REPORT OF AUDIT

DEA CONTROLLED SUBSTANCES

This report memorializes an inspection to ensure that all procurement, distribution, use, security, and record keeping

of DEA controlled substances is in accordance with 21 CFR Parts 1300-1316 and IACUC Principle and Procedure XIV. 1-13.

 All laboratories, storage cabinets, logs of use, and inventory records are subject to unannounced inspections and audits by the

 DEA, Division of Research Integrity & Compliance, or Division of Comparative Medicine to ensure compliance with these procedures.

LOCATION (building, room number): DATE:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PRINCIPLE INVESTIGATOR (name):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| I. REGISTRATION | **S** | **D\*** |
|  A. Faculty members requesting, possessing, or using any controlled substances are registered |  |  |
|  B. Registration is on file with Division of Comparative Medicine  |  |  |
|  C. Registration files are maintained in an orderly manner and are current and accessible |  |  |
|  D. Registration files are current (i.e., current personnel and storage location identified) |  |  |
|  |  |  |
| **II. DISTRIBUTION RECORDS** |  **S** | D\* |
|  A. Logs of controlled substances maintained in inventory for distribution are accurate and complete |  |  |
|  B. Record of use log sheets are available for all substances awaiting dispersal |  |  |
|  C. Records of dispersal are chronologically arranged and indexed by substance and PI |  |  |
|  |  |  |
| **III. MASTER INVENTORY RECORDS** |  **S** | D\* |
|  A. Procured controlled substances are assigned a unique identification number upon arrival |  |  |
| B. A master inventory log is maintained identifying each procured controlled substance |  |  |
|  C. Procured controlled substance vials are labeled with assigned identification number  |  |  |
|  D. Inventory logs are complete, chronologically arranged and indexed by substance  |  |  |
|  E. Inventory logs of dispersals are complete, chronologically arranged and indexed by facility |  |  |
|  F. Completed record of use log sheets are archived and accessible |  |  |
|  G. Unused DEA 222 forms are secured and copies of completed forms are accurately maintained |  |  |
|  H. Biennial Inventory of all stocks on hand conducted at least every 2 years |  |  |
|  |  |  |
| **IV. LABORATORY RECORD KEEPING** |  **S** | D\* |
|  A. Record of use log sheets are available for each DEA controlled substance in inventory |  |  |
|  B. Record of use log sheets are accurate and current |  |  |
|  C. Each DEA controlled substance vial is labeled with an assigned identification number |  |  |
|  E. Expired DEA controlled substances, intended for use in animals, or unused controlled substances associated with a completed IACUC protocol are forfeited to Comparative Medicine for disposal  |  |  |
| F. Expired DEA controlled substances, intended for laboratory use only, are labeled as such |  |  |
|   |  |  |
| **V. SECURITY** |  **S** | **D\*** |
|  A. DEA controlled substances are securely locked in a substantially-constructed, non-portable  cabinet/drawer (primary storage) |  |  |
|  B. Primary storage is secured behind a second lock (i.e., lab/office doors if kept locked while unattended) |   |  |
|  C. Access is limited to authorized personnel |  |  |
|   |  |  |

S – Satisfactory D\* -- Deficiency (describe briefly) NA – Not Applicable

**Deficiencies Noted From Prior Review:**

**Comments:**

**Recommendation:**

**Signatures of Auditors** (Report must be signed by the auditors and their name typed or printed under their signature.)

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