

1.02 Advanced Compliance Strategies for Academic Medical Centers

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Topics

- I. Adverse Events
- II. Other Regulatory Reviews
- III. FDA Notification
- IV. Examples of Exculpatory and Acceptable Language

I. Adverse Events

A. Reporting Strategies

- Electronic Adverse Events (AE) Reporting
- Is it the future?

B. Coordination/Cross-pollination with Clinical Pharmacy Services

- Research AE reports
- Clinical Pharmacology AE reports

C. Pharmacist participation in the IRB process

D. Clinical Pharmacology Fellows

- Clinical Pharmacology rotations
- Assisting with AR/AE review

Georgetown University Institutional Review Board Reporting Form for Adverse Event/Unanticipated Problem Occurring at Georgetown or Affiliate Study Site

Section 1: Description of the Adverse Event or Unanticipated Problem

Date of the event _____

The Event/Problem was:

- Mild
- Moderate
- Severe
- Fatal (Date of Death: _____)

Adverse Event/Unanticipated Problem Occurring at Georgetown or Affiliate Study Site [Continued]

Relationship to Research Intervention (**Definitions are provided in
IRB Policies for Assessing Adverse Events**)

<http://macpost.odr.georgetown.edu>

- Causative
- Probable
- Inconclusive
- Unlikely
- Negative

Georgetown University Institutional Review Board Reporting Form for Adverse Event/Unanticipated Problem Occurring at Non-Georgetown Sites

Section 1: Description of the Adverse Event or Unanticipated Problem

Date of Event _____

How were you notified of this event?

- Medwatch
- Sponsor
- Other (specify)

Please attach the Report

**Georgetown University Institutional Review Board Reporting
Form for Adverse Event/Unanticipated Problem
Occurring at Non-Georgetown Sites**

**Causality Assessment by Non-Georgetown
Evaluators**

Assessment by Non-Georgetown investigator who reported the event:

- Causally related
- Causal relationship cannot be eliminated (equivalent to “inconclusive” or “possible”)
- Causal relationship unlikely
- Not causally related
- Assessment not provided

Causality Assessment by Non-Georgetown Evaluators [Continued]

Assessment by sponsor:

- Causally related
- Causal relationship cannot be eliminated
(equivalent to “inconclusive” or “possible”)
- Causal relationship unlikely
- Not causally related
- Assessment not provided

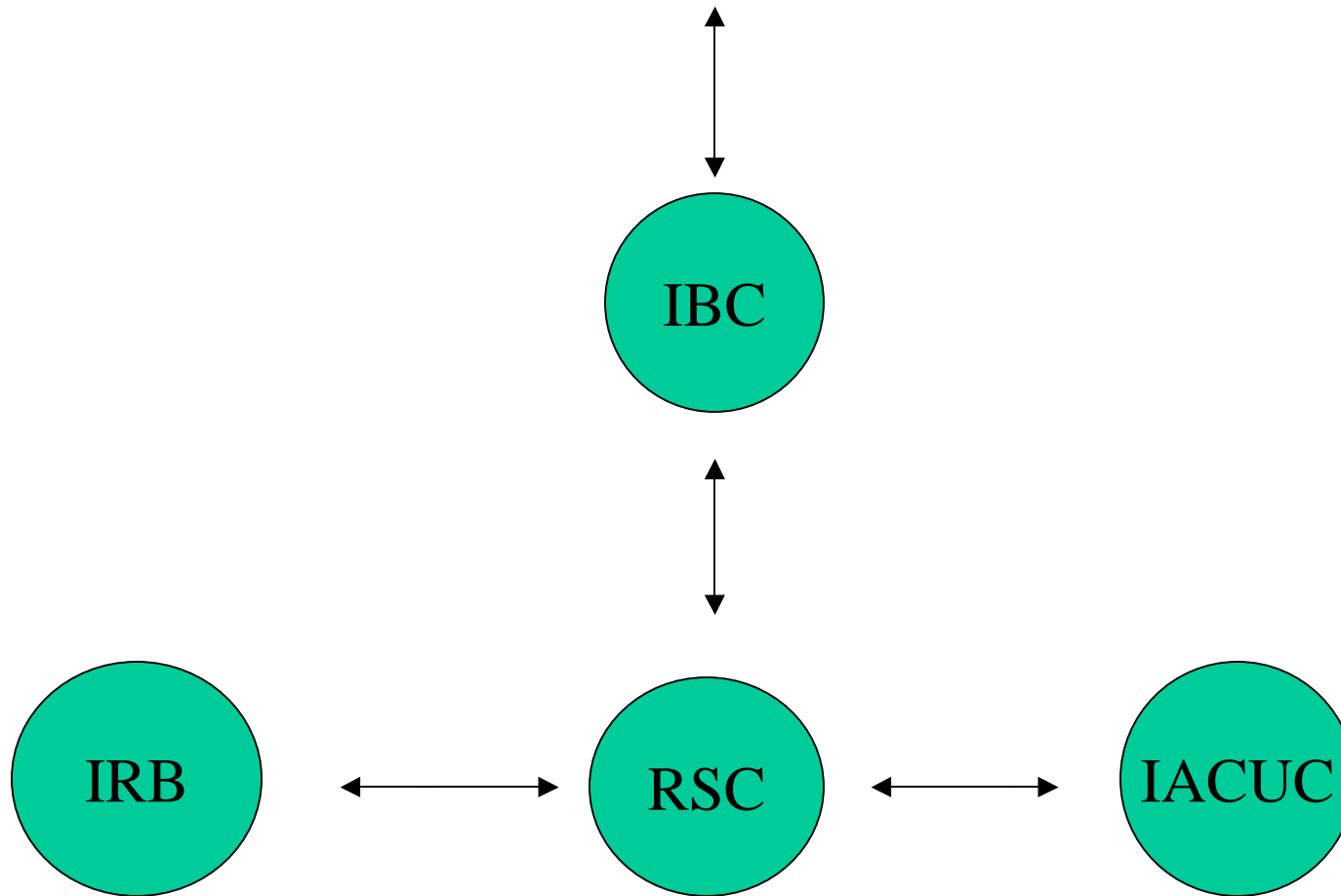
Georgetown University Medical Center Medication Occurrence Information Report/PI

- Type of Error
- Breakdown Point
- Error Severity/Outcome

II. OTHER REGULATORY REVIEWS

- Radiation Safety Review
- Institutional Biosafety Review

Georgetown University Regulatory Affairs



Georgetown University Institutional Review Board Application Protocol for Biomedical IRB Review

Section Two: Additional Georgetown University Regulatory Information

- 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:**
- 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
- Has the Radiation Safety Committee approved the protocol?

Approved **Date Approved:**
Application Pending **Date Submitted:**

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? ⁽¹⁾

Will this protocol involve the use of Animals?⁽²⁾

Will this protocol involve Human Subjects? (Clinical Trials)⁽³⁾

⁽¹⁾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.

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

⁽³⁾For research involving Human Subjects, IRB [prior] approval must be demonstrated.

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.

Overall Approaches to Facilitate these Interactions

- Cross-representation by committee members
- Communication between administrative personnel
- Committee oversight by the Director of Regulatory Affairs and the Office of Environmental Health and Safety

III. FDA Notification
March 6, 2002 Advanced Notice
of Proposed Rulemaking:
Notification of other IRB Reviews

(www.fda.gov)

IV. Examples of Exculpatory Language

- By agreeing to this use, you should understand that you will give up all claim to personal benefit from commercial or other use of these substances.
- I voluntarily and freely donate any and all blood, urine, and tissue samples to the U.S. Government and hereby relinquish all rights, title, and interest to said items.
- By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.
- I waive any possibility of compensation for injuries that I may receive as a result of participation in this research.

Examples of Acceptable Language

- Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.
- By consenting to participate, you authorize the use of your bodily fluids and tissue samples for the research described above.
- This hospital is not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research.
- This hospital makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge.