violation of the act, which has been reported.

Recent University Audits

In descending order by date of news article

Institution	Headline	Source	Date	Executive Summary
University of Pittsburgh's School of Nursing	<i>ORI Sanctions Former Nursing Professor for Plagiarism</i>	Report on Research Compliance	Oct 6, 2011	The Office of Research Integrity (ORI) reported that Scott Weber, former assistant professor at the University of Pittsburgh's School of Nursing, was sanctioned for plagiarism. Weber "falsified and fabricated tables and figures by using all or nearly all of the data in tables and graphs from plagiarized articles while altering numbers and changing text to represent data as if from another subject population" and submitted two manuscripts based on false information. Weber admitted to committing research misconduct and agreed to restrictions for 3 years, including not contracting or subcontracting with any agency of the federal government. The restrictions also prohibit Weber as serving at a PHS peer reviewer. In addition, the blog Retraction Watch reports that Weber recently lost a part-time position at Walden University, an online institution.
University of Alaska-Anchorage	<i>NSF OIG Recommends Agency Exercise Greater Oversight of COI, Reviews University of Alaska-Anchorage</i>	Report on Research Compliance	Oct 6, 2011	The Office of Inspector General (OIG) conducted a limited scope review of the University of Alaska-Anchorage as part of a series "to provide oversight of funds" authorized by the Recovery Act. OIG reviewed 8 NSF grants totaling \$3.4 million the university had received as of March. OIG found that the University "has generally established sound grant management policies and procedures to ensure compliance with federal and NSF award requirements," but it identified three areas for improvement. OIG recommended that the University needs to "(i) improve management of its \$1.3 million minority alliance awards, (ii) revise its labor effort reporting process to ensure reliable confirmation of all salary charges to NSF grants, and (iii) improve its property management system to safeguard equipment purchased with NSF funds." The University has agreed with the audit findings and recommendations and is taking appropriate corrective actions.

Recent University Audits

In descending order by date of news article

Institution	Headline	Source	Date	Executive Summary
The University of Texas Medical Branch	<i>University of Texas Medical Branch Confirms USDA Investigation, Disputes Findings</i>	<i>Report on Research Compliance</i>	Sept 15, 2011	The U.S. Department of Agriculture (USAD) is investigating the University of Texas Medical Branch (UTMB) for alleged mistreatment of research animals. In January, PETA filed a nine-page complaint, which prompted USDA's investigation. USAD conducted an unannounced inspection and found four violations of the Animal Welfare Act. Although UTMB disagrees with some of the findings, UTMB is taking the matter seriously and has communicated their remedial steps to alleviate concerns. Since the original inspection, USDA has re-inspected UTMB's facilities on two separate occasions and cited only minor findings, which was immediately corrected. The investigation is ongoing and USAD will not release findings until its conclusion.
Harvard University	<i>Harvard Researchers Disciplined for COI Violations</i>	<i>Report on Research Compliance</i>	July 7, 2011	Psychiatrists from the Harvard Medical School and Massachusetts General Hospital are being investigated for failing to comply with conflict of interest policies. They allegedly accepted payments from pharmaceutical companies while working on federal grants that involved the same research medications made by the firm. All three psychiatrists have claimed that it was an "honest mistake." They wrote a letter to their colleagues, divulging this information to them and letting them know that refraining from participating in industry-sponsored activities for the next year.

Financial Conflict of Interest

Financial Conflict of Interest

See Document entitled "Old DHHS COI Regulations vs. New COI Regulations"

Exercise #2

Ranking Risks

What is your organization sensitive to?

- Executive leadership
- Prior experience

What would you change?

How does your organization prioritize risks?

Who prioritizes?

- Executive leadership
- Committee
- Individual

Ranking Risks

See Word Document entitled "Areas of Risk"

Exploring Complex Risks

What is a complex risk?

High profile = complex?

When you're doing something right, it doesn't seem complex

Conducting the Risk Assessment

Benefits of the Risk Assessment

Federal Sentencing Guidelines:

- “Organizations shall periodically assess the risk of criminal conduct and shall take appropriate steps...”

OIG Program Guidance

- “Institutions should consider conducting risk assessments to determine where to devote audit resources...”

Benefits of the Risk Assessment

- Being proactive has a number of benefits
- Supports improved enterprise risk management
- Increases compliance awareness and support a culture of compliance
- Raises awareness of program value
- Helps mitigate penalties and show good faith efforts
- Supports a program of continuous improvement

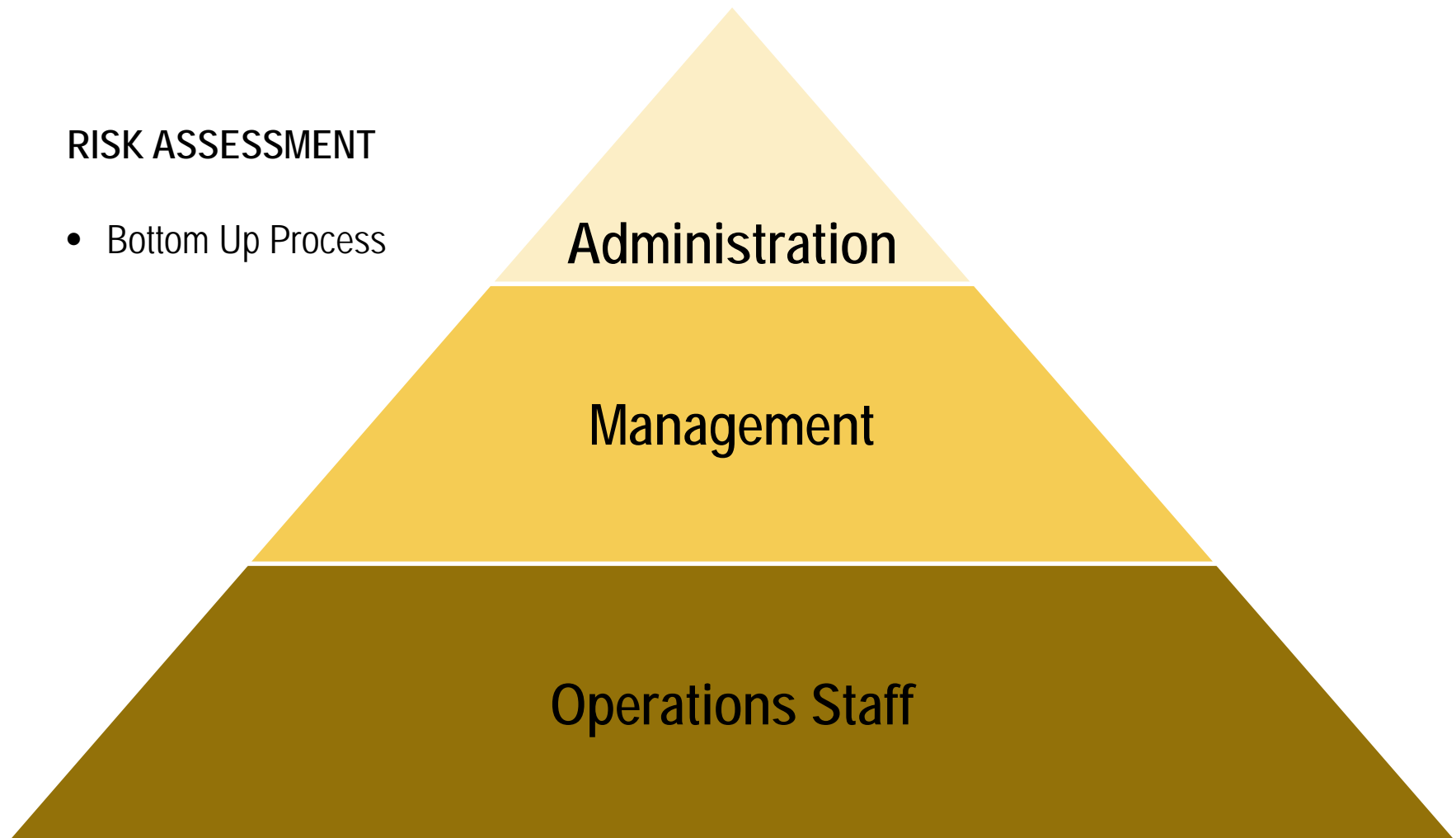
Auditing and Monitoring

Visuals:



RISK ASSESSMENT

- Bottom Up Process



NOW IS THE BEST TIME

- Fiscal Year Process
- Last Risk Assessment
- Competing Initiatives
- Regulatory Overviews



THE MORE THE MERRIER

- Compliance Team
- Legal
- Administration
- Researchers / PIs
- Research Staff
- Institutional Review Board
- Others...
- Risk Management
- Human Resources
- Quality
- Revenue Cycle
- Facilities
- External Counsel / Advisors
- Etc., Dependent on Organization Structure

Where

- Individually
- Content Group
- All

- Face-to-face Interviews
- E-mail
- Survey
- Group Setting



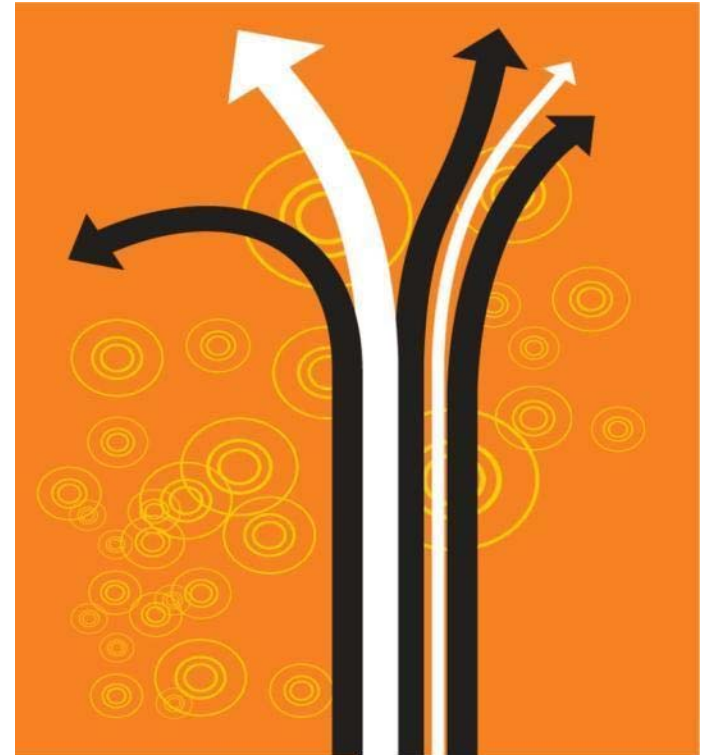
IDENTIFICATION...making a list

- Draw on experience
- Regulations
- OIG
- DOJ
- Policies
- Prior Risk Assessment
- OHRP/FDA/ORI



ASK QUESTIONS

- What can go wrong?
- Where most vulnerable?
- Where is the greatest exposure?
- What keeps you awake at night?



ASSESSMENT/PRIORITIZATION

- Type:
 - Experimental
 - Commercial
 - Ranking
 - Low
 - Medium
 - High
 - Quantitative Scoring



RESULTS

- Participants in Process
- Compliance Committee
- Administration
- Board Compliance & Audit Committee
- Build-Your-Own Audit/Work Plan



Exercise #4
“Bringing It All Together”
Ranking Risks with UT Health’s Tool

Wrap-up

Special Thanks!!!

HuronLifeSciences

Leslie K. Ball, MD

Director

Leslie.Ball@fda.hhs.gov

Division of Scientific Investigations

Office of Compliance, Center for Drug
Evaluation and Research (CDER)

Food and Drug Administration

Karena Cooper, JD, MSW

Acting Team Leader, Enforcement Policy Team

Regulatory Counsel

Karena.Cooper@fda.hhs.gov

Division of Scientific Investigations

Office of Compliance, Center for Drug Evaluation and
Research (CDER)

Food and Drug Administration

Conclusions / Questions

HuronLifeSciences

Jodi S. Ogden, MBA, CRA

Executive Director

Sponsored Projects Administration

UTHealth | The University of Texas Health Science Center
at Houston

O: 713 500 3968

Jodi.Ogden@uth.tmc.edu

Matthew Lester, MBA, MHA

Managing Director

Higher Education and Life Sciences Advisory Practice

O: 267-872-7021

mlester@huronconsultinggroup.com

Thank you for your participation.

HuronLifeSciences