JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. **103.19a**	Title: **Drug Use and Control in Clinical Investigation (DUCI)**	Date of Approval 12/1/08	Approved By Janet DiPietro

Definitions:

Dispensing Drugs: This occurs when a supply of drug that is not patient-specific, or that requires manipulation (counting, mixing, preparing, etc.), is given to a specific patient. By law, dispensing may only be done by a pharmacist, physician, nurse practitioner, podiatrist, or dentist. Examples of dispensing drugs include: (a) selecting a quantity of drug from a general bulk supply and placing it in another container for a patient, and (b) reconstituting a drug with a quantity of water before giving it to the patient.

Distributing Drugs: A drug is distributed when it is given to the patient in a prelabeled container with specific patient identification (patient's name or patient- specific identification code), and does not require manipulation (counting, mixing, preparing, etc.) before giving it to the patient. Drugs may only be distributed upon the order of an authorized prescriber and should be distributed only by a nurse, physician assistant or other personnel trained to do so by the principal investigator.

DUCI (Drug Used in a Clinical Investigation): Any drug, biological, botanical or other substance used specifically for a clinical investigation as described in the investigational protocol. Such drugs shall be either commercially available or not commercially available and used according to, or outside of, FDA-approved indications.

IDS pharmacist: Refers to a pharmacist in investigational drug services at JHM.

Investigational Drug: Any drug for which the Food and Drug Administration has granted Investigational New Drug (IND) status.

Pharmacy: Refers to a pharmacy controlled by Johns Hopkins Medicine.

General

All clinical research conducted by full-time faculty members of The Johns Hopkins University (JHU) shall be reviewed by an IRB as specified by the reciprocity agreement dated July 12, 2002. Clinical research conducted by faculty members of JHSPH are obliged to obtain JHSPH IRB approval of all human subjects activities conducted under the auspices of their Hopkins' appointment, by which is meant use of Hopkins' personnel

or space or the use of the faculty appointment in correspondence, agreements with sponsors, etc.

The Pharmacy and Therapeutics Committee Members of the JHM and Bloomberg School of Public Health (JHSPH) Institutional Review Boards (IRB)

1. The membership of all JHM and JHSPH IRBs reviewing Research Protocol applications involving a DUCI will include at least one member who serves jointly on the IRB and either the site-specific P&T Committee or Investigational Drug Service (IDS) ["P&T/IDS IRB member'].

2. All applications reviewed by a JHM or JHSPH IRB involving the clinical use of DUCIs require approval by an IRB before they may begin. The P&T/IDS IRB member shall review the DUCI-associated drug issues either (i) prior to the IRB meeting and have the review incorporated into the IRB review process, or (ii) at the convened IRB meeting. The review process conducted by the P&T/IDS IRB member must include specific IRB issues related to (a) drug safety, (b) drug management, (c) study design, (d) IND status, (e) drug data sheet review for INDs, (f) informed consent documents, and (g) any other relevant material.

3. The IRB will be responsible for reviewing reports of unanticipated problems (including adverse drug effects that occur during a clinical investigation) in accord with the JHSPH policy on Reports of Unanticipated Problems (Policy 103.6).

Selection Process and Qualifications of the P&T/IDS IRB member on a JHM or JHSPH IRB

4. P&T Committee members or IDS members selected to serve as P&T/IDS members shall be appointed by the Institutional Official. The Institutional Official shall consult with the Chair of the site-specific P&T Committee/IDS to identify individuals who may be appointed as IRB members, but IO has the final appointment authority.

5. Selection of candidates for P&T/IDS members shall include in the evaluation: (a) expertise in the concepts of pharmacology and study design (as may be indicated by the attainment of relevant academic degrees or by specific training); or clinical investigation experience; or at least two years of IDS activity, (b) commitment to attendance at 80% or more of convened IRB meetings, and (c) demonstrated ability to effectively communicate and to think clearly regarding medication-related issues.

P&T/IDS IRB Member Approval of Studies Involving Devices

6. Device studies that do not contain a DUCI do not require review and approval by the P&T/IDS IRB member.

7. In cases where a device study includes a DUCI, the study must be approved per paragraph 2 above. In such cases of review of a device study that includes a DUCI, the P&T/IDS IRB member will base approval on the appropriateness of use involving the drug(s) and not on the use of the device per se.

Reports of the P&T/IDS IRB Member to the P&T Committee

8. The P&T/IDS IRB members are fully accountable and responsible to their respective organization P&T Committees. An appropriate mechanism for reporting liaison activities to the P&T Committee must be established by each P&T Committee.

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

9. Inpatient Studies:

a. INDs: The pharmacy shall store, control, prepare and dispense all investigational drugs and all study specific drug inventory supplied by a study sponsor. Exceptions may be granted by the P&T/IDS IRB member (see below).

b. Non-INDs: For DUCIs that are not investigational drugs or study specific inventory supplied by a sponsor, the pharmacy may be required to control and dispense the medication if the P&T/IDS IRB member believes this to be appropriate.

10. Outpatient Studies: All outpatient DUCIs requiring manipulation (e.g., mixing, formulating, counting, compounding, etc.) shall be stored, controlled, prepared and dispensed by the pharmacy unless an exception is granted by the P&T/IDS IRB member (see below).

11. In a situation where an investigator wishes to store, control or dispense the DUCI, the investigator must describe, at the time of application submission, the procedures for performing these functions. In situations where the investigator may want to control dispensing of a DUCI, such as when a medication needs to be dispensed urgently or the study is conducted at a distant geographic site, both the P&T/IDS IRB member and the IRB must approve this arrangement.

The Drug Data Sheet (DDS)

12. A drug data sheet shall be completed for all investigational new drugs. The purpose of the DDS is to provide sufficient information to allow the investigational drug to be administered safely.

13. Completed drug data sheets shall be reviewed by a P&T/IDS IRB member as part of the application review process.

14. Clinicians administering an investigational new drug shall be familiar with the contents of the DDS prior to drug administration. If the investigational product will be administered in a JH facility, the DDS shall be placed into every study patient's paper medical record. It is the responsibility of the principal investigator to assure that the most current version of the DDS is placed into the inpatient paper chart of study subjects.

Authorization to Prescribe an Investigational Drug

15. Principal investigators shall identify those individuals authorized to prescribe investigational drugs used in their study. For each investigational drug, a DDS shall be

completed and shall indicate those authorized to prescribe the investigational drug or indicate the location of a current list of those authorized to prescribe.

16. Anyone who dispenses or administers an investigational drug shall verify that the prescriber is authorized to do so prior to dispensing or administering the drug.

Principal Investigator Auditing

17. In situations where an investigator has been approved to control a DUCI at a JHH, JHBMC, Howard County General Hospital, or JHUSOM facility, an IDS pharmacist shall audit the storage, control, preparation and dispensing of the investigational drug to assure that all regulatory and hospital requirements are met.

18. For studies based at a JHH, JHBMC, Howard County General Hospital, or JHU SOM facility where DUCIs are controlled by the principal investigator, audits of studies shall be conducted (a) prior to the study beginning, (b) within 1 month of the beginning of patient accrual, (c) within one month of each yearly renewal, and (d) upon termination of the study. If unsatisfactory audit findings are discovered which cannot be resolved during the audit, additional audits shall be scheduled until the identified problem(s) is resolved. Audit results should be forwarded to the IRB.

19. When a principal investigator receives a study audit report from a regulatory agency or from a study sponsor (or agent of the sponsor), the principal investigator must provide a copy of the report to the IRB within 5 working days.

20. When a principal investigator receives a notice that the FDA wishes to audit/inspect study records, the IRB must be notified before the inspection visit occurs.

Pharmacy Quality Control

21. In situations where a Hopkins pharmacy controls a DUCI, an IDS pharmacist will perform monthly quality control of the procedures used by the pharmacy. A pharmacist, who is not directly involved with dispensing the DUCI(s) in question, will perform quality control.

Communication of Audit Findings

22. Audit findings shall be reported at least quarterly to the IRB Chairs, to P&T Committee chairs, and to P&T/IDS IRB members.

Funding

23. The principal investigator has fundamental responsibility to secure funding for clinical investigation. Resource assessment and indemnification issues affecting the viability of each clinical investigation involving DUCIs will not be the responsibility of the P&T/IDS IRB member.