BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY	CRC POLICY 8.2	PAGE 1 OF 2
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SUBJECT: Drug Accountability: Procurement, Dispensing and Disposal of Pharmaceuticals	REVIEWED BY: M. Genoa	
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1.0 POLICY:

Appropriate measures shall be applied when procuring, transporting, storing, using and disposing of controlled substances (see Attachment A, CRC Policy 8.1). The Central Pharmacy is the control point and the CRC Pharmacist has responsibility for all BSA controlled substances which are used for research at BNL. Brookhaven Science Associates holds the only Drug Enforcement Administration License (DEA) that allows for controlled substances to be used in research at BNL. BSA must assure that employees who handle controlled substances (i.e. those substances defined in 21 CFR 1300 – end) do so in a safe manner that is in compliance with Federal and State regulations. Failure to comply with regulations in any program at any level puts BSA's DEA license in jeopardy. Loss of this license would have devastating effects on major biomedical research programs at the Laboratory. All controlled substances will be ordered and controlled through the CRC Pharmacist. Orders are placed using a "Controlled Substance Order" form (CRC form C012). Before a controlled substance order can be placed, an IRB approved human protocol, IACUC approved animal protocol, or an approved ESR for chemical research describing the use of the substance must be on file with the CRC Pharmacist. Controlled substances will be dispensed only to pre-approved Satellite Pharmacies which are authorized by the Pharmacist. The primary investigator, or responsible person will control access to the satellite pharmacy and is responsible for controlled substances within the satellite facility. Upon receipt of the properly executed "Controlled Substance Order" form (CRC form C012) at the Pharmacy the Pharmacist will dispense the substances to the authorized recipient. The authorized recipient must immediately secure the substance in the satellite facility.

"Trading" or "transferring" of the controlled substances between different BNL investigators is discouraged and requires the proper authorization and documentation from the Central CRC Pharmacist and CRC Manager.

2.0 **PROCUREMENT:** (see Attachment A, CRC Policy 8)

2.1 Procurement of non controlled substances requiring the Pharmacy's license or BSA's DEA license shall be approved by the CRC Pharmacist and delivered to the CRC Pharmacy.

2.2 The Pharmacist shall restrict procurement of controlled substances to those for which there is an approved IRB protocol, an approved IACUC protocol or an ESR for chemical and biochemical research on file with the Pharmacist. Once the PI receives the approvals of the protocols from IRB, IACUC, and ESR, the Pharmacist shall be able to procure any controlled substances under Schedule I to V category as long as a valid BSA Schedule I to V controlled substances license exists.

2.3 The Pharmacist shall restrict procurement of DEA Schedule I controlled substances to those substances that have been listed on current and valid BSA DEA Researcher Schedule I Controlled Substances license. If any new Schedule I controlled substances are to be added to our current DEA Schedule I license, the protocol using such substances must be submitted to the DEA for review and approval before start of the research. Once a new Schedule I controlled substance has been approved by DEA and added on our DEA license, no further approval by DEA is required. The CRC Pharmacist will be able to procure such Schedule I Controlled Substances for any further usages by the same PI or other BNL PIs.

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2.4 All procurement or transfer of controlled substances from outside collaborators must be approved by the CRC Pharmacist, the CRC Manager, and conform to all NYS and Federal regulations. This approval must be done before any transfer can take place. All transfers or procurements of controlled substances from outside collaborators are to be discouraged.

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3.0 **DISPENSING**: (see PI Manual section 8.7)

3.1 Principal Investigators and their designates must complete a Pharmacy Order Form (CRC Form C012) in order to initiate the procurement and/or dispensing of controlled substances from the Central Pharmacy. These order forms or other prescriptions which provide written documentation of all items dispensed from the Central Pharmacy shall be maintained on file in the Central Pharmacy by the CRC pharmacist.

3.2 At the time a controlled substance is dispensed from the Central Pharmacy, the Pharmacist shall provide a log sheet to the approved personnel. The log sheet shall be referred to as the "Controlled Substance Running Inventory Log" (previously the "Controlled Substance Administration Record") (CRC Form C013 A-1, C013 A-2, C013 B-1, C013 B-2, C013 C-1, C013 C-2) for controlled substances.

3.3 It is the responsibility of the Investigator to maintain the log sheets referred to in Section 3.2.

3.4 The above referenced log sheet, along with the empty containers (as applicable), shall be returned to the CRC Pharmacist when the inventory level is deemed inadequate. Failure to maintain and properly return the log sheet and unused containers to the CRC Pharmacist on a timely basis may prevent or delay the dispensing of additional controlled substances to such approved personnel.

4.0 **DISPOSAL/RETURN OF CONTROLLED SUBSTANCES** (See Attachment A, CRC Policy 8.1)

4.1 It is the Investigator's responsibility to insure that any unused or expired Controlled Substances be returned to the CRC Pharmacist in a timely fashion. No controlled substance issued from the CRC Pharmacy shall be disposed of directly by the Investigator or other approved personnel without the informing of the CRC Pharmacist.

4.2 The waste or disposal of any controlled substance must be documented on the Controlled Substances Running Inventory Log or Controlled Substance Administration Record as soon as possible.

5.0 RECORD KEEPING OF CONTROLLED SUBSTANCES: (See Attachment A, CRC Policy 8.1)

5.1 A controlled substances running inventory log shall be maintained for inventories dispensed from the CRC Pharmacy and removed from Satellite Pharmacies. The PI or authorized research staff must document the amount of controlled substances used each time (CRC Form C013 A-1, C013 A-2, C013 B-1, C013 B-2, C013 C-1, C013 C-2).

5.2 These above-mentioned records must be readily accessible for the PI and or his/her authorized research staff to conduct the semi-annual Inventory and provide the pharmacist with the resultant Investigator Initiated Lockbox Report (CRC C016) or for any inspection or inventory by the CRC Pharmacist.

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