To: Animal Research Investigators, ACHRI **Revised 9/17/2012**
From: Blake Harrison

Using Controlled Substances in Animal Research: Guidance and Information

This email is to provide information to investigators regarding the use of controlled substances in animal research. If you are using controlled substances or planning to use controlled substances for animal research purposes, please email Blake Harrison or call him at 364-2710.

This email contains information on the following topics related to controlled substances:

Responsibilities of the Principle Investigator
The ACHRI Controlled Substances Policy
DEA Registration
State License/Registration
Research Personnel
Purchasing
Dispensing Records/Recordkeeping
Physical Inventory Count
Physical Security
Wastage and Controlled Substances Destruction

For more information on these topics review the information below:

It is the responsibility of the Principal Investigator to know, understand, and follow the Drug Enforcement Administration (DEA) and State of Arkansas rules and regulations pertaining to all aspects of controlled substances, and keep all required registrations, certificates, licenses, and records in force. Failure to comply with the DEA and Arkansas Department of Health (ADH) regulations may result in forfeiture of DEA registration and Arkansas Department of Health Registration. Failure to produce complete disposition records at the request of Arkansas Children's Hospital Research Institute (ACHRI) management or ACH Audit Services may result in assumption that drugs were potentially diverted and the suspension of your research activities.

DEA Registration

Per DEA regulations, every person engaged in prescribing, dispensing, distributing, administering, or conducting research with respect to controlled substances must be registered with the DEA; the registrant may only conduct aforementioned activities with controlled substances for only those schedules authorized by their DEA registration, and they are required to have a separate registration for each place of business or professional practice.

State License/Registration

All Research investigators utilizing controlled substances for purpose of research must be licensed with the Arkansas Department of Health, and if a study has a change in drug used, an addendum is required from the ADH.
ACHRI Investigators must maintain state license/registration and keep registration current based on the proper schedules related to their active protocols.

Others involved that work with the Investigator

Investigators must ensure all research personnel who purchase, receive, administer, waste, witness waste, or otherwise handle controlled substances are listed by name in the approved animal use protocol.
In addition, if a principle investigator authorizes research personnel to act on his or her license/registration, there must be a power of attorney letter indicating this relinquishment of authority signed and dated by the DEA licensed Principle Investigator and available in the lock box for purpose of inspection and audit.

Purchasing

The DEA requires a triplicate order form (DEA Form 222) for the transfer (purchasing and receiving) of all Schedule II controlled substances. The order forms must be completed properly and bear no material alteration; if errors occur, all three copies should be marked as **VOID** and the three part order form filed with executed forms. Forms should be signed only by the registrant or someone the registrant has granted power of attorney. Carbon copies of all order forms must be maintained and readily accessible for two years. Lost or stolen order Form 222s must be reported to the DEA.

The DEA allows limited quantities of controlled substances to be procured via transfer from another DEA registrant. Schedule II transfers require the completion of DEA order Form 222, as is done for routine purchases. Schedule III-V controlled substance transfers between registrants should be documented on an internally standardized document, to include all information present on the DEA order Form 222. This should include the date of the transaction, the name, form, and quantity of the controlled substance. Documentation should also include the names, addresses, and DEA registration numbers of the registrant transferring out of their stock and that of the registrant receiving the stock. Amounts to be transferred out by a registrant over a 12 month

period must not exceed 5% of all controlled substances dispensed by that registrant; otherwise the registrant must be licensed as a distributor in addition to a practitioner.

Dispensing Records/Recordkeeping

Per DEA regulations, all registrants engaged in storing and utilizing controlled substances are required to keep complete and accurate records of all receiving and dispensing transactions; all records for controlled substance procurement, dispensing, inventories and all other required activities must be maintained and readily accessible for a period of two years; and records of schedule II documentation must be maintained separately from records of schedules III-V activities.

According to the Arkansas Department of Health (ADH) dual signatures are recommended on dispensing records.

Physical Inventory Count

Per DEA regulations, an initial inventory (actual physical count) is required on the date when controlled substances activity is first engaged. A physical count is required, at a minimum, every two years following the general physical inventory date. Note that only maintaining perpetual inventory records is not sufficient to meet the requirement of an actual physical count. Inventory records must be maintained and readily accessible for two years.

When taking the inventory of Schedule II controlled substances, an exact count or measure must be made. Unopened schedule II containers with seals intact are not required to be opened. For schedules III-V, an estimated count may be made. If the container holds more than 1,000 dosage units, an exact count must be made if the container has been opened.

Per the DEA, specific information about the drug is required to be documented with inventory. This includes the investigator's name, the date and time inventory was taken, and the signature of the person(s) responsible for taking the inventory. Inventory records should also include the name of the controlled substance, the dosage form and unit strength, and number of units or volume of each on hand.

Physical Security

Per the DEA and ADH regulations, Schedules II, II N (non narcotic), III, III N (non narcotic), IV, and V controlled substances are required to be kept in a locked cabinet. Schedule II controlled substances are required to be kept under a double lock and this is recommended for all controlled substances. *(A door lock counts as one lock.)* Additionally, good internal controls dictate that access to keys where controlled substances are stored should be secure and limited to authorized personnel. The ACHRI Director of Animal Research and Facility Operations will issue locked cabinets for controlled substances. Blake Harrison can be reached at ext. 42710. If drug boxes are no longer in use for the storage of controlled substances, the keys must be returned to ACHRI administrative staff (Director of Animal Research and Facility Operations) and the drugs disposed of in accordance with established procedures.

Wastage and Controlled Substance Destruction

Per ADH rules and regulations, unused controlled substances drawn from the original container (such as a syringe) are to be wasted on-site in the presence of a witness and documented in the dispensation/inventory records. When breakage or wastage of a controlled substance occurs, the amount given and the amount wasted shall be recorded by the authorized person who wasted the medication and verified by the signature of the person who witnessed the wastage. *(As so authorized by the protocol to handle controlled substances.)* Documentation must include or policy shall delineate how the medication was wasted. If a witness is not available, or if controlled substances are no longer usable due to expiration, deterioration, or not needed, they must be properly packaged and submitted to Arkansas Department of Health, Pharmacy Services and Drug Control, and include the proper completion of the Report of Drugs Surrendered form (available from the ADH).

For all investigators utilizing controlled substances in animal research experimentation at ACHRI, please sign this acknowledgement that you fully understand the controlled substance policy and that you fully intend to comply with all rules and regulations associated with utilizing controlled substances at ACHRI.

_____Principle Investigator _____Date

If you have any questions please contact Blake Harrison, ACHRI Director of Animal Research and Facility Operations at 364-2710 or Barry Brady, ACHRI Vice President at 364-6517.