

**Institutional Biosafety Committee
(IBC)/Institutional Review Board
(IRB) Coordination**

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The purpose of this policy and procedure is to describe the coordination between the IRB/OPRS and the IBC/OACIB on protocols involving transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA (human gene transfer), and/or infectious agents into human research participants. For the purposes of this policy and procedure, recombinant DNA molecules are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above and infectious agents are defined as any microorganism or toxin produced by a microorganism that is potentially pathogenic to humans, such as a live vaccine.

POLICY:

- I. The UIC IBC reviews all research involving the use of rDNA in compliance with the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (NIH Guidelines). The IBC is also responsible for the safe conduct of research involving infectious agents, including select agents and toxins.
- II. Through an Agreement between the UIC and the JBVAMC, the JBVAMC utilizes the UIC IBC to review research involving rDNA conducted by a UIC-affiliated investigator or supported by funds administered by the University. Research involving human subjects and engaging the JBVAMC that is submitted for UIC IRB and IBC review will follow the policies and procedures outlined below, as well as, the MOU and *Operating and Coordinating Procedures for the Administration of the Collaborative JBVAMC/NU/UIC IRB (UIC IRB #4)* SOP between UIC and JBVAMC regarding human subject protections.
- III. An investigator must have an UIC affiliation to submit a protocol to the UIC OACIB for review by the UIC IBC. Further, if IBC approval is needed for a research study, the UIC IRBs, including the JBVAMC/NU/UIC Collaborative IRB (UIC IRB#4), will only review research protocols reviewed and approved by the UIC IBC. The IBC approval from other institutions will not be accepted in place of UIC IBC approval.

PROCEDURES:

The OACIB Director, IBC Biological Safety Specialist (BSS) or designee, OPRS Staff, OPRS Assistant Director of Quality Assurance/Quality Improvement, OVCR Associate Director for Research Compliance, and PI/Study Personnel are responsible for this process.

I. Committee Membership.

- A. The OACIB Director is a voting member on the IBC and serves as a non-voting, ad hoc consultant to the Biomedical IRBs (IRB #1, IRB #3, and IRB #4). The OACIB Director will provide the IRB with information related to biosafety issues to consider in relation to human subject protections, including risk assessment, in research involving recombinant DNA, infectious agents, and/or human gene transfer protocols and select vaccines.
- B. The Senior BSS or designee of the EHSO serves as voting member of the IBC. The BSS or designee may also be asked to serve as an *ad hoc* consultant to the Biomedical IRBs.

II. Initial Protocol Submission and Review.

- A. When a PI proposes research involving human subjects, which falls under the purview of the IBC, the PI must submit the protocol to the IBC and obtain provisional approval (“approval pending” status) before submitting the application to the IRB (OPRS) for review. Documentation of IBC review and provisional approval should be submitted with the IRB application.
- B. If OPRS staff receives an IRB application, which in their judgment may require IBC approval and the PI has not provided documentation of submission to the IBC, OPRS staff will contact the OACIB Director for assistance in determining whether IBC review is required. If it is determined that the proposal does fall under the purview of the IBC, OPRS will send written notification to the PI of the requirement for IBC review and approval and will return the IRB application to the PI.
- C. Although the IRB may review a protocol prior to final IBC approval, IRB approval will not be granted without documentation of IBC approval. The UIC IBC will provide a copy of all correspondence related to the protocol to the OPRS Assistant Director of the Biomedical IRB assigned to review the protocol.
- D. Upon receipt of an appropriately completed protocol submission that falls under the IBC’s purview, OPRS staff will assign an IRB number to the protocol. The protocol will also be identified in the OPRS information system, RiSC, as falling under the IBC’s purview. This will ensure that the IBC will be copied on all correspondence between the PI and the IRB.
- E. OPRS staff will be responsible for providing the OACIB Director with agenda notices and IRB protocol review materials for protocols that fall under the jurisdiction of the IBC prior to the IRB meeting.
- F. The OACIB Director, EHSO BSS, or designee from UIC will provide the IRB with safety related information, especially with respect to risk assessment. These individuals will attend the convened IRB meeting or send comments in writing.

- G. Once the protocol receives IRB approval, the IBC will receive a copy of the approval notice, the approved final version of the informed consent document, and final version of the approved protocol. Additionally, the OACIB will be copied on any subsequent correspondence sent on behalf of the IRB to the PI.
- H. If a research protocol is subject to NIH RAC review and UIC and/or JBVAMC is the initial clinical trial site, then the OPRS staff will include the following statement in the IRB approval notice. "The IRB has approved [the research, the amendment]. However, the Sponsor/Sponsor-Investigator(s) must submit the following documentation to NIH OBA no later than 20 working days after enrollment of the first research participant in a human gene transfer experiment:
1. A copy of the informed consent document approved by the IRB;
 2. A copy of the protocol approved by the IBC and IRB;
 3. A copy of the final IBC approval from the clinical trial site;
 4. A copy of the final IRB approval;
 5. A brief written report that includes the following information:
 - a) How the investigator(s) responded to each of the RAC's recommendations on the protocol (if applicable); and
 - b) Any modifications to the protocol as required by the FDA;
 6. Applicable NIH grant number(s);
 7. The FDA IND number; and
 8. The date of the initiation of the trial. Enrollment is defined as the "process of obtaining informed consent from a potential research participant, or a designated legal guardian of the participant, to undergo a test or procedure associated with the gene transfer experiment and date of initiation of the trial is defined as first day of treatment/dosing."

Upon submission to the RAC, the principal investigator must submit an amendment to the IRB and IBC notifying them of completion of this requirement.

- I. If a research protocol is subject to NIH RAC review and UIC and/or the JBVAMC is added as a clinical trial site (multi-center trial), the OPRS staff will include the following statement in the IRB approval notice: "The IRB has approved [the research/ the amendment]. However, subject enrollment, including recruitment, at UIC and/or JBVAMC cannot begin until the following documentation has been submitted to NIH OBA by the Sponsor/Sponsor-Investigator(s):
1. IBC approval (from the clinical trial site);
 2. IRB approval;
 3. IRB-approved informed consent document;
 4. curriculum vitae of the principal investigator(s) (no more than two pages in biographical sketch format); and
 5. NIH grant number(s) if applicable."

Upon submission to the RAC, the principal investigator must submit an amendment to the IRB and IBC notifying them of completion of this requirement.

III. Amendments to Approved Protocols.

- A. The PI is responsible for dually submitting all amendments to the approved research protocol to the IRB and IBC.
- B. An amendment that requires convened IRB approval often requires IBC approval prior to the issuance of IRB approval. Amendments requiring IBC approval prior to IRB approval include, but are not limited to, changes to the recombinant agent (agent's characteristics, source and nature of the inserted sequence, host and vector being used), type of manipulations with agent that are planned, changes in the amount or route of recombinant agent to be administered, changes in the risk associated with recombinant agent, and containment conditions. When such an amendment is received by OPRS, the OPRS staff will contact the OACIB Director for assistance in determining whether IBC provisional approval is needed prior to IRB review and approval. If an amendment does not require review by the IBC, the OACIB will send the PI an acknowledgement of receipt with the determination that amendment is outside the scope of review by IBC.
- C. If an amendment requires review by the IBC, the amendment will follow Steps C - G as outlined under *Initial Protocol Submission and Review* procedures.

IV. Unanticipated Problems, Subject Complaints and Allegations of Research Non-compliance.

- A. The PI is responsible for dually reporting to the IRB and IBC UPIRSOs or a complaint from a subject, subject family member, staff, or researcher concerning subject rights and welfare or alleged research non-compliance.
- B. The IBC will review adverse events or unanticipated problems of the following nature:
 - 1. Adverse events which are serious, unanticipated, and related or possibly related to the use of the gene transfer product,
 - 2. A major protocol violation/deviation involving human gene transfer use,
 - 3. Non-compliance with the *NIH Guidelines*,
 - 4. An external event determined to be reportable by DMSB, DMC, or other oversight committee, or
 - 5. Findings from laboratory animal testing that suggest significant risk for human subjects.
- C. When an UPIRSO, a subject complaint or an allegation of research non-compliance is received in a protocol under joint IRB and IBC jurisdiction, the OACIB Director and the OPRS Director will ensure the other is notified within two working days of receiving the report. The OACIB and/or OPRS Director may confer with the Associate Director for Research Compliance or the IO to assess whether the incident falls under the purview of the IRB, IBC, or both committees.
- D. If the Associate Director for Research Compliance receives an allegation of non-compliance involving an IRB/IBC protocol, the OPRS and OACIB Directors will be immediately notified (i.e., within two working days).
- E. If the unanticipated events/complaint/non-compliance allegation falls under the IRB's purview, the IRB/OPRS will initiate an inquiry following the

applicable human subject protections policies (i.e., Protocol Deviations, Violations, and Exceptions; unanticipated events and Other Adverse Events: Investigator Reporting Responsibilities and OPRS/IRB Processing and Reporting; and Handling Complaints and/or Allegations of Potential Non-compliance with Human Subject Protection Regulations, Policy and Procedures).

- F. After the review of the unanticipated events/ subject complaint/non-compliance allegation is completed, the findings will be communicated to the other respective review committees (IRB or IBC) and the Associate Director for Research Compliance and Institutional Officials, as appropriate.
- G. The HPA will determine whether the incident meets requirements for reporting to the federal regulatory agencies. In making the determination, the policy on Reporting Requirements to Institutional Officials, Supporting Agency Heads, and Regulatory Agencies for Unanticipated Problems Involving Risks to Subjects or Others, Serious or Continuing Non-compliance, and Suspensions or Terminations and/or the NIH Guidelines will be followed. The reporting requirements to the JBVAMC and VA officials will follow the *Operating and Coordinating Procedures for the Administration of the Collaborative JBVAMC/NU/UIC IRB (UIC IRB#4) SOP*.

V. Quality Assurance/Improvement Audit Findings.

- A. If the OPRS or OVCR conducts a directed or routine audit of an IRB/IBC protocol, the UIC OACIB Director will receive a copy of the findings of the audit.
- B. If the EHSO or any IBC personnel audits or inspects an IRB/IBC protocol, the EHSO is responsible for providing the OACIB Director with a copy of the report. If relevant deficiencies are found, the OACIB Director is responsible for sending the report to the IRB to determine whether additional IRB action is necessary.

REFERENCES:

[NIH Guidelines for Research Involving Recombinant DNA Molecules \(NIH Guidelines\)](#)

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 06/18/09	1.0, 12/18/08	Edited to reflect appointment of HPA and deletion of the term "UPIRSO," as it is not used any longer by UIC OPRS.