

Analyzing Everyday Compliance Issues

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Agenda

- Introductions
- Case Studies
 - Set-up
 - Discussion
 - Debrief
- Closing

Compliance

- Animal Use
- Human Subjects Research
- Biological Safety
- Stem Cell Research
- Radiation Safety
- Chemical Safety
- Environmental Safety
- Financial Conflict of Interest
- Export Controls
- Effort Reporting
- Financial Administration
- Responsible Conduct of Research
- Research Misconduct

Summary from 2013 session

- FCOI
 - Intellectual property
 - Publication
- Responsible conduct of research
 - Mentorship
 - Compliance (Biosafety, IACUC)
 - Fabrication of results

Incidents

- Awards were suspended due to concerns about violations of human subjects regulations...poor record keeping, unapproved protocol or consent form modifications, and the over-enrollment of human subjects...[eventually] the suspended grants were terminated...\$310,454 recovered (*NSF OIG Semiannual Report, March 2012*)
- PI improperly subcontracted work to a company in which he had 25 percent ownership...PI had falsely represented that company was selected competitively... [university review concluded] PI's work...did not justify the funds...expended...\$386,200 returned (*NSF OIG Semiannual Reports, Sept. 2011 & March 2012*)

Our role...

“Research administrators help safeguard the university from possible regulatory noncompliance by early detection of issues which could potentially result in extremely high fines, audit findings, and tarnished reputations.”

(Nichols, 2013)

Case Study #1

What are the key compliance issues?

NSF funding

- Cost sharing
- Subawardee audit issues
- Conflict of interest
 - Reporting procedures
 - Management method

NIH funding

- Cost sharing – not an issue
 - Salary cap?
- Subawardee audit issues
- Conflict of interest
 - Reporting procedures
 - Management method

Proposed Actions

NSF Funding

- Dr. Lloyd could request scope of work reduction.
- Dr. Lloyd could bring up cost sharing issue to SPO, who might contact NSF.
- PI's institution should review the subawardee's audit report.
- Institution should ensure that COIs are reduced, managed, or eliminated.

NIH Funding

- Dr. Lloyd could request scope of work reduction.
- Dr. Lloyd could provide cost sharing.
- PI's institution should review the subawardee's audit report.
- Institution should follow NIH FCOI requirements.

Case Study #2

What are the key compliance issues?

- Subaward versus procurement relationship
- Significantly changed scope of work without funding agency's approval
- Foreign IRB
- Foreign travel
- Experiments outside of US (Export control)

Proposed Actions

- Make determination of sub-award or procurement relationship:
<https://www.rsp.wisc.edu/awardmgt/subagmts.html>
- Contact agency regarding change in scope of work
- Contact X University IRB
- Contact sponsored programs office, may or may not need approval:
<http://www.nsf.gov/awards/managing/rtc.jsp>
- Contact X University export control officer

Case Study #3

What are the key compliance issues?

- Consistent treatment
- Allocability
- Reasonableness

- Accuracy in budget preparation

Proposed Actions

PROJECT BUDGET [Print All Pages](#) [Print Totals Page](#)

Sponsor: **Federal**
 Project Title: **The Project that Will Revolutionize Science as We Know It**
 Project Period: Begin: **01/01/15** End: **12/31/15**
 Principal Investigator: **Ron Weasley**

	Year 1	Year 2	Year 3	Year 4	Year 5	Cumulative
Salaries & Wages	\$ 14,500	\$ -	\$ -	\$ -	\$ -	\$ 14,500
Fringe Benefits	\$ 4,066	\$ -	\$ -	\$ -	\$ -	\$ 4,066
Equipment & Other Capital	\$ 10,000	\$ -	\$ -	\$ -	\$ -	\$ 10,000
Supplies	\$ 11,050	\$ -	\$ -	\$ -	\$ -	\$ 11,050
Travel - Domestic	\$ 4,000	\$ -	\$ -	\$ -	\$ -	\$ 4,000
Travel - Foreign	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Other Direct Charges	\$ 14,500	\$ -	\$ -	\$ -	\$ -	\$ 14,500
Sub-Agreements	\$ 4,300	\$ -	\$ -	\$ -	\$ -	\$ 4,300
Direct Costs	\$ 62,416	\$ -	\$ -	\$ -	\$ -	\$ 62,416
MITDC Costs	\$ 44,416	\$ -	\$ -	\$ -	\$ -	\$ 44,416
Indirect Costs (50.50% of MITDC)	\$ 22,430	\$ -	\$ -	\$ -	\$ -	\$ 22,430
Total Costs	\$ 84,846	\$ -	\$ -	\$ -	\$ -	\$ 84,846

Discussion

- Where do you turn to help you figure out how to handle compliance issues?
- What tools or resources are available at your institution to help ensure that sponsored projects are in compliance?

Summary

- Cost sharing – agency dependent
- Subrecipient monitoring
- Conflict of interest – agency dependent
- Appropriate determination of subaward or procurement
- Scope of work change – agency approval required
- Foreign travel – may require prior approval
- IRB
- Export controls
- Financial compliance

Compliance

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In closing...

“Regulatory compliance and excellence in the conduct of research can only be achieved by cooperation between the research office, the principal investigator, the compliance officer and committees, and an institutional climate that fosters a high level of integrity.”

(Nichols, 2013)

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Reference

- Nichols, C. Compliance – Cooperation and Collaboration.
NCURA Magazine, XLV(1), 14-15.