

# **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

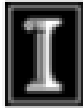
# Research Funding

- 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



UNIVERSITY OF ILLINOIS  
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)  
Proposal for Activities Involving Animals

FOR ADMINISTRATIVE USE ONLY

Protocol #

Approval Date:

Proposal Title:

Submission Type:  New  Renewal. If this is a Renewal, what is the previous protocol number?

Project Type:  Research  Teaching  Breeding  Other (describe):

Principal Investigator (PI):

Department:  Campus Phone:

e-mail:

Emergency Contact (other than PI):

Department:  Campus Phone:

e-mail:

Administrative Contact (optional):

Department:  Campus Phone:

e-mail:

Funding source:

## INVESTIGATOR RESPONSIBILITIES

In the context of IACUC protocols and compliant animal use, someone may be considered as the PI if they have responsibility and authority for the research or teaching activities being conducted, and for the staff and students participating in the work. This level of control and responsibility typically falls to a faculty member that reports directly to a Department or Unit Head. There are occasional exceptions when someone other than a faculty member has the required authority. If you have any questions, please contact the IACUC Office at

**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.**

# Animal Care Form

## 2. USE OF REGULATED AGENTS OR MATERIALS

If animal use involves any of the following, check all that apply:

- Chemical Hazards (submit copies of the [DRS Chemical Safety](#) form, [Chemical Review for Animal Protocols](#), with your protocol - see the [DRS Chemical Safety List of Chemicals that require review](#))
- Radioisotopes ([Radioactive Materials License](#) required)

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University of Illinois M/CDC Animal Use Protocol Form

- Recombinant DNA (even if exempt) - [IBC](#) Registration date:
  - Pathogens (human/animal/plant) - [IBC](#) Registration date:
  - Biotoxins - [IBC](#) Registration date:
  - Human/Non-Human Primate Materials - [IBC](#) Registration date:
  - CDC regulated select agents - [IBC](#) Registration date:
  - Cell lines or tumors for implantation ([Pathogen testing may be required](#))
  - Transgenic plants, plant tissues, seeds - [IBC](#) Registration date:
  - Transgenic animals - [IBC](#) Registration date:
- List strains:

- 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



Published or Mandated Sponsor Deadline postmarked by receipt by electronic submission due 10/27/10 *Specify Time Zone*  
 Verification of published deadline should be made available with guidelines

Submit one original PTF fully complete on both pages with proposal package. Do not staple to proposal documents. The original signature must be kept on file for audit purposes until further notice.

Has preliminary review occurred? Yes  No

(Preliminary review service is only available prior to stated internal deadlines.)

If yes, indicate OSPRA coordinator name: \_\_\_\_\_

UI eRA Number assigned \_\_\_\_\_ NetFiles name \_\_\_\_\_

**IDENTIFICATIONS:**

BANNER ORGANIZATION CODE # for Responsible Dept. [REDACTED]

Principal Investigator Name:

(ATTACH LIST IF MORE SPACE IS NEEDED)

Last Name	First and Initial	UIN	Initiating Dept/Division	E-mail Address	Phone
Wheeler	Matthew	<span style="background-color: black; color: black;">[REDACTED]</span>	Institute for Genomic Bio	<span style="background-color: black; color: black;">[REDACTED]</span>	_____
Cameron	Jo Ann	<span style="background-color: black; color: black;">[REDACTED]</span>	Institute for Genomic Bio	<span style="background-color: black; color: black;">[REDACTED]</span>	_____

Proposal Title: 1 Engineering Chemo-Mechanical Dynamics of Preimplantation Embryo Environments

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

*(If an Incoming subaward, specify the name of originating sponsor in parentheses after the Prime Recipient's name, e.g. University X (NSF))*

Sponsor/Agency Mailing Address: \_\_\_\_\_  
 (Include street address if express mail is to be used) \_\_\_\_\_

Agency RFP#,BAA#,RFQ#,Program Announcement #: PAR-10-276 [Complete Guidelines **MUST** be attached or URL provided.]

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

Supports a program of: (check one)  Basic Research <sup>2</sup>  Instruction <sup>2</sup>  Public Service  Applied Research <sup>2</sup>  
 Product Development <sup>2</sup>  Technical Testing <sup>2</sup>  Other (specify) \_\_\_\_\_

Proposal Type: (check one)  New  Renewal <sup>3</sup>  Continuation <sup>3</sup>  Revised proposal or Budget  Supplement

Send Agreement with Proposal: <sup>6</sup>  Yes  No If Yes:  Draft  Sponsor Specific

For renewal or continuation, please provide previous UI eRA# \_\_\_\_\_, sponsor grant/contract \_\_\_\_\_ and current Grant Code \_\_\_\_\_

**PRINCIPAL INVESTIGATOR RESPONSIBILITY:** It is understood that if an award results from this application, the principal investigator will perform the administrative duties normally associated with the project. The principal investigator assures that he/she makes this submission with the understanding that any resulting award will contain no provision restricting the University's right to publish research results, and that if any question of such restriction arises in subsequent negotiation he/she will assist in arranging the further review that will be required.

**NOTE TO PRINCIPAL/CO-PRINCIPAL INVESTIGATOR(S):** By signing this transmittal form, you are certifying that 1) the information submitted herein is true, complete and accurate to the best of your knowledge, 2) any false, fictitious, or fraudulent statements or claims may subject you to criminal, civil, or administrative penalties, 3) you agree to accept responsibility for the scientific conduct of the project and to provide progress reports, and 4) you have submitted a listing of your known Significant Financial Interest (and those of your spouse and dependent children) that might reasonably appear to be affected by the research being proposed.

(Attach additional pages for multiple signatures (i.e., PI/Co-PI and affected Colleges and Departments), if necessary)

Approved By:

Date	Principal/Co-Principal Investigator(s) or Initiator(s) of Proposal (Signature may not be delegated)	Date	Executive Officer(s) of Department(s)
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Date	Dean or Director	Date	Other Signatures If Required <sup>4</sup>
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Office of Sponsored Programs and Research Admin

Research Board Authorization

For information on this proposal call: Rochelle Bilbrey at (217) 244-3161, rbilbrey@igb.uiuc.edu

**SPECIAL MAILING INSTRUCTIONS** (Attach special instructions if needed)

Banner FOAP (Grant codes may not be used for shipping purposes) to charge for shipment:

# Transmittal Form Compliance Section

PROPOSAL CHARACTERISTICS, COMPLIANCE, AND OTHER APPROVALS: (check all that apply). Work performed under this proposal involves the following:

<input type="checkbox"/>	Use of human subjects, or HHS Exemption # 0	<input type="checkbox"/>	Corrosive gases	<input type="checkbox"/>	Subaward; If yes, should include Scope of Work, Budget and Authorized Administrative Approval. Must have once award is issued, or may expect delay in Subaward issuance.
<input checked="" type="checkbox"/>	Use of live vertebrate animals <sup>5</sup>	<input type="checkbox"/>	Pyrophoric gases	<input type="checkbox"/>	Consultant payment
<input type="checkbox"/>	Human <input type="checkbox"/> and/or Non-Human Primate materials <input type="checkbox"/>	<input type="checkbox"/>	Extremely toxic gases (Zone A or B)	<input type="checkbox"/>	Use of Background Intellectual Property
<input checked="" type="checkbox"/>	Stem Cells <input type="checkbox"/> Human <input checked="" type="checkbox"/> Animal	<input type="checkbox"/>	Explosives	<input type="checkbox"/>	Patent considerations
<input type="checkbox"/>	Recombinant DNA: Proposal page # _____	<input type="checkbox"/>	Discharge of unusual pollutants in waste water	<input type="checkbox"/>	Copyright issues
<input type="checkbox"/>	Transgenic Animals <input type="checkbox"/> , Seeds <input type="checkbox"/> , or Plants <input type="checkbox"/>	<input type="checkbox"/>	Requirement for environmental statement	<input type="checkbox"/>	Use of proprietary or confidential information Space: will require additional be made available to the department of that existing space be renovated.
<input type="checkbox"/>	Biotoxins	<input type="checkbox"/>	Other safety or health hazard	<input type="checkbox"/>	International program 4
<input type="checkbox"/>	Dioxins	<input type="checkbox"/>		<input type="checkbox"/>	Chicago Imprint
<input type="checkbox"/>	Pathogens: Human <input type="checkbox"/> , Animal <input type="checkbox"/> Plant <input type="checkbox"/>	<input type="checkbox"/>	Small Business Subcontracting Plan Equipment acquisition only	<input type="checkbox"/>	EXPORT Control: ITAR/EAR <input type="checkbox"/> Use of Foreign Nationals <input type="checkbox"/> Covered Technology
<input type="checkbox"/>	Chemical hazard	<input type="checkbox"/>	Construction of Building	<input type="checkbox"/>	Potential conflict of interest has been identified and addressed
<input type="checkbox"/>	Biological hazard	<input type="checkbox"/>	Limited Submission	<input type="checkbox"/>	American Recovery and Reinvestment Act of 2009
<input type="checkbox"/>	X-Ray or Laser Registration	<input type="checkbox"/>	Multiple Principal Investigators (NIH only)	<input type="checkbox"/>	STTR/SBI
				<input type="checkbox"/>	NONE OF THE ABOVE

(1), (2), (3),(4) and (5) See definitions on attached sheet.

(6) Submit lab animals care form IACUC-1 to the Institutional Animal Care and Use

- Boxes must be checked before grant will be submitted.
- Once done then 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**

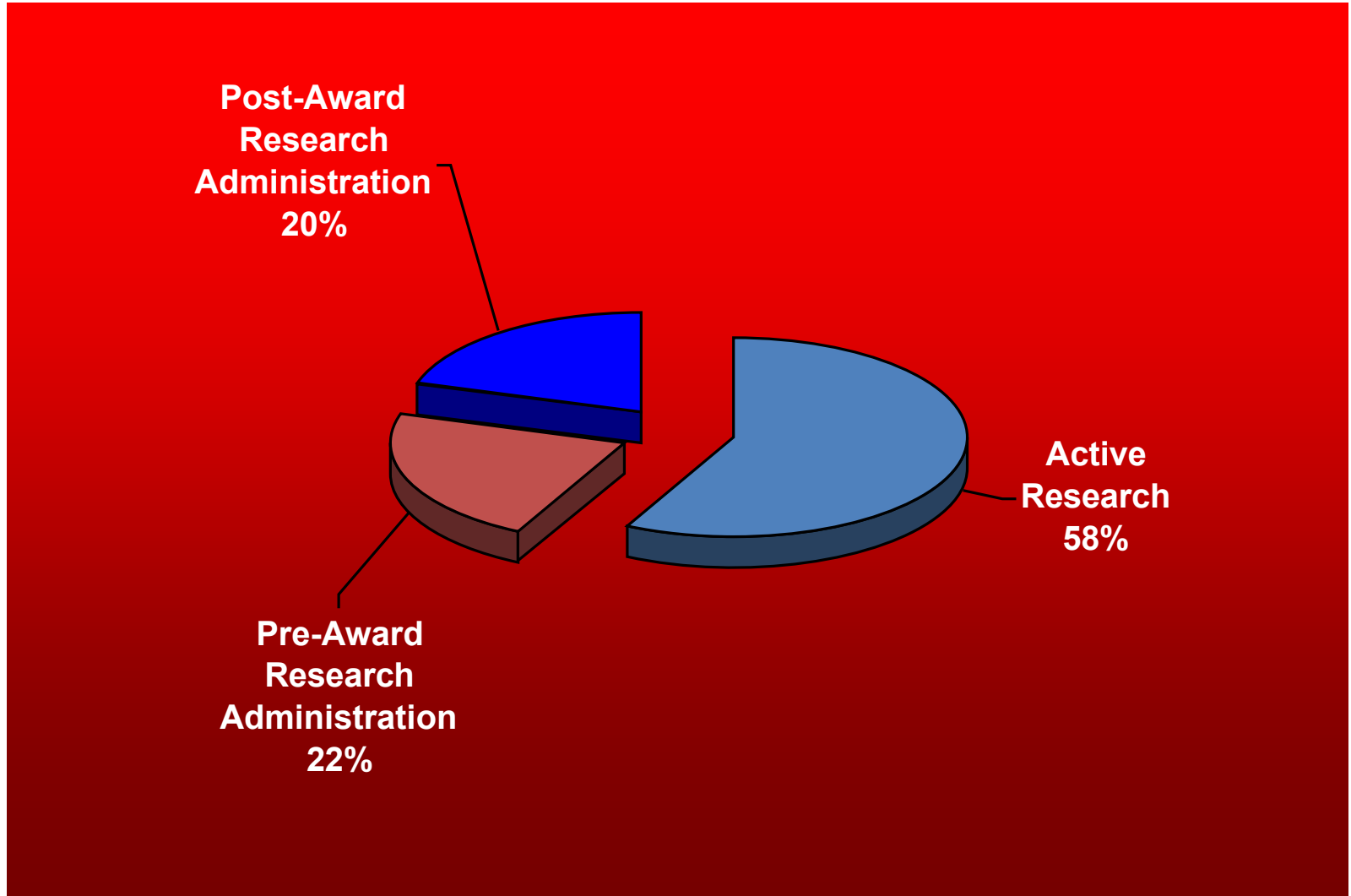
- regulations are federal laws that prohibit the unlicensed export of certain commodities or information for reasons of national security or protections of trade.

- **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**
  - 7<sup>th</sup> most burdensome of the 25 burdens
  - 2<sup>nd</sup> 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.*