Regulatory Burdens for Faculty: Focusing on Research

Matthew B. Wheeler, Chair
University Senates Conference
Faculty Research Activity

- Activity has dramatically increased
- FY10 awards up 48% (UIUC)
- $668,696,494
- 4,216 awards
Research Compliance

- Human Subjects
- Animals
- Chemicals
- Biological Safety
- Radiation
- Other
Research Compliance

• Compliance regulations, rules, requirements, guidelines, reporting, oversight and monitoring continue to increase

• University required by statute(s) to enforce research compliance regulations

• Not clear how much latitude institutions have to achieve compliance

• It is CLEAR that the costs for compliance have skyrocketed
Research Funding

• Money for research has been a continuous decline for the past 20 years
• Faculty have to **pay more** and more of the **compliance costs**:
  – Animal care
  – Waste disposal
  – Training
  – Time filling out forms and reporting

❖ **Result is less resources, especially direct costs and time spent, for actual research**
Research Compliance

- Academic integrity in research and publication policy and procedures
- Animal Subject Care and Use
- Conflict of interest and commitment policy
- Division of Research Safety
- Institutional Review Board for the Protection of Human Subjects
- Responsible conduct of research
Animal Care Form

Ten (10) form pages, plus 3 appendices a total of 20 form pages unfilled.

My typical protocols are in excess 35 pages and up to 60+ pages.
• Needs to be submitted before grant funding status is known.

• There is duplication with other compliance groups, IRB and Research safety.

• Cannot currently be submitted online, form is locked, only “cut & paste” capable.

• *Can take 6-8 weeks to get a protocol approved.*
Division of Research Safety

- *Emergency Spill Response*
- IBC Project Registration
- Biological Safety
- Chemical Safety
- Radiation Safety
- General Lab Safety
- Hazardous Materials Transport
- Regulated Waste
- Safety Training
- Forms
- *Safety Fact Sheets*
BIOLOGICAL SAFETY

- **Institutional Biosafety Committee (IBC)** About the IBC, registration requirements, forms, instructions, deadlines, and monthly meeting schedule.
- **Biological Waste** Online pick-up request for full sharps disposal containers, information on handling and disposal of sharps, non-contaminated glassware, personal use needles and syringes, and treatment and disposal of biological materials.
- **Biological Safety Related Training** Courses offered: Understanding Biosafety, Safe Handling of Human Cell Lines/Materials in a Research Laboratory, and Occupational Exposure to Bloodborne Pathogens (for non-laboratory personnel).
- **Biological Safety Cabinets** Information regarding selection and certification of biosafety cabinets.
- **Bloodborne Pathogens Program** The campuswide Exposure Control Plan, FAQs on Hepatitis B vaccination series, campus-related forms, and an overview of the program.
- **Transport of Biological Materials** Training requirements, definitions, classification guide to infectious substances, intra-campus transportation, transport by personal or University vehicle, packaging unregulated biological material.
- **Viral Vectors** Registration requirements, definitions, and information about the virus/viral vectors, practices and biosafety approaches.
Institutional Biosafety Committee
Biological Safety Section- Division of Research Safety
Project Registration

1. Basic Information
• What is the title of your project?
• Campus Address:
• After hours phone number (required if research is at Biosafety Level 2 or higher):
• Please enter the Principal Investigator's Degrees and Fields of Expertise:
• Please enter the Principal Investigator's training and experience relative to their responsibilities:
• Please list all personnel working on this project, along with their degrees and areas of experience:
Biological Safety Section - Division of Research Safety Project Registration

3. Project Introduction

• Provide an overview of the project (including animal work if applicable) in layperson terms using 1,000 words or less:

• Describe the experimental methods in sufficient detail for this work (include animal work if applicable). Focus on the biohazards you may encounter while performing this research and what steps you will take to minimize exposure to those hazards (i.e. working in a biosafety cabinet, wearing personal protective equipment, specific field precautions, etc): DO NOT COPY AND PASTE THE GRANT PROPOSAL.

THE FORM IS 32 PAGES LONG – not all used by everyone, but most used.

Form can currently be submitted online, but no database for background (PI, investigators) information currently.
Technology Commercialization, Management, and Transfer

- **Office of Sponsored Programs & Research Administration (OSPRA)**

- **Grants and Contracts Office (post award)**

- **Office of Technology Management**
# UIUC Grant Transmittal Form

**Identifications:**
- Principal Investigator Name: Wheeler Jo Ann
- UIN: [Redacted]
- Initiating Dept/Division: Institute for Genomic Bio
- E-mail Address: [Redacted]
- Phone: [Redacted]

**Proposal Title:** Engineering Chemo-Mechanical Dynamics of Preimplantation Embryo Environments

**Sponsor/Agency Name:** Email to Rochelle when signed
- University of Michigan/NIH

**Sponsor/Agency Mailing Address:** [Redacted]

**Agency RFP#, BAA#, RFQ#, Program Announcement #:** PAR-10-276

**Begin Date:** Jul 1, 2011
**End Date:** Jun 30, 2016

**Supports a program of:**
- Basic Research
- Instruction
- Public Service
- Applied Research
- Product Development
- Technical Testing
- Other (specify)

**Proposal Type:**
- New
- Renewal
- Continuation
- Revised proposal or Budget
- Supplement

**Send Agreement with Proposal:**
- Yes
- No

**Send Agreement with Proposal:**
- [Redacted]

**Principal Investigator Responsibility:**
- [Redacted]

**NOTE TO PRINCIPAL/CO-PRINCIPAL INVESTIGATOR(S):**
- [Redacted]

**Approved By:**
- [Redacted]

**Office of Sponsored Programs and Research Admin:**
- Research Board Authorization
- [Redacted]

**Special Mailing Instructions:**
- Banner FOAP (Grant codes may not be used for shipping purposes) to charge for shipment:
Transmittal Form Compliance Section

- Boxes must be checked before grant will be submitted.
- Once done then all the paperwork must be done whether the grant is funded or not.
Other Issues

• **Chemical Biosafety**
  – Many chemicals are now tightly controlled and require permits for purchase, transport and storage
  – Many also now have security requirements
  – Makes it difficult to have storeroom with readily available supplies for investigator purchase, which can delay or even stop research activities
  – *List of chemicals requiring review is 20 pages long.*

• **Export Control**
  – Regulations are federal laws that prohibit the unlicensed export of certain commodities or information for reasons of national security or protections of trade.

• **Proliferation and Number of Audits**

• **Difficulties from Our Own Hiring Processes**
Of the time they spent on federally-sponsored research, 42% was actually spent administering the project.
Top Administrative Burdens (Average)

1. Grant progress report submission
2. Personnel hiring
3. Project revenue management
4. Equipment and supply purchases
5. IRB protocol approvals and training
6. Training personnel and students
7. Personnel evaluations

BUT: If human subjects or animals were used IRB or IACUC became the #1 burden.
Burden vs. Existing Administrative Assistance

• Faculty report low levels of support across all administrative tasks, with variations by disciplinary context very evident

• **Most assistance = financial management**
  – Payroll, budget transfers, cost accounting issues, cost sharing agreements, project revenue management
  – Project revenue management remains a top burden

• **Least assistance = research-related activities**
  – Conflict of interest monitoring, grant progress reports, patent/copyright applications, intellectual property applications, IRB, IACUC
  – Grant progress submission is the #1 reported burden

• Personnel evaluations
  – 7th most burdensome of the 25 burdens
  – 2nd lowest level of assistance
Administrative Support

• 97% of faculty stated that at least some time they spend managing Federal grants could be conducted by administrative personnel. **Note: Not secretaries; project managers with expertise in the area of the research project**

• 95% of reporting faculty believed that they could devote 4-8 additional hours each to week to active research if they had more support with project management

• 76% of faculty would be willing to reallocate direct costs from their grants to pay for project managers if this were allowed
No Single Culprit
(The death of a thousand cuts)

Burdens come from several sources

- Federal regulations
- Agency implementation of regulations
- Differences in agency requirements
- Institutional requirements and implementation
- Audit fears and auditor interpretations
- Inherent part of research
- Lack of administrative support

84% of faculty members reported that the administrative burdens associated with their research have increased in recent years.
The Cost of this Faculty Time is Divided

- Sponsor share
  
  Paid effort spent on administration of project (42%)

- University share
  
  Effort diverted from other tasks

- Societal share
  
  Effort diverted from actual research and teaching

- Personal share
  
  Effort added (and taken from family/life)
These Burdens Have Impacts on Students

62% of the respondents felt that students are less likely to pursue academic research careers now than in the past

– Multiple causes (workload, salary, funding competition, sense of job worth)

– A particular challenge for American-born students

– “They’ve seen what we really do and they don’t want to do that.”
Conclusions

• Faculty spend about **42% of their federally-funded research time** on administrative tasks directly related to that federally-funded research.

• No single overriding burden; pressure comes from many sources **(death of a thousand cuts)**.

• Significant costs are associated with these burdens.

• **Savings could accrue from decreasing the burdens**.
Conclusions (cont.)

• Saving could accrue from providing faculty with more administrative support

• Potential gain from identifying and replicating best practices at different funding agencies and institutions

• Potential gain from harmonizing the requirements of different agencies

  Funding agencies, auditing agencies, accrediting agencies, universities

• Potential gain from optimizing/harmonizing procedures for different offices within a university
Final Thoughts

• Compliance costs money and time
• Costs are higher to do Bio/Med-related research
• *Research $$* have not increased but have actually decreased
• Reputation is what keeps the best students coming and the grant and contract $$ flowing into the institution
Pensions

• The pension issue is really not pension reform but rather pension responsibility.
• What the public and others don't realize is that pensions are not gifts but represent sums reflective of salaries paid and actuarial tables that work, provided that both sides live up to the contractual agreement.
• In fact, from the point of view of the pensioner, the contribution to the pension is actually deferred salary, a point recognized by the IRS.
• The problem in Illinois arises from neither an overblown pension payment or from a false concept.
Pensions

• The problem is a direct result of the fact that the State essentially defaulted on paying it's "contractual share" of the pension.

• In fact, the actual numbers support this assertion. The pension system in Illinois is 45% funded, reflecting the pay in of the pensioners.

• If some of the bills now in committee are likely to be taken seriously and become law, our most productive faculty and administrators see no other option but to rapidly retire early to protect their pension rights.

• This will devastate both the Urbana and Chicago campuses and also make it impossible to recruit or retain faculty.
The COGR, AAU, and APLU ten recommendations:

1) Harmonize regulations and information systems between agencies and statutes where reasonable and eliminate unnecessary duplication and redundancy.

2) Eliminate regulations which do not add value or enhance accountability.

3) Provide targeted exemptions for research universities similar to protections provided for small entities under the Regulatory Flexibility Act (RFA).

4) Ensure that regulations are meeting their goals in terms of performance, rather than simply in terms of process.

5) Extend coverage provided under the Unfunded Mandates Reform Act (UMRA) to research universities and allow institutions to better account for new regulatory costs, and to charge these costs to Federal awards.
The COGR, AAU, and APLU ten recommendations:

6) **Simplify sub-recipient monitoring requirements.**

7) **Reinforce the original intent of the Single Audit Act.**

8) **Prohibit voluntary committed cost sharing across the Federal government and create a mandatory cost sharing exemption for research universities.**

9) **Establish protocols to address statutorily-mandated regulatory concerns.**

10) **Designate a high level official within OMB’s Office of Regulatory Affairs (OIRA) to serve as a Federal Ombudsman, responsible for addressing university regulatory concerns and for seeking ways to increase regulatory efficiency.**