INVESTIGATOR DISPENSING & STUDY DRUG MANAGEMENT REQUIREMENTS

When a Principal Investigator chooses to utilize Investigational Drug Services (IDS) in the “Registration Only” capacity, it is his/her responsibility to ensure that all of the following guidelines are met.

1. **Study Drug Dispensing**
   - Per Minnesota Statute: Medication may only be dispensed by a physician, physician’s assistant (in agreement with the physician), or a nurse practitioner (in agreement with the physician) – if not dispensed by a pharmacist.
   - Physician must certify the completed prescription prepared for the patient, if prepared by someone other than herself/himself, physician’s assistant, or a nurse practitioner. Physician must maintain documentation that this was done.
   - Physician must reduce all drug orders to a written prescription that should be numbered and filed in an organized manner when dispensed (A patient’s chart records do not qualify as a prescription record).
   - Medication needs to be dispensed in packaging in accordance with the federal Poison Prevention Packaging Act and US Pharmacopeia requirements.

2. **Drug Procurement** – The principle investigator must ensure that the supplier of the study medication used in the study be licensed/registered by the Minnesota State Board of Pharmacy as a Non-resident Pharmacy or as an Out-of-State Wholesale Drug Distributor.

3. **Labeling Study Medication** – along with label affixed by the study sponsor, drug must be labeled with information required by State Board of Pharmacy.
   - Name, address and telephone number of clinic or physician’s office
   - Prescribing physician’s name
   - Patient’s name
   - Date of dispensing
   - ‘Prescription’ number – may be a visit number with a date. Has to be unique to the patient and patient’s visit
   - Directions for use
   - Drug name/study name/protocol name or number
   - Name of manufacturer or distributor of finished dosage form (if this information is contained on the sponsor’s label it does not have to included on the label affixed by the dispenser)
   - Any auxiliary labels – i.e. Caution: New Drug - Limited by Federal Law to Investigational Use

4. **Blind** – If the study is a blinded study.
   a. Where will the blind be maintained
   b. The mechanism for unblinding in the case of an emergency
c. The ability to unblind a medication must be available 24 hours a day, seven days a week in a timely manner
d. Inform sponsor, in a timely manner, if the blind is broken

5. Storage 3, 4, 5, 6, 18, 19
   - Medication must be stored in a secured (locked) separate area
     - It must accessible to authorized study personnel only
   - Room temperature logs must be maintained if required by sponsor
   - Refrigerator and freezer temperature logs must be maintained
   - Refrigerated or frozen study medications may not be stored in a refrigerator or freezer with lab specimens or food – and it must be secured
   - Maintain expiration, retest, recall notices
   - Storage of returned, used medication in a secure area until monitored by study sponsor, returned to the sponsor or destroyed by instruction of the study sponsor

6. Records
   - Maintain records of product’s delivery to trial site (packing slips)
   - Maintain receipt of order confirmation records
   - Maintain confirmation of receipt of medication returned to sponsor
   - Maintain copies of medication requests from the sponsor (ordering and re-ordering of drug supplies)
   - Maintain records of drug returned to sponsor or drug destruction
   - Maintain a prescription record of drugs dispensed
     - Filed by number or date
     - Showing patient’s name and address
     - Date of prescription
     - Name of drug and strength
     - Quantity dispensed
     - Directions for use
     - Signature of practitioner (and DEA number if applicable)

7. Inventory Forms
   - Perpetual inventory
   - Record the use by each subject
     - Date
     - Quantity
     - Batch/serial/kit number
     - Expiration date
     - Unique code numbers assigned to the investigational product(s) and subjects
References:

1. ICH Guidelines E6 4.6.3
2. Minnesota Rules 6800.9954
3. Minnesota Rules 6800.9951
4. ICH Guidelines E6 4.6.4
5. ICH Guidelines E6 5.13.2
6. ICH Guidelines E6 5.13.4
7. ICH Guidelines E6 1.52
8. Minnesota Rules 6800.3100
9. Minnesota Rules 6800.9952
10. Minnesota Statute 151.37 subd. 2
11. Minnesota Statute 151.37 subd. 2a
12. Minnesota Rules 6800.9952 subpart 1
13. Minnesota Rules 6800.9952 subpart 4
14. Minnesota Rules 6800.3400
15. Minnesota Statute 151.212
16. ICH Guidelines E6 5.13.4
17. ICH Guidelines E6 4.7
18. Minnesota Rules 6800.1440 subpart 5
19. Minnesota Rules 6800.7700
20. Minnesota Statute 151.19 subd. 2
21. Minnesota Statute 151.48