

Federal Research Regulations and Reporting: University Perspective



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University of Washington Context

- \$1.4 B/yr research funding
- \$1.1B/yr federally-funded research
- Over 5000 new proposals per year (excluding non-competing renewals and preapplications)
- Ancient (40 yr old) electronic systems
- Goal of the Office of Research
 - Decrease administrative burden to researchers and their support staff, while maintaining strong compliance
 - Give researchers back time to do research

Wasteful!

- Causing our best and brightest researchers to spend 42% of their research time on administration is wasteful, expensive, and poor use of taxpayer's money
- Focus should be on how to give researchers back time to do research

Major Issues for University of Washington

- Subrecipient monitoring
- PHS conflict of interest
- Human subjects research
- Animal research
- Effort reporting
- Data reporting (financial, outcomes, etc.)

UW worked with the AAU/COGR joint team on specific recommendations to the Office of Information and Regulatory Affairs (White House), all of which we endorse

Example: PHS FCOI

- FY14 PHS funding: >\$700M
- >1300 current PHS grants and contracts
- >1500 new PHS proposals submitted in FY14
- Annual disclosures went up 100-fold
- Annual disclosures requiring management plans went up only slightly (less than 10%)
- Annual cost before: \$167,500
- Annual cost after: \$762,000
- Travel disclosures: 2/3 are between \$5K and \$10K; none required management plans
- 3330 hours/year for the Office of Research

UW Response to FCOI

Focus on minimizing researcher burden while maintaining compliance

Developed and now maintain an electronic disclosure and posting system, online training system, website, and help line

- Proposal submission to central office → email to all Investigators with link → no SFI, 20 sec

Cost

- \$1M to develop the system, website, helpline
- \$600,000 annual ongoing cost
- 2 new FTE

How do we cut the cost of research administration, while increasing service to researchers and maintaining strong compliance?

Example at UW: Human Subjects Office

- 7 IRBs
- >3300 non-exempt protocols in FY14
- 2400 protocols undergoing annual reapproval in FY14

Project Compass

Human Subjects Office

University of Washington



Three-pronged set of projects designed to streamline and reorganize as we implement a new electronic system

- Delta: “more experts, more expertise”
 - reorganize; low-level work will be gone; shift to service and expertise providers
- Streamline: “sensible simplification”
 - Revision of all forms and processes
- Zipline: “a clear path”
 - new electronic system

Goal: decrease time and effort for researchers to develop an application and shepherd it through approval, implementation, and closeout

Side-benefit: net costs to the Office of Research will decrease 10-20%

On the Horizon

- More regulatory changes on the way
 - IRB Common Rule
 - DATA act reporting requirements
 - Agency-specific exceptions to Uniform Guidance
- Each requires changes to multiple electronic systems
 - Cost of implementation, training
 - Constantly changing work environment

Recommendations

- Endorse recommendations of AAU-COGR joint statement to ORIA
- Holistic approach
 - Assess total burden (FDP survey)
 - Realistic assessment of cost to implement
- Remove requirements that do not add value
- Create a funding program for multi-institutional projects to decrease administrative burden to researchers while cutting the costs of research administration