

**The Carle Foundation
IRB Policy 803**

Subject	Storage, Handling and Dispensing of Investigational Agents				
Approval	Dec 2006	Review	Jun 2009	Revision	Jun 2009
Scope	These policies and procedures apply to all Clinical Investigations conducted under the jurisdiction of the Carle IRB.				
Purpose	To describe procedures for the handling of investigational agents.				

Statement of Policy

1. The Carle Foundation Hospital Department of Pharmacy is responsible for the receipt, accountability and record-keeping for all investigational drugs or biologics used in research studies involving humans at CFH. No drugs should be kept at the patient's bedside or in the Investigator or research team member's offices or clinics, unless the Carle IRB, in consultation with the Department of Pharmacy, expressly permits such storage.

Specific Policies

1. **Applicability.** Any investigational drug or biologic under investigation at CFH or at Carle facilities shall be stored and dispensed in accordance with this policy. This includes all in patient and outpatient research studies involving FDA approved or unapproved investigational pharmaceutical or biological agents, including radioactive agents used therapeutically or diagnostically.
2. **Establishment of Research Pharmacy Arrangements**
 - a. **Protocol.** Each protocol using investigational drugs or biologics submitted for IRB review shall include a description of the investigational drug or biologic to be studied; information regarding any prior use of the drug or biologic, whether or not approved for marketing in the United States; if the drug or biologic has been approved for marketing in the United States, a description of the approved uses, dosages and routes of administration; a brief description of the pharmacological characteristics of the drug or biologic; any special considerations regarding preparation, mixing or storing of the drug or biologic; and information regarding source, purity, quality, and method of preparation or delivery.
 - b. **Consultation with Research Pharmacist.** As appropriate, the IRB shall seek the expertise of a pharmacist qualified to prepare, mix and dispense the investigational drug or biologic, to assist the IRB in evaluating risks and benefits of a proposed study and to protect human subjects. The research pharmacist should be provided a copy of the protocol, the Investigator's brochure, and any information provided by Sponsor regarding the investigational drug or biologic, including any study-related forms. In the case of radiopharmaceuticals, the IRB may also consult with the radiation physicist as appropriate.
 - c. **Establishment of Procedures.** Upon approval of the study by the IRB, the Investigator shall meet with the research pharmacist to establish procedures for obtaining stock of the investigational drug or biologic, receipt, storage, physician orders for the investigational drug or biologic, preparation and admixture, and administration. The Investigator must provide to the pharmacy the IRB approval letter, the full protocol, the investigators' brochure, and IND/IDE documentation. In the case of radiopharmaceuticals, the research pharmacist shall consult and coordinate with the radiation physicist regarding storage, preparation and dispensing of the radiopharmaceutical.
 - d. **Obtaining Investigational Drugs and Biologics.** The research pharmacy will be responsible for ordering from the Sponsor investigational drugs and biologics, based on information from the Investigator regarding anticipated need. All investigational drugs or biologics must be delivered directly to the research pharmacy. If a drug is incorrectly shipped directly to an Investigator or any member of the research team, immediately (within 24 hours) hand-deliver the drug to the research pharmacy. It is a violation of institutional policy for Investigators or any member of the research team to maintain investigational drug or biologic supplies in their area unless such storage has been expressly approved by the IRB and the research pharmacy.
 - e. **Physician Orders for Investigational Drugs and Biologics**
 - **Inpatient.** The research pharmacy must be promptly notified of the admission of any research participant as an inpatient. The research pharmacy shall establish procedures for preparing and distributing investigational drugs or biologics to inpatients. **In no event shall investigational drugs or biologics be placed in an automated drug dispensing system, such as a Pyxis medication cabinet.**
 - **Outpatient.** All outpatient prescriptions must be written on prescription pads pre-printed with the Investigator's name and, as appropriate, practice entity and signed by the Investigator. Include the following information on the prescription:
 - Patient name
 - Home address

Specific Policies (cont.)

- Drug allergies
- Refill status
- Abbreviated protocol name
- Protocol Number
- Prescribing information

The prescription should be hand-delivered to the Research Pharmacy at least 48 hours in advance of the research participant's scheduled visit. If this is not possible, notify the research pharmacy as soon as possible. A copy of the research participant's signed informed consent document and/or children's assent document must be on file in the research pharmacy or the drug will not be dispensed.

- **Pre-Signature of Prescriptions.** Each prescription must be individually prepared and signed. Investigators should not pre-sign prescription pads. Pre-signature of prescriptions for investigational drugs or biologics may result in corrective action against the Investigator.
- f. **Return and Disposal of Investigational Drugs and Biologics.** When a research participant is terminated from a study for any reason (including natural conclusion of participation, suspension or termination of the study, or any other reason) the Investigator must recover from research participants any investigational drug or biologic in the possession of the research participant. The Investigator shall return to the research pharmacy within 24 hours all investigational drug or biologic, including any not previously dispensed but in the Investigator's possession or control. The research pharmacy will inventory, store and coordinate return or destruction of the investigational drug or biologic with the Investigator and the Sponsor.
- g. **Reports to Research Pharmacy.** The Investigator shall promptly report to the research pharmacist any serious and unexpected adverse drug reactions. The Investigator should, when appropriate, freely consult with the research pharmacist regarding less serious adverse drug reactions to attempt to minimize risk to participants.

Reference

21 CFR 312, 21 CFR 812, 21 CFR 50, FDA Form 1572

Approval On File

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