DAIT PHARMACY ESTABLISHMENT PLAN (FORM A)

The Pharmacy Establishment Plan should be completed by the Pharmacist of Record (PoR) for each participating DAIT-funded/sponsored clinical research site and submitted directly to the DAIT Project Manager (PM) for review and approval. Pharmacy Establishment Plan approval will always be required before a site can receive investigational products (IPs) from the DAIT Clinical Products Center (CPC) or other sources as determined by the protocol. The signed copy must be sent to the PM for filing in the clinical study file, and copies of the official document will be filed in the pharmacy binder and SECDs.

The pharmacist at each DAIT-funded/sponsored clinical research site, designated as the PoR, is the primary individual who is responsible for performing the day-to-day dispensing and accountability activities; establishing internal policies and procedures for developing and maintaining an IP management system, which includes the technical procedures for product ordering, adequate and safe receipt, handling, storage, dispensing, retrieval of unused products from subjects, and disposition or return of IPs and the documentation thereof; and the implementation of this document. The PoR is encouraged to work with other staff members to coordinate the logistics required for the conduct of clinical trials.

If there are any changes in pharmacy information after PM approval of the site's DAIT Pharmacy Establishment Plan, the Notification of Change form should be completed and submitted immediately to the PM for further assessment and approval *(See Forms A, B, C).* These forms are to be used in place of a revised Pharmacy Establishment Plan; however, upon review by the PM, submission of a revised DAIT Pharmacy Establishment Plan may be required for approval.

In the event that the Pharmacist is responsible for the dispensing of IPs to participants enrolled on protocols at another site (hospital or clinic), a letter describing the dispensing procedures must be co-signed by the Institutional Review Board (IRB) Chairman and the Director of Pharmacy at the other site. This letter serves to document the concurrence of these individuals with the proposed plan for dispensing of IPs to participants at that site. This letter also serves to notify the DAIT that all parties have been properly notified of these procedures.

The following MUST be submitted to the PM:

- ☐ Completed Pharmacy Establishment Plan
- ☐ *Curriculum Vitae* (CV) of the Pharmacist of Record and Back-up Pharmacist
- ☐ Pharmacy Standard Operating Procedures (SOP). If site is unable to provide copies, the SOPs must be reviewed by sponsor during the qualification or initiation visit.

Please sign and date below, and attach this cover sheet with the applicable documents for your submission.

_____ _____

Signature of Pharmacist of Record **Date (MM/DD/YY)**

A. Background Information of Personnel/ Pharmacist

1. Name, mailing address, and site number (if available) of the clinical research site.

2. Name, degree, title or position, pharmacy site mailing address, email address, telephone, and fax number(s) of the Pharmacist of Record (PoR) who is responsible for this Pharmacy Establishment Plan. Note: For all pharmacy-related correspondence, provide the shipping address where all IPs will be shipped.

3. Provide the address for the physical location of the research pharmacy if different from the pharmacy site mailing address or shipping address.

4. Name, degree, title or position, pharmacy site mailing address, email address, telephone, and fax numbers of the Back-up Pharmacist who will assume these responsibilities when the PoR is not available.

5. List other pharmacy staff, under the direct supervision of the PoR, who may assist with the day-to-day activities devoted to DAIT-sponsored protocols. Please include their credentials. Make sure they get all the required trainings and include them in the delegation log.

6. Who does the PoR report to? Please include name and credentials (attach an organizational chart if available).

B. General Policies and Procedures

1. Attach any written pharmacy policies and procedures for handling IPs such as:

   a. Validation and calibration of storage equipment (refrigerators and freezers).

   b. Back-up plan for equipment malfunction or power failure.

   c. Maintaining the cold chain including continuous monitoring and recording, alarms, and security.

   d. Transport of IPs to satellite or study site(s).

   e. Temperature excursions and communication with the sponsor.

   f. Preparation and dispensing of IP.

   g. Pharmacy quality assurance (QA) and quality management (QM) processes.

   h. Investigational product return and destruction.

2. Describe the system for organizing protocol information, such as: the current IRB-approved version of the protocol, Letters of Amendments, Clarification Memos, randomization lists, order forms, packing slips, accountability records, prescriptions, return records, letters and memos from DAIT, Investigator's Brochures, package inserts, etc.

   a. Describe the process for keeping this information up to date, where it will be located, and who will have access.

3. How is the PoR informed of the IRB approval of a protocol? How does the PoR verify that s/he is working with the current IRB-approved version of a protocol?

4. How is an authorized prescriber identified for a protocol to prevent the unauthorized prescribing of IPs?

5. Which procedures are followed by the PoR to maintain confidentiality of a participant's pharmacy file and the IP accountability records?

6. Does the pharmacy utilize a computerized study drug system, for example, for accountability records, inventory, study information, or medication order entry?
   ☐ Yes ☐ No

If yes, does the system meet all requirements of 21 CFR part 11? ☐ Yes ☐ No

7. Will the PoR be involved in participant consultation and/or counseling?
   ☐ Yes ☐ No
   Please describe.

C. General Information on Facilities for Control of Investigational Product

1. Is there a biological safety cabinet or an isolator available that can be used solely for preparing IP? ☐ Yes ☐ No

2. Is there a sink or washbasin available in the pharmacy where equipment and other utensils can be washed? ☐ Yes ☐ No

3. Is there a suitable source of hand washing facilities available? ☐ Yes ☐ No

4. In the event that power is lost or a black-out occurs, please describe the back-up or generator system.

5. Which mechanisms are in place to notify the PoR of any temperature deviations in the storage areas when pharmacy staff is present?

6. Which mechanisms are in place to notify the PoR of any temperature deviations in the storage areas when pharmacy staff is not present?

7. Are certification, validation, and/or maintenance performed on the equipment on a regular basis? ☐ Yes ☐ No

8. When was the last certification/validation/maintenance done on any of the equipment described?

    a. Refrigerator(s)

    b. Freezer(s)

    c. Biological safety cabinet(s)

    d. Generator(s)

    e. Temperature monitoring device(s)

    f. Are the IPs stored in more than one room/area or building? ☐ Yes ☐ No
    Please list.

    g. Describe the current pharmacy area and any other rooms/areas, listed above, that may be used for IP storage. Include physical location, dimensions, floor plans, and pictures if available.

Instructions for completing Section D1 through D4:

If more than one room/area or building is listed in question A1, make additional copies of questions D1-D4 and answer independently. Please title the additional copies according to the area being described.

D1: Room Temperature Storage [20ºC to 25ºC (68ºF to 77ºF)]

a. Describe the current type of storage for the IPs (e.g., cabinets, shelving, etc.)

b. Who will have access to these storage areas?

c. Who will have access to the IPs in these areas?

d. How will access to the IPs be limited to only those listed in c) above?

e. At what temperature range is the storage area(s) maintained?

f. Is there continuous temperature monitoring of the storage area(s) 24 hrs. per day, 7 days per week)? ☐ Yes ☐ No
Please describe.

g. How is the temperature monitoring documented for the storage area(s)?

h. How is the humidity monitored and controlled where the IPs are stored?

i. What is the back-up storage plan for storage unit failure?

j. How will the active *vs*. placebo IP storage be separated?

k. If prescriptions are received and IPs are prepared by the pharmacist prior to a participant's visit and sent to the clinic, where in the clinic will the prepared IPs be stored?

l. Who will have access to these prepared IPs?

m. How will access to the IPs be limited to only those listed in b) above?

D2: Refrigerated Storage, Controlled Cold Temperature [2ºC and 8ºC (36ºF and 46º F)]

a. Is there a pharmacy refrigerator available that can be used solely for IP storage?
☐ Yes ☐ No

b. Where is the refrigerator located?

c. Who will have access to the refrigerator?

d. How will access to the refrigerator be limited to only those listed in c) above?

e. At what temperature range is the refrigerator maintained?

f. Does the pharmacy refrigerator(s) have a continuous temperature monitoring system (24 hours per day, 7 days per week)? ☐ Yes ☐ No
Please describe.

g. How is the temperature monitoring documented for the refrigerator(s)?

h. Is there a method of differentiating each shipment separately in the storage area? ☐ Yes ☐ No

i. What is the backup storage plan for storage unit failure?

j. How will the active *vs*. placebo IP storage be separated?

k. How will access to the IPs be limited to only those listed in c) above?

l. If prescriptions are received and IPs that require refrigeration are prepared by the pharmacist prior to a participant's visit and sent to the clinic, will refrigeration be available in the clinic? ☐ Yes ☐ No

m. Who will have access to these prepared IPs in the refrigerator?

D3: Freezer Storage (Only answer the following "Freezer" questions if the study IP is stored in the freezer)

a. Freezer Storage: Is there a -20°C to -10°C (-4°F to 14°F) pharmacy freezer available that can be used solely for IP storage? ☐ Yes ☐ No

b. Where is the freezer located?

c. Is this a cycling (frost-free) or non-cycling freezer?

d. Who will have access to the freezer?

e. How will access to the freezer be limited to only those listed in d) above?

f. What is the minimum temperature and maximum temperature that can be set on the freezer?

g. At what temperature range is the freezer maintained?

h. Does the pharmacy freezer(s) have a continuous temperature monitoring system (24 hours per day, 7 days per week)? ☐ Yes ☐ No
Please describe.

i. How is the temperature monitoring documented for the freezer(s)?

j. Is there a method of differentiating each shipment separately in the storage area?
☐ Yes ☐ No

k. What is the backup storage plan for storage unit failure?

l. How will the active *vs.* placebo investigational product storage be separated?

m. If prescriptions are received and IPs that require refrigeration are prepared by the pharmacist prior to a participant's visit and sent to the clinic, will refrigeration be available in the clinic? ☐ Yes ☐ No

n. Who will have access to these prepared IPs in the refrigerator?

o. How will access to the IPs be limited to only those listed in n) above?

D4: Minus 70°C Freezer Storage

a. Is there a -70°C pharmacy freezer available that can be used solely for IP storage?
☐ Yes ☐ No

b. Where is this -70°C freezer located, and what are the interior dimensions?

c. Who will have access to the -70°C freezer?

d. How will access to the -70°C freezer be limited to only those listed in c) above?

e. What is the minimum temperature and maximum temperature that can be set on the freezer?

f. At what temperature range is the -70°C freezer maintained?

g. Does the pharmacy freezer(s) have a continuous temperature monitoring system (24 hours per day, 7 days per week)? ☐ Yes ☐ No
Please describe.

h. How is the temperature monitoring documented for the freezer(s)?

i. Is there a method of differentiating each shipment separately in the storage area?
☐ Yes ☐ No

j. What is the backup storage plan for storage unit failure?

k. How will the active *vs.* placebo investigational product storage be separated?

l. If prescriptions are received and IPs that require refrigeration are prepared by the pharmacist prior to a participant's visit and sent to the clinic, will refrigeration be available in the clinic? ☐ Yes ☐ No

m. Who will have access to these prepared IPs in the -70°C freezer?

n. How will access to the IPs be limited to only those listed in m) above?

E. Investigational Product (IP) Dispensing (Activities)

1. The PoR is required to keep complete written records (accountability records) of all IPs that are received, and all IPs that are dispensed to participants. The count or quantity of IPs that you have at the pharmacy must match the quantity on the accountability records at all times. At a minimum, a physical inventory must be done and documented once per month. Please describe how this will be documented.

2. An authorized prescriber who is listed on the FDA form 1572 for IND studies or an authorized prescriber's list for non-IND studies must sign a written prescription at the time that a participant is registered/randomized to the protocol, or when there is a change in treatment, in order for the pharmacist to dispense IPs. How will the PoR receive this written prescription? If electronic prescriptions are used, describe this process.

3. Describe the step-by-step procedure followed from the time a prescription is received in the pharmacy to when the IP is dispensed for a participant.

4. How will the PoR ensure that an informed consent form was signed by a participant prior to dispensing the IP(s)?

5. How will the PoR be informed that subsequent prescriptions/refills need to be prepared (if applicable)?

6. How will IPs be delivered to the participant for follow-up visits?

7. Once a dose is changed, the PoR must receive a written prescription before dispensing medication. How will the PoR receive this written prescription?

8. How will the PoR dispense the IPs? (check all that apply)

   ☐ Directly to participants

   ☐ Deliver IPs to other healthcare providers who will distribute it to participants

   ☐ Through other procedures (describe)

9. How will the PoR receive IP returned by the participant? (check all that apply)

   ☐ Directly from participants

   ☐ From other healthcare providers

   ☐ Through other procedures (describe)

10. If the IP is not immediately returned to the pharmacy once received from the participant, please describe the area where product returns will be segregated and quarantined. Who has access to this area?

The PoR is responsible for ensuring that all the information s/he has provided in the DAIT Pharmacy Establishment Plan is followed, and that the procedures and operations outlined are in compliance with local laws, regulations, and professional practice standards.

_____ _____

Signature of Pharmacist of Record **Date (MM/DD/YY)**

NOTE: This document will not be approved without the PoR's dated signature. A copy of the PoR's and the Back-up Pharmacist's curriculum vitae should be included with this document. A copy of this completed, signed, and dated DAIT Pharmacy Establishment Plan must be kept on file in the pharmacy.

I have on file a copy of the "Investigational Product & Pharmacy Guidelines," dated _____, which I have read and understand. I will follow these guidelines to maintain standardization and quality.

_____ _____

Signature of Pharmacist of Record **Date (MM/DD/YY)**

Return to:

Email: **DAIT Project Manager's email and/or hamrahsd@niaid.nih.gov**

OR

FAX: **301-402-2571**

OR

U.S. Postal Mailing Address: **DAIT Project Manager**
DAIT/NIAID
5601 Fishers Lane Room #7D30
Bethesda, MD 20892 ***(for U.S. mail)***
Rockville, MD 20852 ***(for courier deliveries)***
U.S.A.