Investigational Drug Services (IDS)

Registration Only (RO) — Principal Investigator Responsibilities

Self-Managed Drug Handling in Clinical Research

M Health Fairview | IDS Pharmacy, 2631 Territorial Rd, St Paul MN 55114

Version: 2.1 | **Supersedes:** RO Investigator Dispensing & Study Drug Management Requirements (undated) | **Owner:** Dustin Kakach, PharmD, IDS Manager | **Contact:** IDSPharmacy@Fairview.org

Purpose and choice of path

Any clinical research study at the University of Minnesota or Fairview that administers, dispenses, or otherwise causes a product to be taken by a human participant is conducting drug-handling activity. This is true whether the product is prescription, over-the-counter, an investigational new drug (IND), a dietary supplement, or a botanical preparation. The University Administrative Policy Clinical Research Using Drugs places primary responsibility for compliance with the principal investigator (PI).

The PI has two paths:

- **Full IDS service —** IDS Pharmacy procures, receives, stores, labels, dispenses, accounts for, and destroys investigational product on the PI's behalf. The PI delegates the operational drug-handling activities described in the IDS SOPs to IDS personnel via the Delegation of Authority (DOA) log.
- **Registration Only (RO) —** IDS registers the study, assigns an IDS number for record-keeping, and provides this document. IDS performs no operational drug management. The PI personally retains every responsibility listed in Sections B, C, and D below, for the full duration of the study and the records-retention period that follows.

This form documents what RO entails. Read all sections before signing. If at any point during the study a condition listed in Section A becomes applicable (for example, the protocol amends to enroll a Fairview-affiliated participant), the PI must contact IDS immediately to transition to full service.

Who RO is for

The Research and Innovation Office and the Office of Academic Clinical Affairs strongly encourage investigators to contract with Fairview IDS as the coordinating and control center for research drugs. RO exists for a narrow set of studies, typically a study conducted entirely at a non-Fairview site, using a commercially marketed or over-the-counter product that is not controlled, not hazardous, not biologic/gene-based, not requiring sterile compounding, and not requiring sponsor-managed dispensing systems. Per University policy, a study at a non-Fairview site must at minimum hold RO status with Fairview IDS and be entered into OnCore. If any part of the study touches the applicable areas below, the eligibility screen in Section A will route it to full service.

This form applies to research protocols. Expanded access, compassionate use, and emergency-use INDs are handled separately; contact IDS. Drug-device combination products carry additional device (IDE) requirements outside the scope of this form.

Section A — RO Eligibility Self-Screen

Mark each item below YES or NO. If *any* item is marked YES, RO is not available for this study; IDS full service is required and this form cannot be signed. Continue to Section B only if all items are NO.

#	Condition — RO is not available if this applies to your study	Mark	Authority
A1	The study will enroll any Fairview-affiliated participant — inpatient OR outpatient — for whom study drug will be administered, dispensed, or taken.	☐ YES	UMN Policy Clinical Research Using Drugs; FV Policy Ref #12562
A2	Any drug-handling activity (receipt, storage, preparation, dispensing, administration, or return) will occur in Fairview-controlled space — UMMC, Masonic Children's, the Clinics and Surgery Center, the Clinical Research Unit, any FV inpatient unit, or any FV ambulatory clinic.	☐ YES	UMN Policy Clinical Research Using Drugs
A3	Any drug order, dispense, MAR entry, treatment plan, or research medication build will be placed or constructed in Epic (Willow, Beacon) or visible to the participant through MyChart.	☐ YES	FV institutional system policy
A4	The investigational product is, contains, or delivers recombinant or synthetic nucleic acid molecules, a viral vector (e.g., AAV, lentivirus), genetically modified cells, an attenuated infectious agent, or otherwise meets the NIH definition of Human Gene Transfer. Examples: CAR-T, recombinant AAV gene therapy, oncolytic virus, modified-cell therapy.	☐ YES	NIH Guidelines for r/sNA Research; UMN IBC scope
A5	The product appears on the NIOSH List of Hazardous Drugs in Healthcare Settings (2024, DHHS Pub. 2025-103), OR the manufacturer's package insert includes Manufacturer's Special Handling Information (MSHI).	☐ YES	NIOSH 2024 List; USP <800>
A6	The product requires sterile compounding or any preparation step subject to USP <797> (any sterile manipulation beyond a single immediate-use transfer from a labeled vial to a labeled syringe administered without delay).	☐ YES	USP <797>
A7	The product is a Schedule I, II, III, IV, or V controlled substance under the federal Controlled Substances Act or MN Statute 152.02. Controlled-substance research is governed by the UMN Controlled Substances Management policy and Health, Safety & Risk Management (HSRM); the IDS RO process does not authorize or oversee controlled-substance handling.	☐ YES	21 CFR Part 1301; MN Statute 152; UMN Controlled Substances Management policy
A8	The protocol uses a blinded or masked treatment assignment scheme that requires 24/7 emergent unblinding capability for participant safety.	☐ YES	ICH E6(R3) Annex 1 §2.11; 21 CFR 312.61

#	Condition — RO is not available if this applies to your study	Mark	Authority
A9	The product is a radioactive drug, radiopharmaceutical, or PET drug, or the study otherwise falls under Radiation Safety Committee oversight.	☐ YES	21 CFR 361; MN Rules 4731; UMN Radiation Safety
A10	The sponsor, the sponsor's pharmacy manual, or the protocol requires institutional pharmacy management, dispensing-system documentation (e.g., Vestigo, a sponsor-mandated electronic accountability system), continuous temperature monitoring beyond the PI's documented capability, or chain-of-custody records the PI cannot independently produce.	☐ YES	Sponsor protocol / pharmacy manual; 21 USC 360eee

If *all* ten items are NO, continue to Section B. If *any* item is YES, contact IDSPharmacy@Fairview.org to initiate full IDS service.

Section A is the controlling eligibility list. Where Sections D and Appendix A restate these conditions, they do so for convenience; if any conflict arises, Section A governs.

PI attestation: I have reviewed conditions A1 through A10. By initialing, I confirm that none applies to this study (no box above is marked YES). PI initials: _____ Date: _____

Section B — What IDS does that the PI must do under RO

Each row describes a single drug-handling domain and contrasts how it is handled under full IDS service versus how the PI must handle it personally under RO.

Domain	Under full IDS service	Under RO — PI responsibility
Procurement & provenance	IDS orders through DSCSA-compliant wholesalers, verifies authorized trading partners, and retains the Transaction Information / History / Statement (T3) documents required under 21 USC 360eee-1. Investigational (IND) product supplied by a sponsor is tracked under 21 CFR 312.57.	PI verifies the supplier is licensed by the MN Board of Pharmacy as a Non-resident Pharmacy (MN Stat. 151.19) or Out-of-State Wholesale Drug Distributor (MN Stat. 151.47). For commercially marketed Rx drugs the PI procures, DSCSA applies — retain T3 documents for at least 6 years. Investigational (IND) product supplied by a sponsor is outside DSCSA but requires the sponsor's chain-of-custody documentation and PI records per 21 CFR 312.62. OTC products and dietary supplements are outside DSCSA but still require documented provenance.
Receipt & verification	Two-staff verification against shipping manifest; temperature-logger review for cold-chain shipments; entry into the Vestigo dispensing system with manifest upload and double-verification per IDS SOP §10.	PI verifies each shipment against the manifest, documents date received, quantity, lot, expiration, condition; reviews temperature-logger data for cold-chain shipments; retains all manifests.
Secure storage	DEA-rated vault for controlled substances; restricted-access space (keycard + biometric); continuous SonicU temperature/humidity monitoring with dual NIST-traceable probes, 5-minute sampling, 24/7 multi-channel alerting; alarmed forced-entry response.	PI maintains a locked, access-restricted, research-only storage area separated from food and lab specimens; documented temperature monitoring meeting USP <659> for the product's storage class (room temp 20–25 °C, refrigerated 2–8 °C, frozen −25 to −15 °C); written logs reviewed during business days; returned product segregated from new inventory.

Domain	Under full IDS service	Under RO — PI responsibility
Labeling & dispensing	Vestigo-generated dispense labels meeting MN BOP requirements; pharmacist-led order verification in Epic; chemotherapy double-verification; tamper-evident packaging for controlled substances.	Every dispensed unit bears a label with: clinic/practitioner name, address, telephone; prescribing practitioner; participant identifier (PSN); date of dispensing; unique prescription number; directions for use; drug name and study/protocol identifier; manufacturer/distributor; and the auxiliary statement "Caution: New Drug — Limited by Federal Law to Investigational Use" where applicable. Dispensing is performed only by a practitioner, or by a person acting under the practitioner's direction, per MN Stat. 151.37 subd. 2(a).
Records & accountability	21 CFR Part 11–compliant Vestigo audit trail with time-stamped electronic signatures; perpetual electronic inventory with subject-level dispensing records; monthly cycle counts; Vestigo Verify portal for monitor review.	PI maintains a prescription record (filed by number or date) showing patient name and address, date of prescription, drug name and strength, quantity dispensed, directions, practitioner signature (and DEA# where applicable) per MN Rules 6800.3400 / 6800.7700. Perpetual inventory captures batch / serial / kit / vial number, expiration, and the unique participant code that received each unit, per 21 CFR 312.62 and ICH E6(R3) Annex 1 §2.10 and §2.12.
Lot-to-participant traceability	Vestigo links each dispense to lot, kit, and participant; recall search executable in minutes; output exportable to monitor and sponsor.	PI maintains records sufficient to identify, within 24 hours of a recall notice, every participant who received product from a recalled lot, and to contact those participants per the protocol and the IRB-approved recall communication plan.

Domain	Under full IDS service	Under RO — PI responsibility
Returns, destruction & disposal	Institutional regulated-medical-waste contractor; pharmaceutical waste segregated per RCRA P-, U-, and non-listed categories; Certificate of Destruction generated from Vestigo for monitor review.	PI documents all participant returns (date, quantity, condition); coordinates destruction or sponsor return per protocol; segregates pharmaceutical waste per applicable RCRA categories; retains return manifests and destruction documentation. Controlled-substance destruction is by DEA-registered reverse distributor only, documented on DEA Form 41.
Recall response	FDA, sponsor, or manufacturer contacts IDS directly; affected product is immediately quarantined in Vestigo; lot-level participant identification produced within hours.	PI monitors FDA enforcement reports, sponsor notices, and manufacturer recalls; quarantines affected product immediately upon notice; identifies and contacts affected participants; documents the response and notifies sponsor and IRB.
Audit access	Monitor remote access via Vestigo Verify; IDS facilitates on-site monitor visits, FDA inspections, MN BOP inspections, and sponsor audits.	PI personally hosts sponsor monitors, FDA inspectors, MN BOP inspectors, and FV IDS audit staff; produces all source records, storage logs, and procurement documentation on request, including outside normal business hours when required by inspection.
Records retention	Per 21 CFR 312.62(c): 2 years after FDA approval of the drug, or 2 years after IND discontinuation, whichever is later — frequently 7 or more years post-study close.	Same retention horizon, in a location and format that survives PI departure, retirement, sabbatical, or grant closeout. Loss of records before the retention horizon is a reportable compliance event.

Section C — PI responsibilities under RO, in detail

C1. The legal definition of “drug” is broader than most investigators assume.

For purposes of this form and applicable federal and Minnesota law, “drug” includes any product administered to a research participant under the IRB-approved protocol as a study intervention, regardless of whether it is prescription or over-the-counter, an investigational new drug or a commercially marketed product, or a finished pharmaceutical, a dietary supplement, a nutraceutical, or a botanical.

Under the Federal Food, Drug, and Cosmetic Act §201(g)(1)(B)–(C), a product becomes a drug when it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. The intended use under the protocol controls, not the product's marketing category.

Practical consequences:

- A study giving over-the-counter acetaminophen to participants as part of a post-surgical pain protocol is dispensing a drug. All RO responsibilities in Sections B and C apply, including labeling, accountability, and lot-to-participant traceability.
- A study giving curcumin to participants to evaluate effects on inflammation is dispensing a drug.
- A study giving melatonin to participants to evaluate effects on post-operative sleep is dispensing a drug.
- “It is available at Target” is not a defense. Retail availability does not exempt the product from research drug-handling obligations once it is named in the IRB-approved protocol as an intervention.

Whether a given product legally requires an IND is a determination made through the IRB process, not by this form. The University's instrument for that determination is IRB Toolkit Worksheet HRP-306 (Drugs and Biologics Worksheet). For a dietary supplement studied for an effect on a disease, the product is being studied as a drug and an IND may be required; for a supplement studied only for a structure/function effect, it may remain a supplement. Regardless of the IND determination, once the product is named in the IRB-approved protocol as a study intervention, the handling, accountability, and traceability responsibilities in this document apply. When in doubt, complete HRP-306 and consult the IRB and IDS.

C2. Procurement and provenance.

- Supplier must be licensed by the MN Board of Pharmacy as either a Non-resident Pharmacy (MN Stat. 151.19) or an Out-of-State Wholesale Drug Distributor (MN Stat. 151.47). PI retains documentation of the supplier license.
- For commercially marketed prescription drugs the PI procures, the supplier must be DSCSA-compliant and the PI retains the Transaction Information, Transaction History, and Transaction Statement (T3) for at least six years per 21 USC 360eee-1.
- Investigational (IND) product supplied by a sponsor is outside the DSCSA “product” definition; it is governed by 21 CFR 312.57 (sponsor records) and 312.62 (investigator records). The PI retains the sponsor's shipping and chain-of-custody documentation rather than DSCSA T3 records.
- OTC and dietary supplement products fall outside DSCSA but still require documented provenance: manufacturer, lot number, expiration date, purchase date, supplier identity, and quantity received per acquisition.
- Retail purchase of product is permissible only if the protocol explicitly authorizes a retail source and the PI documents lot and source per dispensing event. Even then, retail purchase is discouraged because lot consistency cannot be guaranteed across a study and recall traceability is degraded.

- Procurement from compounding pharmacies, 503B outsourcing facilities, or international sources is not within default RO scope and requires sponsor and IRB pre-authorization plus IDS notification.
- If the PI holds the IND (a sponsor-investigator), additional University obligations apply under the UMN policy University Sponsor and Sponsor-Investigator IND/IDE and FDA Pre-Submission Requirements, including IND/IDE Central File submission.

C3. Storage and security.

- Storage area is locked, access-restricted to named study personnel, and physically separated from clinical care areas, lab specimens, and food.
- Temperature class matches the product's labeled storage requirement per USP <659>: controlled room temperature (20–25 °C), refrigerated (2–8 °C), or frozen (−25 to −15 °C). Tighter ranges per sponsor or manufacturer override these defaults.
- Temperature logs are maintained continuously (electronic preferred). Daily review on business days. Records retained for the full records-retention horizon.
- Refrigerated and frozen product is not stored in the same unit as laboratory specimens or food, even with physical separation.
- Expired, recalled, returned, and quarantined product is segregated from active inventory and clearly labeled.
- Recall, expiration, and retest notices are tracked and acted on within the timeframe required by the sponsor or manufacturer.

C4. Labeling and dispensing.

Per MN Statute 151.212 and MN Rules 6800.1440 / 6800.7700, every dispensed unit bears a label including:

- Name, address, and telephone of the dispensing clinic or practitioner office;
- Prescribing practitioner's name;
- Participant identifier (PSN, subject number, or initials per the IRB-approved scheme — never a full medical record number);
- Date of dispensing;
- Prescription number — unique to the participant and the dispensing event; a visit number plus date is acceptable;
- Directions for use;
- Drug name plus study or protocol identifier;
- Manufacturer or distributor of the finished dosage form (may be on the sponsor's label if already present);
- Auxiliary labels as applicable, including “Caution: New Drug — Limited by Federal Law to Investigational Use” for unapproved investigational products.

Dispensing is performed only by a licensed practitioner, or by a person acting under the practitioner's direction and supervision (nurse, medical student, resident, or appropriately licensed health professional within their scope), per MN Stat. 151.37 subd. 2(a). A practitioner who dispenses for profit must additionally have filed the statement required under MN Stat. 151.37 subd. 2(c). Pharmacy practice law does not permit lay study staff to dispense drugs.

C5. Records, accountability, and lot-to-participant traceability.

- Maintain a prescription record, filed by number or date, showing for each dispensing event: patient name and address, date of prescription, drug name and strength, quantity dispensed, directions for use, and practitioner signature (and DEA# where applicable) per MN Rules 6800.3400 and 6800.7700.

- Maintain a perpetual inventory recording use by each subject: date, quantity, batch / serial / kit / vial number, expiration date, and the unique IP code or kit number per 21 CFR 312.62 and ICH E6(R3) Annex 1 §2.10 (Investigational Product Management) and §2.12 (Records).
- Maintain shipping manifests, receipt-of-order confirmations, and confirmations of medication returned to sponsor.
- Maintain copies of sponsor medication requests (orders and re-orders).
- Maintain records of any drug returned to sponsor or destroyed.
- Retain all of the above per 21 CFR 312.62(c): two years after FDA approval of the marketing application referenced in the IND, or two years after the IND is discontinued, whichever is later. In practice this frequently exceeds seven years from study close. Records must remain accessible across PI departure, retirement, sabbatical, or grant closeout.

C6. Returns, disposal, and destruction.

- Participant returns are recorded by date, identity of the returning person, quantity returned, and condition. Empty containers are counted in the return event.
- Returned product is segregated from active inventory and clearly marked.
- Destruction or return-to-sponsor is performed per the protocol. The PI documents destruction with date, witness, quantity, and method. Pharmaceutical waste is segregated per applicable RCRA P-list, U-list, and non-listed categories and routed through a regulated medical waste pathway.
- Hazardous-drug waste (NIOSH-listed product, hazardous-handling-flagged product) requires RCRA-compliant disposal; if this disposal stream is not available to the PI, the study is not eligible for RO.
- Controlled-substance destruction is performed only via a DEA-registered reverse distributor and documented on DEA Form 41 per 21 CFR 1317.

C7. Recalls.

- PI subscribes to applicable FDA recall notifications and sponsor product-quality communications.
- Upon notice of a recall affecting any lot received under the study, PI immediately quarantines all affected product, identifies the participants who received product from the affected lot using the perpetual inventory and prescription record, and follows the protocol's recall communication plan and IRB notification requirements.
- The recall response is documented and retained with the study records.

C8. Blinding (if applicable).

- The blinding mechanism is described in writing, including who holds the unblinding key, where the key is stored, and how the unblinding workflow is initiated.
- Emergent unblinding capability is available 24 hours per day, 7 days per week, in a timely manner.
- Unblinding events are documented (requestor identity, recipient, rationale, date, time) and reported promptly to the sponsor.
- Loss of blinding integrity is reported to the sponsor and IRB per the protocol.

C9. Adverse events and protocol deviations related to drug handling.

Drug-handling errors are reportable. Examples include: wrong product dispensed, wrong dose, wrong participant, missed dose, temperature excursion, expired or recalled product dispensed, lost or stolen product, and any preparation or administration deviation. The PI reports these events to the sponsor and the IRB per the protocol and per 21 CFR 312.64.

C10. Audit access.

By signing this form, the PI authorizes inspection of drug-handling records, procurement documentation, storage areas, dispensing logs, return records, and destruction documentation by:

- Fairview Investigational Drug Services;
- Fairview Research Administration (FRA);
- The University of Minnesota Research Integrity and Compliance office (RIC), as authorized under the UMN Clinical Research Using Drugs policy;
- The study sponsor and the sponsor's designated monitors;
- The Institutional Review Board of record;
- The Minnesota Board of Pharmacy, the U.S. Food and Drug Administration, and the U.S. Drug Enforcement Administration as applicable.

Section D — Special categories

If your study involves any of the following product categories, additional restrictions apply. Note that conditions A4 through A9 above already exclude these from RO eligibility; this section exists to make the rules explicit.

D1. Controlled substances (Schedule I–V).

RO is not available for studies involving controlled substances. Controlled-substance research at the University is governed by the UMN *Controlled Substances Management* policy and Health, Safety & Risk Management (HSRM), under a DEA registrant / authorized-user structure that IDS does not administer. The IDS RO process does not authorize, register, or oversee controlled-substance handling.

An investigator whose study requires a controlled substance must work through HSRM (not the IDS RO form) and, separately, contact IDS to determine whether full IDS service is required. The HSRM framework requires, among other things: a department-appointed DEA registrant and authorized users; secure storage (Schedule II in a DEA-compliant safe or cabinet per 21 CFR 1301.71/1301.75); separate disposition records and the DEA biennial inventory; ordering of Schedule I–II via DEA Form 222 or CSOS; reporting of theft or significant loss to DEA (Form 106) and the MN Board of Pharmacy; and destruction only via a DEA-registered reverse distributor (DEA Form 41, 21 CFR 1317).

Primary HSRM contact for controlled substances: Sabine Fritz (612-625-7227). See the UMN Controlled Substances Management policy and the HSRM controlled-substances resources linked in the References.

D2. Hazardous drugs (USP <800>, NIOSH 2024 List).

RO is not available if the product is on the NIOSH List of Hazardous Drugs in Healthcare Settings, 2024 (DHHS Pub. 2025-103), or if the manufacturer's package insert includes Manufacturer's Special Handling Information. Hazardous drug handling requires engineering controls (biological safety cabinet, compounding aseptic containment isolator, or containment ventilated enclosure), USP <800>–compliant facility design, RCRA-compliant pharmaceutical waste streams, and occupational exposure surveillance that are not available outside IDS infrastructure.

D3. Biohazardous agents and Human Gene Transfer.

RO is not available if the product meets the NIH definition of Human Gene Transfer (deliberate transfer of recombinant or synthetic nucleic acid molecules into human research participants — including CAR-T cell therapies, recombinant AAV, attenuated infectious agents, and antisense oligonucleotide therapies that meet the criteria), or otherwise involves potentially hazardous biological agents (live or attenuated virus, viral vector, genetically modified cell, biologically-derived toxin).

These products require University of Minnesota Institutional Biosafety Committee (IBC) review and approval prior to initiation per UMN Board of Regents Policy on Recombinant DNA, the UMN administrative biosafety policy, the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, and the BMBL. Preparation and dispensing of these products occur within IDS ISO 7 cleanroom space using closed-system isolators.

D4. Radioactive drugs, radiopharmaceuticals, and PET drugs.

RO is not available for radioactive drugs, radiopharmaceuticals, or PET drugs. These are excluded from the DSCSA “product” definition and fall under separate radiation-safety oversight (UMN Radiation Safety Committee / Department of Radiation Safety) and applicable FDA (21 CFR 361) and MN (Rules 4731) requirements. Contact Radiation Safety and IDS.

Section E — Acknowledgment

By signing below, the Principal Investigator acknowledges:

- I have read this document in full, including Sections A through D and the references.
- I have completed the Section A eligibility self-screen truthfully. No condition listed in A1–A10 applies to this study at signing.
- If any condition listed in A1–A10 becomes applicable during the study — through protocol amendment, scope change, change of enrollment population, or change of study location — I will notify IDS immediately at IDSPharmacy@Fairview.org to transition the study to full IDS service.
- I assume personal responsibility for the responsibilities described in Sections B, C, and D (as applicable) for the duration of the study and the records-retention period that follows.
- I authorize the audit access described in Section C10.
- I understand that failure to meet these responsibilities may result in study suspension or termination by the IRB, regulatory citation, loss of institutional privileges, referral for academic misconduct review, or reporting to external licensing authorities, per the UMN Clinical Research Using Drugs policy.

Study identifiers

IDS # (assigned by Fairview IDS): _____

OnCore # / Protocol #: _____

ETHOS / IRB #: _____

Sponsor: _____

Study title: _____

Principal Investigator signature

Printed name: _____

Title / role: _____

Department: _____

Signature: _____

Date: _____

Fairview IDS use only

Received and reviewed by: _____

Date: _____

IDS # assigned: _____

Notes: _____

References and resources

Federal

- 21 CFR Part 312 (Investigational New Drug Application) — https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312
- 21 CFR 312.60–312.69 — investigator responsibilities; 312.62 — recordkeeping and record retention
- 21 CFR Part 1301 (DEA registration of manufacturers, distributors, dispensers, researchers) — https://www.ecfr.gov/current/title-21/chapter-II/part-1301
- 21 CFR Part 1317 (Disposal of controlled substances) — https://www.ecfr.gov/current/title-21/chapter-II/part-1317
- Drug Supply Chain Security Act (21 USC 360eee–eee-4) — FDA overview — https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa
- Federal Food, Drug, and Cosmetic Act §201(g) — definition of “drug” (21 USC 321(g))

International (ICH)

- ICH E6(R3) Good Clinical Practice (Step 4, 6 Jan 2025) — https://database.ich.org/sites/default/files/ICH_E6(R3)_Step4_FinalGuideline_2025_0106.pdf
- Investigator obligations: Annex 1 §2.10 (Investigational Product Management), §2.11 (Randomisation Procedures and Unblinding), §2.12 (Records). The parallel sponsor provisions are at §3.15 (Investigational Product(s)).

Minnesota state law and rules

- MN Statute Chapter 151 — Pharmacy Practice and Wholesale Distribution Act — https://www.revisor.mn.gov/statutes/cite/151
- MN Stat. 151.01 — definitions — https://www.revisor.mn.gov/statutes/cite/151.01
- MN Stat. 151.19 — Nonresident pharmacy — https://www.revisor.mn.gov/statutes/cite/151.19
- MN Stat. 151.37 — Legend drugs; who may prescribe, possess, dispense — https://www.revisor.mn.gov/statutes/cite/151.37
- MN Stat. 151.47 — Wholesale drug distributors — https://www.revisor.mn.gov/statutes/cite/151.47
- MN Stat. 151.212 — Prescription drug label — https://www.revisor.mn.gov/statutes/cite/151.212
- MN Statute Chapter 152 — Controlled Substances — https://www.revisor.mn.gov/statutes/cite/152
- MN Rules Chapter 6800 — Board of Pharmacy — https://www.revisor.mn.gov/rules/6800/

Standards

- USP <659> Packaging and Storage Requirements
- USP <797> Pharmaceutical Compounding — Sterile Preparations
- USP <800> Hazardous Drugs — Handling in Healthcare Settings
- NIOSH List of Hazardous Drugs in Healthcare Settings, 2024 (DHHS Pub. 2025-103) — https://www.cdc.gov/niosh/docs/2025-103/default.html

NIH and DEA

- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules — https://osp.od.nih.gov/biotechnology/nih-guidelines/
- DEA Researcher's Manual — https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-057)(EO-DEA217)_Researchers_Manual_Final_signed.pdf

University of Minnesota

- UMN Administrative Policy: Clinical Research Using Drugs — https://policy.umn.edu/research/investigationaldrugs
- UMN Policy Appendix: Using Drugs for Clinical Research — Requirements for Drug Management — https://policy.umn.edu/research/investigationaldrugs-appa
- IRB Toolkit Worksheet HRP-306: Drugs and Biologics Worksheet (drug/biologic determination) — https://research.umn.edu/units/irb/toolkit-library/worksheets
- UMN Administrative Policy: University Sponsor and Sponsor-Investigator IND/IDE and FDA Pre-Submission Requirements — https://policy.umn.edu/research/indide
- UMN Administrative Policy: Controlled Substances Management — https://policy.umn.edu/research/controlledsubstance
- UMN HSRM: Controlled Substances in Research (contact: Sabine Fritz, 612-625-7227) — https://hsrm.umn.edu/research-safety/controlled-substances-research
- UMN OBAO: Institutional Biosafety Committee (IBC) — https://research.umn.edu/units/obao/research-oversight-areas/institutional-biosafety-committee-ibc-0
- UMN OBAO: Clinical Trials and the IBC — https://research.umn.edu/units/obao/research-oversight-areas/clinical-trials-and-ibc

Fairview

- FV Policy Ref #12562 — Investigational Drugs
- Fairview IDS Pharmacy SOPs and Policies (current version available from IDS upon request)
- Contact: IDSPharmacy@Fairview.org

Appendix A — RO eligibility decision tree

Work through the steps in order. Stop at the first YES.

Step 1. Will any Fairview-affiliated participant (inpatient OR outpatient) receive study drug?

If YES → Full IDS service required. Stop here.
If NO → Continue to Step 2.

Step 2. Will any drug-handling activity occur in Fairview-controlled space (UMMC, MCH, CSC, CRU, infusion, any FV inpatient unit or FV ambulatory clinic)?

If YES → Full IDS service required. Stop here.
If NO → Continue to Step 3.

Step 3. Will any drug order, dispense, treatment plan, or research medication build be placed or built in Epic (Willow, Beacon) or shown in MyChart?

If YES → Full IDS service required. Stop here.
If NO → Continue to Step 4.

Step 4. Is the product a cell or gene therapy, viral vector, recombinant or synthetic nucleic acid molecule, genetically modified cell, or attenuated infectious agent (any Human Gene Transfer product)?

If YES → Full IDS service AND UMN IBC review required. Stop here.
If NO → Continue to Step 5.

Step 5. Is the product on the NIOSH 2024 hazardous drug list, or does the package insert specify hazardous handling (MSHI)?

If YES → Full IDS service required. Stop here.
If NO → Continue to Step 6.

Step 6. Does the product require sterile compounding or USP <797> preparation?

If YES → Full IDS service required. Stop here.
If NO → Continue to Step 7.

Step 7. Is the product a Schedule I–V controlled substance?

If YES → RO is not available. Controlled-substance research is governed by the UMN Controlled Substances Management policy and HSRM, not the IDS RO process. Contact HSRM and IDS.
If NO → Continue to Step 8.

Step 8. Is the product a radioactive drug, radiopharmaceutical, or PET drug?

If YES → RO is not available. Contact Radiation Safety and IDS.
If NO → Continue to Step 9.

Step 9. Is the study blinded with a 24/7 emergent-unblinding requirement?

If YES → Full IDS service required. Stop here.
If NO → Continue to Step 10.

Step 10. Does the sponsor require institutional pharmacy management, sponsor-system documentation (e.g., Vestigo, a sponsor-mandated electronic accountability system), or chain-of-custody records the PI cannot independently produce?

If YES → Full IDS service required. Stop here.
If NO → RO may be permissible. Complete and sign Sections A–E.

Document control

Owner: Dustin Kakach, PharmD, IDS Manager Effective date: _____ Next review: _____ Approved by: _____ (per FV governance)