

SOP: 502B
CATEGORIES OF RESEARCH
BIOLOGICS

1. POLICY

The IRB shall review all human participant research involving biologics. These studies pose greater than minimal risk and therefore require convened IRB review.

The category of research covered by this policy involves methodologies that either requires additional considerations or for which there are federally-mandated determinations that IRBs are required to make and document.

All investigational biologics used in human participant research shall be stored, handled, and dispensed in accordance with institutional policy, and state and federal laws and regulations. If the investigational pharmacy is not utilized for dispensing the investigational biologics, the investigator shall assure that dispensing is in accordance with institutional, state, and federal laws and regulations.

Specific Policy

1.1 Clinical Research Involving Biologics

The review of studies involving biologics requires convened IRB review. Additional review by other institutional committees may be required.

1.1.1 Determination of a Valid IND

The IRB requires investigators to provide the IND number when submitting new protocols for investigator initiated or industry-sponsored research. The IRB requires investigators to provide documentation of a valid IND number by submitting a letter from the FDA, a letter from the sponsor, or a commercial protocol with the IND number.

1.1.2 Investigator Responsibilities for Biologic Dispensing and Accountability

The investigator shall administer the biologic only to participants under the investigator's personal supervision or under the supervision of a sub-investigator responsible to the investigator.

The investigator shall not supply the investigational biologic to any person not authorized to receive it.

The investigator shall maintain adequate records of the disposition of the biologic, including dates, quantity, and use by the participants.

If the research is terminated, suspended, discontinued, or completed, the investigator shall return the unused supply of the biologic to the sponsor or otherwise provide for the disposition of the unused supplies of the drug consistent with the terms of the underlying research agreement.

All investigational biologics shall be stored in the hospital pharmacy.

The IRB shall review and approve the plan for storing, dispensing, and disposing of the investigational biologic.

Investigators shall receive the proper training for dispensing and accounting for investigational biologics during the required institutional seminar on Human Research Participant Protections during the presentation on Good Clinical Practices. The OUHSC IBC website has additional and more detailed information.

For VA Research:

The investigator shall inform the pharmacy service that IRB and the Research and Development Committee (R&D) approval has been obtained through the use of VA Form 10-1223. The investigator shall provide the pharmacy with a signed copy of the VA Form 10-1086 to document each participant's consent to participate in the study. The investigator shall inform the Chief, Pharmacy Service, and the R&D Committee when the research has been terminated.

1.1.3 Investigational Use of Marketed Biologics

All investigator-initiated research in which a biologic is being used for other than its approved indication requires submission of an Investigational New Drug (IND) application to the FDA. The FDA may grant an exemption or may assign an IND number. When the investigator holds the IND, additional FDA reporting responsibilities are required of the investigator.

The investigator and IRB shall evaluate the research for the need of an IND application. In the case of a disagreement regarding the need for an IND, the IRB shall make the final determination of the need for an IND application.

The IRB requires investigators to provide the IND number when submitting new protocols for investigator initiated or industry-sponsored research.

1.1.4 Investigational Biologic Protocols

An investigational new biologic is a new product or biologic that is used in a clinical investigation that has not been approved by the FDA to be marketed,

The IRB shall carefully scrutinize the following for all studies involving the use of biologics:

- A. Scientific soundness – research validity and value.
- B. Study design to the study population, trial phase, and mechanism for data analysis and surveillance.
- C. Risk/benefit analysis and review of the procedure for obtaining informed consent.
- D. Investigator qualifications – Investigator experience and resources to carry out protocol.
- E. Conflicts of interest that must be addressed.
- F. Confidentiality safeguards – how information will be handled.
- G. Data and safety monitoring – the level of monitoring for the level of risk.
- H. Participants must be advised in the informed consent form that the FDA may access their medical records as they pertain to the study.

1.1.5 Gene Transfer

All gene transfer protocols shall be reviewed and approved by the Institutional Biosafety Committee prior to IRB approval. All gene transfer research projects require review by the convened IRB.

2. SCOPE

This policy and these procedures apply to all research regarding drugs and biologics submitted to the IRB.

3. RESPONSIBILITY

The HRPP Director is responsible for maintaining up-to-date review tools for review of this type of research.

The IRB Chair or designee is responsible for providing IRB members adequate submission review training and ongoing guidance and for selecting one primary and one secondary reviewer with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If the IRB Chair or designee cannot select primary and secondary reviewers with the relevant expertise the IRB Chair or designee defers the review to another IRB with primary and secondary reviewers with the relevant expertise or obtains consultation for that expertise.

The IRB Reviewer is responsible for conducting appropriate review of research planned for these categories in consultation with any appropriate experts and resources.

Communication with the FDA is the responsibility of the IRB, the sponsor, and the sponsor-investigator, as appropriate.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46

21 CFR 50, 56

OHRP Guidance Document, IRB Guidebook

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301, Research Submission Requirements.

6. ATTACHMENTS

203-A	New Study Reviewer Checklist – Full Board (HSC)
203-A-1	New Study Reviewer Checklist – Full Board (NC)
203-D	VA Research Reviewer Checklist
203-E	Reviewer Checklist for Research Involving Pregnant Women, Fetuses & Neonates (HSC)
203-E-1	Reviewer Checklist for Research Involving Pregnant Women, Fetuses & Neonates (NC)
203-F	Reviewer Checklist for Research Involving Prisoners (HSC)

- 203-F-1 Reviewer Checklist for Research Involving Prisoners (NC)
- 203-G Reviewer Checklist for Research Involving Children (HSC)
- 203-G-1 Reviewer Checklist for Research Involving Children (NC)

7. PROCESS OVERVIEW

IRB Staff makes sure all documents are reviewed for submission per SOP 301, Research Submission Requirements.

The IRB Administrator provides to the IRB Chair, designee or the IRB the item to be reviewed and the tools to conduct the review.

- 7.1 The study is received in the IRB office and assigned to an appropriate IRB. The IRB Administrator reviews the submission for completeness and type of review. An Investigator Brochure is required for all IND research, when available. The IRB Administrator makes a new file and pre-reviews the submission to determine what additional institutional committee review or information is required. The IRB Administrator communicates with the investigator what, if any, additional materials or reviews are required. The IRB Administrator checks whether the documentation provided supports a valid IND number.
- 7.2 The study is assigned to an agenda or given to the IRB Chair or designee for review. The Investigator Brochure is assigned to the pharmacy IRB member or a primary reviewer with the expertise to properly evaluate the information included in this document. The IRB reviewer utilizes the New Study Reviewer Checklist – Full Board to confirm documentation of a valid IND.
- 7.3 Modifications may be required before final approval. Once the modifications are received into the IRB, the IRB Administrator puts the modifications in the file and presents the file to the IRB Chair for review/approval.
- 7.4 If an IND is required, the IRB will not grant final approval until the IND application process is complete. The Investigator must forward to the IRB a copy of all communication with the FDA.
- 7.5 Final IRB approval will not be granted until all required institutional committees have completed their review and the contract is signed, if applicable. Evidence of these reviews and ORA release are placed in the file.
- 7.6 Once the IRB review is completed, the IRB Administrator generates the appropriate letter to notify the Investigator of the results of the review.

APPROVED BY: _____ **DATE:** 09/01/2009

NEXT ESTABLISHED REVIEW DATE: MAY 2012