

Compliance for the PUI NCURA PRA III, 2008

Track: Predominantly Undergraduate Institutions

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Learning Outcomes

- Identify compliance needs at the PUI
- Explore strategies for operating a one-person compliance office
- Discuss how to utilize existing resources to the fullest



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Office of One

- PUI's traditionally have fewer resources than large research institutions
- Usually the "Compliance Office" consists of one person that has to become an expert in many different fields
- Consequently, this person doesn't have the luxury in becoming an expert in one area, but has to become efficient in multiple fields



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Typical PUI Compliance Duties?

- IRB
- IACUC
- IBC
- RCR
- Export Controls
- Research Integrity
- Website Maintenance
- Training/Education
- Cost Transfer/Reallocations
- Cost Sharing
- Technical/Final Reports
- Environmental Health & Safety
- Financial Conflicts of Interest
- Time & Effort Reporting
- Banking
- HIPPA

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More Typical

- IRB
- IACUC
- IBC
- RCR
- Export Controls
- Research Integrity
- Website Maintenance
- Training/Education
- Others?



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Does this sound like your day?

- 8:00 – Check Email
- 8:01 – Receive phone call from faculty who wants IRB approval on a project by tomorrow.
- 8:28 – Recheck Email
- 8:29 – DOJ program officer calls to inform you that all DOJ funds have been frozen due to delinquent annual report.
- 8:50 – You call faculty member about delinquent DOJ annual report.
- 9:00 – IACUC meeting
- 10:30 – Recheck Email
- 10:31 – Unexpected visit from panicked faculty member who needs assistance submitting delinquent DOJ report
- 11:15 – Receive 4 IRB applications that need to be reviewed.
- 11:45 – Receive reallocation request on a USDA grant to buy equipment that was not in original budget.
- 11:55 – Attempt to contact USDA program officer to determine if expense is allowed.
- 12:15 – Lunch
- 12:16 – Receive phone call from irrational faculty member who wants to know why you have not approved USDA budget reallocation request.
- 1:00 – Conduct a Protection of Human Subjects in Research Workshop
- 3:00 – Recheck email
- 3:01 – Receive phone call from upset faculty who does not understand why you will not authorize him to ship GPS equipment to a colleague to use for an archeological dig in Syria.
- 3:45 – Recheck email.
- 3:46 – Notified by Director that several links on Compliance website are not functional and need to be updated.
- 4:16 – Recheck email
- 4:17 – Receive phone from a faculty member who asked you to do a Research Ethics lecture for her research methods class tomorrow.
- 4:28 – Recheck email—remember that you ought to check your voice mail
- 4:30 – Unexpected visit from a graduate student who is requesting help to complete his IRB application.
- 5:10 – Computer crashes due to the amount of emails that have yet to be checked.
- 5:11 – Turn off computer and check email from home.

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There are only so many hours in the day

- With so many things that requires immediate attention and organization, how does anyone get anything done without missing anything?



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Strategies on How to Avoid Singing the "I'm Only One Person" Blues



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Strategies:

1. Get Support from the Top “When the Provost talks, people listen”

- Support from the Provost is vital
- The research community will not respect the rules in place unless they know it is backed, at minimum, by the Provost
- New compliance policies should be sent to the research community by the Provost with the expectation that the policies will be followed
- Gives the committees legitimacy, authority, and respect



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2. Visibility

“If you’re not easy to find, they will not look for you”

- The easier you are to find, the more questions you will receive
- If you are hard to find, researchers will feel they have to do it on their own
- You become the “face” of university compliance



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3. User Friendly

“Easy to complete forms on an accessible user friendly website means less work for you”

- Easy to complete forms will result in fewer edits
- Train users on correctly completing forms
- Make all policy and procedures accessible
- Keep track of questions and use them for your FAQs
- Look at other bench mark schools and “borrow” information from their website (giving credit where credit is due)

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4. Advertise Compliance

“To be able to get the university community involved in compliance you must be able to market compliance”

- Offer compliance workshops that focus on a variety of areas
- Meet with department chairs and graduate committees offering to give guest lectures
- Advertise trainings on the website and university-wide email
- Offer training not only to faculty, but to staff and students

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5. Rely on the Experts

“Remember: you’re the administrator, not the chair”

- Members on your IRB, IBC, IACUC, etc., are experts in the field. If policy and procedures need to be revised, rely on them for input.
- If you receive a question or have a problem you don’t have the answer to, rely on the board
- Attempt to create incentives to encourage campus wide participation in the committees (i.e., course release, letters of appreciation)

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6. Know the Rules

- Although you may not be an expert in the field, know your role on the committee
- Be familiar with assurance due dates
- Submit all required documents in a timely fashion
- Become familiar with the federal policy and governing Code of Federal Regulations (CFR)
- Use the resources of NCURA, SRA, and others

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7. Save Time for Recordkeeping

- Save certain days of the month to exclusively do record keeping, data basing, and report notifications
- Develop a system that works for you
- Involve other departments in your efforts if needed
- Document everything. If you don't write it down, it never happened.

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At Miami University

- Associate Dean for Research & Scholarship
 - Financial Conflicts of Interest
- Research Compliance Officer
 - Institutional Review Board (IRB)
 - Institutional Animal Care & Use Committee (IACUC)
 - Responsible Conduct of Research (RCR)
 - Radiation Safety Committee (RSC)
 - Institutional Biosafety Committee (IBC)

http://www.units.muohio.edu/oars/compliance_committee/index.php

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At Georgia Southern

- Associate VP for Research
 - Director of Research Compliance
 - IACUC
 - IRB
 - IBC
 - Research Misconduct
 - Financial Conflicts of Interest
- Public Safety
 - Office of Environmental Safety
 - Biomedical Safety
 - Bloodborne Pathogens
 - Chemical Safety
 - Electrical Safety
 - Fire Safety
 - Hazardous Waste
 - Material Safety Data Sheets (MSDS)
 - Pesticide Use

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