


**POLICY & PROCEDURE**

 University of Wisconsin Hospital and Clinics	Effective Date: August 2000	X Administrative Manual ? Nursing Manual ? Other _____	Policy #: 12.10 NEW
	X Original ? Revision	Page <u>1</u> of <u>3</u>	Title: Research Safety Committee Authority & Function

**I. PURPOSE**

To establish a process by which clinical (human) research protocols possessing potential health hazards are identified, reviewed and approved before entrance into the University of Wisconsin's Hospital and Clinics (UWHC) health system network.

**II. POLICY**

Research protocols involving drugs, agents, devices and/or procedures and possessing potential health hazards must be reviewed by and approved by the Research Safety Committee (RSC) before said research could begin at UWHC. This committee will focus on research protocols possessing safety concerns that are not adequately covered by existing biohazardous or cytotoxic policies and/or where safety policies do exist but the research location, route of administration or employees involved deviate from standard operating procedures. Research protocols affected by this policy are:

- Protocols requiring Institutional Biosafety Committee (IBC) approval (eg., gene transfer protocols)
- Research protocols intentionally exposing subjects to infectious agents
- Other research protocols as deemed necessary by the Research Safety Committee

**III. FORMS USED**

RSC Application form

**IV. PROCEDURE**


**A. Identification of research protocols that require RSC review and approval**

1. Affected protocols will be identified as they are processed through the Human Subjects Committee (HSC) by HSC participants (1staff/1member) who are also members of the RSC
2. Affected protocols may also be identified in advance of HSC submission by:
  - a. The Investigational Drug Services (IDS) program
  - b. Principal investigators (PI) and/or study coordinators

**B. Submission process for RSC review**

1. Once identified, PI will be informed that their protocol requires RSC review and approval and will be instructed to submit to the RSC Chair, the following information:
  - a. Eight (8) copies of the protocol
  - b. Four (4) copies of the investigational drug brochure (if applicable)
  - c. A completed RSC application form depicting all involved areas as well as the movement of the research subject from the point of UWHC arrival to discharge and subsequent study visits.

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2. RSC review and approval is **protocol specific**, not agent specific. Therefore if an investigator is conducting two protocols with the same agent, and that agent meets criteria for RSC review and approval, then each protocol must be submitted.
3. The RSC meets every third Wednesday of the month from 1300-1430
4. Submission to the RSC does not obviate the need for HSC approval or other committee approvals mandated by federal regulations or institutional policy.

**NOTE:** RSC approval process takes considerable time ( may be in excess of two months) and PI/study groups should plan accordingly.


C. Review requirements

1. Review is comprehensive and multidisciplinary in nature and involves representatives from all UWHC areas exposed to the research protocol and/or subject
2. PI and study personnel are required to take part in the review process. This discussion will either take place the regularly scheduled monthly meeting (3<sup>rd</sup> Wednesday) and/or at a time mutually acceptable for all involved individuals.
3. The RSC, PI, study group and involved area representatives will collaboratively:
  - a. review of the proposed flow of the research subject through the institution
  - b. determine if subjects must be handled under any isolation categories
  - c. determine appropriate protective procedures for all involved areas
  - d. determine disinfectant and biohazard destruction procedures
  - e. determine if professional and/or subject informational documents are required (if yes, a member of the RSC will draft such a document, which subsequently requires full committee and PI review/approval)
  - f. determine Employee health instructions
  - g. determine if other safety considerations and precautions other than those noted above are required
  - h. determine the involved areas that will require educational forum(s)
4. The RSC will summarize all of the recommendations and instructions for the safe handling of the research protocol into a final protocol-specific RSC instruction worksheet.

D. Approval requirements

1. Mandatory educational forums
  - a. Once the final protocol-specific RSC instruction worksheet has been developed, the PI/study group must conduct educational forums (number and location to be determined by RSC) to review the protocol and RSC safety procedures.
  - b. One member of the RSC must be present at each educational forum. contact the RSC Chair for appropriate RSC member identification
  - c. Any questions and/or concerns raised at the educational forum(s) must be appropriately addressed before final approval can be given
2. Upon fulfillment of educational forum requirements, the RSC will provide the PI with a protocol approval notice and subject recruitment may begin.
3. RSC protocol approval notices will be carbon copied to
  - a. HSC

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- b. Employee Health
- c. IBC ( if applicable)
- d. UW Comprehensive Cancer Center’s Clinical Affairs Committee (if applicable)
- e. Others as needed

E. Changes of protocol/ adverse event procedures/ protocol review/ withdrawal of approval.

RSC approval of a protocol shall continue as long as HSC approval continues, unless withdrawn. Annual reapproval by the RSC is not required. Approval must be obtained from the RSC Chair before protocol modifications can be implemented. The RSC can withdraw its approval of a protocol at any time. The HSC will forward to the RSC any adverse event report forms, continuing review forms, any proposed protocol modifications, and any resulting HSC action on any protocol that has been approved by the RSC. Investigators do not have to separately report to the RSC any such information that is timely reported to the HSC. Any such information that is not timely reported to the HSC must be promptly reported to the RSC.

**V. REFERENCE**

**VI. COORDINATION**

Sr. Management Sponsors: General Counsel  
 Sr VP Professional and Support Services  
 Authors: Director of Safety and Hazard Control  
 Pharmacy Clinical Assistant  
 Review/Approval Committee:  
 UWHC Safety Committee  
 Administrative Policy and Procedure Committee



Donna K. Sollenberger  
 President and CEO