

Auditing and Monitoring for Grants

HCCA Research Compliance Conference

September 17, 2006

Why do we monitor research?

Research at our universities:

- Comprises a significant and material part of our activities;
- Represents the area of our operations that management least understands;
- Is highly complex and may be the least consistently managed part of the business.

Why do we monitor research?

Adequacy of information resources

Application and interpretation of research regulations

Professional pressures on faculty investigators (*and administrators!*)

Clarity of roles and responsibilities

How can we improve?

Define roles and responsibilities

Create accountability

Establish expectations

Understand and communicate research risks

Identify the risks and opportunities

What type of review?

Grant Review v. Topical Review

- Consider impact of external reviews
- Evaluate and prioritize in conjunction with other university assessment processes

Where is the focus?

- Personnel and practices in a discrete unit
- Assessing policies and controls throughout the institution

A few risk areas

Effort Reporting

- Clarify the universe of activity – *and share information*
- Review highly-committed individuals
- Evaluate commitments v. reported effort
- Assess timeliness of completion
- Ensure appropriate “certifiers”
- Compare reported effort with actual charges
- Scientific and budgetary overlap

A few risk areas

Cost Transfers

- Assess volume relative to total transactions
- Examine the timing of transfers
- Evaluate the “route”
- Review justification (*especially in light of the timing and route*)

A few risk areas

Direct Charging

- Apply the notions of allocability, allowability, reasonableness, and consistency
- Know the institution's general practice
- Understand unlike circumstances
- Understand the laboratory setting (*especially when there's no lab*)

A few risk areas

Subcontractor Monitoring

- Applicability of regulations
- Consider the subcontractor
 - Another university or federal contractor
 - A commercial organization that is not a federal contractor

A few risk areas

Biohazards

- Assess physical security and controls
- Confirm appropriate training
- Evaluate lab review processes
- Coordinate tests of the process
- Evaluate IBC procedures

A few risk areas

Conflicts of Interest and Commitment

- The most dangerous of these are non-financial
- Know how the university defines conflicts
- Understand and apply both federal requirements and accepted practice
- Know what the university expects from conflicts management processes
- Evaluate *all* reporting mechanisms

A few risk areas

Human Subjects

- Confirm appropriate training
- Confirm conflicts disclosures
- Evaluate informed consent processes
- Ensure subject eligibility
- Review payments to subjects
- Confirm appropriately documented IRB review

A few risk areas

Animal Subjects

- Confirm appropriate training
- Assess adequate knowledge of the protocol
- Confirm appropriately documented IACUC review
- Monitor timely and accurate census and billing
- Review the use of appropriate species and numbers of animals

A few risk areas

Scientific Misconduct

- Data falsification
- Data fabrication
- Plagiarism
- Other serious deviations from accepted practice?
 - Understand the university's definition
 - Evaluate the process for reviewing and responding to misconduct

A few risk areas

Authorship, Mentorship and
Collaboration

What about risk assessments?

One Model for Assessment

1. General risk survey
2. Facilitated discussion
3. Review of data
4. Closing meeting

Why are you conducting the assessment?

What will you do with the results?

Impact on training

Risk assessment activities highlight risk areas that can inform training and education

Training and education activities communicate institutional expectations

Risk assessment helps evaluate the success of training activities

Other Considerations

Support from legal counsel

Coordination with other university entities

General plan for prioritizing and responding to issues

Proactive v. reactive approach

Helpful orientation

Questions?

Tim Fournier, EdD

Associate Vice President for Research Integrity

Northwestern University

312.503.0054

nu-ori@northwestern.edu