

# Role of Collaborative IRB Members in the Human Subjects Protection Program

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Improvement

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# Purpose and Goals

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- The purpose of this educational module is to provide an overview of the IRB responsibilities within the human subjects protection program at UIC.
- At the end of this training module, IRB members should be able to:
  - Articulate how the UIC HSPP operates and interacts with Northwestern University and the JBVAMC Offices and committees;
  - Identify their role and responsibilities as part of an HSPP; and
  - Be familiar with the individual components of the human subjects protection program to realize when a protocol submission is incomplete.

# What is a human subject protection program?

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- The UIC HSPP is an integrated system that has organization-wide and agency support and encompasses all aspects of human subjects research enterprise, spanning the continuum of research design to study closure.

# Who is the institutional official and what is his role?

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- Dr. Larry Danziger
- The IO is ultimately responsible for the development and implementation of the HSPP Plan and the coordination of all its components.



# Who is the Human Protections Administrator and what does this individual do?

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- Dr. James Fischer
- The UIC faculty member or academic staff identified by the IO as the point of contact with OHRP for human subjects protection issues, including the investigation and reporting of non-compliance matters, and plays a key role in ensuring that the institution fulfills its responsibilities under its FWA.



# What is the function of OPRS?

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- OPRS is the primary coordinating office for the HSPP.



# Assistant Directors, IRB Coordinators, and OPRS Support Staff

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- Roles and responsibilities include, but are not limited to:
  - Data entry
  - Prepare review guides
  - Assemble meeting packets and agendas
  - Filing
  - Pre-Reviews
  - Convened meeting minutes
  - Expedited submission letters
  - Meetings with investigators/ coordinators
  - Answering emails and telephone calls
  - Administrative work related to IRB members

# Institutional Review Boards

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- All research involving human participants that is not determined to be exempt from IRB oversight is reviewed by one of four UIC IRBs that are responsible for considering the Criteria for Approval (including but not limited to DHHS, FDA, and VA) when reviewing all submissions (initial review, continuing review, amendments, modifications, unanticipated events).
- One board is dedicated to social and behavioral research, another is dedicated to VA Research, one is dedicated to biomedical research and the fourth is dedicated to health sciences and social behavioral research

# OVCR: Associate Director for Research Compliance

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- Dr. Clyde Wheeler
- performs for-cause and not-for-cause audits, with a focus on on-site investigator audits
- focus is primarily in developing practical tools and guides for investigators once the research is approved by OPRS
- as part of auditing investigator activities, OPRS files are also audited

# Assistant Director of Quality Assurance/ Quality Improvement

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The Assistance Director of Quality Assurance/ Quality Improvement:

- designs and implements the OPRS internal compliance plan,
- leads the research accreditation process,
- drafts policies and procedures,
- audits and monitors,
- provides regulatory support,
- collaborates on educational materials and presentations for OPRS staff, IRB members, investigators, and research coordinators,
- drafts corrective action plans with government agencies,
- assists the JBVAMC R&D Office with policies and procedures on an as needed basis, and
- evaluates the UIC HSPP.
- This individual provides monthly reports of findings to the Director of OPRS and semi-annual reports to the IO or as needed.

# Differences between OPRS QA/QI and OVCR Associate Director of Compliance Roles

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- OPRS QA/QI focuses only on internal OPRS issues,

while

- the focus of the OVCR Associate Director of Compliance is on external investigator compliance

# Office of Research Services (1 of 2)

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- ORS is responsible for providing general grant, contract, and agreement administration with project sponsors.
- In addition, ORS is responsible for the following HSPP functions: monitoring funding agency assurance/certification requirements and ensuring compliance;
- posting federal and state regulatory guidelines relevant to sponsored research;
- coordinating with the IRB to ensure accuracy of completed assurances and certifications through the grant matching process;

# Office of Research Services (2 of 2)

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- maintaining agency-required documentation; and
- maintaining a working knowledge of the types of projects needing IRB review.
- ORS is responsible for negotiating the terms of all sponsored agreements, including clinical study agreements on behalf of UIC.
- ORS also prepares subagreements with collaborators, which include provisions for adherence to human research protections, the research protocol, and applicable federal and state regulations.

# JBVAMC R&D Committee (1 of 3)

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- The function of the R&D Committee is in flux.
  - Currently, the JBVAMC R&D Committee reviews all research under the auspices of the JBVAMC, initially and at least once a year, including research determined exempt by the Collaborative IRB.
  - All NU, UIC, or JBVAMC research that engages the JBVAMC as a recruitment and/or performance site, including research involving only human biological specimens, must have the approval of the JBVAMC R&D Committee and its appropriate subcommittees before the research may begin.
  - The Collaborative IRB functions as the Human Studies Subcommittee for the JBVAMC R&D Committee, the findings of which are recorded and reported to the JBVAMC R&D Committee.

# JBVAMC R&D Committee (2 of 3)

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- The JBVAMC R&D Committee reviews and provides to the JBVAMC Director an evaluation of all JBVAMC R&D Subcommittees, including committees at external entities. Communication exists between the JBVAMC R&D Committee and the Collaborative IRB, including the timely exchange of meeting minutes and board actions as outlined in this SOP.
- The JBVAMC R&D Committee can accept or reject an decision, but cannot reverse an IRB disapproval of the research. If the R&D Committee disapproves the research, the R&D Committee must notify the Collaborative IRB in writing of the reason(s) for disapproval in accordance with the appropriate VHA Handbook.

## R&D Committee, Continued (3 of 3)

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- The Collaborative IRB functions as the Human Studies Subcommittee for the JBVAMC R&D Committee, the findings of which are recorded and reported to the JBVAMC R&D Committee.



# Executive Committee

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- The EC has been organized to coordinate communication regarding human subjects protection among the Collaborative IRB Chair and Vice-Chair and the JBVAMC, UIC and NU staff and administration in accordance with the executed MOUs.
- The EC also may make recommendations regarding Collaborative IRB resources and review, draft, or recommend revision of UIC OVCR policies and procedures related to the Collaborative IRB.
- The EC may assist the IRB in the review of allegations of non-compliance and the appropriate members of the EC coordinate compliance investigations with their respective institutions as necessary and as directed by the Collaborative IRB Chair and/or the Collaborative IRB.



# JBVAMC R&D Office

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- The JBVAMC R&D Office verifies that applicable items on the application packet checklist are properly submitted and, when applicable, verified.



# Scientific and Scholarly Review

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- Protocols containing certain areas of concern, procedures, or risk levels require scientific and scholarly review by other components of the UIC HSPP before the IRB may approve the protocol.

# What additional reviews are required?

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- Cancer Center
- Radiation Safety
- Radioactive Drug Research Committee
- Institutional Biosafety Committee
- Investigational Drug Service
- Departmental Review

# Cancer Center Protocol Review Committee: Overview

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- Description:
  - The Cancer Center Protocol Review Committee (CC-PRC) reviews each cancer-related protocol at the time of initial review and continuing review, and reviews amendments that involve revisions to the protocol or Investigator's brochure. The goals of the CC-PRC are:
    1. to conduct a scientific review of all proposed cancer research,
    2. to monitor all clinical cancer research protocols for sufficient progress,
    3. to monitor all clinical protocols as to their observance of all the requirements established by the regulatory bodies, and
    4. to terminate cancer protocols not achieving goals in a reasonable time frame.

# Cancer Center

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- Practical Implication:
  - The application form prompts the investigator to submit this form when required.
  - The designated IRB Coordinator or Assistant Director verifies that the form is present before IRB member review and documents findings in the pre-review guide.
  - For cancer-related protocols, the IRB members must ensure that the pre-review indicates that documentation of cancer center review has occurred.
  - The Cancer Center review replaces Departmental Review for cancer-related protocols.
  - This review process is distinct from the IRB review process; however, the IRB reviews the determinations of the CC-PRC, and as the IRB membership includes members of the CC-PRC, the IRB is adequately informed of any issues or concerns related to a particular protocol. The two review processes complement each other and together work to improve the human subjects protection program.



# Radiation Safety Committee

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- Description:
  - This committee authorizes the use radiation-producing devices and radioactive material in operations, education, research, and development activities.
  - The RSC establishes radiation policies and procedures for the University in accordance with state and federal regulatory requirements governing the procurement, use, storage, and disposal of radiation-producing devices and radioactive material.
  - The RSC authorizes individual investigators and study personnel to use these devices in the conduct of their research; however, prospective users must submit proposals to the RSC for review and approval.

# Radiation Safety Committee

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- Practical Implications:
  - The investigator is prompted by the application form to undertake this review when appropriate.
  - The appropriate IRB Coordinator or IRB Assistant Director will verify whether this document is present when it is needed.
  - The pre-review form completed by the IRB Coordinator or IRB Assistant Director will capture whether or not this document is present.
  - If you read a protocol and you believe a radiation safety committee is required, verify that the pre-review sheet indicates that this document is present. If not, please speak with an IRB Coordinator or IRB Assistant Director.
  - The RSC review is completed prior to initial review conducted by the IRB, which may not approve research requiring RSC review without prior approval from the RSC.

# Radioactive Drug Committee

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- Basic research designed to study the metabolism of a radioactive drug or to gain information about
  - human physiology,
  - pathophysiology, or
  - biochemistry
- in response to radioactive drug use is subject to review by the UIC Radioactive Drug Research Committee, as well as the IRB.

# Radioactive Drug Committee: Practical Implications

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- Practical Implications:
  - The investigator is prompted by the IRB application form to submit this document.
  - The appropriate IRB Coordinator or IRB Assistant Director verify that the investigator has submitted this document when appropriate.
  - The pre-review guide will indicate whether this document is present or absent.
  - The IRB will not approve research subject to the radioactive drug committee without prior written approval from this committee.
  - Please inform the appropriate IRB Coordinator or Assistant Director if you do not find this material present.



# Institutional Biosafety Committee

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- The UIC IBC reviews all research involving the use of rDNA in compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules.
- The IBC is also responsible for the safe conduct of research involving infectious agents, including select agents and toxins.



# Institutional Biosafety Committee

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- The IRB will not approve research subject to the IBC without prior written approval from the IBC.

# Investigational Drug Service

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## Overview:

- This unit is a component of the UIC Medical Center.
- All drugs that are the focus of the research or that are prescribed solely because the subject is enrolled in the research must be registered with IDS via Appendix E before IRB review.
- If IDS services will be used, IDS registers the research, makes arrangements for distribution, and coordinates matters with the PI and coordinator.
- IRB approval of the particular protocol is communicated to IDS.

# Investigational Drug Service

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## ○ Practical Implications:

- The investigator is prompted in the application to fill out and complete the appropriate appendices.
- The designated IRB Coordinator or Assistant Director ensure that this form is in the protocol file before the protocol is review by the IRB.
- It is important to read not only the application, but also the protocols submitted with the applications to ensure that investigators are properly following investigational drug service requirements.



# Departmental Review

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The primary purpose of the Departmental Review process is to have persons with similar areas of expertise and knowledge review the research for scientific merit and research design.

- The UIC HSPP requires Departmental Review for all protocols that are submitted for convened review, unless the protocol qualifies for review by the Cancer Center Protocol Review Committee (CC-PRC).
- If the protocol involves cancer or cancer patients, then the CC-PRC review is required and may be substituted for Departmental Review.
- Likewise if the research protocol involves the utilization of the Clinical Research Center (CRC), then review is required in addition to Departmental Review. Protocols that are submitted for exempt or expedited review do not require Departmental Review, but individual departments may continue to use the Departmental review system for protocols in these categories.

# Departmental Review

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- Practical Implications:
  - If any issues are noted in the Departmental Review, they are to be addressed before the research is submitted to the IRB.
  - The IRB receives copies of the Departmental Review forms and a summary of any revisions made as a result of the Departmental Review in the initial review submission packet.
  - Ask the IRB Coordinator or IRB Assistant Director if you do not see that a departmental review is checked on the pre-review sheet and you believe that one is needed.

# Fulfillment of Mission: HSPP Goal

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- These components work together to create a comprehensive, integrated human subjects protection plan.
- The mission of the OPRS is to ensure that there are mechanisms developed and maintained to ensure an effective HSPP, which in turn should ensure the protection of the rights and welfare of all human subjects involved in research.
- The OPRS works with the institution, investigators, research staff, students, institutional units and the institutional review committees (IRBs, IBC, ACC, ESCRO, Radiation Safety, RDRC) as stakeholders in the HSPP, working together toward accomplishing this goal.
- The OPRS recognizes its clientele is first and foremost the subjects, and also includes the public, research sponsors and agencies, the UIC investigators and research staff, and the UIC IRBs.