Conduct of research is inherently risky
- Creating knowledge and exploring the application of that knowledge
- New materials, compounds, devices and technology
- Participation of research subjects
- Competing roles, interests and goals
  - Faculty independence
  - Voluminous regulations
  - Rules and policies are not consistent

Drivers of Risky Behavior
- Insufficient resources
- Struggling economy
- Diminished/insufficient training and education programs
- Increased oversight, reporting requirements and public demand for accountability
MAJOR RISKS & HOT TOPICS
CONFLICT OF INTEREST
- Revised PHS Financial Conflict of Interest Regulations
  - Scope of significant financial interests expanded
  - Lower disclosure thresholds
  - Shift of responsibility for making related determinations
  - New disclosure requirements for reporting travel
  - Mandated training and public disclosure
  - Conflicting guidance issued by NIH
- Increased NSF OIG scrutiny of NSF’s response to FCOIs reported by grantees
- SBIR/STTR Proposals and Awards
  - Increased involvement by UC faculty
  - Dual COI disclosure requirements may apply (Federal v. State)
  - Increased risk for misuse of UC resources
  - Risk assessments

MAJOR RISKS – SPONSORED PROJECTS
- Ensuring Compliance with Award Terms and Conditions
  - Costing practices
    - Allowable, allowable, and reasonable costs
    - Spending rates
    - Cost transfers
    - Cost sharing
  - Project reporting
    - Delinquent reporting
    - False statements/data
    - Compliance with public access requirements for publications
  - Subrecipient monitoring
    - Debarment/suspension reviews
    - Research progress and expenditure monitoring
    - FFATA reporting requirements

HOT TOPICS – SPONSORED PROJECTS
- Federal Budget and Sequestration
- New Federal Initiatives and Mandates
  - Grants reform
    - Consolidation of OMB circulars
  - Grants reporting information project
  - NASA restriction on bilateral activities with China
### MAJOR RISKS & HOT TOPICS
#### HUMAN RESEARCH PROTECTIONS

- Major Risks
  - Informed consent process
  - Privacy and confidentiality
  - Registries and repositories

- Hot Topics
  - Genetic research
  - Whole genome sequencing
  - Incidental findings
  - Single IRB review of multi-site clinical trials
  - Local context
  - Shared vs. non-shared models

### MAJOR RISKS & HOT TOPICS
#### ANIMAL CARE AND USE

- Major Risks
  - Concurrence between proposed use of animals in grants/contracts and actual/reported use
  - Promoting research protections while facilitating the conduct of research – the challenge presented by experimentalists

- Hot Topics
  - Animal facility disaster plans
  - Animal rights activism

### MAJOR RISKS & HOT TOPICS
#### HUMAN STEM CELL RESEARCH

- Provenance
  - Source/Origin of tissue/cells
  - Did donor(s) provide informed consent?
  - Are the materials being used as described in the informed consent?

- Promoting/facilitating compliance in a quickly changing field
  - New discoveries and improved technology
  - Stem cell therapies in clinical trials – merging of human stem cell and human research oversight
Facilitating research and promoting compliance in an ever changing regulatory landscape

Engaging principal investigators as research managers
- The most important and valuable research administrators at any institution are its principal investigators

Impact of stagnant/shrinking resources
- Training & education programs
- Maintaining oversight and quality improvement programs

ON-GOING CHALLENGES

HHS OIG AUDIT PLANS – FY 2013

GRANTEE FINANCIAL & ADMINISTRATIVE COMPLIANCE

- Compliance with ARRA special requirements
- Focus on construction grants and claims for equipment costs
- College and University Compliance with Cost Principles
- Input from HHS operating divisions to be considered in selecting grantees
- Inappropriate Salary Draws from Multiple Universities
- In response to recent indictment of two professors who were drawing salary from two universities
- Cost Sharing Claimed by Universities
- Focus on grantee practice of waiving F&A costs to meet cost sharing obligation
- Continue Monitoring Grantee A-133 Audit Reports
RESEARCH CONDUCT & COMPLIANCE

- Human Subjects Protections Practices – Grantees Collecting Biospecimens
  - Determine the extent to which research involving bio specimen collection complies with human subjects protection regulations with emphasis on informed consent documents
  - Review PI and IRB measures to address the unique risks of biospecimen collection and use

- Use of Data Safety Monitoring Boards in Clinical Trials
  - How and to what extent are grantees complying and how NIH is ensuring such compliance

- Protections of Human Research Subjects
  - Review of HHS Office of Human Research Protections’ oversight of institutional compliance with federal human research subject protection requirements
  - Follow up to a 1998 report that identified vulnerabilities in federal oversight

NSF OIG AUDIT PLANS – FY 2013

TWO WORDS

Data Analytics
TWO PHASE APPROACH

RISK IDENTIFICATION THROUGHOUT THE PROJECT LIFECYCLE

NSF OIG AREAS OF FOCUS

- ARRA-funded awards
  - Increased risk due to accelerated spending
  - Academic Research Infrastructure Program
- Federal Information Security Management Act (FISMA)
  - Focus on NSF’s information security program and practices
  - Negative findings may lead to downstream challenges for universities
- Project Reporting Follow-up
  - Focus on NSF implementation of internal controls in response to 2004 finding – 47% of final/annual project reports submitted late or not at all
  - On-going and planned audits of universities (and other grantees)
  - Cost principles
  - Internal controls
  - Compliance with award terms and NSF requirements
- Continue Monitoring Grantee A-133 Audit Reports
REDUCING RISKS TOGETHER

- Successful and productive partnerships between campus IAS and Office of Research
  - Create and implement outreach and education programs
  - Engage in mutually beneficial educational/training opportunities
  - Communication
    - Subject matter experts for information and advice
    - Collaborative risk identification and reduction efforts
    - Assistance with quality improvement programs
  - Develop analytics
  - Consider designating certain audit staff to become broadly knowledgeable regarding research administration and compliance
  - Consider research administration and research conduct experience when recruiting vacancies
  - Expand continuing education for audit staff to include research administration and compliance issues

RESOURCES

- OIG Work Plans
  - HHS OIG Work Plan – FY 2013
  - NSF OIG Work Plan – FY 2013
- News, Information and Advocacy
  - Council on Governmental Relations
  - Federal Demonstration Partnership
  - Report on Research Compliance
- Research Administration educational programs and networking
  - National Council of University Research Administrators
  - Society of Research Administrators International

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