Investigational Drug Service Registered Only (RO) Form

University of Minnesota Medical Center, Fairview
Department of Pharmaceutical Services

****All Drug and Biological Product studies must, at a minimum be registered with the Investigational Drug Service (IDS), 612-273-6212. This is true whether the Drug or Biological Product is approved or not. The number assigned by the Investigational Drug Service must be submitted to the IRB in order to receive final approval for this study. ****

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1. **Study title:**

2. **Sponsor name and protocol number:**

3. **Study Medication(s) and dosages *(Ok to provide final protocol to IDS for reference*):**

4. **PI contact information:**

5. **Study coordinator contact information:**

6. **Is the IDS Pharmacy coordinating the dispensing of study medication, either IND drug or commercially available medication that will be charged to the study?**

   ☐ **Yes –** ***Submit TASCS request to obtain quote for IDS Service. This form is not needed.***

   ☐ **No**

   Check the box indicating who will dispense the study medication.

   ☐ Study medication(s) is/are all commercial medications and will be dispensed by a licensed pharmacy. Drug(s) will be charged to the patient/insurance. ***No additional information needed to be provided, submit to IDS***

   ☐ Study medication(s) will be dispensed by physician. **(If study medication(s) will be dispensed by a physician, please complete ALL of section 7).**

7. Study Medication Storage, Labeling and Dispensing (complete only if medication will not be dispensed by a licensed pharmacist):

A. Per Minnesota Statute: If medication is not dispensed by a pharmacist, 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). List the person(s), along with their degree (and who they have a written practice agreement with – if applicable), responsible for dispensing medication to the patient:

B. Good Clinical Practice (GCP) requires medication to be stored at the proper temperature. To meet expectations, GCP also requires that the daily temperatures be monitored and recorded

a. What are the temperature requirements for storage of study medications?

i. Room temperature (20-25°C or 68-77°F): ☐

ii. Refrigerator temperature (2-8°C or 36-46°F): ☐

iii. Freezer temperature (-20°C): ☐

iv. Ultra-low freezer temperature (-70 to -80°C): ☐

b. Please indicate which recording method is used to record daily temperatures:

i. Chart recorder: **Yes** ☐ **No** ☐

ii. Minimum/maximum thermometer: **Yes** ☐ **No** ☐

iii. Other (explain):

c. If medication is stored at refrigerator or freezer temperatures:

i. Is there a back-up power source in the event of a power outage?
Yes ☐ **No** ☐

ii. Is the refrigerator or freezer alarmed to alert staff in the event of a power outage?
Yes ☐ **No** ☐

iii. **Medications may not be stored in a refrigerator or freezer that contains food or lab samples – the only thing allowed to be stored in the refrigerator or freezer is medication. Confirm medication will be stored in a dedicated medication storage refrigerator:**
Yes ☐ No ☐

C. **Per Minnesota Board of Pharmacy Rules medications need to be stored in a separate locked drug storage area. Access shall be limited to persons who have legal authority to dispense and to those under their direct supervision. Provide information on storage and access of study medication:**

D. **Is the study medication blinded?**
No ☐
Yes ☐ Emergency Unblinding: In the event of an emergency how will the contents of a drug container be identified? This information is expected to be available 24 hours a day/7 days a week (24/7) in a timely manner – EXPECTED TURN-AROUND TIME FOR THE UNBLINDING PROCESS TO BE COMPLETED IS 20 TO 30 MINUTES.

a. **Explain the process to be followed – including the telephone numbers and contact information – to unblind a subject in the event of an emergency.**

b. **How will the subject know who to contact in the event of an emergency? How is this information going to be provided to the subject (this information may be provided in the consent form – but also must be provided in an additional manner):**
Examples of acceptable methods: the emergency unblinding contact number is printed on the medication bottle dispensed to the patient/subject; OR the patient/subject is given a wallet card with emergency unblinding contact information; OR the patient/subject is given the study team/PI's 24/7 contact telephone number.

E. Labeling of study medication: In addition to the Federal requirements for proper labeling of study medication, Minnesota State Board of Pharmacy rules and statutes must also be followed. Some of the information may be on the sponsor's label. Additional information will need to be affixed to the drug container. The following information must be on the medication container dispensed to the subject/patient:

a. **Name, address, and telephone number of clinic of physician's office**
b. **Prescribing physician's name**
c. **Patient's name – may be initials or subject number**
d. **Date of dispensing**
e. **'Prescription number' – may be a visit number with a date – has to unique to the patient and the patient's visit**
f. **Directions for use**
g. **Drug name or study name or protocol name or protocol number**
h. **Name of manufacturer or distributor of finished dosage form**
i. **Any necessary auxiliary labels**
j. **A 'prescription order' must be made – this is in addition to any notes/records made in the patient's chart.**

Verify that all the above information is on the drug container:

Yes ☐ No ☐

Complete the above form and email to idspharmacy@fairview.org to obtain an IDS RO number.

FOR IDS USE ONLY

IDS # _____ DATE: _____ STAFF INT: _____

Note: Returned to Investigator with copy of IDS developed 'Investigator Dispensing and Study Drug Management Requirements' document.

PLEASE NOTE: in addition to Sponsor, State, and Federal Rules and Regulations regarding the conduction of studies, the PI is also responsible for Minnesota State Statutes and Rules regarding the labeling and dispensing of legend drugs. Please refer to 'Investigator Dispensing and Study Drug Management Requirements'.