## Policy No. 103.19a - Drug Use and Control in Clinical Investigation (DUCI)

*Definitions:*

**DUCI (Drug Used in a Clinical Investigation):**  Any drug, biological, botanical, or other substance used for a clinical investigation as named in the investigational protocol/IRB application and a dose, or frequency is specified, or if designated by the P & T IRB liaison.  Such drugs might be either commercially available or not commercially available and used according to, or outside of, the FDA-approved indications.

**Investigational New Drug (IND):**  Any drug or biological product for which the FDA issues an Investigational New Drug (IND) number to allow the drug to be used in a clinical investigation.

**Pharmacy:**  Refers to a pharmacy under the leadership of Johns Hopkins Medicine (JHM).

**IDS pharmacist:**  Refers to a pharmacist in Investigational Drug Services (IDS) at JHM.

**Dispensing Drugs:**  Drug dispensing occurs when a supply of drug that is not patient-specific or that requires manipulation (counting, mixing, preparing, reconstituting, etc.) is given to a study participant.

1. Examples of dispensing drugs include:
* Selecting a quantity of drug from a general bulk supply and placing it in another container for a study participant; or
* Measuring or packaging a drug before giving it to a study participant.

(b) Unless the IRB grants a specific exception, dispensing may only be done by a pharmacist or other practitioner who is licensed/or has a permit to dispense. State and local laws dictate who may dispense medications.

(c) Drugs may only be dispensed upon receipt of a valid order or prescription per the policy of the entity where the research is being conducted. There must always be a retrievable study participant specific record (order or prescription) of the drug being ordered by an authorized prescriber.

**Distributing Drugs: For the purpose of this document,** a drug is distributed when it is given to the recipient in a pre-labeled container with specific study participant identification (participant’s name or participant- specific identification code), and does not require manipulation (counting, mixing, preparing, etc.) before it is given to the recipient.

(a) Drugs may only be distributed by personnel who have received training about the distribution process and are listed as study team members

(b)  Non-licensed study personnel MAY NOT manipulate drugs within or between containers, may not apply prescription labels to drug containers, or count/confirm counts of study drug. They may transport drugs dispensed by an authorized person to the recipient.

(c)  Drugs may only be distributed after they have been properly dispensed as above and upon receipt of a valid order or prescription per the policy of the entity where the research is being conducted. There must always be a retrievable study participant specific record (order or prescription) of the drug being ordered by an authorized prescriber.

**Administering Drug:** Drug administration occurs when a drug is ingested, injected or enters a study participant through any route of administration.

1. Unless an exception is granted by an IRB P&T liaison, drug administration may only be performed by a person who has a current state license that permits drug administration, or by a person who is credentialed to administer drugs by the entity where the research is being conducted (e.g., nurse, physician, respiratory therapist, nurse practitioner, physician assistant, dentist, podiatrist, or optometrist).
2. Study team members not authorized to administer medications based on the criteria described in (a) above, MAY NOT administer study drugs.

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

Inpatient Studies:

A pharmacy shall store, control, prepare, and dispense all DUCI’s unless a limited exception is granted by the P&T IRB liaison during the IRB application and approval process.

Outpatient Studies:

(a) 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 IRB liaison during the IRB application and approval process.

(b) In situations where the investigator wishes to store, control, distribute or dispense their own DUCI, such as when a study drug needs to be dispensed or distributed urgently or the study is conducted at a distant geographic site, the investigator must describe, at the time of IRB application submission, their procedures for performing these functions. Both the P&T IRB liaison and the full IRB committee must approve this arrangement.

**Controlled Substances**

All controlled substances which are used in research must be managed and dispensed by a pharmacy to assure compliance with the Maryland Prescription Drug Monitoring Program and other federal, state, and institutional regulations.

**The Investigational Drug Data Sheet (IDDS)**

(a) An Investigational Drug Data Sheet shall be completed for all IND drugs or when requested by the IRB P&T liaison. The purpose of the IDDS is to provide sufficient information to allow the investigational drug to be dispensed and administered safely.

(b) Completed IDDS shall be reviewed by a P&T IRB liaison as part of the IRB application review process.

(c) Clinicians administering an IND drug shall be familiar with the contents of the IDDS prior to drug administration.  It is the responsibility of the Principal Investigator to assure that the IDDS is available in the patient’s medical record (e.g., research tab of Epic) and/or the clinical area where study drug will be administered.

**Authorization to Prescribe an Investigational Drug**

(a) Principal Investigators shall identify those individuals authorized to prescribe investigational drugs used in their study. For each investigational drug, the completed IDDS shall indicate those authorized to prescribe the investigational drug.

(b) Anyone who dispenses an investigational drug shall verify that the prescriber is authorized to do so prior to dispensing the drug. This can be accomplished by referencing the IDDS.

**Principal Investigator Auditing**

(a) In situations where a JHM investigator has been approved to control a DUCI during the conduct of a BSPH IRB approved study, an IDS pharmacist may be asked to audit the storage, control, preparation and dispensing of the investigational drug to assure that all regulatory and local institutional requirements are met. The frequency and nature of the audits will be determined by the IRB in consultation with the P & T IRB liaison and the Investigational Drug Service. The P&T IRB liaison in collaboration with the IRB committee will determine how drug control will be audited for studies conducted outside of Johns Hopkins.

(b) Audits of IND studies may 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 problems are resolved. If the identified problems cannot be resolved, the audit results shall be forwarded to the IRB, which will determine further actions if necessary.

 (c)  A copy of the audit report will be sent to the Principal Investigator.

 (d) When a Principal Investigator receives a study audit report from a regulatory agency or from a study sponsor (or agent of the sponsor), the PI must provide a copy of the report to the IRB with the Continuing Review/Progress Report Application. If there are significant findings, the PI must provide the copy within 5 working days.

 (e) 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.