Division of Microbiology & Infectious Diseases (DMID)

Study Product Management Plan

Site Name: Click here to enter text.

The Study Product Management Plan (SPMP) must be completed for each research pharmacy that is a component of a DMID-funded clinical research site. Each Pharmacy Management Plan must be completed by the Site Research Pharmacist (SRP) assigned for that pharmacy for the study product management of DMID-sponsored/funded protocols. The pharmacist must be licensed and/or registered to practice pharmacy in the jurisdiction in which s/he is working.

The SRP is the primary individual whose responsibilities include:

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

The completed Study Product Management Plan must be submitted directly to the Contracting Officer Representative (COR) for the clinical research site for subsequent DMID review and approval. The DMID Product Support Team (DMID PST) should also be copied on all submissions, which should include the following:

* Completed DMID Study Product Management Plan (SPMP)
* List of Pharmacy Standard Operating Procedures (SOP)
* If applicable, any addendums or additional information to describe protocol-specific study product management processes or procedures not captured in the DMID SPMP

***For any questions, contact the DMID PST at:***

[***DMIDProductSupportTeam@niaid.nih.gov***](mailto:DMIDProductSupportTeam@niaid.nih.gov)

# **ADMINISTRATIVE**

1. Clinical Research Site Information.  
     
   Complete the table below.

|  |  |
| --- | --- |
| Name of Clinical Research Site: | |
| Clinical Research Site Mailing Address: | |
| Name of Principal Investigator: | |
| Email Address: | |
| Telephone Number: | Fax Number: |

1. Site Research Pharmacist Information  
     
   Complete the table below.

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Site Research Pharmacist: | | | |
| Degree: | Title or Position: | | |
| Email Address: | | | |
| Telephone Number: | | Fax Number: | |
| Mailing Address: | | | |
| To whom does the pharmacist report? | | | |
| Name: | | | |
| Title or Position: | | | |
| Email address: | | | Phone Number: |

1. Alternate Pharmacist Information.  
     
   Complete the table below.

This section should provide the information of the pharmacist assigned to DMID protocols in the event that the Site Research Pharmacist is not available. Designated Alternate Pharmacists are limited to two per site research pharmacy.

|  |  |
| --- | --- |
| Name of Alternate Pharmacist: | |
| Degree: | Title or Position: |
| Email Address: | |
| Telephone Number: | |
| Mailing Address: | |

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

If the answer is ‘No’, please explain Click here to enter text.

1. Is the printer located in the pharmacy area or the pharmacy office? Yes  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  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.

Click here to enter text.

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

Click here to enter text.

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Document** | **Format**  (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 |  |  |  |  | Yes  No |
| Accountability records |  |  |  | Yes  No | Yes  No |
| Product Orders |  |  |  | Yes  No | Yes  No |
| Invoices |  |  |  | Yes  No | Yes  No |
| Packing slips |  |  |  | Yes  No | Yes  No |
| Returns to DMID Clinical Materials Services (CMS) |  |  |  | Yes  No | Yes  No |
| Final, Verified Study Product Destruction Forms |  |  |  | Yes  No | Yes  No |
| Study treatment assignment information and/or randomization records |  |  |  | Yes  No | Yes  No |
| Chain of custody records |  |  |  | Yes  No | Yes  No |
| Original study prescriptions, prescribing order, or request for study product |  |  |  | Yes  No | Yes  No |
| Current version of the Investigator’s Brochure (IB) or product Package Insert (PI) for the study products |  |  |  |  | Yes  No |
| Written communications with clinic staff |  |  |  | Yes  No | Yes  No |
| Written communications with DMID |  |  |  | Yes  No | Yes  No |
| Record of inventory review, performed at least monthly |  |  |  | Yes  No | Yes  No |
| Record of expiration review, performed at least quarterly |  |  |  | Yes  No | Yes  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 | Click here to enter text. | Click here to enter text. |
| Current version of the Investigator’s Brochure (IB) or product Package Insert (PPI) for the study products | Click here to enter text. | Click here to enter text. |

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

| **Method**  (check all that apply) | | **Source of information** |
| --- | --- | --- |
| Hard Copy | Electronic | Click here to enter text. |

1. How is the Site Research Pharmacist informed of site activation for a protocol?

| **Method**  (check all that apply) | | **Source of information** |
| --- | --- | --- |
| Hard Copy | Electronic | Click here to enter text. |

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

| **Method**  (check all that apply) | | **Source of information** |
| --- | --- | --- |
| Hard Copy | Electronic | Click here to enter text. |

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

Click here to enter text.

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 | FDA 1572  Authorized Prescriber list/log  Other: Click here to enter text. | Click here to enter text. |
| Non-IND Studies | IoR Agreement  Authorized Prescriber list/log  Other: Click here to enter text. | Click here to enter text. |

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

Click here to enter text.

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

Click here to enter text.

1. Complete the table below and indicate whether or not the research 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 | Yes  No | Yes  No  If yes, what type? \_\_\_\_\_\_\_\_\_\_ |
| Inventory | Yes\*  No | Yes  No | Yes  No  If yes, what type? \_\_\_\_\_\_\_\_\_\_ |

1. Will the Site Research Pharmacist be involved in participant consultation and/or counseling?

Yes  No  Upon Request

# **STUDY PRODUCT ACCOUNTABILITY AND DISPENSING**

1. Is a physical inventory conducted of all study products *at least* monthly?  Yes  No

If ‘No’, please explain: Click here to enter text.

1. How is the physical inventory documented?

Click here to enter text.

1. Is an expiration date review of all study products conducted of all study products *at least* quarterly?  Yes  No If ‘No’, please explain: Click here to enter text.
2. How is the expiration date review documented?

Click here to enter text.

1. How will the Site Research Pharmacist receive a written prescription, prescribing order, or request for study product in accordance with institutional, local and/or country regulations? Click here to enter text.

|  | **Initial Prescription, Prescribing Order, or Study Product Request** | **Prescription, Prescribing Order, or Study Product Request indicating a change** |
| --- | --- | --- |
| Electronically | Yes  No | Yes  No |
| Faxed | Yes  No | Yes  No |
| Faxed with hard copy received prior to study product leaving pharmacy control. | Yes  No | Yes  No |
| Hard Copy/ Hand Delivered | Yes  No | Yes  No |

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

Click here to enter text.

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

Click here to enter text.

1. How are refills/repeats documented?

Indicated on the original prescription, prescribing order, or study product request

New prescription, prescribing order, or study product request required

Other procedures (describe): Click here to enter text.

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

Directly to participants

Deliver to other healthcare providers who will distribute it to participants

Other procedures (describe): Click here to enter text.

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

Directly from participants

From other healthcare providers

Other procedures (describe): Click here to enter text.

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

From other healthcare providers

Other procedures (describe): Click here to enter text.

1. If study product is not immediately returned to the pharmacy once it is received from the participant, is the Site Research Pharmacist 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 at least a weekly basis?

Yes (describe): Click here to enter text.

No (explain): Click here to enter text.

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

# **FACILITIES AND EQUIPMENT**

1. Is there a sink or washbasin available in the pharmacy where equipment and other utensils can be washed? Yes  No  If ‘No’, please explain: Click here to enter text.
2. Is there a suitable source of hand washing facilities available? Yes  No

If ‘No’, please explain: Click here to enter text.

1. Is there suitable space for the preparation of study product(s)? Yes  No

If ‘No’, please explain: Click here to enter text.

**ROOM TEMPERATURE STORAGE – HEATING**

1. Is heating available? Yes  No  Not needed  (If the answer is ‘No’ or ‘Not needed’ Please explain, then skip to section ‘*Room Temperature Storage- Cooling*’.) Click here to enter text.
2. The following mechanism(s) are used to heat the room temperature storage area:

Central Heating

Portable Heater, Qty: Click here to enter text.

Air Con, Qty: Click here to enter text.

Other: Click here to enter text.

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

If ‘No’, please explain. Click here to enter text.

1. What range can the room temperature be maintained? Click here to enter text. and Click here to enter text.

**ROOM TEMPERATURE STORAGE – COOLING**

1. Is cooling available? Yes  No  Not needed  (If the answer is ‘No’ or ‘Not needed’ Please explain, then skip to Section *‘Room Temperature- Primary Continuous Temperature Monitoring and Recording Device’* section.) Click here to enter text.
2. The following mechanism(s) are used to cool the room temperature storage area:

Central Air Conditioning

Air Con, Qty: Click here to enter text.

Portable Air Con Units, Qty: Click here to enter text.

Other: Click here to enter text.

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

If ‘No’, who has access? Click here to enter text.

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

If ‘No’, please explain. Click here to enter text.

1. What range can the room temperature be maintained? Click here to enter text.°C and Click here to enter text.°C

**ROOM TEMPERATURE STORAGE:  
PRIMARY CONTINUIOUS TEMPERATURE MONITORING AND RECORDING DEVICE**

1. The primary device used to continuously monitor and record (i.e., device monitors temperatures 24/7/365 and also records/logs temperatures at least every 15 minutes) the room temperature storage is a:

|  |  |
| --- | --- |
| Chart Recorder | Integrated Facility System |
| Data Logger | Other: Click here to enter text. |
| USB Data Logger |  |

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

|  |  |
| --- | --- |
| Hard Wired | Plugged into a power supply |
| Battery Operated | Other: Click here to enter text. |

1. The interval at which the temperature is recorded is every Click here to enter text. minutes.
2. For data captured electronically, what is the frequency which the Site Research Pharmacist prints and/or reviews the temperature documentation for the primary device?

|  |  |
| --- | --- |
| Daily |  |
| Weekly | Other: (please explain): Click here to enter text. |
| Monthly | N/A |

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

|  |  |
| --- | --- |
| Daily |  |
| Weekly | Other: (please explain): Click here to enter text. |
| Monthly | N/A |

1. For chart recorded data, what is the frequency which the Site Research Pharmacist replaces the chart paper for the primary device?

|  |  |
| --- | --- |
| Daily |  |
| Weekly | Other: Click here to enter text. |
| Monthly | N/A |

**ROOM TEMPERATURE STORAGE:  
SECONDARY/BACK-UP TEMPERATURE MONITORING, RECORDING & REVIEW**

1. Indicate the type of documentation of temperatures from the secondary/backup device conducted on a daily basis?

Manual

Electronic

1. From which of the following secondary/back-up devices are temperatures manually recorded?

|  |  |
| --- | --- |
| Chart Recorder | Digital min/max thermometer: Click here to enter text. |
| Data Logger | Mercury min/max thermometer |
| USB Data Logger | Other: Click here to enter text. |
| Integrated Facility System |  |

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

|  |  |
| --- | --- |
| Monday | Friday |
| Tuesday | Saturday |
| Wednesday | Sunday |
| Thursday | Official Holidays |

**REFRIGERATED STORAGE:  
PRIMARY REFRIGERATED STORAGE**

1. The type of refrigerator used as primary storage is:

Scientific grade refrigerator

Walk-in refrigerator

Other: Click here to enter text.

None or N/A (*skip to -20oC Freezer section*)

1. Is the refrigerator located in the research pharmacy? Yes  No

If ‘No’, describe the location: Click here to enter text.

1. Is access to the contents of the refrigerator limited to pharmacy staff only? Yes  No

If ‘No’, please explain: Click here to enter text.

1. Is the refrigerator supported by a generator or back-up power source? Yes  No

If ‘No’, please explain: Click here to enter text.

1. What range can the refrigerator temperature be maintained? Click here to enter text. °C and Click here to enter text.°C

**REFRIGERATED STORAGE:  
ADDITIONAL REFRIGERATED STORAGE**

1. Is there additional refrigerated storage? Yes  No  (If ‘No’, skip to ‘*Refrigerated Storage-Primary Continuous Monitoring and Recording Device’* section)
2. The type of refrigerator used as primary storage is:

Scientific grade refrigerator

Walk-in refrigerator

Other: Click here to enter text.

1. Is the refrigerator located in the research pharmacy? Yes  No

If ‘No’, describe the location: Click here to enter text.

1. Is the refrigerator supported by a generator or back-up power source? Yes  No

If ‘No’, please explain: Click here to enter text.

1. What range can the additional refrigerator temperature be maintained? Click here to enter text.°C and Click here to enter text.°C

**REFRIGERATED STORAGE:  
PRIMARY CONTINUOUS TEMPERATURE MONITORING AND RECORDING DEVICE**

1. The primary device used to continuously monitor and record (i.e., device constantly monitors temperatures and also records/logs temperatures at least every 15 minutes) the temperature of the primary refrigerator is a:

|  |  |
| --- | --- |
| Chart Recorder | Integrated Facility System |
| Data Logger | Other: Click here to enter text. |
| USB Data Logger |  |

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

|  |  |
| --- | --- |
| Hard Wired | Plugged into a power supply |
| Battery Operated | Other: Click here to enter text. |

1. The interval at which the temperature is recorded is every Click here to enter text. minutes.
2. For data captured electronically, what is the frequency which the Site Research Pharmacist prints and/or reviews the temperature documentation for the primary device?

|  |  |
| --- | --- |
| Daily |  |
| Weekly | Other: Click here to enter text. |
| Monthly |  |

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

|  |  |
| --- | --- |
| Daily |  |
| Weekly | Other: Click here to enter text. |
| Monthly | N/A |

1. For chart recorded data, what is the frequency which the Site Research Pharmacist replaces the chart paper for the primary device?

|  |  |
| --- | --- |
| Daily |  |
| Weekly | Other: Click here to enter text. |
| Monthly | N/A |

**REFRIGERATED STORAGE:  
SECONDARY/BACK-UP TEMPERATURE MONITORING, RECORDING AND REVIEW**

1. Indicate the type of documentation of temperatures from the secondary/backup device conducted on a daily basis?

Manual

Electronic

1. From which of the following secondary/back-up devices are temperatures manually recorded?

|  |  |
| --- | --- |
| Chart Recorder | Digital min/max thermometer: Click here to enter text. |
| Data Logger | Mercury min/max thermometer |
| USB Data Logger | Other: Click here to enter text. |
| Integrated Facility System |  |

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

|  |  |
| --- | --- |
| Monday | Friday |
| Tuesday | Saturday |
| Wednesday | Sunday |
| Thursday | Official Holidays |

**-20oC FREEZER STORAGE:  
PRIMARY -20oC FREEZER STORAGE**

1. The type of -20oC freezer used as primary storage is:

Scientific grade -20oC freezer

Walk-in -20oC freezer

Other: Click here to enter text.

N/A (skip to *‘-70°CFreezer Storage: Primary -70°C Freezer Storage’* section)

1. Is the -20oC freezer located in the research pharmacy? Yes  No

If ‘No’, describe the location: Click here to enter text.

1. Is access to the contents of the -20oC freezer limited to pharmacy staff only? Yes  No

If ‘No’, please explain: Click here to enter text.

1. Is the -20oC freezer supported by a generator or back-up power source? Yes  No

If ‘No’, please explain: Click here to enter text.

1. What temperature range can the -20oC freezer be maintained? Click here to enter text.°C and Click here to enter text.°C
2. Is the -20oC freezer an auto-defrost (frost-free) or manual defrost freezer?

Auto-defrost

Manual defrost

**-20oC FREEZER STORAGE:  
ADDITIONAL -20oC FREEZER STORAGE**

1. Is there additional -20°C storage? Yes  No  (If ‘No’, please explain, then skip to ‘*-20oC Primary Continuous Monitoring and Recording Device’* section): Click here to enter text.
2. The type of -20oC freezer used as primary storage is:

Scientific grade -20oC freezer

Walk-in -20oC freezer

Other: Click here to enter text.

1. Is the -20oC freezer located in the research pharmacy? Yes  No

If ‘No’, describe the location: Click here to enter text.

1. Is the -20oC freezer supported by a generator or back-up power source? Yes  No

If ‘No’, please explain: Click here to enter text.

1. What temperature range can the additional -20oC freezer be maintained? Click here to enter text.°C and Click here to enter text.°C
2. Is the additional -20oC freezer an auto-defrost (frost-free) or manual defrost freezer?   
    Auto-defrost

Manual defrost

**-20oC FREEZER STORAGE:  
PRIMARY CONTINUOUS TEMPERATURE MONITORING & RECORDING DEVICE**

1. The primary device used to continuously monitor and record (i.e., device constantly monitors temperatures and also records/logs temperatures at least every 15 minutes) the temperature of the primary refrigerator is a:

|  |  |
| --- | --- |
| Chart Recorder | Integrated Facility System |
| Data Logger | Other: Click here to enter text. |
| USB Data Logger |  |

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

|  |  |
| --- | --- |
| Hard Wired | Plugged into a power supply |
| Battery Operated | Other: Click here to enter text. |

1. The interval at which the temperature is recorded is every Click here to enter text. minutes.
2. For data captured electronically, what is the frequency which the Site Research Pharmacist prints and/or reviews the temperature documentation for the primary device?

|  |  |
| --- | --- |
| Daily |  |
| Weekly | Other: Click here to enter text. |
| Monthly |  |

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

|  |  |
| --- | --- |
| Daily |  |
| Weekly | Other: Click here to enter text. |
| Monthly | N/A |

1. For chart recorded data, what is the frequency which the Site Research Pharmacist replaces the chart paper for the primary device?

|  |  |
| --- | --- |
| Daily |  |
| Weekly | Other: Click here to enter text. |
| Monthly | N/A |

**-20oC FREEZER STORAGE:  
SECONDARY/BACK-UP TEMPERATURE MONITORING, RECORDING AND REVIEW**

1. Indicate the type of documentation of temperatures from the secondary/backup device conducted on a daily basis?

Manual

Electronic

1. From which of the following secondary/back-up devices are temperatures manually recorded?

|  |  |
| --- | --- |
| Chart Recorder | Digital min/max thermometer |
| Data Logger | Mercury min/max thermometer |
| USB Data Logger | Other: Click here to enter text. |
| Integrated Facility System |  |

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

|  |  |
| --- | --- |
| Monday | Friday |
| Tuesday | Saturday |
| Wednesday | Sunday |
| Thursday | Official Holidays |

**-70oC FREEZER STORAGE:  
PRIMARY -70oC FREEZER STORAGE**

1. The type of -70oC freezer used as primary storage is:

Scientific grade -70oC freezer

Walk-in -70oC freezer

Other: Click here to enter text.

N/A (skip to *‘Notification System’* section)

1. Is the -70oC freezer located in the research pharmacy? Yes  No

If ‘No’, describe the location: Click here to enter text.

1. Is access to the contents of the -70oC freezer limited to pharmacy staff only? Yes  No

If ‘No’, please explain: Click here to enter text.

1. Is the -70oC freezer supported by a generator or back-up power source? Yes  No

If ‘No’, please explain: Click here to enter text.

1. What temperature range can the -70oC freezer be maintained? Click here to enter text.°C and Click here to enter text.°C
2. Is the -70oC freezer an auto-defrost (frost-free) or manual defrost freezer?   
    Auto-defrost

Manual defrost

**-70oC FREEZER STORAGE:  
ADDITIONAL -70oC FREEZER STORAGE**

1. Is there additional -70oC freezer storage? Yes  No  (If ‘No’, Please explain, then skip to ‘*-70oC Primary Continuous Monitoring & Recording Device* section)
2. The type of -70oC freezer used as primary storage is:

Scientific grade -70oC freezer

Walk-in -70oC freezer

Other: Click here to enter text.

1. Is the -70oC freezer located in the research pharmacy? Yes  No

If ‘No’, describe the location: Click here to enter text.

1. Is the -70oC freezer supported by a generator or back-up power source? Yes  No

If ‘No’. please explain: Click here to enter text.

1. What range can the additional -70oC freezer be maintained? Click here to enter text.°C and Click here to enter text.°C
2. Is the additional -70oC freezer an auto-defrost (frost-free) or manual defrost freezer?   
    Auto-defrost

Manual defrost

**-70oC FREEZER STORAGE:  
PRIMARY CONTINUOUS TEMPERATURE MONITORING & RECORDING DEVICE**

1. The primary device used to continuously monitor and record (i.e., device constantly monitors temperatures and also records/logs temperatures at least every 15 minutes) the temperature of the primary refrigerator is a:

|  |  |
| --- | --- |
| Chart Recorder | Integrated Facility System |
| Data Logger | Other : Click here to enter text. |
| USB Data Logger |  |

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

|  |  |
| --- | --- |
| Hard Wired | Plugged into a power supply |
| Battery Operated | Other: Click here to enter text. |

1. The interval at which the temperature is recorded: Click here to enter text.
2. For data captured electronically, what is the frequency which the Site Research Pharmacist prints and/or reviews the temperature documentation for the primary device?

|  |  |
| --- | --- |
| Daily |  |
| Weekly | Other: Click here to enter text. |
| Monthly |  |

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

|  |  |
| --- | --- |
| Daily |  |
| Weekly | Other: Click here to enter text. |
| Monthly | N/A |

1. For chart recorded data, what is the frequency which the Site Research Pharmacist replaces the chart paper for the primary device?

|  |  |
| --- | --- |
| Daily |  |
| Weekly | Other: Click here to enter text. |
| Monthly | N/A |

**-70oC FREEZER STORAGE:  
SECONDARY/BACK-UP TEMPERATURE MONITORING, RECORDING AND REVIEW**

1. Is manual documentation of temperatures from the secondary/backup device conducted on a daily basis? Yes  No  If ‘No’, please explain: Click here to enter text.
2. From which of the following secondary/back-up devices are temperatures manually recorded?

|  |  |
| --- | --- |
| Chart Recorder | Digital min/max thermometer |
| Data Logger | Mercury min/max thermometer |
| USB Data Logger | Other: Click here to enter text. |
| Integrated Facility System |  |

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

|  |  |
| --- | --- |
| Monday | Friday |
| Tuesday | Saturday |
| Wednesday | Sunday |
| Thursday | Official Holidays |

**NOTIFICATION SYSTEM – ALL STUDY PRODUCT STORAGE AREAS & EQUIPMENT:**

1. The monitoring device(s)/system(s) used to alert the Site Research Pharmacist of temperature deviations for all IP storage locations function 24hrs/day-7days/week-365days/yr (check all that apply and explain any differences between primary and back-up notification systems for all IP storage locations):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notification Type** | **Room Temperature Storage** | **Refrigerated Storage** | **-20C Freezer Storage** | **Ultra-low Freezer Storage** |
| Audible alarm | ☐ Primary  ☐ Backup | ☐ Primary  ☐ Backup | ☐ Primary  ☐ Backup | ☐ Primary  ☐ Backup |
| Auto dialer alarm to call Pharmacist | ☐ Primary  ☐ Backup | ☐ Primary  ☐ Backup | ☐ Primary  ☐ Backup | ☐ Primary  ☐ Backup |
| Integrated facility alert system | ☐ Primary  ☐ Backup | ☐ Primary  ☐ Backup | ☐ Primary  ☐ Backup | ☐ Primary  ☐ Backup |
| Other | ☐ Primary  ☐ Backup | ☐ Primary  ☐ Backup | ☐ Primary  ☐ Backup | ☐ Primary  ☐ Backup |

Explain Other and/or clarifications for notification systems: Click here to enter text.

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

|  |  |
| --- | --- |
| Automated text message to mobile phone or pager | Audible alarm within the pharmacy  storage area |
| Automated voice message to mobile phone or land line | Audible alarm outside the pharmacy |
| Automated Email | Other, include any clarifications between notification systems: Click here to enter text. |
| Audible alarm within  pharmacy |  |

* 1. How soon after the deviation is the Site Research Pharmacist contacted?

|  |  |
| --- | --- |
| Within 1 – 15 minutes | Within 46 – 60 minutes |
| Within 16 – 30 minutes | More than 60 minutes |
| Within 31 – 45 minutes | Other, include any clarifications between notification systems: Click here to enter text. |

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

|  |  |
| --- | --- |
| Automated text message to mobile phone or pager | Audible alarm within the pharmacy  storage area |
| Automated voice message to mobile phone or land line | Audible alarm outside the  pharmacy |
| Automated Email | Other, include any clarifications between notification systems: Click here to enter text. |
| Audible alarm within  pharmacy |  |

* 1. How soon after the deviation is the Site Research Pharmacist contacted?

|  |  |
| --- | --- |
| Within 1 – 15 minutes | Within 46 – 60 minutes |
| Within 16 – 30 minutes | More than 60 minutes |
| Within 31 – 45 minutes | Other, include any clarifications between notifications systems: Click here to enter text. |

1. What happens if the Site Research Pharmacist cannot be reached?

Click here to enter text.

**BIOSAFETY CABINET/ISOLATOR:**

**PRIMARY BIOLOGICAL CABINET/ISOLATOR:**

1. The type of primary Biosafety Cabinet or Isolator used for preparing study product is:

* Class II, Type: Click here to enter text.
* Class III
* Isolator, Type: Click here to enter text.
* Other: Click here to enter text.
* None (If ‘None’, explain how a study product requiring this is to be prepared, then skip to *‘Transportation/ Chain of Custody’* section.): Click here to enter text.

1. Is the Biological Cabinet or Isolator located in the research pharmacy? Yes 🞎 No 🞎

If ‘No’, describe the location: Click here to enter text.

1. Is access to the Biological Cabinet or Isolator limited to pharmacy staff only? Yes 🞎 No 🞎

If ‘No’, please confirm that use by other groups does not adversely affect use for study product preparation: Click here to enter text.

1. Is the Biological Cabinet or Isolator supported by a generator or back-up power source?

Yes 🞎 No 🞎 If ‘No’, please explain: Click here to enter text.

1. Is the Biological Cabinet or Isolator in good working order? Yes 🞎 No 🞎

If ‘No’, provide additional information:Click here to enter text.

**ADDITIONAL BIOLOGICAL CABINET/ISOLATOR:**

1. Is there any additional Biological Cabinet of Isolator? Yes  No  (If ‘No’, skip to *‘Transportation/ Chain of Custody’* section)
2. The type of additional Biological Cabinet(s) or Isolator(s) used for preparing study product is:

Class II, Type Click here to enter text.

Class III

Isolator, Type Click here to enter text.

Other: Click here to enter text.

1. Is the additional Biological Cabinet of Isolator located in the research pharmacy? Yes  No

If ‘No’, describe the location: Click here to enter text.

1. Is access to the Biological Cabinet or Isolator limited to pharmacy staff only? Yes 🞎 No 🞎

If ‘No’, please confirm that use by other groups does not adversely affect use for study product preparation: Click here to enter text.

1. Is the Biological Cabinet or Isolator supported by a generator or back-up power source?

Yes 🞎 No 🞎 If ‘No’, please explain: Click here to enter text.

1. Is the Biological Cabinet or Isolator in good working order? Yes 🞎 No 🞎

If ‘No’, provide additional information:Click here to enter text.

# **TRANSPORTATION / CHAIN OF CUSTODY**

1. Will pharmacist-dispensed study products (unused or prepared) be transported from the pharmacy to a clinic or other location? Yes  No

If ‘Yes’, continue completing this section. If ‘No’, please explain and then stop here. Click here to enter text.

1. Who transports the pharmacist-dispensed study products from the pharmacy to the clinic?

|  |  |
| --- | --- |
| Pharmacist | Courier |
| Pharmacy Staff | Other: Click here to enter text. |
| Clinic Staff |  |

1. Are the pharmacist-dispensed study products transported in a container that enables the appropriate storage conditions to be maintained? Yes  No  (If you answered Yes, continue completing the follow up questions 3.a-c. Stop here if you answered No.)
   1. Name and address of clinic or other location to which study product will be transported: Click here to enter text.
   2. Distance between pharmacy and clinic to which study product will be transported

(specify miles or kilometers): Click here to enter text.

* 1. Travel mode and time between pharmacy and clinic to which study product will be transported:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (time: ☐ minutes ☐ hours)

☐ driving ☐ walking ☐ bicycling ☐ other

* 1. Who transports the pharmacist labeled, participant specific study product from the pharmacy to the clinic?

☐Pharmacist

☐Pharmacy staff

☐Clinic staff

☐Courier

☐Other: Click here to enter text.

1. When temperature monitoring is required, is a temperature monitoring device included in the container when pharmacist-dispensed study products are transported? Yes  No  (If ‘No’, explain why monitoring would not be used if required per study Protocol/MOP, then skip to question #5)
   1. Is the temperature documented at the time of departure from the pharmacy?

Yes  No

* 1. Is the temperature documented upon arrival at the clinic or other location? Yes  No

Please provide explanation for a No answer to a. or b.: Click here to enter text.

1. Is there a *Transport/ Chain of Custody* SOP? Yes  No  (If ‘No’, please explain: Click here to enter text.
2. Is there a chain of custody document? Yes  No  (If ‘No’, please explain: Click here to enter text.
3. Is there a *Cold Chain Management* SOP? Yes  No  (If ‘No’, please explain): Click here to enter text.
4. Does the Site Research Pharmacist receive confirmation that the pharmacist-dispensed study products were delivered intact, and at the appropriate temperature? Yes  No  (If ‘No’, please explain): Click here to enter text.
5. Is the pharmacist-dispensed study product transported only after the participant arrives for the study visit or are they stored in the clinic?

Prepared only after the participant arrives for the study visit

Stored in the Clinic.

If pharmacist-dispensed study product is prepared in advance and stored in the clinic, answer the following questions:

* 1. Is there a temperature monitoring device located in the storage area to which IP was delivered? Yes  No  (If ‘No’, please explain): Click here to enter text.
  2. What is the frequency in which the storage area temperature is reviewed and recorded?

☐ Daily ☐ Weekly ☐ Monthly ☐ Other: Click here to enter text.

: Click here to enter text.

* 1. If refrigeration is required, is there a temperature monitoring device located in the refrigerator?

Yes  No  (If ‘No’, please explain): Click here to enter text.

* 1. What is the frequency in which the refrigerator temperature is reviewed and recorded?

☐ Daily ☐ Weekly ☐ Monthly ☐ Other: Click here to enter text.

* 1. Is the temperature monitoring record keeping being maintained at the clinic? Yes  No  (If ‘No’, please explain): Click here to enter text.
  2. Is access limited to pharmacy staff and study clinicians? Yes  No  (If ‘No’, please explain): Click here to enter text.
  3. Is there a sufficient security system in place to ensure limited access? Yes  No  (If ‘No’, please explain): Click here to enter text.

1. What is the procedure for handling the pharmacist-dispensed study product if the participant does not attend the study visit?

Click here to enter text.