



Hot Compliance Topics for a Cold February Day

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NCURA Region I RADG Meeting

February 14, 2008

What's Research Compliance?

Scientific Integrity

Principle:

*Ensures validity of results/
Maximizes return on public investment*

Conflict of Interest
Conflict of Commitment
Research Integrity
Data, Resource Sharing, Cyber Security
Public Access to Publications

Welfare of Subjects and the Environment

Principle:

*Provides safety/welfare of
subjects and environment*

Human Subjects
Animal Welfare
HIPAA
Environmental Health & Safety
Select Agents
Radiation Access

Social and Political Requirements

Principle:

*Meets National Social, Economic,
Security Interests*

SEVIS/Visas
Export Controls
Race, Gender & Handicap Equality
and Education
Lobbying
Debarment
Drug Use

Cost Policy/ Financial Management

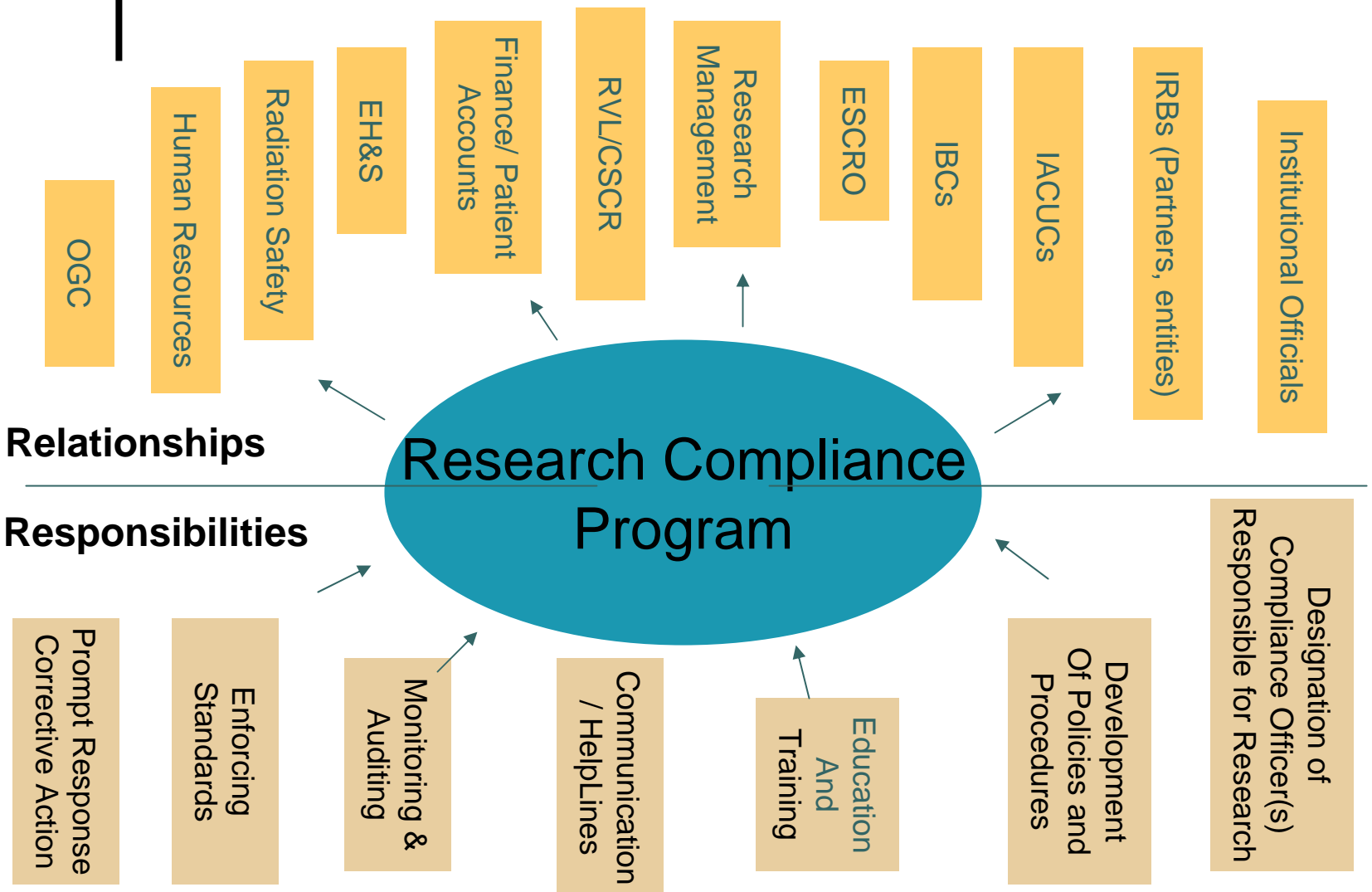
Principle:

*Ensures fair and reasonable costs
to the Government*

Cost Principles
Salary Charges/Effort Reporting
Indirect Costs
Cost Sharing
Clinical Trials Billing

*Adopted with permission from Geoff Grant

Relationship Matrix





Why All the Current Emphasis on Compliance?

- Compliance is part of the bargain we make when we accept federal funds
- When we accept sponsored funding, we accept statutes, regulations, policies, award terms and conditions...



What is the Effect of Non-Compliance?

- Loss of grant funding
- Vulnerability to audit/suit
- Large settlements/fines and corrective actions
- Administrative sanctions
- Adverse publicity— damage to reputation
- Loss of public confidence
- Loss of donor confidence

The Results of Non Compliance: Significant Audits/Settlements

University of Minnesota
Misuse federal funds
\$32 million

Florida International Univ
Effort Certification &
Direct Costs
\$11.5 million

Johns Hopkins Univ
Effort Certification
\$2.7 million

Univ of Southern California
Questioned Costs
HHS/OIG Audit
\$400,000

Univ California/San Francisco
Animal Care Allegations
\$92,500 fine

New York University Medical
Center
Inflated research grant costs
\$15.5 million

East Carolina Univ
Questioned Costs
HHS/OIG Audit
\$2.4 million

Public Demand
for
Improved Control

Mayo Foundation
Mischarging federal grants
\$6.5 million

Univ
Alabama/Birmingham
Effort Certification &
Clinical Research Billing
\$3.4 million

Cornell Medical
Clinical Research Issues
\$4.4 million

Harvard/BIDMC
Costing Issues
Self-Reported
\$3.25 million

Northwestern University
Committed Time/Effort
\$5 million



What Has Changed?

- Largest research budgets in history brought additional scrutiny
- Increased public demand for accountability (e.g. Enron)
- Increasing use of qui tam provisions of False Claims Act
- Increasing level of unfunded mandates putting pressure on us to “do more with less”



Financial Compliance Issues



High-risk Audit Areas (per DHHS OIG 2007 Workplan)

- **Direct Charging:** Are university administrative and clerical salaries being appropriately charged?
- **Level of Commitment and Effort Reporting:** Determining whether salary charges to NIH grants accurately reflect researchers' efforts spent on those grants
- **Cost Transfers:** Do cost transfers follow NIH policy, University policy, and provide adequate written documentation/explanation?
- **Compensation of Graduate Students Involved in NIH-Funded Research:** Does compensation exceed a market level of a postdoctoral researcher doing comparable work at the same institution?



NIH Top Compliance Issues

- Inaccurate Effort Reporting
- Misallocation of Costs
- Excessive Cost Transfers
- Unallowable Costs
- Inadequate Subrecipient Monitoring
- Incomplete Forms Describing Existing Support on Applications
- Delinquent Reporting to Sponsor
- Adherence to Special Award Requirements
- Inadequate Institutional Oversight



Cost Sharing



What Is Cost Sharing?

Definition: “that portion of project or program costs not borne by the Federal Government” OMB A-110

● Key Terms

- Mandatory
- Voluntary Committed
- Voluntary Uncommitted

Regulatory References

- OMB Clarification (January 5, 2001)
- OMB Circular A-110, __.23
- A-21, J section (for allowability of cost)
- NSF Policy



Requirements for Cost Sharing (A-110, section .23)

- Verifiable from recipient's records
- Not included as contributions for any other federal program
- Necessary & reasonable for accomplishment of the project and allowable under cost principles
- Not paid by gov't under another award
- Provided for in the approved budget
- Conform to other provisions



The Cost Sharing Cycle

- Starts with a commitment in a proposal
- Cost sharing commitment may be “mandatory”, “voluntary”, or “inadvertent”
 - Mandatory—required by agency in program announcement
 - Voluntary—not required by agency, offered by PI or Institution
 - Inadvertent—statements in a proposal that are interpreted as a commitment
- Once a proposal is awarded, all commitments become mandatory
 - A condition of the Award
 - Must be documented and reported



A Suggestion to Minimize Cost Sharing

- **Suggested wording for Harvard proposals (to avoid cost sharing):**

“The full academic year salaries of members of the Faculty of Arts and Sciences are paid by the University with the understanding that they will ordinarily teach and conduct research freely and flexibly and not make substantial, specific quantified commitments of time and effort to specific organized research projects. “



Payroll Distribution and Certification (“Effort Reporting”)



A-21 Section J.10

- **Compensation for employees:**
 - Payroll distribution (not called “effort reporting” in A-21)
 - Salaries, wages & fringe benefits distributed to benefiting activities
 - Estimates with a “degree of tolerance” is appropriate



Effort Reports

A-21 J.10b.(2)

- Reports will reasonably reflect the activities for which employees are compensated by the institution
- Reports will be signed by the employee, PI or responsible official(s) using suitable means of verification that the work was performed.

Question: Who can sign the certification at your institution? If it's not the PI, what means of verification?



Effort Reports

45 CFR Part 74, App. E

- “...estimates of effort...must be prepared by the individual who performed the services or by a responsible individual such as a department head or supervisor having first-hand knowledge of the services performed on each research agreement.” 45 CFR Pt 74, App. E

Question: Who can sign the certification at your institution? If it's not the PI, what means of verification?



Effort Reporting Requirements

- Your institution's effort reporting system must provide for modification of an individual's salary distribution commensurate with a significant change in the employee's work activity.

Question: What constitutes a ***significant change*** at your institution? Is this in your policy?



Effort Reporting Requirements

- Effort reporting system
 - Should be part of institution's official records
 - Provide for independent internal evaluations to ensure compliance
 - May reflect workload as a percentage distribution of total activities (rather than hours)
 - Frequency of reporting varies depending upon method of certification—this is an institutional decision



Effort Certification Areas of Risk

- Individuals assigning and certifying effort do not understand the requirements, or don't care...
 - Policy not followed, e.g late certification
 - Effort not commensurate with salary
 - Individual certifying does not have "suitable means of verification
 - Certify budgeted effort, not actual
 - Compensated vs. uncompensated effort



Effort Certification – Areas of Risk

- Multiple sources of pay (e.g., affiliated entities, hospitals, faculty practice plan)
- NIH salary cap
- NIH K awards
- Summer salaries
- Cost transfers after certification
- Charging 100% salary to grants
- No such thing as the 40 hour week!



Direct Charging of Administrative and Clerical Costs



Direct-Charging of Administrative and Clerical Costs

OMB Guidance on A-21 Revision to section F.6.b. (July 1993)

“In developing the departmental administration cost pool, special care should be exercised to ensure that costs incurred for the same purpose in like circumstances are treated consistently as either direct or F&A costs....”



A-21 Revision - July 1993

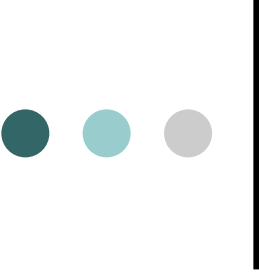
- “The salaries of administrative and clerical staff should normally be treated as F&A costs. Direct charging of these costs may be appropriate where a major project or activity explicitly budgets for administrative or clerical services and individuals involved can be specifically identified with the project or activity.
- Items such as office supplies, postage, local telephone costs, and memberships shall normally be treated as F&A costs.”

[Ref: A-21:F6(b)]



Implications of F.6.b. Guidance

- OMB: “Direct charging....may be appropriate where a major project or activity explicitly budgets for administrative or clerical services”
 - Do we explicitly budget for these costs in the research proposal?
 - Does the the proposal include a written justification (i.e. why the normally indirect costs are necessary for project performance)?
 - Is this a “major project” as defined in Exhibit C of A-21?



Administrative and Clerical Salaries for Hospitals...

NIH Prohibition DOES NOT APPLY!!!!!!!

But be careful. Salaries *can* be direct charged (if not included as part of your F&A rate), but still must be:

- Reasonable
- Allowable
- Allocable
- Conform with institutional policies



Allocability and Allowability Issues



A-21 Allocation and Documentation Standards


- C.4.d.(1) Cost principles. The recipient institution is responsible for ensuring that costs charged to a sponsored agreement are allowable, allocable, and reasonable under these cost principles.

C.4.d.(2) Internal controls. The institution's financial management system shall ensure that no one person has complete control over all aspects of a financial transaction.



Consistency in Budgeting and Direct Charging

- Practices used in estimating costs in a proposal must be consistent with practices used in charging the project
 - The Budget is the “financial expression of the project as **approved** during the award process” (OMB Circular A-110)
 - Terms of the award describe how much flexibility the PI has to “rebudget”
 - Cost adjustments will be made if the institution fails to comply with A-21 or its established practices



Caution: Some Costs are Indirect Only or Direct Only

- Expenses gov't considers to be always indirect, never direct
 - Salaries attributable to the administrative work of faculty and other professional personnel...Including “bid and proposal preparation”
- Expenses that gov't considers to be always direct, never indirect
 - Salaries of technical staff, lab supplies, whenever identifiable to a particular project



Cost Overruns: Always Unallowable

- OMB Circular A-21, section C.4.b.

“Any costs allocable to a particular sponsored agreement under the standards provided in this Circular may not be shifted to other sponsored agreements in order to meet deficiencies caused by overruns...or for other reasons of convenience.”



Examples of Reviewable Expenditures

- Administrative and clerical salaries
- Office supplies
- Food
- Late charges or fines
- Entertainment costs
- Foreign travel
- Awards and prizes



Examples of Reviewable Expenditures

- Memberships
- General purpose equipment, including computers
- Subscriptions and books
- Local telephone costs
- Communications costs (cell phone, pager, internet service, pda)
- Visa costs, including expedited visa



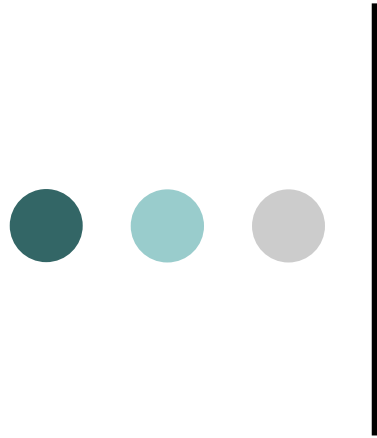
Other Allocability Issues

- Expenditure patterns-accelerated or delayed
- Charging costs at the end of the grant (especially equipment)
- Inadequate documentation/explanation of benefit for charges made to grants (e.g. procurement card purchases)
- Inadequate substantiation of proportional benefit (i.e. “reasonable basis”) for allocation of costs among interrelated projects
 - “rotation” of charges among grants unacceptable
 - No federal funds for ineligible stem cell work



Procurement Cards

- Issues with Procurement Cards
 - Justify why the expense is allocable to the award—what is the direct benefit?
 - Make sure there are detailed receipts that describe the benefit to the project
 - Is a cost transfer required (or are these posted directly to a grant)?
 - How are unallowable costs monitored on procurement cards?
 - How are reconciliations handled?



Cost Transfers



Cost Transfers

- Definition: transfer of cost from one institutional account to another
 - Greatest risk is when costs are transferred to a sponsored account
 - It may be wise to narrowly define cost transfer
- Cost transfers may be symptomatic of problems—why didn't we get it right the first time?



Cost Transfers

- Harvard Definition of Cost Transfer
 - A transfer to a federally funded account of a charge previously recorded elsewhere
- NIH Policy
 - Cost transfers are “corrections of errors”
 - Transfers must be timely (within 90 days of the discovery of the error) and supported by documentation that fully explains how the error occurred
 - Explanation that the transfer was made “to correct error” or “to transfer to correct project” is not sufficient



Cost Transfers

- Do you have a written policy?
- Do you monitor compliance with, and enforce, your policy?
- What happens to the effort certification after salary costs are transferred to another grant?
- What are the audit issues?
- What is the effect of late transfers?



Subawards, Subrecipients, Subrecipient Monitoring



Subaward (to a Subrecipient)

- Used when a portion of a project is performed by another entity
- States work to be performed, conditions to be imposed on subrecipient, flow-down of regulations and laws, terms and conditions
- A subaward transfers a portion of a sponsored award to another entity for the purpose of programmatic effort on the project
- “Pass Through Entity” (issuing the sub) is responsible for the subrecipient’s performance



Subrecipients

- Another organization (not individual) which assists in carrying out a portion of the proposal's scope of work
- Has programmatic decision making
- Responsible for adhering to federal compliance requirements
- Different than a vendor or consultant, which involves procurement of goods/services



Subrecipient Monitoring

- A requirement in OMB Circulars A-110 and A-133
- Special challenge: foreign subrecipients
 - Issues related to payment and billings, monitoring of performance, audits, etc.
 - Potential legal and tax issues
 - No A-133 audit report to rely on
- Federal Audit Clearinghouse to assess subrecipient
 - <http://harvester.census.gov/sac/>
- PI must be involved in monitoring!



PI's Role in Subrecipient Monitoring

- Ensure subrecipient's costs are reasonable
- Review and approve subrecipient's invoices
- Monitor subrecipient's performance to ensure satisfactory progress with subrecipient's statement of work
- Receive and review subrecipient's technical reports
- Facilitate close-out, i.e. final technical reports and final invoices



Service/Recharge Centers, Core Facilities



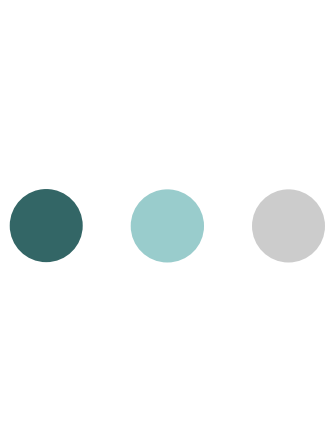
Service/Recharge Centers, Core Facilities

- Departments or units that provide goods and services to users (and grants) and recover the costs through user fees/service center rates
- Federal Requirements (A-21, J.47)
 - Charges based on actual usage
 - Rates that don't discriminate against federally supported activities
 - Rates designed to recovery costs
 - Rates adjusted at least biennially



Service/Recharge Centers, Core Facilities

- Potential compliance issues
 - Rates exceed actual costs (profit)
 - Federal programs charged for usage associate with non-federal activities
 - Surplus used for unrelated activities
 - Inadequate documentation of actual costs and usage
 - Rates applied inconsistently
 - Rates not adjusted periodically



Conflict of Interest



Conflict of Interest Requirements

- Institutions Must:
 - Review all Disclosures
 - Determine whether the financial interests are significant
 - Determine whether there is a reasonable likelihood that the significant financial interests disclosed will directly and significantly affect the design, conduct, or reporting of the research
 - Take appropriate action to reduce, manage, or eliminate potential conflicts of interest
 - Report to the Federal Agency the existence of the conflict and provide assurances it will be managed



Conflict of Interest New Trends

- FY '06 Targeted OER Reviews
 - Redefine “investigator”
 - Most difficult reporting conflicts after the project is underway
- January 2008 HHS OIG Report. Findings:
 - NIH could not provide an accurate count of financial conflict-of-interest repots
 - NIH is not award of the types of financial conflicts of interest that exist at grantee institutions
 - Many Institutes’ primary method of oversight is reliance on grantee institutions’ assurances that regulations are followed.



We're Almost There....

- Summary and Conclusion
- Your Questions???
- The End!



What Can Our Institutions do to Ensure Compliance?

- Maintain a ‘culture of compliance’
- Accept that we all are accountable, especially the principal investigator
- Monitor the high risk transactions, compliance with institutional policies
- Implement effective training programs
- Participate in development/revision of institutional policies
- Communicate current information
- Keep in mind that compliance starts at the beginning of a project, not the end

● ● ● | **Ostriches may feel safe**



but, they don't live longer!



What We All Can Do

- Understand the law
- Ask Questions
- Do the Right Thing
- Document, Document, Document