The Pharmacy Establishment Plan must be completed for each pharmacy that is a component of a DAIDS-Funded Clinical Research Site. Each Pharmacy Establishment Plan must be completed by a Pharmacist of Record (PoR) for that pharmacy. The pharmacist must be licensed and/or registered to practice pharmacy in the jurisdiction in which s/he is working.

The PoR is the primary individual whose responsibilities include:

* performing the day to day dispensing and accountability activities
* establishing internal policies and procedures
* developing and maintaining a study product management system

The completed Pharmacy Establishment Plan must be submitted directly to the DAIDS Pharmaceutical Affairs Branch (PAB) for review and approval. In addition, the following must be submitted to the PAB:

* Curriculum Vitae (CV) of the PoR and Associate Pharmacist
* Pharmacy Standard Operating Procedures (SOP)

***If you have any questions, contact the PAB at:***

***DAIDSPABPEP@niaid.nih.gov***

**For PAB Use Only**

|  |  |
| --- | --- |
| Pharmacy Name: Click here to enter text. | CRS Name: Click here to enter text. |
| Pharmacy Org. I.D. # Click here to enter text. | CRS#: Click here to enter text. |
| Initial PAB Reviewer: Click here to enter text. | PAB Pharmacist: Click here to enter text. |
| Date Initial PEP Received: Click here to enter text. | Date of Initial Review: Click here to enter text. |

1. **Background (Personnel/Pharmacist)**
2. Pharmacist of Record Information

***Complete the table below. If there are different Pharmacists of Record for different networks then include additional ‘Pharmacist of Record Information’ sheets to your pharmacy plan.***

|  |
| --- |
| **Network(s):** Click here to enter text. |
| **Name of Pharmacist of Record:** Click here to enter text. |
| **Degree:** Click here to enter text. | **Title or Position:** Click here to enter text. |
| **Email Address:** amy.dill@uc.edu  |
| **Telephone Number:** Click here to enter text. | **Fax Number:** Click here to enter text. |
| **Mailing Address:** Click here to enter text. |
| **To whom does the Pharmacist of Record report?** |
| **Name:**   |
| **Title or Position:** Click here to enter text. |
| **Email address:** Click here to enter text. | **Phone Number:** Click here to enter text. |
| x I am the Pharmacist of Record that is completing and submitting this plan for this pharmacy location. |

1. Associate Pharmacist Information

***Complete the table below. If there are different Associate Pharmacists for different networks then include additional ‘Associate Pharmacist Information’ sheets to your pharmacy plan. Associate Pharmacists are limited to two per network.***

|  |
| --- |
| **Name of Associate Pharmacist:**  |
| **Network(s):**  | **Degree:**  | **Title or Position:**  |
| **Email Address:**  |
| **Telephone Number:**  |
| **Mailing Address:**  |

1. Is the telephone located in the pharmacy area or the pharmacy office? Yes x No ☐

If the answer is no, please explain: Click here to enter text.

1. Is the fax machine located in the pharmacy area or the pharmacy office? Yes x No ☐

If the answer is no, please explain: Only the pharmacist of record and the associate pharmacist have access to the dedicated pharmacy fax machine above.

1. Is the printer located in the pharmacy area or the pharmacy office? Yes x No ☐

If the answer is no, please explain: Click here to enter text.

1. Is the computer used to access email located in the pharmacy area or the pharmacy office?

Yes x No ☐ If the answer is no, please explain: Click here to enter text.

1. Provide the address to which all study products will be shipped. This address should not be a P.O. Box.

1. Provide the address for the physical location of the research pharmacy. This address cannot be a P.O. Box.

1. Is the access to the pharmacy limited to only pharmacy personnel? Yes x No ☐

If the answer is no, please explain: Click here to enter text.

1. Is the access to study products limited to only pharmacy personnel? Yes x No ☐

If the answer is no, please explain: Study product is restricted to pharmacy personel until it is dispensed. Only the pharmacist of record and the associate pharmacist have keys to the pharmacy. Monitors, State Board of Pharmacy personnel and others with vaild credenitals will be granted access to the pharmacy in the presence of the pharmacist of record or the associate pharmacist.

1. What are the security measures in place limiting study product access to only authorized pharmacy personnel?

Study product is restricted to pharmacy personnel until it is dispensed. Only the pharmacist of record and the associate pharmacist have keys to the pharmacy. Monitors, State Board of Pharmacy personnel and others with valid credentials will be granted access to the pharmacy in the presence of the pharmacist of record or the associate pharmacist.

1. Complete the table below and indicate whether the documents are maintained electronically or hard copy in the pharmacy.

|  |  |  |  |
| --- | --- | --- | --- |
| **Document** |  **CHECK ALL THAT APPLY** | **Does anyone other than authorized pharmacy personnel have access to these documents?** | **Are the documents organized by protocol?** |
| **Hard Copy** | **Electronic** | **N/A** |
| Most recent version of a protocol | x | x |  |  | Yes x No ☐ |
| Letters of Amendment (LoAs) | x | x |  |  | Yes x No ☐ |
| Clarification Memos (CMs) | x | x |  |  | Yes x No ☐ |
| Accountability records | x | ☐ |  | Yes ☐ No x  | Yes x No ☐ |
| Orders | x | ☐ |  | Yes ☐ No x  | Yes x No ☐  |
| Invoices | x | ☐ |  | Yes ☐ No x  | Yes x No ☐ |
| Packing slips | x | ☐ |  | Yes ☐ No x  | Yes x No ☐ |
| Transfers | x | ☐ |  | Yes ☐ No x  | Yes x No ☐ |
| Returns to CRPMC - DAIDS Study Product Return Forms (US sites) | x | ☐ | ☐ | Yes ☐ No x  | Yes x No ☐ |
| Final, Verified Study Product Destruction Forms (International sites) | ☐ | ☐ | x | Yes ☐ No x  | Yes ☐ No ☐ |
| Study treatment assignment information and/or randomization records | x | x |  | Yes ☐ No x | Yes x No ☐ |
| Chain of custody records | x | ☐ | ☐ | Yes No x | Yes ☐ No x |
| Current Form FDA 1572 or Investigator of Record (IoR) Agreement  | x | ☐ | ☐ |  | Yes x No ☐ |
| Current Authorized Prescriber’s Signature List | x | ☐ |  |  | Yes No x |
| Current version of the Investigator’s Brochure (IB) or product Package Insert (PI) for the study products | x | x |  |  | Yes x No  |
| Original study prescriptions | x | ☐ |  | Yes ☐ No x | Yes x No ☐ |
| Drug Supply Statement (DSS) | x | ☐ |  | Yes ☐ No x | Yes x No ☐ |
| Written communications with clinic staff | x | x |  | Yes ☐ No x | Yes x No ☐ |
| Written communications with PAB | x | x |  | Yes ☐ No x | Yes x No ☐ |
| Record of inventory at least every 30/31 days | x | ☐ |  | Yes ☐ No x | Yes x No ☐ |
| Closeout Letters | x | ☐ |  | Yes ☐ No x | Yes x No ☐ |

1. Use the table below to describe the process for keeping the following protocol information up to date in the pharmacy files:

| **Document** | **Process** | **Who provides this information or by what mechanism is the information obtained?** |
| --- | --- | --- |
| Most recent version of a protocol |  Regulatory personnel duplicate protocol versions and distribute them. An email communication is sent regarding any new approvals or updates.   |  Regulatory personnel and ACTG logon provide this information. Email and delivery of print copies are the mechanism by which information is shared.   |
| Letters of Amendment (LoAs) | Regulatory personnel send an email communication regarding any new IRB approvals or updates. Pharmacy personnel print updates from the ACTG Website. Document updates are also noted from protocol logon emails.  |  Regulatory personnel and ACTG logon provide this information. Email is the mechanism by which information is shared.  |
| Clarification Memos (CMs) | The pharmacist is added to every protocol team logon at study initiation at the CRS. All CMs are sent to the Protocol team logon. The Pharmacist downloads all CM emails and the CM is printed by the pharmacy. |  The ACTG logon provides this information. Email is the mechanism by which information is shared.  |
| Current Form FDA 1572 or Investigator of Record (IoR) Agreement |  Regulatory personnel send updated copies of 1572 documents as they are updated via email.   |  Regulatory personnel provide this information. Email is the mechanism by which information is shared.  |
| Current Authorized Prescriber’s Signature List | The CRS leader determines the investigators who participate in studies as PI or subinvestigator. A current list is maintained in the pharmacy. New authorized prescribers are asked to sign the Current Authorized Prescribers' Signature List as they are added to the 1572 or IoR Form. This form is completed for each study. |  Each study has a 1572 or IoR form that provides documentation of site Principal Investigator and all authorized subinvestigators that are able to sign prescriptions. This information is provided to the pharmacist by the Regulatory personnel by email.   |
| Current version of the Investigator’s Brochure (IB) or product Package Insert (PI) for the study products |  Site Regulatory personnel place Investigator Brochures and Package Inserts for study products and places them in a secured share drive for the research unit. An email communication is sent by Site Regulatory Personnel regarding any new or updated Investigator Brochures or Package Inserts for study products. The Regulatory Support Center is accessed for the most recent approved study product Package Insert.  |  Site regulatory personnel email the pharmacist when the Regulatory Support Center provides updated information. Email is the mechanism by which information is shared. For Investigator Brochures and Package Inserts the Pharmacist has access to the secured share drive for the research unit to view or print documents.  |

1. How is the Pharmacist of Record informed of the initial IRB approval of a protocol?

| **Method**(check all that apply) | **Source of information** |
| --- | --- |
|  Hard Copy | xElectronic | Regulatory personnel notify all site staff of IRB approval via email. IRB status is also discussed at bi-weekly staff meetings.   |

1. How is the Pharmacist of Record informed of subsequent IRB approvals of a protocol?

| **Method**(check all that apply) | **Source of information** |
| --- | --- |
| ☐Hard Copy | xElectronic |  Regulatory personnel notify all site staff of any subsequent IRB approvals via email. IRB status is also discussed at bi-weekly staff meetings.  |

1. How does the Pharmacist of Record verify s/he is working with the current IRB-approved version of the protocol?

The Pharmacist of Record verifies that she is working with current IRB-approved version of the protocol via the ePAS Website. The ePAS Website is a Website maintained by the University of Cincinnati IRB that clearly notes the current IRB approved documents including the protocol and any amendments.

1. Indicate in the table below how an authorized prescriber for a protocol is verified prior to dispensing study product for both IND and non-IND studies:

|  | **Documents**(check all that apply) | **How is the information updated?** |
| --- | --- | --- |
| IND Studies | x FDA 1572 xAuthorized Prescriber list/log ☐ Other: Click here to enter text.  |  Site regulatory personnel send new and updated FDA 1572 documents via email. Only the Site Principal Investigator and subinvestigators authorized to prescribe are listed on these documents.  |
| Non-IND Studies | x IoR Agreement x Authorized Prescriber list/log ☐ Other: Click here to enter text.  |  Site regulatory personnel send new and updated IoR documents via email. Only the Site Principal Investigator and subinvestigators authorized to prescribe are listed on these documents.  |

1. What procedures are followed by the PoR to maintain confidentiality of participant records that may contain personal identifiers?

 All paper pharmacy records are retained behind two locked doors. Only informed consents contain full patient names. Prescription labels utilize participant initials (first initial of first name and first three initials of last name). An electronic prescription database does contain participant names; this database is password protected.

1. What procedures are followed by the PoR to maintain confidentiality of study related materials, such as but not limited to accountability records and randomization information?

Accountability records contain participant initials, PID, and SID but they do not contain full participant names. All study related materials are stored behind two locked doors, one of the two doors is to the pharmacy to which only the pharmacist of record and back up pharmacist have access.

1. Complete the table below and indicate whether or not the pharmacy utilizes a computerized study drug system for any of the following:

|  |  | **\*If yes to any - answer the following questions** |
| --- | --- | --- |
| Is it password protected? | Is there a data back-up? |
| Accountability Records | **Yes\***   **No** x | **Yes**   **No**  | **Yes** X **No**  If yes, what type?   |
| Inventory | **Yes\***   **No** x | **Yes**   **No**  | **Yes** X **No**  If yes, what type? Click here to enter text. |

1. Will the Pharmacist of Record be involved in participant consultation and/or counseling?

Yes x No ☐ Upon Request ☐

1. **Study Product Dispensing (Activities)**
2. Is a physical inventory conducted of all study products *at least* every 30/31 days? Yes x No ☐
3. How is the physical inventory documented?

A single line on the inventory is designated "INVENTORY" at the time of inventory and the quantity is noted in the appropriate column. For ease identification "INV" is noted in the comments column of the inventory sheet.

1. Complete the table below and indicate how the Pharmacist of Record will receive a written prescription in accordance with institutional, local and/or country regulations:

|  | **Initial prescription** | **Prescriptions indicating a change** |
| --- | --- | --- |
| Electronically | Yes ☐ No x  | Yes ☐ No x  |
| Faxed | Yes ☐ No x  | Yes ☐ No x  |
| Faxed with hard copy received prior to study product leaving pharmacy control. | Yes ☐ No x  | Yes ☐ No x  |
| Hard Copy/ Hand Delivered | Yes x No ☐  | Yes x No ☐  |

1. Describe the step by step procedure followed from the time a prescription is received in the pharmacy to when the study product leaves the custody of the pharmacy?

Once a prescription arrives at the pharmacy it is reviewed for completeness including subject initials, SID, and PID. The protocol number is noted and the products ordered are compared to what is ordered in the protocol. The prescriber is verified as an authorized prescriber for the study. The date of signature is verified as being on the same day as randomization or after. Current approval of the protocol is verified. The first and signature pages of the current informed consent are visually inspected. The randomization sheet is used to verify the SID number. The study product randomization is verified on the SID-PID log. If the result of this review is that the prescription contains all of the necessary information (i.e., it was written and signed by an authorized prescriber); it matches a currently IRB approved protocol; the informed consent is appropriately completed; and the randomization sheet is in hand; then the prescription will be filled. If any problems are noted, the study nurse and/or prescriber will be contacted and the prescription will not be filled until all problems are resolved.

Once a prescription is found to meet all requirements, prescription information will be entered into an electronic database. Labels will be printed in accordance with Ohio Pharmacy Law. Prescription labels will bear the date, study number, PID, SID, initials of the subject (first letter of first name and first 3 letters of last name), study product (with "or placebo" for blinded studies to maintain the blind), directions, quantity, physician name, pharmacist initials, beyond use date of the study product, and the following statement "Limited by Federal Law to Investigational Use Only. All remaining medication and empty bottles must be returned at each visit". Appropriate product based on the prescription and SID-PID log allocations will be selected from the pharmacy shelf and labeled. Inventory logs will be updated to reflect medication dispensed and subject specific file will be started including the prescription, randomization sheet, first and signature pages of the informed consent, and a log of product dispensed. Identification stickers from any blinded product will be kept in the subject's file if available. Site staff do not have access to study logs or subject specific files for ACTG studies.

Prepared prescriptions are delivered directly to the participant and counseling is provided.

1. How is the pharmacy notified that refills/repeats are required?

A central calendar lists all subsequent visits with an indication of study visit number. The central calendar is used by pharmacy personnel to prepare for refills.

1. How are refills/repeats documented?

☐ Indicated on the original prescription

☐ New prescription required

x Other procedures (describe): Refills are documented on the subject specific inventory log.

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

x Directly to participants

x Deliver to other healthcare providers who will distribute it to participants

☐ Other procedures (describe): The pharmacist of record delivers most study product directly to participants; during scheduled absences of the pharmacist, study product is prepared in advance and delivered to the study nurse (please refer to PH-16 SOP which details chain of custody and temperature monitoring process); product given to the study nurse in advance is documented on a chain of custody form.

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

☐ Directly from participants

x From other healthcare providers

☐ Other procedures (describe): Returned study product is first reviewed by the study nurse and then returned to the study pharmacy.

1. How will the Pharmacist of Record receive study product prepared for the participant but not administered or given to the participant? (check all that apply)

x From other healthcare providers

☐ Other procedures (describe): If a participant does not receive study product prepared in advance it will be returned to Pharmacist of Record by the study nurse. The chain of custody form will also reflect that the study product was not given to the participant.

1. If study product is not immediately returned to the pharmacy once it is received from the participant, is the Pharmacist of Record able to ensure that the study product is quarantined and segregated appropriately in the clinic storage area, ensure that access is limited to the storage area, and return the study product to the pharmacy on a weekly basis?

x Yes (describe): Study nurses usually bring participant product returns to the pharmacy on the same day, however when product is not immediately returned it is kept in the locked nursing office to which the pharmacist of record has access. The pharmacist of record may request returns from the study nurses on a weekly basis.

☐ No (explain): Click here to enter text.

☐ N/A – Participant’s study product returns are immediately returned to the pharmacy.

1. **Study Product Control (Facilities)**
2. Is there a sink or washbasin available in the pharmacy where equipment and other utensils can be washed?

Yes x No ☐

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

Room temperature storage – Heating

1. Is heating available? Yes x No ☐ Not needed ☐ (If the answer is no or not needed, skip to section ‘Room Temperature Storage – Cooling’)
2. The following mechanism(s) are used to heat the room temperature storage area:

x Central heating ☐ Air Con Qty: Choose an item.

☐ Portable Heater Qty: Choose an item. ☐ Other: Click here to enter text.

1. The pharmacy staff has access to the temperature controls/thermostat? Yes x No ☐

If no, who has access? Click here to enter text.

1. Is the heating system supported by a generator or back-up power source? Yes x No ☐

Room temperature storage – cooling

1. Is cooling available? Yes x No ☐ Not needed ☐ (If the answer is no or not needed, skip to section ‘Room Temperature Storage – Humidity’)
2. The following mechanism(s) are used to cool the room temperature storage area:

x Central Air Conditioning ☐ Portable Air Con Qty: Choose an item.

☐ Air Con Qty: Choose an item. ☐ Other: Click here to enter text.

1. The pharmacy staff has access to the temperature controls? Yes x No ☐

If no, who has access? Click here to enter text.

1. Is the cooling system supported by a generator or back-up power source? Yes x No ☐

Room temperature storage – Humidity

1. The following mechanism is used to control humidity for the room temperature storage area:

x Air Conditioning: ☐ Other: Click here to enter text.

☐ Air Conditioning with dehumidifier: ☐ None:

☐ Dehumidifier:

Primary continuous temperature monitoring and recording device

1. The primary device used to continuously monitor and record the temperature of the room temperature storage area is a:

☐ Chart recorder: ☐ Integrated facility system:

x Data logger: ☐ Other: Click here to enter text.

☐ USB data logger: ☐ None:

1. The power supply of the device identified in question 1 is:

☐ Hard-wired x Plugged-in to a power supply

x Battery Operated ☐ Other: Click here to enter text.

1. The interval at which the temperature is recorded is: 15 minutes
2. For data captured electronically, what is the frequency in which the Pharmacist of Record *prints* and *reviews* the temperature documentation for the primary device?

 ☐ Daily ☐ Never

 x Weekly ☐ Other Click here to enter text.

 ☐ Monthly ☐ N/A

1. For chart recorded data, what is the frequency which the Pharmacist of Record *reviews* the temperature documentation for the primary device?

 ☐ Daily ☐ Never

 ☐ Weekly ☐ Other Click here to enter text.

 ☐ Monthly x N/A

1. For chart recorded data, what is the frequency which the Pharmacist of Record *replaces* the chart paper for the primary device?

 ☐ Daily ☐ Never

 ☐ Weekly ☐ Other Click here to enter text.

 ☐ Monthly x N/A

Manual temperature monitoring and review

1. Is manual documentation of temperatures conducted on a daily basis? Yes x No ☐
2. From which of the following secondary devices are temperatures manually recorded?

☐ Chart Recorder x Digital min/max thermometer ☐ Data Logger ☐ Mercury min/max thermometer

☐ USB data logger ☐ Other Click here to enter text. ☐ Integrated facility system ☐ None

1. On which days are temperatures reviewed and manually documented? (check all that apply)

x Monday ☐ Saturday x Tuesday ☐ Sunday

x Wednesday ☐ Official Holidays

x Thursday ☐ Never

 x Friday

Notification system

1. The system(s) used to alert the Pharmacist of Record of temperature deviations are (check all that apply):

 x Audible Alarm ☐ Other

 ☐ Auto Dialer Alarm ☐ Never

 ☐ Integrated facility alert system

1. The following mechanism is in place to notify the PoR of any temperature deviations in the storage areas, when pharmacy staff *is* present (check all that apply):

x Audible ringing in the pharmacy storage area x Text message to mobile phone or pager

 ☐ Audible ringing outside of the pharmacy ☐ Email

x Audible ringing in the pharmacy ☐ Other: Click here to enter text. x Audible phone message ☐ None

* + 1. How soon after the deviation is the Pharmacist of Record contacted?

 x Within 1 – 15 minutes ☐ Within 46 – 60 minutes

 ☐ Within 16 – 30 minutes ☐ More than 60 minutes

 ☐ Within 16 – 30 minutes ☐ Never

1. The following mechanism is in place to notify the PoR of any temperature deviations in the storage areas, when pharmacy staff *is* *not* present (check all that apply):

x Audible ringing in the pharmacy storage area x Text message to mobile phone or page ☐ Audible ringing outside of the pharmacy ☐ Email

x Audible ringing in the pharmacy ☐ Other: Click here to enter text. x Audible phone message ☐ None

* 1. How soon after the deviation is the Pharmacist of Record contacted?

 x Within 1 – 15 minutes ☐ Within 46 – 60 minutes

 ☐ Within 16 – 30 minutes ☐ More than 60 minutes

 ☐ Within 16 – 30 minutes ☐ Never

1. What happens if the Pharmacist of Record cannot be reached?

The pharmacist of record and back up pharmacists are both notified of excursions.

**The pharmacy has a copy of the *Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks* dated:** July 2008

I, Amy Dill, have read and understand the *Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks*, and I am responsible for ensuring that all the information I have 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 (dd/mmm/yy)