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| Protocol: |  | Principal Investigator: |  | Department: |  |
| Building: \_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Room: \_\_\_\_\_\_\_\_\_ | | | | | |
| |  |  | | --- | --- | | **Controlled Substance** **Name** | **Schedule** | |  |  | |  |  | |  |  | | | | | | |

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| **Inventory Records (Initial, Annual, Biennial, Closing)** | | | |
| [**21 C.F.R. 1304**](http://www.deadiversion.usdoj.gov/21cfr/cfr/2104cfrt.htm) | **Yes** | **No** | **Comments/Action** |
| Was an initial inventory performed? |  |  |  |
| Are the initial, and DEA biennial inventory records for the last two years on site? |  |  |  |
| Are the inventory records readily retrievable? |  |  |  |
| Was a DEA biennial inventory performed and retained on site? |  |  |  |
| Are schedule I - II inventory records kept separate from schedule III - V inventory records? |  |  |  |
| Were exact inventory quantities and amounts reported for schedule I - II controlled substances? |  |  |  |
| Was a closing inventory performed (moving, transferring, retiring)? |  |  |  |
| **Usage Records (General Inventory, Multi-dose, Diluted Solution)** | | | |
| [**21 C.F.R. 1304**](http://www.deadiversion.usdoj.gov/21cfr/cfr/2104cfrt.htm) | **Yes** | **No** | **Comments/Action** |
| Are the usage records (logs, general inventory) for the last two years retained on site? |  |  |  |
| Are the usage records readily retrievable? |  |  |  |
| Are the usage records for schedule I - II substances kept separate from the usage records for schedule III –V substances? |  |  |  |
| Were the general inventory and usage records recently reconciled for accuracy? |  |  |  |
| Have waste amounts, if any, been identified in the record and signed by both the PI and a witness? |  |  |  |
| Are individual containers or packages labeled with a unique identifier to assist in usage record tracking? |  |  |  |
| Do multi-dose vials have their own usage log? |  |  |  |
| Do diluted solutions of controlled substances have their own usage log? |  |  |  |
| Does the general inventory document transfers of expired or unneeded controlled substances to a reverse distributor for disposal or destruction? |  |  |  |
| **Invoice and Purchase Records** | | | |
| [**21 C.F.R. 1305**](http://www.deadiversion.usdoj.gov/21cfr/cfr/2105cfrt.htm) | **Yes** | **No** | **Comments** |
| Are supplier invoices for controlled substances readily retrievable? |  |  |  |
| Are supplier invoices for schedule I - II controlled substances kept separately from supplier invoices for schedule III - V controlled substances? |  |  |  |
| Do all invoices contain the following: Name, address, DEA registration numbers of supplier and purchaser, order date, drug names, strengths, container forms, and quantities received? |  |  |  |
| Are all invoices signed and dated upon receipt or delivery? |  |  |  |

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| **Disposal** | | | |
| [**21 C.F.R. 1317**](http://www.deadiversion.usdoj.gov/21cfr/cfr/2117cfrt.htm) | **Yes** | **No** | **Comments** |
| Are expired or unneeded controlled substances kept in a substantially constructed cabinet until pick up by the Hazardous Materials Manager? |  |  |  |
| Are all disposal forms sent to the Office of Research to be kept with the Form 222, if applicable? |  |  |  |
| Were non-recoverable waste amounts properly disposed of? |  |  |  |
| Are non-recoverable waste amounts documented in the inventory or usage record with two signatures (PI and one witness)? |  |  |  |
| **Loss or Theft** | | | |
| [**21 C.F.R. 1301.76**](http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_76.htm) | **Yes** | **No** | **Comments** |
| Have all actual or suspected cases of theft or significant loss been reported to the Office of Research, TCU Policy Department, and DEA? |  |  |  |
| Was a DEA Form 106 submitted for actual or suspected cases of theft or significant loss? |  |  |  |
| Have losses incurred during shipment been reported to the supplier? |  |  |  |
| Are non-recoverable losses documented in inventory or usage record with two signatures (authorized agent and witness)? |  |  |  |
| **Security** | | | |
| [**21 C.F.R. 1301.71**](http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_71.htm) **–** [**1301.93**](http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_90.htm) | **Yes** | **No** | **Comments** |
| Have policies or standard operating procedures been developed by the laboratory with respect to storage, administering, and record keeping of controlled substances? |  |  |  |
| Are the controlled substances stored in a securely locked, substantially constructed cabinet or safe that is anchored to a wall or the floor? |  |  |  |
| Does the controlled substance storage location have minimal traffic flow? |  |  |  |
| Is the lab or room with the storage cabinet locked when the registrants or authorized agents are not present? |  |  |  |
| Are controlled substances requiring refrigeration securely stored or locked in a refrigerator? |  |  |  |

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| Is access to controlled substances kept to a minimal number of authorized agents? |  |  |  |
| Are keys to the controlled substance storage cabinet locked up or secured when not in use? |  |  |  |
| Do the locks on the storage room and cabinet have the capability to be reset or rekeyed if an authorized agent resigns, is terminated, or a loss or theft is suspected? |  |  |  |
| Is an authorized personnel log kept on site? |  |  |  |
| Is the authorized personnel log updated frequently? |  |  |  |
| Have background checks been performed on authorized agents and authorized personnel? |  |  |  |
| If a formal background check was not performed, have all authorized agents read and signed an "Authorized Agent Screening Statement? Are screening statements kept on file. |  |  |  |
| Are all screening statements complete and kept on site? |  |  |  |
| Are controlled substances delivered directly to a receiving individual in the laboratory? |  |  |  |