Compliance Risks in Academic Medical Centers

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A Word About Reimbursement Risks

- Outliers
- Coding of E&M services- PATH, upcoding
- Consultations
- Billing insurance only
- Billing for medications
- Medical necessity
- Imaging in the Emergency Room
- Nonphysician practitioners' services
- Services "incident to"
- Physicians financial relationship with ASCs

The Regulatory Environment

- Financial Management of Grants and Contracts
- Human Subjects Protections
- HIPAA
- Financial Conflict of Interest
- Research Misconduct
- Public Policy Obligations
- Billing for Clinical Services
- Intellectual Property - Invention and Patent Reporting
- Tax Exemption
- Animal Care and Use

Topics for Today

- Grants and Contracts Management
- Human Subjects Protections
- Research Misconduct
- Animal Care and Use
- Conflict of Interest

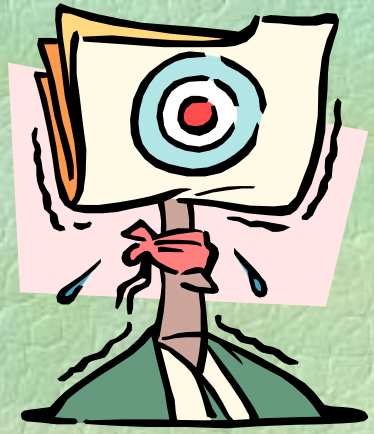
Risks of Noncompliance

- ***BAD***
- Increased oversight
- ***REALLY BAD***
- Increased reporting responsibilities
- Paybacks and fines and funding cuts
- ***REALLY REALLY BAD***
- Suspension / Exclusion from participation in federal programs
- Civil and criminal actions
  - False Claims Action

Grants Administration How Jefferson Got Religion

- Whistleblower complaint / anonymous allegations
- NIH review of grants administration and report
- Audit
- Allegation of scientific misconduct

Overall Criticisms



- Effort reporting
- Improper charging of costs
- Frequent cost transfers
- Poor documentation
- Significant personnel cost Rebudgeting
- Changes in key personnel not reported
- Inaccurate and untimely financial reports
- Lack of internal monitoring
- No formal research education
- Managing grants retrospectively instead of **prospectively**

The Outcome

- HHS - OIG - DOJ
  - Threatened false claims action
- NIH
  - Exceptional Designation

Our Advice

- Know the rules and regulations
- Know roles and responsibilities
- Translate the rules into policies and procedures
- Implement the policies and procedures
- Monitor

Know the Rules & Regulations

- Read the appropriate circulars and grants policy statements
- Know the funding agency's requirements/guidelines
- Know terms of the notice of grant award
- Mandatory training sessions
- Learn institutional policies and institutional processes
- Talk to a program officer
- **When in doubt, ASK**

Federal Regulations Governing Research Administration

- 45 CFR Part 74
- NIH Grants Policy Statement
- PHS Grants Policy Statement
- 48 CFR Subpart 31.2 FAR

Office of Management and Budget Circulars

- OMB A-21 Cost Principles for Educational Institutions
- OMB A-110 Uniform Administrative Requirements for Institutions of Higher Education
- OMB A-133 Audits of Institutions of Higher Education and Other Non-profit Organizations

NIH Grants Policy Statement

- Intended to give policy guidance that serves as the terms and conditions of NIH awards
- Provides information about NIH staff
- Four parts:
  - General information about grants and the review process
  - Standard terms and conditions
  - Special terms and conditions
  - Listing of pertinent offices and officials

Roles and Responsibilities Training and Education

- NIH expectations:
- Define roles and responsibilities in writing
- Communicate roles and responsibilities / guidance / policies and procedures
- Education and continuing education
- Website
- Oversight

Roles and Responsibilities

Principal Investigator

- Primary administrative and scientific responsibility for all aspects of a proposal from submission, to award, to close out.

Department Chairman

- Overall administrative and financial operation o the department.
- Oversight of research activity, time and effort, space and other resources

Department Administrator

- Administrative support to the PI
  - Submission of proposals
  - Management of active sponsored research projects
  - Reviews and counter signs (as designated by the Chairman) sponsored administrative and financial actions

Grants Administration Problems
Translating the Rules into Practice

A. At grant end, the administrator informs the PI that there is $50,000 remaining on an NIH grant A. They decide to transfer the salary of a post doc from the preceding six months where the grant B he is working on is now in deficit. Additionally, the administrator wants to charge a PI to grant A who is currently between projects and unfunded.

Grants Administration Problems

B. PI Smith is committed for 75% effort on two grants. He is also a division chief, and teaches one class a semester. He also spends two days a week consulting for a bio-tech firm. He reports his research effort on the time and effort form as 75%.

C. Test tubes and other supplies are used within a PI's lab who has 3 federal grants. His administrator charges grant A in January for the supplies, grant B in February, and grant C in March.

Grants Administration Problem Areas

- Salary and nonsalary transactions
- Cost allocations
- Cost transfers
- Time and effort

Indicators of Problems

- Unallowable costs charged to project
- Significant rebudgeting, under or overspending
- Frequent delinquent cost transfers or retroactive personnel action forms
- Assigning costs based on fund availability or project expiration
- Charging the budgeted amount versus actual usage
- Charging after grant expiration date
- Equipment purchases near end of project

Status Change for PIs and Key Personnel

- Approval must be requested from federal sponsor BEFORE a PI/key personnel
  - Withdraws from the project
  - Will be absent from the project for three months or more
  - Reduces effort by 25% or more than that approved
- A formal letter must be prepared by the PI, signed by the PI, Chair and Research Administration
- Research Administration will submit the request to the sponsor and require written sponsor approval before changes are processed

Research vs Treatment

- Physician uses “investigational” procedure on patient with life threatening condition. However, the physician considers the procedure to be a novel treatment rather than research, and IRB review is not obtained. The procedure is performed on numerous people and is published.

Research Defined

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.*

*45 CFR 46.102

Research versus Treatment

Research -a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Treatment - interventions designed solely to enhance the well being of an individual patient and that has a reasonable expectation of benefit for the patient

IRBs and the Regulatory Environment

- Biotechnology revolution
- Growth in federal funding
- Increase in number of new drugs and devices
- Growth and complexity of clinical trials

Regulatory Structure
OHRP and FDA Regulations

- 45 CFR Part 46 and 21 CFR Part 50, 56
- Based on “Common Rule” federal policy
- Protects human subjects through:
  - Federalwide Assurance
  - IRB review
  - Informed consent requirements

Regulatory Structure OHRP and FDA Regulations Continued

- IRB membership requirements
  - quorum, expertise, diversity
- Review criteria
  - elements of informed consent
  - exempt
  - expedited
  - waiver of informed consent
- Special Populations - minors, women, prisoners
- Clinical Trials Data and Safety Monitoring

Most Common Findings Resulting in Suspension

- Initial and continuing review
- Expedited review procedures
- Reporting of adverse events
- Review of protocol changes
- Application of exemptions
- Informed consent inadequacies
- IRB membership, expertise, staff support and workload
- Documentation of IRB activities, findings and procedures

Research Integrity Problem

- Researcher with history of employment problems alleged other researchers were presenting data at a national conference that did not support the research conclusion
- Investigator alleges that fellow researcher discarded all of investigator's specimens from lab

Integrity of the Research Process vs Integrity of Science

- Integrity of Research Process
  - use of honest and verifiable methods in proposing, performing, evaluating, and reporting research activities
- Integrity of Science
  - **misconduct in science**
  - questionable research practices
  - other misconduct

What Constitute Scientific Misconduct?

- Includes activities that violate ethical standards of scholarship as established by the academic community
- Defined as:

plagiarism; the fabrication or intentional falsification of data, research procedures or data analysis; other deliberate misrepresentations in proposing, conducting, reporting, or reviewing research

Research Misconduct Is

Fabrication

- Making up data or results

Falsification

- Intentionally changing data or results

  1 + 1 = 3

Plagiarism

- Includes the theft or misappropriation of intellectual property and the substantial unattributed textual copying of another's work.

Questionable Research Practices

- Includes, but is not limited to,:
  - Failure to retain significant data
  - Maintaining inadequate research records
  - Using inappropriate statistical or other methods of measurement
  - Refusing to give peers reasonable access to unique research materials or data that support published papers
  - Inadequately supervising research subordinates or exploiting them

Institutional Responsibilities

- PHS regulation on handling allegations of scientific misconduct (42 CFR, Part 50-A) requires
  - an approved policy and procedure for responding to alleged misconduct in research
  - file annual report on possible research misconduct
  - must report to ORI any investigation of alleged misconduct that appears substantial
  - places responsibility for dealing with and reporting possible misconduct in science on institutions
  - must protect the reputation and position of good faith whistleblowers
  - restore reputations where allegations are not confirmed

Responding to Alleged Misconduct in Research

- Confidentiality
- Inquiry Committee
  - Is there enough substantiation to the allegations?
- Investigation Committee
- Findings:
  - No misconduct in research
  - No misconduct in research but problems were identified that require administrative remedies
  - Misconduct in research occurred.

Potential Outcomes

- Termination from institution
- Suspension
- Debarment from participation in federal programs - usually for a period of 3-10 years

Whistleblower Protection Guidelines

- Institutions must:
  - Establish policies and procedures to protect whistleblowers
    - **TJU Policy on Reporting and Retaliation**
  - Provide fair and objective procedures for resolving the issues
  - Evaluate the concerns of a whistleblower fully and objectively

Animal Care and Use Issues

- An investigator uses animals in a protocol which does not appear related in purpose to the grant charged with the cost of the animals.
- Additionally, the rats are observed chewing on their feet after the experimental treatment is administered.

Regulation of the Care of Animals

- Office of Lab Animal Welfare- NIH
  - PHS Policy on Humane Care and Use of Laboratory Animals
  - Guide for the Care and Use of Laboratory Animals
- Association for Assessment and Accreditation of Laboratory Animal Care (AALAC International)
- Animal Welfare Act and Regulations
  - 7 USC§§2131 et.seq.
  - 9 CFR Volume 1, Part 1-199

Conflict of Interest Problem

PI with a 5 year grant funded at $2 million by Big Bucks Biotech Company, a private company, has $1 million in stock plus 500,000 stock options. He also has a consulting agreement with Biotech company for $40,000 per year.

- 42 CFR Part 50 Subpart F grants
- 45 CFR Part 94 Contracts

TJU's Conflict of Interest Program

- Annual disclosure for trustees, faculty & key personnel
- Sanctions for failure to comply
- Conflicts must be managed
- Threshold conflicts reviewed by Committee
- Must disclose conflicts on IRB consent form

Conclusion

- Numerous risk areas
- Highly regulated
- Under intense public scrutiny
- Requires comprehensive long-term strategy