Division of AIDS (DAIDS), Pharmaceutical Affairs Branch (PAB)
Pharmacy Establishment Plan

The Pharmacy Establishment Plan must be completed by the Pharmacist of Record for each participating DAIDS-Funded Clinical Research Site, and submitted directly to the DAIDS Pharmaceutical Affairs Branch (PAB) for review and approval. Pharmacy Establishment Plan approval will always be required before a site can receive study products from the DAIDS Clinical Research Products Management Center or other source as determined by the protocol.

The pharmacist at each DAIDS-Funded Clinical Research Site, designated as the Pharmacist of Record (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 a study product management system, which includes the technical procedures for product ordering, adequate and safe receipt, handling, storage, dispensing, retrieval of unused product from subjects, and disposition of study products 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.

In the event that the Pharmacist is responsible for the dispensing of study products to participants enrolled on protocols at another site (hospitals and clinics), 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 study products to participants at that site. This letter also serves to notify the DAIDS that all parties have been properly notified of these procedures.

A Notification of Change must be completed and submitted to the DAIDS PAB, if there is a change in the document after it is approved. Go to:

- page 9, for change of PoR
- page 10, for change of Back-up Pharmacist
- page 11, for change in Pharmacy Address or Contact Information
- page 12, for change in SECTION B: Study Product Control (Facilities)

The following is being submitted to PAB:

- ☐ Completed Pharmacy Establishment Plan
- ☐ Curriculum Vitae (CV) of PoR and Back-up Pharmacist
- ☐ Pharmacy Standard Operating Procedures (SOP)
- ☐ Notification of Change Form

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

_____ _____

Signature of Pharmacist of Record Date (dd/mmm/yy)

If you have any questions, contact Ana I. Martinez, R.Ph, Chief, Pharmaceutical Affairs Branch or other branch staff at (01)-301-496-8213.

A. Background (Personnel/Pharmacist)

1. Name, mailing address and site number (if available) of the clinical research site for this Pharmacy Establishment Plan.

   Kilimanjaro Christian Medical Centre
   P.O. Box 3010
   Moshi, Tanzania
   ACTG Site 12901
   IMPAACT Site 12901

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: All pharmacy related correspondence will be sent to the contact information provided.*

   Eva Prosper Muro, BPharm, MS
   Head, Pharmacy Department
   Kilimanjaro Christian Medical Centre
   P.O. Box 3010
   Moshi, Tanzania
   muroeva@hotmail.com
   Telephone: +255 27 275 0008
   Mobile: +255 784 468 553
   Fax: +255 27 275 0008.

   a. Where in the pharmacy is the telephone located?

      Eva Muro's office

   b. Where in the pharmacy is the fax machine located?

      Eva Muro's office

   c. Where in the pharmacy is the printer located?

      Eva Muro's office

   d. Where in the pharmacy is the computer used to access email located?

      Eva Muro's office

3. Provide the shipping address where all study products will be shipped.

   Eva Prosper Muro
   Pharmacy Department
   Kilimanjaro Christian Medical Center
   P.O. Box 3010

Sokoine Road
Moshi, Tanzania

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

   Same as shipping address

5. 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.

   Mr. Lucas Chagula, BPharm
   Pharmacist
   Kilimanjaro Christian Medical Centre
   P.O. Box 3010
   Moshi, Tanzania
   Luhya08@yahoo.com
   Telephone: 255 754 344 339
   Fax: +255 27 275 0008

   Dr. Elton Kisanga, BPharm, PhD
   Pharmacist
   Kilimanjaro Christian Medical Centre
   P.O. Box 3010
   Moshi, Tanzania
   ekisanga@yahoo.com
   Telephone: +255 754 066 345
   Fax : +255 27 275 0008

6. List other pharmacy staff**,** under the direct supervision of the Pharmacist of Record, who may assist with the day to day activities devoted to DAIDS Sponsored protocols. Please include their credentials.

   Mr. Faustin Nassoro Sasi, Pharmaceutical Technician

7. Who does the PoR report to? Please include name and credentials.

   Dr. Mark Swai, MD
   Director Hospital Services

8. Attach any written pharmacy policies and procedures for handling study products.

9. Describe the system for organizing protocol information; for example, the current IRB approved version of the protocol, Letters of Amendments, Clarification Memos, randomization lists, order forms, packing slips, accountability records, written, prescriptions, return records, letters and memos from DAIDS, Investigator's Brochures, package inserts, etc.

Protocol information is organized in protocol specific notebooks containing the following sections (new materials placed uppermost in each section):

a) Master Subject Log

Includes the patient identification number (PID), the subject identification number (SID), the patient's name and date enrolled in the study.

b) Protocol

Includes the current IRB approved version of the protocol and amendments. The pharmacist places the active version of the protocol in the study binder and shreds the old version of the protocol. All previous versions are available through the regulatory coordinator who stores these documents in compliance with DIADS, GCP, and site specific SOPs.

c) Pharmacy Procedures

Pharmacy procedures specific to the protocol.

d) Forms and Labels

Preprinted medication labels and forms to be used in the study.

e) Pharmacist Prescription List

Provided by the Division of AIDS for each study: lists the patient's treatment assignment based on Study Identification Number. Additional treatment assignment lists are added as they are received from DAIDS.

f) Drug Supply Statement

Protocol specific statement provided after DAIDS approval of each new version of the study protocol: lists ordering information for all medications supplied for the study by DAIDS.

g) Prescriber Information

Signed copy of the FDA form 1572, a Prescribers List and Signature Log (names and signatures of providers authorized to prescribe medications for the study).

h) Shipments

Completed order forms and packing slips for each shipment stapled together and filed after the drug shipment has been received, verified and entered on drug accountability records.

i) Records of Drug Destruction

Records of all medications destroyed on site per SOP.

j) Correspondence

Letters and memos to and from DAIDS and other study-specific correspondence.

k) Drug Accountability Records

A separate record is kept for each medication and lot number received for the study.

l) Subject Specific Tabs

Patient specific information including a copy of the signed last page of the informed consent, written prescriptions, copies of the subject enrollment and treatment assignment, patient teaching notes, and pharmacist's notes.

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

The PI and the site coordinator will keep the PoR informed of new versions of protocols, protocol amendments, safety memos, revised package inserts, and any other protocol specific or general DAIDS information pertaining to pharmacy or study medications that is received at the site. This will be done by voice or email either directly to the pharmacist or to the Site Group emails. The site will hold weekly meeting to discuss DAIDS sponsored studies. Site Group emails will be set up to disseminate site specific and study specific information.

The protocol notebooks are stored in Eva Muro's office in locked cabinets to which only the Clinical Research Site (CRS) pharmacists and pharmacy technicians have access.

Investigator's Brochures, package inserts and safety memos are stored with regulatory files of the site. The pharmacists have access to these files. The site coordinators will forward a copy of all emails regarding Investigator Brochures, package inserts and safety memos to the pharmacists for review. In addition, pharmacists may review Investigator's Brochures, package inserts and safety memos on the RCC web site.

10. 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?

The site coordinator forwards a copy of the approval email from DAIDS to the site pharmacist. In addition, the CRPMC sends the site pharmacist a new Drug Supply Statement for each version of the protocol for which the site is approved.

11. How is an authorized prescriber identified for a protocol to prevent the unauthorized prescribing of study products?

The pharmacist checks the FDA from 1572 and the Prescribers List and Signature log to ensure the prescriber is authorized to prescribe for the study

12. What procedures are followed by the PoR to maintain confidentiality of a participant's pharmacy file and the study product accountability records?

Participant's pharmacy files and the study product accountability records are kept in protocol specific pharmacy notebooks that are stored in Eva Muro's office in locked cabinets to which only the CRS pharmacists and pharmacy technicians have access to maintain integrity of any blinded study treatments. Emergency unblinding will be performed per instructions in each study protocol.

13. Does the pharmacy utilize a computerized study drug system, for example for accountability records, inventory, study information, medication order entry? If so, describe.

    No

14. Will the PoR be involved in participant consultation and/or counseling? Please describe.

The pharmacist dispenses study medications and provides patient counseling at each study visit. The pharmacist is responsible for ensuring that all participants are adequately counseled when they receive their first supply of study medication, with information on proper use and storage of each medication, possible side effects, and ways to ensure adherence. This counseling can be done by the pharmacist or by someone delegated by the pharmacist and will be documented. The pharmacist will notify the study nurses if there is a problem with adherence based on estimated measurements/accurate counts of returned medication.

B. Study Product Control (Facilities)

1. Are the study products stored in more than one room/area or building? Please list.

(1) Main Pharmacy Storeroom
(2) Child Centered Family Care Clinic (CCFCC) Pharmacy

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

i. The Pharmacy Storeroom is 7.5 x 10.6 meters. The storeroom contains desks, shelves, locked metal cabinets, and refrigerators

ii. The CCFCC pharmacy is located in the CCFCC clinic. It is a separate room with one door that is kept locked. The room is rectangular in shape. The dimensions are 8.5 x 3.2 meters. There is a counter with a stone counter top that runs the length of the long back wall and the right side wall. There is a sink located in the counter top along the right side wall. Glass cabinets are mounted to the wall above the back counter. Below the back and side counter, running the length of the counter, are a combination of cabinets and drawers. The long front wall contains a bay that juts into the pharmacy by 1.2 meters and is 3.7 meters long. This bay contains a 3.7 meter long counseling desk. Two dispensing/patient counseling windows are above the desk and open to counseling areas along the main hallway of the clinic. These windows are closed and locked when not un use. The counseling areas are surrounded by walls to provide privacy for patient counseling.. There are two computers on the back counter. There is a lockable file cabinet in the pharmacy. An airconditioner has been purchased for this room, but it has not yet arrived at KCMC.

Instructions for completing Section B2 through B5:

If more than one room/area **or building** is listed in question 1, make additional copies of questions B2-B5 and answer independently. Please title the additional copies according to the area being described.

2. Room Temperature Storage

a. Describe the current type of storage for the study products e.g. cabinets, shelving, etc.
Locked metal cabinets.

b. Who will have access to these storage areas?
Only CRS pharmacy staff.

c. Who will have access to the study products in these areas?
Only CRS pharmacy staff.

d. How will access to the study products be limited to only those listed in c) above?
Only CRS pharmacy staff will have keys to the cabinet.

e. At what temperature range is the storage area(s) maintained?
15-30°C

f. Is there continuous temperature monitoring of the storage area(s) (24 hrs per day, 7 days per week)? Please Describe.
Yes. A Sensaphone temperature monitoring and alarm system is in place. If the temperature varies out of range, an audible alarm will sound and the system will automatically and immediately call the hospital operator who will then notify a CRS pharmacist via cell phone of the alarm. In addition, a Dickson temperature recording device constantly records the temperature. Pharmacy personnel check this device regularly to make sure the temperature remains in range.

g. How is the temperature monitoring documented for the storage area(s)?
The temperature is recorded three times daily on a manual temperature log. These logs and the charts from the Dickson recording devices are kept in a notebook in the Main Pharmacy Storeroom.

h. How is the humidity monitored and controlled where the study products are stored?
The humidity is recorded three times daily on a humidity log. A dehumidifier is used to keep the humidity in an acceptable range.

3. Refrigerated Storage in the Pharmacy

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

b. Where is the refrigerator located?

In the main pharmacy storeroom.

c. What are the interior dimensions?
72 cm x 82 cm

d. Who will have access to the refrigerator?
Only CRS pharmacy personnel.

e. How will access to the refrigerator be limited to only those listed in d) above?
Only CRS pharmacy personnel will have keys to the refrigerator.

f. At what temperature range is the refrigerator maintained?
2-8°C

g. Does the pharmacy refrigerator(s) have a continuous temperature monitoring system (24 hrs per day, 7 days per week)? Please Describe.
Yes. It is connected to the Sensaphone monitoring system and a Dickson temperature recording device constantly records the temperature. Pharmacy personnel check this device regularly to make sure the temperature remains in range.

h. How is the temperature monitoring documented for the refrigerator(s)?
The temperature is recorded three times daily on a manual temperature log. These logs and the charts from the Dickson recording devices are kept in a notebook in the Main Pharmacy Storeroom.

4. Freezer Storage in the Pharmacy

a. Is there a –20 to -10° C (-4 to 14°F) pharmacy freezer available that can be used solely for study product storage? Yes? No?
No

b. Where is the freezer located?

c. What are the interior dimensions?

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

e. Who will have access to the freezer?

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

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

h. At what temperature range is the freezer maintained?

i. Does the pharmacy freezer(s) have a continuous temperature monitoring system (24 hrs per day, 7 days per week)? Please Describe.

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

5. Minus 70° Freezer Storage

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

b. Where is this -70°C freezer located?

c. What are the interior dimensions?

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

e. How will access to the -70°C 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 -70°C freezer maintained?

h. Does the pharmacy freezer(s) have a continuous temperature monitoring system (24 hrs per day, 7 days per week)? Please Describe.

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

Instructions for completing Section B2 through B5:

If more than one room/area **or building** is listed in question 1, make additional copies of questions B2-B5 and answer independently. Please title the additional copies according to the area being described.

2. Room Temperature Storage

a. Describe the current type of storage for the study products e.g. cabinets, shelving, etc.
Locked cabinets.

b. Who will have access to these storage areas?
Only CRS pharmacy staff.

c. Who will have access to the study products in these areas?
Only CRS pharmacy staff.

d. How will access to the study products be limited to only those listed in c) above?
Only CRS pharmacy staff will have keys to the cabinet.

e. At what temperature range is the storage area(s) maintained?
15-30°C

f. Is there continuous temperature monitoring of the storage area(s) (24 hrs per day, 7 days per week)? Please Describe.
Yes. A Dickson temperature recording device constantly records the temperature. Pharmacy personnel check this device regularly to make sure the temperature remains in range.

g. How is the temperature monitoring documented for the storage area(s)?
The temperature is recorded three times daily on a manual temperature log. These logs and the charts from the Dickson recording devices are kept in a notebook in the CCFCC Pharmacy..

h. How is the humidity monitored and controlled where the study products are stored?
The humidity is recorded three times daily on a humidity log.

3. Refrigerated Storage in the Pharmacy

a. Is there a pharmacy refrigerator available that can be used solely for study product storage? Yes? No?
Not at this time. A refrigerator will soon be placed in this room. If needed, part of the refrigerator can be used to store CRS medications in a separate locked area or an additional refrigerator with access limited to CRS pharmacy personnel will be added to the room.

b. Where is the refrigerator located?

c. What are the interior dimensions?

d. Who will have access to the refrigerator?

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

f. At what temperature range is the refrigerator maintained?

g. Does the pharmacy refrigerator(s) have a continuous temperature monitoring system (24 hrs per day, 7 days per week)? Please Describe.

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

4. Freezer Storage in the Pharmacy

No

a. Is there a –20 to -10° C (-4 to 14°F) pharmacy freezer available that can be used solely for study product storage? Yes? No?

b. Where is the freezer located?

c. What are the interior dimensions?

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

e. Who will have access to the freezer?

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

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

h. At what temperature range is the freezer maintained?

i. Does the pharmacy freezer(s) have a continuous temperature monitoring system (24 hrs per day, 7 days per week)? Please Describe.

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

5. Minus 70° Freezer Storage

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

No.

b. Where is this -70°C freezer located?

c. What are the interior dimensions?

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

e. How will access to the -70°C 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 -70°C freezer maintained?

h. Does the pharmacy freezer(s) have a continuous temperature monitoring system (24 hrs per day, 7 days per week)? Please Describe.

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

6. Room Temperature Storage of Participant Specific Pharmacist Prepared Study Products in the Clinic

   a. If prescriptions are received and study products are prepared by the pharmacist prior to a participant's visit and sent to the clinic, where in the clinic will the prepared study products be stored?
      Locked wooden cabinets.

   b. Who will have access to these prepared study products?
      Only CRS pharmacy personnel.

   c. How will access to the study products be limited to only those listed in b) above?
      Only CRS pharmacy personnel will have keys to the cabinets.

7. Refrigerated Storage of Participant Specific Pharmacist Prepared Study Products in the Clinic

   a. If prescriptions are received and study products 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?
      Yes

   b. Where in the clinic is the refrigerator located?
      The clinic pharmacy.

   c. Who will have access to these prepared study products in the refrigerator?
      Only CRS pharmacy personnel.

   d. How will access to the study products be limited to only those listed in c) above?
      Only CRS pharmacy personnel will have keys.

8. Is there a biological safety cabinet or an isolator available that can be used solely for preparing study product? Yes? No?
   No.

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

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

11. In the event that power is lost or a black-out occurs, please describe the back-up or generator system.
    The refrigerators in the main pharmacy storeroom are connected to the KCMC emergency generator. The refrigerator in the CCFCC clinic is not connected to the generator. The generator starts automatically when there is a power interruption.

12. What mechanisms are in place to notify the PoR of any temperature deviations in the storage areas, when pharmacy staff *is* present?

The personnel conducting the temperature checks in area will call the PoR's cell phone immediately if there are any temperature deviations.

13. What mechanisms are in place to notify the PoR of any temperature deviations in the storage areas, when pharmacy staff *is not* present?

The PoR will receive a call on her cell phone.

14. Are certification, validation and/or maintenance done on the equipment on a regular basis?

The sensaphone monitoring system is solid state and requires no validation or maintenance. The emergency generator and the refrigerators are maintained regularly according to procedures from the head engineer.

15. 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)

C. Study Product Dispensing (Activities)

1. The Pharmacist of Record is required to keep complete written records (accountability records) of all study products that are received; and, all study products that are dispensed to participants. The count or quantity of study products 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.

Drug Accountability Records will be maintained on KCMC-Duke University Kilimanjaro AIDS Program Study Accountability Record (copy attached) which was adapted from the DAIDS Study Accountability Record. These records will be kept in the Drug Accountability Section of each protocol notebook. A separate record will be used for each product and lot number. The records will track prescription number, date filled, SID, PID, date dispensed, quantity dispensed or received, balance, pharmacist's initials, date returned by patient, quantity returned, date destroyed on site, and comments. A perpetual inventory will be kept so that the balance recorded with each entry will match the inventory on the shelf at that time. In addition, a physical inventory of each study will be conducted monthly, and the inventory will be recorded on the accountability record.

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 study products. How will the Pharmacist

of Record receive this written prescription? If electronic prescriptions are used describe this process.

The study coordinator or designee will deliver a signed prescription to the pharmacist.

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

    a. Prescriptions: The CRS Study Coordinator or designee notifies the CRS pharmacist when a patient is scheduled for study entry. Once the patient is successfully randomized to study treatment, the study coordinator or designee delivers a prescription signed by an authorized prescriber listed on the FDA form 1572 to the pharmacist along with a copy of the signed signature page of the patient's informed consent. The pharmacist cannot dispense study medication until he has received both the prescription and copy of the informed consent. The study coordinator or designee also provides the pharmacist with a copy of the page of the "Network Subject Enrollment System Results" that contains the patient's assigned PID and SID number. The pharmacist uses the SID number to look up the patients assigned treatment in the Pharmacists Prescription List. The pharmacist dispenses the first supply of study medication to the patient.

    b. Dispensing the Initial Supply of Study Medication: The pharmacist fills the initial supply of study medication according to instructions in the protocol. The medications are prepared in the pharmacy. The medications are dispensed in the original container or in prescription vials or bottles that meet DAIDS and the product manufacturer's requirements for storage such as air-tightness, humidity-control and child-proof-closures. The products are labeled according to DAIDS, national and local guidelines. Each label contains the following information: name, address, and phone number of the Pharmacy, patient name, dispensing date, directions, prescriber's name, SID number, number of dosing units dispensed, name and strength of drug, and prescription number. For blinded studies the bottles are labeled with the name of the active protocol drug and the statement "or placebo" (e.g. zidovudine or placebo).

    c. Subsequent Prescriptions Refills: Pharmacists are notified ahead of time of patients' return clinic visits by the study coordinator or designee. Either the patient or the study nurse comes to the pharmacist to pick up the medication and to return unused study medication and/or empty containers.

4. How will the PoR assure that an informed consent was signed by a participant prior to dispensing the study product(s)?

    The study coordinator or designee will give the pharmacist a copy of the signed signature page of the consent.

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

    Buy the study coordinator or designee.

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

   Either the patient or the study nurse comes to the pharmacy to pick up the medication and to return unused study medication and/or empty containers.

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

   The study coordinator or designee delivers the prescription to the pharmacy.

8. How will the Pharmacist of Record dispense the study products? (check all that apply)

   __X__ Directly to participants.
   __X__ Deliver study products to other healthcare providers who will distribute it to participants.
   ____ Through other procedures (describe).

9. How will the Pharmacist of Record receive study product returned by the participant? (check all that apply)

   __X__ Directly from participants.
   __X__ From other healthcare providers.
   ____ Through other procedures (describe).

10. If study product 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?

    In locked cabinets in the CCFCC pharmacy. Only CRS pharmacy personnel have access to these cabinets.

The Pharmacist of Record is responsible for ensuring that all the information s/he has provided in the DAIDS/PAB 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**

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

I have on file a copy of the *Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks* dated _____ which I have read and understand. I will follow these guidelines to maintain standardization and quality.

_____ _____

Signature of Pharmacist of Record **Date**

Temporary / Permanent Notification of Change in Pharmacist of Record
(COMPLETE ONE FORM PER NETWORK)

This memo serves to notify the Pharmaceutical Affairs Branch (PAB) at the Division of AIDS (DAIDS) of a change in the Pharmacist of Record and is to be used in place of a revised Pharmacy Establishment Plan; however, upon review by PAB, submission a revised Pharmacy Establishment Plan may be required for approval.

- **Complete the following information**

Clinical Research Site Name	
Network	**Clinical Research Site Number**

- **Complete the following information and <u>attach the Curriculum Vitae for the NEW Pharmacist of Record:</u>**

Name of PREVIOUS Pharmacist of Record	
Name of NEW Pharmacist of Record	
Mailing Address	
Telephone Number	**Fax Number**
Email Address	

- **Complete the following information (check only <u>one</u> box):**

☐ Permanent change
Date effective (dd/mmm/yy):_____

☐ Temporary change
Dates effective (dd/mmm/yy) from: _____ to _____

- **Please read the following statement and initial in the space provided:**

_____ I agree to comply with all of the information contained in the Previous or Revised Division of AIDS approved Pharmacy Establishment Plan. *If the pharmacy establishment plan was revised, please attach.*

_____ I have on file a copy of the *Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks,* **<u>with the date</u>: _____,** which I have read and understand. I will follow these guidelines to maintain standardization and quality.

_____

_____

Signature of NEW Pharmacist of Record **Date (dd/mmm/yy)**

ONCE THE CHANGES ARE RECEIVED AND THIS FORM IS ACKNOWLEDGED BY PAB, PLEASE ATTACH THIS FORM AND THE ACKNOWLEDGEMENT FROM PAB TO THE APPROVED PHARMACY ESTABLISHMENT PLAN FOR YOUR FILES.

Send:

1) This completed form, and
2) (If applicable) A copy of the C.V. for the **NEW** Back-up Pharmacist to:

Ana I. Martinez, R.Ph.
Chief, Pharmaceutical Affairs Branch
NIH/NIAID/DAIDS Room 4115

6700 B Rockledge Drive MSC 7620
Bethesda, MD 20892-7620 USA
Telephone: (01)-301-496-8213 Fax: (01)-301-402-1506

Temporary / Permanent Notification of Changes in Back up Pharmacist(s)
(COMPLETE ONE FORM PER NETWORK)

This memo serves to notify the Pharmaceutical Affairs Branch (PAB) at the Division of AIDS (DAIDS) of any changes in the Back up Pharmacist(s) and is to be used in place of a revised Pharmacy Establishment Plan; however, upon review by PAB, submission a revised Pharmacy Establishment Plan may be required for approval.

- **Complete the following information:**

Clinical Research Site Name	
Network	**Clinical Research Site Number**

- **Complete the following information and <u>attach the Curriculum Vitae for the NEW Back up Pharmacist (if applicable):</u>**

Name of PREVIOUS/DEPARTING Back up Pharmacist (if applicable)	
Name of NEW/ADDITIONAL Back up Pharmacist (if applicable)	
Mailing Address	
Telephone Number	**Fax Number**
Email Address	

- **Complete the following information (check only <u>one</u> box):**

☐ Permanent change
Date effective (dd/mmm/yy):_____

☐ Temporary change
Dates effective (dd/mmm/yy) from: _____ to _____

- **Please read the following statement and initial in the space provided:**

_____ I agree to comply with all of the information contained in the Previous or Revised Division of AIDS approved Pharmacy Establishment Plan. *If the pharmacy establishment plan was revised, please attach.*

_____ I have on file a copy of the *Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks*, **<u>with the date</u>: _____** which I have read and understand. I will follow these guidelines to maintain standardization and quality.

_____ _____
Signature of NEW Back-up Pharmacist **Date (dd/mmm/yy)**

ONCE THE CHANGES ARE RECEIVED AND THIS FORM IS ACKNOWLEDGED BY PAB, PLEASE ATTACH THIS FORM AND THE ACKNOWLEDGEMENT FROM PAB TO THE APPROVED PHARMACY ESTABLISHMENT PLAN FOR YOUR FILES.

Send:

1) This completed form, and
2) (If applicable) A copy of the C.V. for the **NEW** Back-up Pharmacist to:

Ana I. Martinez, R.Ph.
Chief, Pharmaceutical Affairs Branch

NIH/NIAID/DAIDS Room 4115
6700 B Rockledge Drive MSC 7620
Bethesda, MD 20892-7620 USA
Telephone: (01)-301-496-8213 Fax: (01)-301-402-1506

Notification of Change in Pharmacy Address or Contact Information
(COMPLETE ONE FORM PER NETWORK)

This memo serves to notify the Pharmaceutical Affairs Branch (PAB) at the Division of AIDS (DAIDS) of a change in the pharmacy address, location or contact information and is to be used in place of a revised Pharmacy Establishment Plan; however, upon review by PAB, submission a revised Pharmacy Establishment Plan may be required for approval.

- **Complete the following with all the CURRENT CONTACT INFORMATION:**

Clinical Research Site Name	
Network	**Clinical Research Site Number**
Pharmacist of Record Name	
Telephone Number	**Fax Number**
Email Address	

- **Complete the following for all NEW addresses (if applicable):**

NEW Address:
Please check: ☐ Mailing ☐ Shipping ☐ Physical Location

_____

_____

_____

Other NEW Address (if needed):
Please check: ☐ Mailing ☐ Shipping ☐ Physical Location

_____

_____

_____

_____ _____
Signature of Pharmacist of Record **Date (dd/mmm/yy)**

ONCE THE CHANGES ARE RECEIVED AND THIS FORM IS ACKNOWLEDGED BY PAB, PLEASE ATTACH THIS FORM AND THE ACKNOWLEDGEMENT FROM PAB TO THE APPROVED PHARMACY ESTABLISHMENT PLAN FOR YOUR FILES.

Send this completed form to: **Ana I. Martinez, R.Ph.**
Chief, Pharmaceutical Affairs Branch
NIH/NIAID/DAIDS Room 4115

6700 B Rockledge Drive MSC 7620
Bethesda, MD 20892-7620 USA
Telephone: (01) 301-496-8213 Fax: (01) 301-402-1506

Temporary / Permanent Notification of Change in SECTION B: Study Product Control (Facilities)
(COMPLETE ONE FORM PER NETWORK)

This memo serves to notify the Pharmaceutical Affairs Branch (PAB) at the Division of AIDS (DAIDS) of a change in the Study Product Control section and is to be used in place of a revised Pharmacy Establishment Plan; however, upon review by PAB, submission a revised Pharmacy Establishment Plan may be required for approval.

- **Complete the following information**:

Clinical Research Site Name	
Network	**Clinical Research Site Number**
Pharmacist of Record Name	
Telephone Number	**Fax Number**
Email Address	

- **Indicate below the study product control being changed. If more than one box applies, submit a separate form for each box.**
(Check only <u>one</u> box):

☐ Room Temperature Storage **(B. 2 and B. 6)** ☐ Biological Safety Cabinet **or Isolator (B. 8)**

☐ Refrigerated Storage **(B. 3 and B. 7)** ☐ Generator System **or Back up (B. 11)**

☐ Freezer Storage **(B. 4 and B. 5)** ☐ Other _____

- **Indicate the location in which the study product control is being changed. (Check only <u>one</u> box):**

☐ In the Pharmacy ☐ In the Clinic

- **Complete the following information (Check only <u>one</u> box):**

☐ Permanent change
Date effective (dd/mmm/yy): _____

☐ Temporary change
Dates effective (dd/mmm/yy) from: _____ to _____

- **The following information may be provided as an attachment <u>(PLEASE DO NOT attach the entire Pharmacy Establishment Plan)</u>:**

Write the entire question, including the appropriate number(s) and letter(s), from Section B of the Pharmacy Establishment Plan:
_____
_____

Write the original answer from the approved Pharmacy Establishment Plan:
_____
_____

➔ **Write the new answer here** (**ATTACH ADDITIONAL PAGES IF NECESSARY)**:
_____
_____

_____ _____
Signature of Pharmacist of Record **Date (dd/mmm/yy)**

ONCE THE CHANGES ARE RECEIVED AND THIS FORM IS ACKNOWLEDGED BY PAB, PLEASE ATTACH THIS FORM AND THE ACKNOWLEDGEMENT FROM PAB TO THE APPROVED PHARMACY ESTABLISHMENT PLAN FOR YOUR FILES.

Send this completed form to: **Ana I. Martinez, R.Ph.**

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