

**Western Institutional Review Board
Initiative**

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INTRODUCTION:

- I. The UIC has entered into an agreement with the Western Institutional Review Board (WIRB) to become the IRB of record for Industry Sponsored Clinical Trials.
- II. The WIRB is AAHRPP accredited and is used by many institutions across the country. WIRB conducts rigorous reviews of the materials provided to them and ensures that the informed consent and HIPAA Authorization documents meet the stipulations set forth in the agreement.
- III. The conditions and procedures concerning the IRB review are contained in a memorandum of understanding between UIC and WIRB.
- IV. Western IRB will also serve as the Privacy Board for research protocols sent for their review and approval. The agreement specifies the use of HIPAA language for Research that is included in the current UIC HIPAA Authorization templates that will be provided.
- V. Materials submitted for Western IRB review will be pre-reviewed by a member of the OPRS staff to ensure completeness to the UIC requirements.

POLICY:

- I. The WIRB administrator or designee will perform a pre-review to determine on a protocol-by-protocol basis if the research qualifies for submission to WIRB.
 - A. The criteria for studies from UIC investigators to be eligible for review by the WIRB include:
 1. Research meets the NIH definition of a clinical trial. "A prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices)".
 2. Research is a Phase II / III / IV clinical trial.
 3. Research is designed and research protocol written by the sponsor.
 4. The sponsor is a for-profit entity or company.
 5. The sponsor holds all INDs / IDEs.
 6. The research has not previously been submitted to the UIC IRB for review.
 7. The research is greater than minimal risk.
 - B. Research that includes the following criteria may qualify for submission to WIRB depending up on the design of the study. The OPRS WIRB Administrator will review the Protocol Synopsis to determine eligibility.

1. Phase I studies (including I/II, IIb or similar studies)
 2. Research that involves subjects under the age of 18 (i.e., Children, Minors)
- C. Studies which involve any of the following are not eligible for submission to WIRB:
1. Planned emergency research.
 2. All transplant research, including cadaveric research.
 3. Embryonic stem cell research.
 4. Research that include the Jesse Brown Veterans Administration Medical Center (JBVAMC) as a performance site or recruitment site.
 5. Research that receives funds from a federal or non-profit funding agency.
 6. Research that is investigator-initiated.
 7. Research involves a request for approval for local non-affiliated sites.
 8. Research that involves the use of recombinant DNA and its derivatives, such as vectors, and infectious agents.
- D. UIC may also require local IRB review when the institution deems that the rights and welfare of subjects would be better served by local review.
- II. Submission of the research for WIRB review signifies that:
- A. The WIRB becomes the IRB of Record for the research and is responsible for continuing review as well as review of subsequent amendments and serious adverse events (SAE) as notified by the Principal Investigator and/or the Sponsor.
 - B. The UIC IRB is responsible for local context and oversight, including the review of:
 1. Amendments affecting changes in local research personnel.
 2. Consent documents and HIPAA Authorizations (local context language).

PROCEDURE:

I. Initial Review.

Investigators whose protocols meet the criteria for submission to WIRB must complete the following and email with attachments to uicirb@uic.edu or deliver in person to the OPRS Office. The subject line of the e-mail should be entitled "WIRB Submission":

1. UIC OPRS form *Application for Protocol Review by Western IRB*.
 - a. Note that an Account Number must be provided in order for the application to be processed. If an Account has not yet been created, it is recommended that either the Department ICR (F&A) account be used or an anticipation account be established.
 - b. Note that if the PAF# is identified as "Pending", an amendment must be submitted to OPRS when the PAF# has been obtained.
 - c. The following documents should be submitted for review by the UIC OPRS WIRB administrator with the UIC Application for WIRB Review:
 - d. Appendix P and Appendix E
 - e. Departmental Review (Appendix F) is **not** required.

- f. Documentation of Approval by Investigational Drug Service (IDS), Cancer Center (CC PRC), Clinical Interface Core (CIC), Radiation Safety Committee (RSC) and/or Institutional Biosafety Committee (IBC) approval, as appropriate.
 - g. Sponsor Informed Consent Template
 - i. Note that WIRB will reformat the Sponsor's Consent and incorporate the required UIC language into the final Informed Consent Document.
 - ii. Note that if the research requires approval by the UIC Radiation Safety Committee (RSC), RSC requires that appropriate RS language is incorporated into the Sponsor's Consent Template at the time it is submitted for RSC approval (see Section 5.2 in the following website.
<http://www.uic.edu/depts/envh/Departmental/Documents/HumanSubjectResearchPolicy.pdf>)
 - h. Sponsor- research protocol
 - i. COI Statement of Explanation and Management (SEAM), if applicable.
2. WIRB Initial Review Submission Form and documents.
- a. Please note that the Investigator or individual submitting to WIRB will need to establish a User Name and Password as part of the initial Registration process within the WIRB Web Site.
 - b. Note these documents are completed on-line through the WIRB site;
 - c. A copy of the UIC OPRS Acknowledgement letter will need to be uploaded before submitting the application to WIRB.
3. The review of Clinical Trial Agreements (CTA) will be completed concurrent with the review by WIRB:
- a. Note that WIRB will present the final consent document to OPRS for review by the UIC Legal Counsel to ensure that the injury statement in the CTA and in the Consent Document is consistent.
 - b. Any revisions will be sent to WIRB with a copy to the PI for informational purposes.
 - c. Note that WIRB will coordinate the consent document review between the Sponsor and UIC.

II. Pre-Review Process.

- A. A review of the submission (initial and amendments affecting changes in Principal Investigator and/or Research Personnel) will be undertaken by the WIRB Administrator in OPRS.
- B. The role of the WIRB Administrator is to determine whether local concerns exist that need to be addressed and whether the research meets the criteria for WIRB review. Such a review will ensure UIC compliance with OHRP's guidance that "...an institution relying upon another institution's IRB has a responsibility to ensure that the particular characteristics of its local research context are considered through subsequent review by appropriate designated institutional officials, such as the Chairperson and/or other members of its local IRB." [Guidance document *IRB Knowledge of Local Research Context*, dated August 27, 1998].

- C. The WIRB Administrator will review the informed consent document and HIPAA Authorization for compliance with the required UIC language and the agreed upon format with WIRB. In addition, UIC Legal Counsel will review the informed consent document injury language to assure consistency with the Clinical Trial Agreement.
- D. The WIRB Administrator will ensure that the submission includes all the materials required for review, specifically documentation of Investigational Drug Service (IDS) Approval, and if applicable Cancer Center (CC PRC) Approval, Clinical Interface Core (CIC), Radiation Safety Committee (RSC) Approval, and/or Institutional Biosafety Committee (IBC) Approval.
- E. If deficiencies are noted with the submission (changes needed in the informed consent document, necessary Approvals missing, etc.) the WIRB Administrator will correspond directly with the UIC investigator to obtain the information prior to submission to WIRB for IRB review.
- F. After the submission has been forwarded to Western IRB for IRB review, WIRB will contact the investigator directly with questions about the submission and upon obtaining IRB approval, WIRB will send all approved documents directly to the investigator and a copy will be sent to UIC OPRS.
- G. Once WIRB has approved the research, WIRB becomes the IRB of record and is responsible for review of amendments to the research, documents or personnel; adverse event reports, protocol violations and /or unanticipated problems; continuing review; and study closure.

III. Continuing Review.

- A. The investigator will receive email alerts from the WIRB regarding the need for continuing review of WIRB approved protocols.
- B. Prior to expiration of WIRB approval, the investigator must seek continuing review approval or close out the study by submitting a final report. For continuing review or to close the study, the investigator should submit all protocol documents directly to WIRB following the guidelines provided by WIRB.
- C. WIRB will contact the investigator with questions about the submission after receipt. WIRB will send all approved documents directly to the investigator. A copy will be sent to UIC OPRS by WIRB.

IV. Amendments.

- A. Amendments to the research should be submitted directly to the WIRB following the guidelines provided by WIRB, with the exception of research personnel changes and changing Principal Investigator.
- B. UIC HSPP mandates that all individuals who are engaged in the research, including but not limited to, being involved in the conduct, review, or oversight of human subject research, complete initial and continuing education. Individuals involved in research using PHI must also complete the HIPAA research training requirement.
- C. For Amendments involving Research Personnel and/or a change in the Principal Investigator, the investigator should prepare a submission to UIC OPRS that includes the WIRB Change in Research Form; updated Appendix

P, and, if applicable, updated informed consent document(s), updated HIPAA Authorization(s), and updated recruitment materials.

V. Unanticipated problems or other events requiring prompt reporting.

- A. Unanticipated problems or other events requiring prompt reporting and/or serious or continuing non-compliance that involve the UIC study site must be promptly reported to the WIRB following the guidelines provided by WIRB

VI. Final Report.

- A. The investigator should submit the WIRB Study Closure Report Form and all required protocol documents directly to WIRB. WIRB will contact the investigator with questions about the submission after receipt. WIRB will send all approved documents directly to the investigator. A copy will be sent to UIC OPRS by WIRB.

VII. Payment of Fees.

- A. The OVCR charges a processing/administrative fee for the WIRB review of all industry sponsored human subject research. Charging industry sponsors for their share of the costs associated with the IRB review process allows UIC to continue to provide the level of service required by our faculty.

These fees apply only to industry sponsored research involving human subjects submitted for review by the WIRB.

All PIs submitting industry sponsored human subject research protocols for review by the WIRB should include a line item in the clinical trial agreement/study budget for the IRB review fees. Facilities and University administrative costs (i.e., indirect cost/ICR/F&A) will not be applied to the IRB review fees. Payment of these IRB review fees is considered a contractual obligation of the sponsor.

These processing fees are assessments of real costs associated with protocol review by the IRB and are charged regardless of IRB approval or eventual project funding status.

The PI is required to provide a FOAPAL code, indicating which account OVCR should charge the fees associated with IRB review, on the initial submission application form for each industry-sponsored protocol submitted to the UIC IRB. The OVCR will bill the account at the time of protocol review.

- B. The processing/administrative fee for the WIRB will be determined by Review Type: Initial Review \$3,000.00; Additional Investigator, Multi-Center studies \$1875.00; Additional Consent Forms (each) \$320.00; Continuing Review \$1,450.00; Amendment (Changes to Research Involving or not Involving Consent Form Review) \$500.00; Change in Investigator or adding a Co-PI \$1,000.00.

REFERENCES:

<http://www.wirb.com>