

RESEARCH – RISKS AND HOT TOPICS

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UC'S RESEARCH ENTERPRISE & RISK

- 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 AND HOT TOPICS

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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, allocable, 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

ON-GOING CHALLENGES

- 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

**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

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](#)
 - Association of research universities that provides advice and information to its members and ensures that federal agencies understand academic operations and the impact of proposed and current regulations on the academic research enterprise
 - [Federal Demonstration Partnership](#)
 - [Report on Research Compliance](#)
 - [Guide to Managing Federal Grants](#) and [Federal Grants News](#)
- **Research Administration educational programs and networking**
 - [National Council of University Research Administrators](#)
 - [Society of Research Administrators International](#)

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