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| <b>BROOKHAVEN NATIONAL LABORATORY<br/>CLINICAL RESEARCH CENTER POLICY</b> | CRC POLICY 8.3   | PAGE 1 OF 3 |
|   | PREPARED BY: J. Rowan                                      |             |
| SUBJECT: CRC Satellite Pharmacy: Secured<br>Storage                       | REVIEWED BY: M. Genoa                                      |             |
|   | APPROVED BY: H. Benveniste                                 |             |
|   | EFFECTIVE DATE: 10/11/04                                   |             |
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**1.0 POLICY:**

A Principal Investigator may establish a satellite pharmacy, outside the CRC Central Pharmacy, in order to store controlled substances.

**2.0 ESTABLISHMENT OF SECURED STORAGE SATELLITE LOCATIONS:** (See Attachment A, CRC Policy 8.1)

2.1 The Investigator shall notify the Pharmacist, in writing, of his/her need to establish a satellite location.

2.2 This written notification, along with back-up access capability (i.e. safe combination, key, etc.) to each satellite pharmacy, shall be maintained on file in the CRC Central Pharmacy.

2.3 Establishing an approved Satellite location for controlled substances requires installing an approved, permanently affixed lockable storage device. This device must be either a double-locked box or else a single-locked box that is located in a locked refrigerator in a lockable room.

2.4 The CRC Pharmacy must be notified of the installation or removal of any Satellite locations along with the designation of a person responsible for the Satellite Pharmacy.

2.5 Keys for access to these devices or boxes must be in the control of one designated individual. Other authorized individuals may acquire these keys for obtaining controlled substances. Keys must be secured after hours in a locked room or desk. Duplicate copies of keys must be made available to the CRC Pharmacist.

2.6 Each Satellite Pharmacy must have a running inventory sheet (CRC C013) for each controlled substance. NOTE:

the "Controlled Substance Running Inventory Log" must be used for this running inventory. (See attachment A, CRC Policy 8).

2.7 Transfer of controlled substances between Investigators at BNL is allowed if the following conditions are met:

2.7.1 The investigators first must notify the CRC Pharmacist in regards to the transfer of the controlled substance between the investigators at BNL. If it is an urgent transfer, please refer to 2.8 below.

2.7.2 Both the borrowing and lending investigators must be approved procurers of controlled substances.

2.7.3 The lending investigator must bring the controlled substance that needs to be transferred and its corresponding inventory log sheet (CRC C013) to the CRC Pharmacy. The CRC Pharmacist will ask the lending investigator to log out the controlled substance from his/her "Controlled Substance Running Inventory Log" and write to whom and in what amount the drug is being given to and where the drug is to be stored.

2.7.4 The CRC Pharmacist will dispense this controlled substance to the borrowing investigator with a new "Controlled Substance Running Inventory Log" and a new control number for the controlled substance.

2.7.5 The borrowing investigator must log the controlled substance in his/her lock box and keep tracking of the amount of the substance being used on the "Controlled Substance Running Inventory Log".

2.8 Emergency transfer of controlled substances: In the event that an investigator needs to borrow a controlled substance from another investigator at BNL in an emergency situation (i.e., the investigator needs the drug for an experiment and can not wait for the CRC pharmacist), the following conditions must be met to ensure the proper tracking of the controlled substances:

2.8.1 The borrowing and lending investigators must be approved procurers of controlled substances.

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2.8.2 The lending investigator must log out the entire quantity of the drug from his inventory sheet and write to whom and in what amount the drug is being given and where the drug is to be stored. Partial quantities may not be transferred. The lending investigator must make a copy of this sheet and immediately send it to the pharmacy.

2.8.3 The borrowing investigator must verify the amount of the drug, log the drug in to his/her lock box and maintain the transferred log sheet and fill out a new "Controlled Substance Running Inventory Log" for the controlled substance being borrowed. The borrowing investigator must make a copy of this sheet and immediately send it to the pharmacy.

2.8.4 When an Investigator is transferring a controlled substance from one lock box to another and he/she is responsible for both boxes, the Investigator will write a memo to the Pharmacist detailing the transfer.

The CRC Pharmacist will contact the borrowing investigator and fill in a new control number on the new inventory log sheet for the transferred controlled substance when the pharmacy is open again.

2.8.5 The use of this policy is for bona fide **emergency** situations only and is not to be used indiscriminately. All emergency uses will be reported to the CRC manager. All principal investigators shall well plan their experiments and ask the CRC pharmacist to order the controlled substances in ahead of time to avoid the unnecessary emergency transfer of controlled substances.

**3.0 INVENTORY AT SATELLITE PHARMACY:**

3.1 It is the Principal Investigator's responsibility to insure that the Pharmacist is given adequate reorder notification in order for the Satellite Pharmacy to maintain sufficient inventory levels.

3.2 It is the Pharmacist's responsibility to adjust inventory levels at satellite locations when usage records support such adjustment.

3.3 Inventory and the associated logs maintained by the satellite location shall be accessible for unannounced inspection and/or audit by the CRC Pharmacist and/or CRC Manager.

3.4 It is the responsibility of the PI/Authorized research staff to perform and document a semi-annual inventory of satellite pharmacies. The PI/Authorized research staff will use the "Investigator Initiated Lock Box inspection Report" (CRC Form C016) to document their semi-annual inventories of all CRC satellite pharmacies. The CRC Pharmacist will document his/her review of the PI initiated inventories. Corrective actions will be developed if there are deficiencies discovered during internal inventories, via both PI/Authorized research staff and CRC pharmacist. The results from the semi-annual inventories will be presented at the CRC QAC&S Committee meeting.

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**4.0 REGULATIONS CONTROLLING SATELLITE LOCATIONS:**

(see Attachment A, CRC Policy 8)

4.1 It is the responsibility of the Principal Investigator under Section 2.1, above, to immediately notify the CRC Pharmacist of any of the following:

- Any changes or amendments to the Satellite Pharmacy description.
- Any changes/amendments to the inventory maintained at the satellite location.
- Any breach in security at the Satellite Pharmacy.
- Any missing controlled substances.
- Any change in the PI authorized lockbox user list.

4.2 It is the responsibility of the CRC Pharmacist to notify the Bureau of Controlled Substances (BCS) and Drug Enforcement Administration (DEA) of any theft, significant loss or possible diversion of controlled substances.

4.2 It is the responsibility of the Principal Investigator identified under Section 2.1, above, to insure that the appropriate logs are maintained at the Satellite Pharmacy to document the usage, waste and disposal of all controlled substances issued to the Satellite location by the CRC Central Pharmacy.

4.3 Failure to maintain such documentation in a complete and timely manner may result in the suspension of the Principal Investigator's right to maintain a Satellite Pharmacy. Such suspension shall be determined by the CRC Manager in consultation with the CRC Pharmacist.

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