Proposals to Streamline Rules and Reporting Requirements for Federally Sponsored Research

April 21, 2015
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 found in two successive surveys that faculty spend 42% of research time on administrative duties.
- Vanderbilt found that compliance costs totaled $146 million (of which $117 million is 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.
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.
In a survey of members, 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. This could be addressed in the UG compliance supplement.

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 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 one specific high profile case 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

- AAU/COGR/APLU survey found that 2,593 hours per institution were spent annually in disclosing financial interests, reviewing for conflicts, and managing conflicts. In contrast, PHS estimated the burden at only 82 hours per institution.

- 34 institutions indicated that they 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. The incremental amount likely represents a substantial underestimate because institutions had already begun implementing changes prior to the actual rule change and the fact that large institutions were unable to supply cost data to AAU and COGR.

- A recent Association of American Medical Colleges (AAMC) study found similar time and costs associated with implementation of the PHS COI rule (i.e., 70 institutions alone spent $22.6 million).
Institutions reported a 110% increase in the number of disclosures in the first year after the new rules took effect.

- AAMC reports that the total disclosures at 56 schools rose to 79,035 from 54,354 while the FCOIs reported to NIH rose 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: 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, 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.

Additional Request: The final PHS policy indicates that HHS will evaluate the effect of the COI regulations within 3 years (by August 2015). We urge OIRA to inquire with HHS as to its plans to conduct this review. An evaluation of the effectiveness and impact of the COI rule is critical. We also believe that HHS should actively involve the stakeholder community in this review.
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 cost of $21 million, 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. This can be addressed in Common Rule revisions, currently under OIRA review.
Human Subjects

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.

- A survey found that 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.
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) appears to allow payroll certification in lieu of effort reporting, but there is uncertainty regarding what constitutes an auditable system of internal controls for documenting compensation. The Federal Demonstration Project (FDP) has completed a successful pilot test of an alternative payroll certification system.

Schools in the FDP pilot test reported a significant reduction in administrative burden. However, the Inspectors General have not yet published their review of FDP Payroll Certification Pilots, which could provide a framework for broad adoption.

Proposal: Eliminate separate systems for effort reporting and focus exclusively on payroll reporting. OMB should mediate discussions between institutions and A-133 auditors to identify means by which the payroll certification approach can be implemented. OMB should issue a Memo of Clarification indicating that payroll certification is acceptable to the Federal Government.
Financial reporting is unnecessarily complex because of the variation in systems across agencies. Institutions surveyed cited using, on average, 11 federal payment systems.

Institutions draw down award accounts at least monthly or quarterly, this provides agencies with up-to-date financial information and renders additional financial reports unnecessary.

- 21,627 quarterly federal financial reports filed at 46 institutions
- 39,934 financial status reports filed by 50 institutions in FY14.

**Proposal:** Eliminate multiple federal payment systems. Review financial reporting requirements of federal agencies and eliminate intra-agency redundancy (e.g., NIH quarterly reports in PMS and eRA Commons).
Process Reforms

Proposal: 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 – 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 before a formal rulemaking stage.