

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
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Title: Review and monitoring of research projects	Date Effective 5/21/04	Supercedes P&P dated

Pharmacy and Therapeutics Committee

JHSPH POLICY AND PROCEDURES

All applications for human subjects research that involve a drug used in clinical investigation (DUCI) must be reviewed by a Pharmacy and Therapeutics (P&T) representative, as well as by CHR. A drug used in clinical investigation is any drug, biological, botanical or other substance used specifically for a clinical investigation as described in the protocol. Such drugs may be either commercially available, or not, and used for FDA-approved indications, or not. In their reviews the CHR and the P&T representative will specifically address issues related to: 1) drug safety, 2) drug management, 3) study design, 4) Investigational New Drug (IND) status of the product, 5) the drug data sheet (DDS) review, for INDs, 6) informed consent documents, and 7) any other relevant material.

If the study involves an IND, the research application should include the name of the drug(s), a copy of the sponsor's protocol, the investigator's brochure, and a completed DDS. If the product is not an FDA-regulated product, the product insert or similar background material must be included with the application.

The P&T representative will complete a CHR P&T Review Form for each research application that involves a drug used in clinical investigation.

Storage, Control, Preparation and Dispensing of Drugs Used in Clinical Investigations

Inpatient studies. The Johns Hopkins Hospital Pharmacy shall store, control, prepare and dispense all INDs and any inventory of study-specific drugs provided by the study sponsor. Exceptions will only be granted with prior approval of the P&T representative.

For drugs used in clinical investigation that are not INDs or study-specific inventory provided by the sponsor, the P&T representative, at their discretion, may require the pharmacy to control and dispense the drug.

Outpatient studies. All drugs used in clinical investigation that require manipulation (e.g. mixing, formulating, counting, compounding, etc.) shall be stored, controlled, prepared and dispensed by the Hospital Pharmacy, unless an exception is granted by the P&T representative.

Other studies. For other situations in which the investigator wishes to store, control, or dispense drugs used in clinical investigation, the investigator must describe in the study application the procedures for performing these functions. When the investigator wants to control dispensing of a drug used in clinical investigation, such as when a medication must be dispensed urgently or the study is conducted at a distant site, both the P&T representative *and* the CHR must approve of the arrangement.

Drug Data Sheets

A DDS shall be completed for all INDs. An IND is any drug for which the FDA has granted IND status. The purpose of the DDS is to provide sufficient information to allow the drug to be given safely. Clinicians administering an IND shall be familiar with the contents of the DDS prior to giving the drug and the DDS shall be placed on every study patient's medical record.

Authorization to Prescribe and Investigational Drug

All new applications should identify the persons who will be authorized to prescribe the IND(s). Anyone who dispenses or gives an IND shall verify that the prescriber is authorized to do so prior to dispensing or giving the drug.

Audits

Studies involving a drug under clinical investigation should be regularly audited to ensure appropriate storage, control, preparation and dispensing of the IND. The audit may be performed by an Investigational Drug Service pharmacist according to P&T audit policy, by the sponsor, by a clinical research monitoring group, or by others.

Audit reports must be provided to CHR within 5 working days of notice. CHR should be notified immediately when an investigator receives notice that the FDA wishes to audit or inspect study records.