

# IBCs in a Changing Research Landscape

The Relationship of IBCs to IRBs and  
IACUCs

# **Georgetown University**

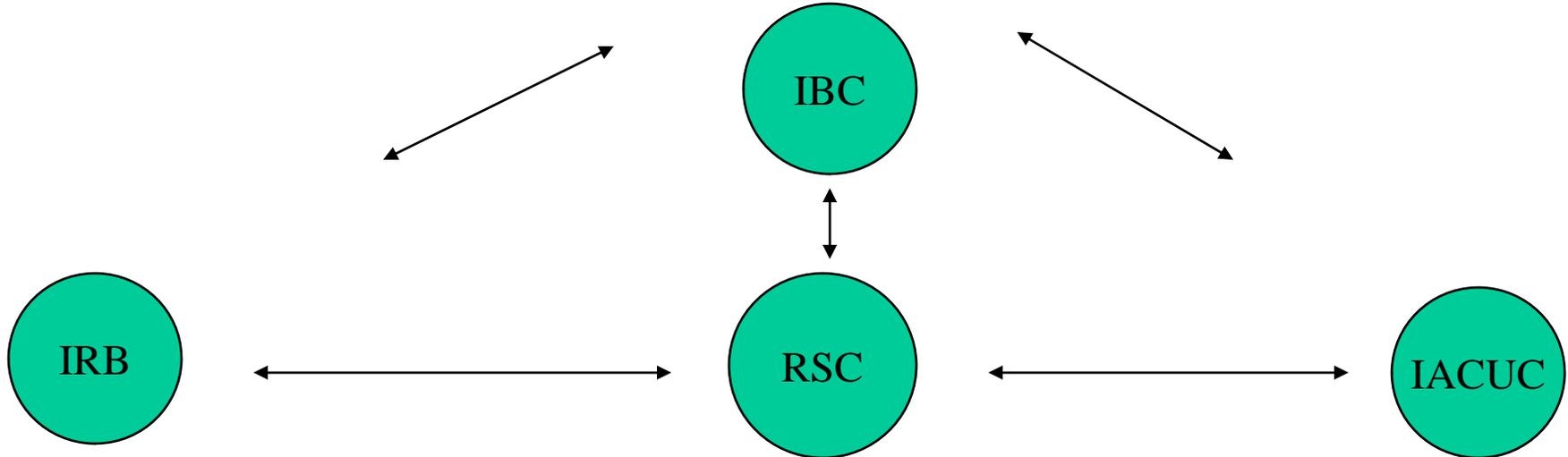
## **Office of Regulatory Affairs**

- Director of Regulatory Affairs
- Director of Research Assurance & Compliance
- IRB
- IACUC
- IBC
- Radiation Safety Committee (“RSC”)
- Research Integrity Committee
- Conflict of Interest
- Environment, Health & Safety (“EH&S”)
- Animal Housing Facility

# Biosafety Interrelationships

NIH/Recombinant Advisory Committee (RAC)

Georgetown University Regulatory Affairs



# **Roles & Responsibilities of the Regulatory Committees**

- IRB
- IACUC
- RSC
- IBC

# Functional Relationships

How do these committees interact?

# Overall Approaches to Facilitate these Interactions

- Cross references in the application forms

# **Institutional Biosafety Committee Protocol for Research Involving Biological Hazards & Chemical Safety Review**

- **Protocols for all research at Georgetown University involving Biological Hazards must be submitted to the Institutional Biosafety Committee (IBC) for review. For purposes of the IBC, Biological Hazards include: A) Recombinant DNA, B) Infectious Agents, C) Hazardous/Carcinogenic Chemicals, and D) Transgenic Animals.** Research protocols involving the use of any of these entities must contain a detailed description of potential danger(s) posed by the agent(s), **And** a summary of safeguards, training, and procedures which will be employed to protect both laboratory personnel and the GU community.

**Will this protocol involve the use of Radioactive Materials? <sup>(1)</sup>**

**Will this protocol involve the use of Animals?<sup>(2)</sup>**

**Will this protocol involve Human Subjects? (Clinical Trials)<sup>(3)</sup>**

**<sup>(1)</sup>For research involving the use of Radioactive Materials or Radiation Producing Equipment . . . , a copy of this protocol must also be submitted to the Radiation Safety Office.**

**<sup>(2)</sup>For research involving Animals, a copy of this protocol must also be submitted to the GUACUC.**

**<sup>(3)</sup>For research involving Human Subjects, IRB [prior] approval must be demonstrated.**

# Georgetown University Institutional Review Board Application Protocol for Biomedical IRB Review

## Section Two: Additional Georgetown University Regulatory Information

1.  Does this project involve the use of biohazardous materials, recombinant DNA and/or gene therapy?  
Yes. If so, Institutional Biosafety Committee (IBC) approval must be obtained.  
 No

Has the Institutional Biosafety Committee approved the protocol?

Approved

Date Approved:

Application Pending

Date Submitted:

1. Does this project include the use of radioisotopes and/or radiation-producing devices regardless of whether the use is incidental to the project?  
 Yes. If so, all protocols must be submitted to the RSC along with a completed RSC-4 or RSC-5 form. The forms require information on the use of radioisotopes and radiation-producing devices and must include dose calculations.  
 No

1. Has the Radiation Safety Committee approved the protocol?

Approved

Date Approved:

Application Pending

Date Submitted:

# Georgetown University Animal Care and Use Committee (GUACUC) Proposal to Use Laboratory Animals in Research and Teaching

## I. Special Concerns

1) Yes  No  Does the project involve recombinant DNA (including transgenic animals), toxic, carcinogenic or infectious agents **in animals**?  
If yes, submit one copy of the Protocol for Research involving Biologic and Chemical Hazards Form to the Institutional Biosafety Committee (IBC).

- If Yes, provide:
- a. a copy of the signed approval letter from the IBC must be provided.
  - b. a completed IBC application with description of **potential dangers**, and **safety precautions and levels** relevant to the animal colony and personnel to the GUACUC.
  - c. a safety strategy meeting is required before animals can be ordered.

# Georgetown University

## Office of Environmental Health and Safety

### Radiation Safety

1. Plan of Investigation as it specifically relates to the use of radioactive materials (provide a brief description of each experimental procedure performed with each isotope).

Does this research involve the use of infectious agents, or recombinant DNA? Yes  No

If yes, provide the Institutional Biosafety Committee (IBC): Approval Date  
\_\_\_\_\_ IBC Protocol Number

# Overall Approaches to Facilitate these Interactions

- Cross representation by committee members
- Communication among administrative personnel
- Committee oversight by the Director of Regulatory Affairs and the office of EH&S

# Overall Approaches to Facilitate these Interactions

- Electronic links
  - Who, What and Where?
- Program orientation and review (initial and annual)
  - Annual training sessions for all faculty and research staff
  - New P.I. (one on one)
  - New research staff
  - New employee support staff

# Overall Approaches to Facilitate these Interactions

- Monitoring to insure compliance

- Pre-inspection

- Quarterly review

- Annual review

- Close-out inspection

- Disciplinary action

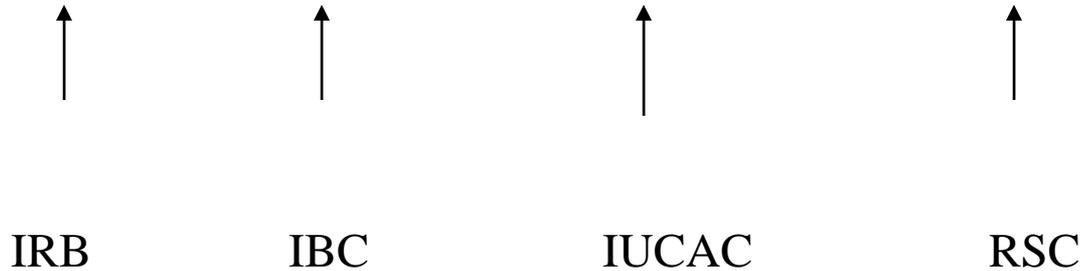
- Suspension

- Termination

# Recommendation #1

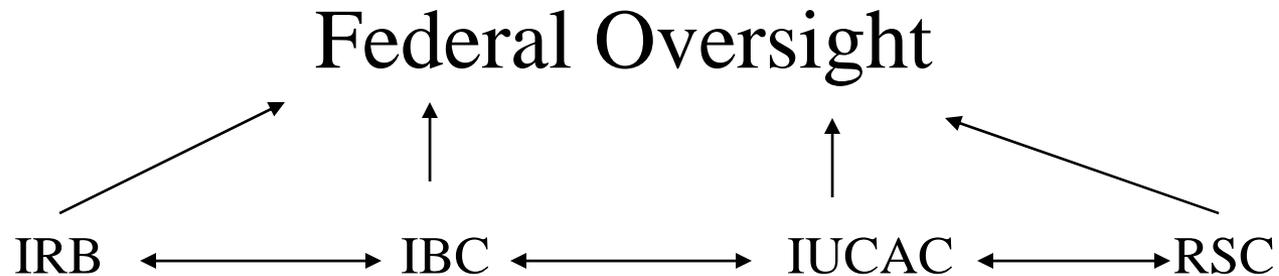
- Current

## Federal Oversight



# Recommendation #1 Continued

- Proposed Recommendation



# Recommendation #2

- Mandated inventory control
- Enhanced security
- Personnel management
- Government initiatives