

## Using Drugs for Clinical Research Procedure: Requirements for Drug Management

The Offices of Academic Clinical Affairs and the Vice President for Research strongly encourage investigators to contract for services with Fairview Investigational Drug Service (IDS) as the coordinating and control center for their research drugs.

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1. All projects using either legend or investigational drugs must either contract for full services with [Fairview IDS](#) or enroll in a “Registered Only” status using the Investigational Drug Service Registered Only (RO) Form.
2. All drugs and biologics included in this policy are in the IRB Toolkit Worksheet [HRP-306](#).
1. All projects must also be entered into OnCore

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4. Investigators who opt for the “Registered Only” status will be held responsible for compliance with University, sponsor, state, and federal rules and regulations regarding the conduct of studies as well as those related to procuring, dispensing, labeling, storage, inventorying and administration of study drugs as outlined in the following slides.

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5. Investigators are responsible for providing IDS access to the study [OnCore](#) record to allow them to enter the IDS identification number, regardless of whether the full service or “Registered Only” option is chosen.
6. Fairview Research Administration is responsible for providing researchers with the IDS identification number as part of their ancillary review and approval correspondence.

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7. Investigators are responsible for entering the IDS identification number into the appropriate study protocol in [ETHOS](#).
8. The IRB will not finalize approval of a protocol until after receipt of the Fairview Research Administration approval correspondence to the researcher which will include the IDS identification number.

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- The Fairview IDS pharmacist may be delegated authority by the Principal Investigator to serve as the coordinating and control center for maintaining records of the drugs delivered to Fairview IDS, inventory of the drug, dispensing of drugs to research subjects, and the return to the sponsor or disposition of unused product.
- Fairview IDS will store and dispense the investigational drug as specified by the sponsor and in accordance with applicable regulatory requirements.
- If Fairview IDS is not coordinating the control of the research drug as outlined above, the principal investigator is responsible for the control of the drug.

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## 1. Research With Fairview Health Services Patients (in- or out-patient)

- A. All projects which recruit and enroll participants affiliated with Fairview Health Services for inclusion as either an in-patient or an out-patient must contract with IDS for drug management. Contact [IDS Research Services](#)
- B. RO status is not an option for these participants.

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## 2. Research at Non-Fairview Health Services Sites

For any studies (inpatient or outpatient) at a non-Fairview Health Services site, the study must, at a minimum, have “Registered Only (RO)” status with the Fairview IDS and be entered into [OnCore](#).

- A. Form to request RO status with IDS can be found here.
- B. Information regarding OnCore registration can be found [here](#).



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## 3. Investigator Dispensing & Drug Management Requirements

The following slides outline the Principal Investigator's responsibilities relative to the use of legend and/or investigational drugs in clinical research if electing the RO option.

Procedures:

- A. Drug Procurement
- B. Study Drug Dispensing
- C. Labeling Study Drugs
- D. Blind Studies
- E. Storing Investigational Drugs
- F. Maintaining Inventory/Records
- G. Drug Administration

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## A. Drug Procurement

The Principal Investigator must ensure that the supplier or wholesale drug distributor of the study medication used in the study be licensed/registered by the Minnesota State Board of Pharmacy or as an Out-of-State Wholesale Drug Distributor.

[\(Minnesota Statute 151.47\)](#)

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### B. Study Drug Dispensing

- 1) Drugs needs to be dispensed in packaging in accordance with the [Minnesota State Board of Pharmacy Rule \(Chapter 6800.9953\)](#).
- 2) Drugs may only be dispensed by a licensed practitioner (licensed doctor of medicine, osteopathic medicine, dentistry, optometry, podiatrist, veterinarian, or advanced practice RN) when the dispensing is not being done in a pharmacy.
- 3) A physician's order is not required for a pharmacy to dispense a research drug unless the study protocol requires the pharmacy to receive such an order.

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## C. Labeling Study Medication

Along with any label affixed by the study sponsor, drug must be labeled with information required by [Minnesota State Board of Pharmacy \(Rule 6800.3400\)](#)

- 1) Prescribing practitioner's name, address and phone number
- 2) Patient's name
- 3) Date of dispensing and expiration
- 4) Prescription number that is unique to the patient and patient's visit
- 5) Directions for use
- 6) Drug name/study name/strength/protocol number or name and expiration date
- 7) Name of the manufacturer or distributor of finished dosage form (if this information is contained on the sponsor's label it does not have to be included on the label affixed by the dispenser).
- 8) Federal Regulations specifies the following labeling requirements: The immediate package of an investigational new drug intended for human use must bear a label with the statement "Caution: New Drug - Limited by Federal (or United States) law to investigational use." [CFR 312.6](#)

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## D. Blind Studies

- 1) Information for unblinding in the case of an emergency and the ability to unblind a medication must be available 24 hours a day, seven days a week in a timely manner.
- 2) Expected turn around time for the unblinding process to be completed is 20-30 minutes.
- 3) Inform sponsor, in a timely manner, if the blind is broken.
- 4) Contact information in the event of an emergency must be provided in one of the following forms:
  - a. Patient consent form
  - b. Printed on the medication bottle
  - c. Patient given study team contact phone number on wallet card

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### E. Storing Investigational Drug

The Investigator must ensure that the investigational product(s) are stored as specified by the sponsor and in accordance with applicable regulatory requirement(s). Storage guidelines include:

- 1) Investigational drug is stored in a locked location.
- 2) Investigational drug is stored separately from other compounds and non-dispensed drug is stored separately from returned dispensed drug.
- 3) Inventory control procedures are used.
- 4) Any environmental controls are maintained.
- 5) Access is limited to persons who have legal authority to dispense and those under direct supervision. ([Minnesota Board of Pharmacy 6800.9950](#))

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### E. Storing Investigational Drug continued...

- 6) Room temperature logs must be maintained if required by sponsor. Good Clinical Practice (GCP) requires medication to be stored at the proper temperature. [\(ICH GCP Guidelines\)](#).
  - a. Room temperature (20-25 C or 68-77 F)
  - b. Refrigerator temperature (2-8 C or 36-46 F)
  - c. Freezer temperature (-20C)
- 7) 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.
- 8) Maintain expiration, retest, recall notices.
- 9) Store returned, used medication in a secure area until monitored by study sponsor, returned to the sponsor or destroyed by instruction of the study sponsor. (Please refer to [Using Controlled Substances for Research](#) and [Minnesota State Board of Pharmacy \(Rule 6800.9951\)](#))

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### F. Records/Inventory Requirements

- 1) Maintain records of product's delivery to trial site, inventory at the site, and receipt of order confirmation records. These records should include dates, quantities, batch/serial numbers, expiration dates, and the unique code numbers assigned to the investigational product(s) and participants.
- 2) Maintain confirmation of receipt of drug returned to sponsor or drug destruction.
- 3) Maintain essential documents and records of drug for period of 2 years after end of investigation. [\(CFR 312.59,62\)](#)



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### F. Records/Inventory Requirements continued...

- 4) Maintain an accountability record of drugs dispensed for use by each participant including:
  - a. Participant's name and address (and any unique participant identification code or number).
  - b. Disposition of drug including dates, specific dosage, and use by each participant.
  - c. Case histories that record all observations and data including signed and dated consent forms, medical records, and progress notes.

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### G. Drug Administration

- 1) Legend and investigational new drugs must be administered in accordance with any applicable State or Federal regulations and research protocols. In addition, drugs must be administered in accordance with any policies or procedures set forth by the University of Minnesota Institutional Review Board as well as with any other hospital or clinic policy pertaining to the administration of drugs.

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### G. Drug Administration continued...

- 2) Only a licensed practitioner within the legal scope of their professional practice must administer a legend or investigational new drug to a participant as defined in Minnesota Statute [\(151.37\)](#)
- 3) A principal investigator may designate the responsibility of administering the drug only after the designee has been given and has demonstrated an understanding of basic pharmacologic information about the drug. This education and delegation of responsibility must be documented.

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## Questions?

### Fairview IDS Questions

- Contact IDS at 612-273-6212 or email [IDSpharmacy@fairview.org](mailto:IDSpharmacy@fairview.org)
- [IDS Forms and Guidance](#)

### Clinical Trial Management System-OnCore

- [OnCore Login](#) and [OnCore Information](#)
- email [OnCore@umn.edu](mailto:OnCore@umn.edu)

### Research Compliance Office

- Contact RCO at (612) 625-4926 or email [ovprcco@umn.edu](mailto:ovprcco@umn.edu)

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## Related Information and Resources:

- Board of Regents Policy: [Research Involving Human Subjects](#)
- Administrative Policy: [Using Controlled Substances for Research](#)
- IRB Toolkit Worksheet Drugs and Biologics [HRP-306](#)
- [Fairview's Investigational Drug Policy](#)
- [Fairview IDS Registration-Investigator Dispensing & Study Drug Management Requirements](#)
- [Investigational New Drug Application \(21 CFR 312, subparts A-F\)](#)
- [Code of Federal Regulation \(312.59,62\)](#)
- [Minnesota Statutes \(151\)](#)
- [Minnesota State Board of Pharmacy, Chapter 6800\)](#)
- [ICH GCP Guidelines](#)