

SOP: 502	CLINICAL RESEARCH INVOLVING INVESTIGATIONAL DRUGS AND DEVICES
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Approved by IRB executive committee: November 16, 2007
Supersedes Document Dated: December 1, 2005, May 1, 2004
AAHRPP Elements I.5.A and I.5.B

POLICY

The University of Utah IRB requires investigators to provide a plan to ensure the proper handling of investigational or unlicensed test articles.

The University of Utah IRB ensures compliance with federal, state or local regulations governing investigational or unlicensed test articles.

PROCEDURES

1. Procedures for Review of Clinical Research Involving Investigational Drugs and Biologics

All initial requests for IRB approval of a study that includes the use of an investigational drug, agent, or biologic will be reviewed and approved by the convened IRB.

An investigator responsible for a drug study where drugs are stored and dispensed by the research Investigational Pharmacy must abide by FDA regulations. The investigator must also abide by the University of Utah Hospitals and Clinics Policy Manual (Department of Pharmacy Services Policy Manual Investigational Drug Studies Program) and Investigational Drug Studies (SOP 18.31) for Primary Children's Medical Center.

Investigator responsibilities for drug studies are provided for the investigator/study staff on the IRB website.

- 1.1. Investigators must submit all information and documents required by the IRB for the use of investigational test articles in the New Study Application (including, as applicable, the Protocol Summary Template, Informed Consent Template, etc.).
- 1.2. The convened IRB will review the proposed research, informed consent documents, the procedure for obtaining informed consent, and additional information, when applicable, to determine whether the study meets criteria for approval. The IRB reviewer(s) will complete the Reviewer Checklist documenting how the criteria are met.
 - 1.2.1. The assigned IRB reviewer(s) of the research protocol involving the investigational drug will evaluate whether the plan to control for the investigational drug is adequate, and may seek clarification from a representative of the Investigational Drug Studies (IDS) Pharmacy or other qualified representatives who are not IRB members that are knowledgeable about the control of investigational drugs.
 - 1.2.2. The assigned IRB reviewer(s) may contact a qualified person who is not an IRB member that is knowledgeable about the drug with any concerns that may affect the risk/benefit assessment. They may also request a

literature review from a medical librarian at the Spencer S. Eccles Health Sciences Library at the University of Utah Health Sciences Center.

- 1.3. If the Investigator is requesting the drug, agent, or biologic be exempt from IND requirements, the convened IRB will discuss the conditions for an exemption and determine if the Investigator's justification meets the criteria for exemption from the IND requirements. The IRB reviewer(s) will complete the Reviewer Checklist (IND Determination portion) documenting how the exemption criteria are met.

2. Procedures for Review of Clinical Research Involving Investigational Devices

All initial requests for IRB approval of a study that includes the use of an investigational device will be reviewed and approved by the IRB. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling may be reviewed using expedited review procedure.

Investigator responsibilities for device studies are provided for the investigator/study staff on the IRB website.

- 2.1. Investigators must submit all information and documents required by the IRB for the use of investigational test articles in the New Study Application (including, as applicable, the Protocol Summary Template, Informed Consent Template, etc.).
- 2.2. The IRB will review the proposed research, informed consent documents, the procedure for obtaining informed consent, and additional information, when applicable, to determine whether the study meets criteria for approval. The IRB reviewer(s) will complete the Reviewer Checklist documenting how the criteria are met.
 - 2.2.1. The assigned IRB reviewer(s) of the research protocol involving the investigational device will evaluate whether the plan to control for the investigational device is adequate, and may seek clarification from other qualified representatives who are not IRB members that are knowledgeable about the control of investigational devices.
 - 2.2.2. The assigned IRB reviewer(s) may contact a qualified person who is not an IRB member that is knowledgeable about the device with any concerns that may affect the risk/benefit assessment. They may also request a literature review from a medical librarian at the Spencer S. Eccles Health Sciences Library at the University of Utah Health Sciences Center.
- 2.3. The IRB will determine whether, in the context of the study or by the nature of the investigational medical device (see significant risk devices list), the study presents a significant risk (SR) or a non-significant risk (NSR) of harm to study subjects. This assessment will be based on the information provided by the Investigator and/or the Sponsor. In deciding whether or not a medical device is a significant risk, the IRB considers if the device:
 - Is intended as an implant and presents a potential for serious risk to health, safety, or welfare of a participant.
 - Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a participant.

- Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents the potential for serious risk to the health, safety, or welfare of a participant.
 - Otherwise presents a potential for serious risk, safety, or welfare of a participant.
- 2.4. The assigned IRB reviewer or designated expedited reviewer completes the board reviewer checklist (Risk Determination for Devices portion) documenting the risk determination. If the convened IRB disagrees with the determination made in the checklist, the minutes will reflect the discussion, resolution and final risk determination.
 - 2.5. If the IRB determines that an investigation, presented for approval as a non-significant risk device involves a significant risk device, the IRB administrator or IRB coordinator notifies the investigator, the sponsor and the FDA within seven business days of the board meeting. No further action will be taken by the IRB on the research until the Sponsor or Investigator has met the requirements for an SR study described in 21 CFR 812 (Investigational Device Exemption regulations).

3. Procedures for Review of Clinical Research Involving a Humanitarian Use Device

An approved Humanitarian Device Exemption (HDE) authorizes marketing of a Humanitarian Use Device (HUD). An HUD is a device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or is manifested in fewer than 4,000 individuals in the United States per year.

The statute and implementing regulation (see 21 CFR 814.124(a)) require IRB review and approval before an HUD is used. Therefore, IRB review and approval are required for the use of an HUD at the University of Utah.

- 3.1. The convened IRB must review the initial application. A continuing review of an HUD may be done by way of an expedited procedure (section 56.110) unless the IRB determines that a convened board must review the application.
- 3.2. The IRB does not require a review and approval process for each individual use of an HUD. The IRB may approve the use of the HUD without any further restrictions, use of the device under a protocol, or use of the device on a case-by-case basis. The use of the HUD must remain within the FDA approved indication, approved by the convened IRB, and will not exceed the scope of the FDA approved indication.
- 3.3. The IRB requires that full informed consent and documentation of consent be obtained when treating or diagnosing a patient with an HUD. The convened board will consider exceptions to the requirement of full informed consent and documentation of consent on a case by case basis.