AAU-COGR-Yale Survey of Compliance Costs Presentation Thursday Afternoon June 2015

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Initial Findings of the AAU-COGR-Yale Survey of Compliance Costs

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Principal Concerns

The proliferation of significant regulations, policies, and guidance imposes substantial burden and expense on extramural institutions. This is amplified by a lack of harmonization across agencies.

- The Federal Demonstration Partnership (FDP) found in two successive surveys that faculty spend 42% of research time on administrative duties.
- Vanderbilt found that compliance costs totaled $146 million ($117 million related to research) or 11% of non-clinical expenditures.
- Yale's spending on core compliance offices rose by 9.6% per year, on average, from 2000 to 2010.

The Obama Administration has embraced the goal of simpler, smarter, and more cost-effective regulation. There are several clear opportunities for reform in the area of research compliance.

Survey Respondents

- 53 institutions provided data in response to our survey. Few institutions provided every data element requested. A number of institutions were unable to provide data on compliance costs (e.g., total cost of compliance with PHS FCOI regulations and maintenance costs for electronic ERS)
- We included FY13 Federal R&D expenditures (NCSES HERD data) which ranged from $10,983,000 to $1,898,927,000
- 6 Low Research ($1-50M); 14 Medium Research ($50-150M); 33 High Research (>$150M)
- Targeted six areas

Subrecipient Monitoring

Collaborative research is increasingly common, and involves use of subawards.

The "Prime" recipient is expected to monitor the business practices and internal controls of the subrecipient.

- May be necessary for subrecipients that do not meet the threshold for Federal Single Audit ($750K in 2 CFR 200)
- Unnecessary for subrecipients that have completed a Federal Single Audit.

Subrecipient monitoring is a costly practice that has persisted, for unknown reasons, despite consistent calls to eliminate it.

Subrecipient Monitoring

In response to our survey, 51 institutions reported:

- 3,578 subrecipients with federal awards not subject to an A-133 audit in FY14, but
- 8,409 subrecipients with federal awards subject to A-133 audit in FY14.
- An average of 2.8 FTE are dedicated to subrecipient monitoring; the fully burdened cost of such staff was $7,524,944 in FY14. (Central staff only; excludes investigators and departmental staff.)

***Proposal*:** Where a subrecipient has a current Single Audit report, allow prime recipients to rely on the subrecipient's auditors and cognizant agencies for routine audit follow-up and management decisions.

Expand on NSF's practice of directly issuing collaborative/linked awards rather than having grantees issue subawards.

PHS COI Disclosure

- In 2011, the Department of Health and Human Services (HHS) amended the Public Health Service (PHS) regulations on conflict of interest (COI) regulation (42 CFR Part 50 and 45 CFR Part 94).
- This action was taken largely in response to growing Congressional concerns driven largely by 1-2 specific high profile/high value cases of non-disclosure.
- Among other changes, the revised rule which took effect in August, 2012, lowered the *de minimis* threshold to $5,000 and required disclosure of travel as well as payments from non-profits.
- The new rule also required investigators and subrecipients to disclose FCOIs no later than the time of application.
- AAU and COGR findings suggest that the costs and negative impacts of the new rule far exceed what HHS anticipated and that minimal benefits have been achieved.

PHS COI Disclosure

- The survey found that institutions spent an average of 2,593 hours annually disclosing financial interests, reviewing for conflicts, and managing conflicts. In contrast, PHS estimated the burden at only 82 hours per institution.
- 34 institutions spent $10,555,993 on COI in the year subsequent to implementation of the revised PHS policy with an increase of $2,682,090 in costs from the year prior.
  - This increase likely represents a substantial underestimate because institutions had already begun implementing changes prior to the rule change and a number of institutions with large programs were unable to provide cost data.
- A recent Association of American Medical Colleges (AAMC) study also found costs associated with implementation of the PHS COI rule far exceeded expectations (i.e., 70 institutions alone spent $22.6 million).

PHS COI Disclosure

- AAMC reports that the total disclosures at 56 schools rose 45% to 79,035 from 54,354 while the FCOIs reported to NIH rose 13.3% to 997 from 880. Only 0.5% of the incremental disclosures revealed a reportable FCOI, compared to 1.6% of disclosures under the prior $10,000 threshold.
- Travel and Income from non-profits: In our survey, schools reported 5,784 disclosures that involve only travel and outside income from non-profits (including foreign universities). Only 20 disclosures warranted a management plan. 29 of 35 schools found no conflicts related to travel and income from non-profits.
- $5K Threshold: Of the 2,929 disclosures between 5K and 10K reported from 33 institutions for FY14, 249 resulted in COI to manage, including 185 from 3 of the 33 institutions.

Proposal: Eliminate the requirements for disclosure of travel and to disclose income from non-profits. Assess appropriateness of current $5,000 threshold.

PHS COI Disclosure

PHS requires completion of COI disclosure at the time of application with NIH or other PHS agencies. (50.604(e)(1))

- Yet NIH success rates for proposals are under 20% and even 10% for some institutes.
- The rule imposes unnecessary burden on investigators and review processes.
- Also requires negotiations with subrecipients for projects that may not be funded.

Proposal: Allow PIs to file disclosures prior to award activation instead of at time of application, thereby saving unnecessary work for PIs and institutions.

The final PHS policy indicates that HHS will evaluate the effect of the COI regulations within 3 years (by August 2015 if three years from implementation). An evaluation of the effectiveness and impact of the COI rule is critical.

Human Subjects Research

Institutions surveyed by AAU and COGR reported extensive workload in review of non-exempt human subjects protocols:

- 51 institutions reviewed 95,812 protocols in FY14.
- 70,628 protocols underwent annual reapproval (~74% of non-exempt protocols)
- 40 institutions reported that faculty, staff, and members of the IRB spent a total of 254,961 hours in IRB reviews in 2014.
- Vanderbilt estimated total compliance costs of $21 million for FY14, including effort of faculty, staff, and trainees.

***Proposal*:** Eliminate the requirement for annual continuing review. Allow IRBs the authority to determine the frequency of review for all research, regardless of risk.

Human Subjects Research

120 Veterans Administration (VA) Medical Centers are affiliated with medical schools in longstanding collaborations in teaching and patient care.

VA requires dual review by VA and university IRBs for research conducted at the VA with engagement of university investigators.

- 1,890 protocols underwent dual review by the VA and institutions in FY14 at 18 schools.
- Faculty, staff, and members of the institutional IRBs spent 6,330 hours reviewing those protocols.

Proposal: Eliminate dual review; change VA policy to allow VA to be the IRB of record in cases where the institution of higher education is "engaged" in research that is taking place solely at the VA.

Animal Research

Schools surveyed by AAU and COGR identified significant effort in reviewing animal research:

- Faculty and staff at 42 schools spent 11,447 hours reviewing 4,322 research protocols subject to USDA oversight in FY14.
- 3,887 triennial reviews were conducted.

Proposal: Eliminate the re-review process (USDA annual and PHS triennial), relying on modifications; instead tie approval to the project length.

Animal Research

- 86% of institutions responding to the survey indicated that they require a full re-write of the protocol for triennial review. Some indicated that they require a re-write but not a full review, others a re-write and full review.
- A few institutions suggested existing approved protocols were easily copied and modified and review is necessary to ensure the research meets current standards.
- In response to comments from investigators included in a National Science Board report that federal agencies should be encouraged "to clarify that animal care and use protocols do not need to be completely re-written to satisfy the requirements for annual and/or triennial re-review." OLAW indicated that while requiring a re-write would be considered a best practice, PHS Policy requires does not require that the protocol be rewritten.

Institutions might consider whether a re-write and full review are needed and, if so, whether the associated administrative work can be reduced.

Effort Reporting

Effort reporting is burdensome and poorly understood by faculty, and it adds little value to financial controls. 52 institutions reported submitting an average of 11,370 effort reports per school in FY14.

- Total faculty effort in reviewing and verifying effort reports averaged about 2,800 hours per school.
- The (central) staff costs were approximately $105,000 per school. Central staff effort averaged 2.1 FTE per institution.
- Staff in academic departments spent an average of 8,600 hours per school reviewing and verifying effort reports.
- 30 institutions reported spending $2,226,101 in maintenance costs for electronic effort reporting systems in FY14.

Effort Reporting

- OMB Uniform Guidance (2 CFR 200) offers greater flexibility in accounting for salaries and wages charged to Federal awards.
- Institutions participating in the FDP Payroll Certification Pilot report a significant reduction in associated administrative work. Inspectors General have not yet published their review which might facilitate widespread adoption.

Proposal: OMB should issue a Memo of Clarification indicating that payroll certification and other alternatives to effort reporting that meet the UG standards of documentation are acceptable to the Federal Government or codify the preamble indicating that personal activity reports are not required.

OMB, cognizant agencies for indirect costs and pertinent Federal offices should document in writing that institutions do not require approval of proposed alternatives to effort reporting that meet the standards in the UG.

Financial Reporting

Financial reporting is unnecessarily complex because of the variation in systems across agencies. Institutions have to report financial data in multiple financial reporting systems, sometimes more than one system per agency.

- 48 institutions reported using an average of approximately 8 payment systems in FY14; Low research: 6.5; Medium 8.5; High 8.4.
- Institutions were not asked to indicate which systems they use. Among those who did, roughly a dozen systems were identified.

Payment Management Systems

AGENCIES	PMS	ACM$; Research.gov	ASAP	G5	GPRS	VIPERS	Payweb	WAWF	eLOCCS	Delphi	PARS
	NIH (EA)										
	NASA										
	USDA (Forest Service requires paper invoicing)		USDA/NIFA								
	Department of State										
	Homeland Security										
		NSF									
			DOE			DOE					
			NIST								
				DoEd							
					DOJ						
							Navy	Navy/SPAWAR			
							Army	Army			
								Army/US Military Academy			
								Air Force			
			NOAA								
			EPA								
			Interior								
									HUDD		
										DOT/FAA	
											FEMA

Financial Reporting

Institutions draw down cash by award accounts on a regular basis, typically monthly. This provides agencies with up-to-date financial information and renders additional financial reports unnecessary.

- 39,934 separate federal financial status reports were filed by 50 institutions in FY14.
- 46 institutions reported filing 21,627 quarterly financial reports for which cash is already drawn down on an account or document level (and reports are therefore redundant/unnecessary).

Proposal: Federal payment systems should be consolidated and quarterly financial reports eliminated once agencies have transitioned to subaccounts. Agencies should consider whether there is a need for annual and final financial reports.

Invention Reports

Institutions are filing multiple invention reports, even in the absence of an invention.

- 45 institutions reported filing 6,000 paper invention reports. An average of 133 per institution.
- 4,739 iEdison reports filed across 43 institutions in FY14.
- Institutions responding indicated that a staff reduction of 0.75 FTE could be realized with elimination of invention reports.

Proposal: Eliminate redundant reports on inventions (progress reports, paper final invention reports and iEdison). The government should utilize the USPTO database (and/or iEdison) to quantify federally funded inventions/patents; and institutions should not be required to separately report discoveries that may not be patentable.

Property Reports

Institutions have title to most property used in Federal research. Property reports appear not to be utilized by Federal agencies.

- 3,513 property reports filed across 39 institutions in FY14.
- Institutions responding indicated that a staff reduction of 0.25 FTE could be realized with elimination of property reports.

Proposal: Rely on internal controls to properly inventory and categorize federally owned/purchased equipment.

Budgets

- Does your institution require a detailed budget even where not required by the federal awarding agency (e.g., where the investigator is submitting a modular budget to NIH or a preliminary proposal to NSF)?
- Federal agencies may consider deferring detailed budgets until notice of award (only 10-20% of proposals are funded).
- Would institutions consider doing the same to reduce administrative work?

Process Reforms

Establish a central office, possibly within OIRA, for ongoing oversight of federal agencies funding and regulating research to oversee the development, implementation and reform of major regulations, policies and guidance. It should have a mandate to:

- Standardize regulations, policies, guidance, systems and forms across federal agencies that regulate and fund research.
- Periodically reassess policies and major guidance that apply to federally supported research.
- Reduce agencies' overreliance on guidance functioning as regulation (e.g., OLAW and OHRP) – institutions need the flexibility to use their best judgement.
- Ensure that agencies provide the research community a meaningful opportunity for substantive engagement on policies and major guidance prior to a formal rulemaking stage.