Administrative Burden of Research Compliance

Measuring and Minimizing

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FDP Faculty Burden Survey (X2)

PIs estimated that an average of 42% of their research time associated with federally-funded projects was spent on meeting requirements rather than conducting active research.

Recent Studies on Regulatory Burden

• 2016 - Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements (GAO)

• 2016 - Optimizing the Nation’s Investment in Academic Research (NAS)

• 2015 - Sustaining Discovery in Biological and Medical Sciences (FASEB)

• 2014 - Reducing Investigators' Administrative Workload For Federally Funded Research (NSB)
Regulations, reporting requirements, and congressional mandates often overlap, resulting in duplication of effort, multiple reporting of the same information in different formats, and multiple submissions of information on different schedules.
Regulatory Areas

- Sponsored Programs – Grants, Contracts, MTA’s
- Post Award Grants Management
- Effort Reporting
- Recharge Centers
- IRB
- HIPAA
- Billing Compliance
- IACUC
- IBC
- Other Biosafety (select agents, etc.)
- Export Controls
- COI
- Technology Transfer – IP, Licensing, etc.
- Radiation Safety
- Chemical Safety
- General Lab Safety
- Research Misconduct

FDP Survey ”Pain Points”

- Finances
- Personnel
- Effort reporting
- Human subjects
- Animal subjects
- Laboratory safety
- Contract-related requirements
- National security
- Proposal or report preparation
- Clinical trials
- Subcontracts
- Cross-agency differences
Optimizing the Nation’s Investment in Academic Research (cont.)

Conflicting guidance on compliance requirements has created uncertainty and confusion, often leading universities to implement overly prescriptive procedures in an effort to avoid penalties and thereby adding additional burden.

We start out developing tools to meet our needs...
But end up exceeding the rule. 
More does not mean better!

PI Perspective

How does the research community look at this?
Pre-Award Workflow Analysis (Clinical Trials Only)

Pre-Award Data Flow (Clinical Trials Only)
Compliance

• Most regulations and policies are not clearly “black and white.” There are almost always “shades of grey.”

What shade do you pick?

Step 1
• Read the regulations, rules, policies & guidance!

Step 2
• Talk with colleagues to get a sense of how others interpret and apply them.
Key Considerations

- A program that
  - Operates according to ethical standards
  - Meets compliance needs and institutional requirements
  - Has realistic operational requirements (including for customers)
  - Stands up to the test of “daylight”
  - Achieves economic realities

Assessing Implementation

- Look beyond the theory of what the program is supposed to do and, instead, evaluate how the program is being implemented
- Determine whether the components identified as critical to the success of the program are being implemented
- An ongoing process in which repeated measures may be used to evaluate whether the program is being implemented properly
Assessing the Impact (Effectiveness)

- Measure if the program has achieved its intended outcomes
- Performance metrics
- Customer feedback
- External audits/assessments (FDA, OHRP, AAHRPP, AAALAC, OLAW, IND Sponsor Audits, etc.)

Assessing Efficiency and Associated Burden

- Process to regularly, critically, and in a disciplined way evaluate
  - unit work flow
  - functions, and
  - operational processes
to assess efficiency or resource needs.

Consider carefully and implement a regular schedule for evaluation!
Metrics

• Receipt until first response – Que vs processing time
• Receipt of information back from first response – Can you influence this?
• How many “back-and-forths” occur? Why?
• Completion of your portion awaiting another process or unit. Is the same unit always last? Is that OK?

Example A – Study Timeline
How is your institution viewed by external contacts/customers?

- Example – Clinical Trials

- The sponsor measures time from mailing of protocol to PI until the enrollment of the first human subject.

- Your internal steps are your issue, not theirs.
Streamlining Examples

• IACUC - Three-year reviews on species not covered under USDA AWA
• IACUC - Use designated reviewer system for IACUC
• IRB - Grant two- or three-year approval periods for non-federally supported and non-FDA regulated studies.
• IRB - Only regulate research that meets the definition of human research.

Streamlining (cont.)

• EHS - Consolidate laboratory inspections for various disciplines
• EHS - Develop risk-based policies and procedures for laboratory specific hazards
• OSP - Utilize the Federal Demonstration Partnership's (FDP) standardized subaward agreement templates
• All - Offer modular training
• Questions?