|  |
| --- |
| Division of Microbiology & Infectious Diseases  (DMID) |
| Study Product Management Plan |
| The Study Product Management Plan 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 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:

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

If the answer is ‘No’, please explain:

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

If the answer is ‘No’, please explain:

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:

1. Provide the address to which all study products will be shipped. This address should not be a P.O. Box.
2. Provide the address for the physical location of the research pharmacy. This address cannot be a P.O. Box.
3. 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 Agents Repository (CAR) | 🞎 | 🞎 | 🞎 | 🞎 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 |  |  |
| Current version of the Investigator’s Brochure (IB) or product Package Insert (PPI) for the study products |  |  |

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 |  |

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 |  |

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 |  |

1. How does the Site Research Pharmacist verify s/he is working with the current IRB-approved version of the protocol?
2. 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: \_\_\_\_\_\_\_\_\_\_\_ |  |
| Non-IND Studies | 🞎 IoR Agreement  🞎 Authorized Prescriber list/log  🞎 Other: \_\_\_\_\_\_\_\_\_\_\_ |  |

1. What procedures are followed by the Site Research Pharmacist to maintain confidentiality of participant records that may contain personal identifiers?
2. 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?
3. 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
2. How is the physical inventory documented?
3. Is an expiration date review of all study products conducted of all study products *at least* quarterly? 🞎 Yes 🞎 No
4. How is the expiration date review documented?
5. 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?

|  | **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?
2. How is the research pharmacy notified that refills/repeats are required?
3. 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):

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):

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):

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):

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):

🞎 No (explain):

🞎 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 🞎
2. Is there a suitable source of hand washing facilities available? Yes 🞎 No 🞎
3. Is there suitable space for the preparation of study product(s)? Yes 🞎 No 🞎

**ROOM TEMPERATURE STORAGE- Heating**

1. Is heating available? Yes 🞎 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:

* Central heating
* Portable heater Qty:\_\_\_\_
* Air Con Qty:\_\_\_\_
* Other: \_\_\_\_\_\_\_\_\_\_

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

If ‘No’, who has access? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

**ROOM TEMPERATURE STORAGE- Cooling**

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

* Central Air conditioning
* Air Con Qty:\_\_\_\_
* Portable Air Con Units Qty:\_\_\_\_
* Other: \_\_\_\_\_\_\_\_\_\_

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

If ‘No’, who has access? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

**room temperature –**

**Primary Continuous Temperature Monitoring and Recording Device**

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

* Chart recorder
* Data logger
* USB data logger
* Integrated facility system
* Other: \_\_\_\_\_\_\_\_\_\_
* None

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

* Hard-wired
* Battery Operated
* Plugged-in to a power supply
* Other: \_\_\_\_\_\_

1. The interval at which the temperature is recorded is: every \_\_\_\_\_minutes
2. For data captured electronically, what is the frequency which the Site Research Pharmacist *prints* and *reviews* the temperature documentation for the primary device?
   * Daily
   * Weekly
   * Monthly
   * Never
   * Other: \_\_\_\_\_\_\_\_\_\_
   * N/A
3. For chart recorded data, what is the frequency which the Site Research Pharmacist *reviews* the temperature documentation for the primary device?
   * Daily
   * Weekly
   * Monthly
   * Never
   * Other: \_\_\_\_\_\_\_\_\_\_
   * N/A
4. For chart recorded data, what is the frequency which the Site Research Pharmacist *replaces* the chart paper for the primary device?
   * Daily
   * Weekly
   * Monthly
   * Never
   * Other: \_\_\_\_\_\_\_\_\_\_
   * N/A

**room temperature –**

**Secondary/Back-Up Temperature Monitoring and Review**

1. Is manual documentation of temperatures conducted on a daily basis? Yes 🞎 No 🞎
2. From which of the following secondary/back-up devices are temperatures manually recorded?
   * Chart recorder
   * Data logger
   * USB data logger
   * Integrated facility system
   * Digital min/max thermometer
   * Mercury min/max thermometer
   * Other: \_\_\_\_\_\_\_\_\_\_
   * None
3. On which days are temperatures reviewed and manually documented? (check all that apply)

* Monday
* Tuesday
* Wednesday
* Thursday
* Friday
* Saturday
* Sunday
* Official Holidays

**REFRIGERATED STORAGE-**

**Primary Refrigerated Storage**

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

* Scientific grade refrigerator
* Walk-in refrigerator
* Other:
* None or N/A (skip to *‘-20°C Freezer Storage’* section)

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

If ‘No’, describe the location:

1. Is access to the contents of the refrigerator limited to pharmacy staff only? Yes 🞎 No 🞎
2. Is the refrigerator supported by a generator or back-up power source? Yes 🞎 No 🞎
3. What range can the refrigerator temperature be maintained? \_\_\_°C and \_\_\_°C

**REFRIGERATED STORAGE-**

**Additional Refrigerated Storage**

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

* Scientific grade refrigerator
* Walk-in refrigerator
* Other:

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

If ‘No’, describe the location:

1. Is the additional refrigerator supported by a generator or back-up power source? Yes 🞎 No 🞎
2. What range can the additional refrigerator temperature be maintained? \_\_\_°C and \_\_\_°C

**REFRIGERATED STORAGE –**

**Primary Continuous Temperature Monitoring and Recording Device**

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

* Chart recorder
* Data logger
* USB data logger
* Integrated facility system
* Other: \_\_\_\_\_\_\_\_\_\_
* None

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

* Hard-wired
* Battery Operated
* Plugged-in to a power supply
* Other: \_\_\_\_\_\_\_\_\_

1. The interval at which the temperature is recorded is: every \_\_\_\_\_minutes
2. For data captured electronically, what is the frequency which the Site Research Pharmacist *prints* and *reviews* the temperature documentation for the primary device?
   * Daily
   * Weekly
   * Monthly
   * Never
   * Other: \_\_\_\_\_\_\_\_\_\_
   * N/A
3. For chart recorded data, what is the frequency which the Site Research Pharmacist *reviews* the temperature documentation for the primary device?
   * Daily
   * Weekly
   * Monthly
   * Never
   * Other: \_\_\_\_\_\_\_\_\_\_
   * N/A
4. For chart recorded data, what is the frequency which the Site Research Pharmacist *replaces* the chart paper for the primary device?
   * Daily
   * Weekly
   * Monthly
   * Never
   * Other: \_\_\_\_\_\_\_\_\_\_
   * N/A

**REFRIGERATED STORAGE-**

**Secondary/Back-Up Temperature Monitoring and Review**

1. Is manual documentation of temperatures conducted on a daily basis? Yes 🞎 No 🞎
2. From which of the following secondary/back-up devices are temperatures manually recorded?
   * Chart recorder
   * Data logger
   * USB data logger
   * Integrated facility system
   * Digital min/max thermometer
   * Mercury min/max thermometer
   * Other: \_\_\_\_\_\_\_\_\_\_
   * None
3. On which days are temperatures reviewed and manually documented? (check all that apply)

* Monday
* Tuesday
* Wednesday
* Thursday
* Friday
* Saturday
* Sunday
* Official Holidays

**-20°C FREEZER STORAGE-**

**Primary -20°C Freezer Storage**

1. The type of -20**°**C freezer used as primary storage is:

* Scientific grade -20**°**C freezer
* Walk-in -20**°**C freezer
* Other:
* None or N/A (skip to *‘-70°C Freezer Storage’* section)

1. Is the -20**°**C freezer located in the research pharmacy? Yes 🞎 No 🞎

If ‘No’, describe the location:

1. Is access to the contents of the -20**°**C freezer limited to pharmacy staff only? Yes 🞎 No 🞎
2. Is the -20**°**C freezer supported by a generator or back-up power source? Yes 🞎 No 🞎
3. What range can the -20**°**C freezer temperature be maintained? \_\_\_°C and \_\_\_°C
4. Is the 20**°**C freezer a cycling (frost-free) or non-cycling freezer? Cycling 🞎 Non-cycling 🞎

**-20°C FREEZER STORAGE-**

**Additional -20°C Freezer Storage**

1. Is there additional -20**°**C freezer storage? Yes 🞎 No 🞎 (If ‘No’, skip to *‘-20°C Freezer- Primary Continuous Temperature Monitoring and Recording Device’* section.)
2. The additional type of -20**°**C freezer is:

* Scientific grade -20**°**C freezer
* Walk-in -20**°**C freezer
* Other:

1. Is the additional -20**°**C freezer located in the research pharmacy? Yes 🞎 No 🞎

If ‘No’, describe the location:

1. Is the additional -20**°**C freezer supported by a generator or back-up power source? Yes 🞎 No 🞎
2. What range can the additional -20**°**C freezer temperature be maintained? \_\_\_°C and \_\_\_°C
3. Is the additional -20**°**C freezer a cycling (frost-free) or non-cycling freezer? Cycling 🞎 Non-cycling 🞎

**-20°C FREEZER STORAGE-**

**Primary Continuous Temperature Monitoring and Recording Device**

1. The primary device used to continuously monitor and record the temperature of the -20**°**C freezer is a:

* Chart recorder
* Data logger
* USB data logger
* Integrated facility system
* Other: \_\_\_\_\_\_\_\_\_\_
* None

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

* Hard-wired
* Battery Operated
* Plugged-in to a power supply
* Other: \_\_\_\_\_\_\_\_\_

1. The interval at which the temperature is recorded is: every \_\_\_\_\_minutes
2. For data captured electronically, what is the frequency which the Site Research Pharmacist *prints* and *reviews* the temperature documentation for the primary device?
   * Daily
   * Weekly
   * Monthly
   * Never
   * Other: \_\_\_\_\_\_\_\_\_\_
   * N/A
3. For chart recorded data, what is the frequency which the Site Research Pharmacist *reviews* the temperature documentation for the primary device?
   * Daily
   * Weekly
   * Monthly
   * Never
   * Other: \_\_\_\_\_\_\_\_\_\_
   * N/A
4. For chart recorded data, what is the frequency which the Site Research Pharmacist *replaces* the chart paper for the primary device?
   * Daily
   * Weekly
   * Monthly
   * Never
   * Other: \_\_\_\_\_\_\_\_\_\_
   * N/A

**-20°C FREEZER STORAGE-**

**Secondary/Back-Up Temperature Monitoring and Review**

1. Is manual documentation of temperatures conducted on a daily basis? Yes 🞎 No 🞎
2. From which of the following secondary/back-up devices are temperatures manually recorded?
   * Chart recorder
   * Data logger
   * USB data logger
   * Integrated facility system
   * Digital min/max thermometer
   * Mercury min/max thermometer
   * Other: \_\_\_\_\_\_\_\_\_\_
   * None
3. On which days are temperatures reviewed and manually documented? (check all that apply)

* Monday
* Tuesday
* Wednesday
* Thursday
* Friday
* Saturday
* Sunday
* Official Holidays

**-70°C FREEZER STORAGE-**

**Primary -70°C Freezer Storage**

1. The type of -70**°**C freezer used as primary storage is:

* Scientific grade -70**°**C freezer
* Walk-in -70**°**C freezer
* Other:
* None or N/A (skip to *‘Notification System’* section)

1. Is the -70**°**C freezer located in the research pharmacy? Yes 🞎 No 🞎

If ‘No’, describe the location:

1. Is access to the contents of the -70**°**C freezer limited to pharmacy staff only? Yes 🞎 No 🞎
2. Is the -70**°**C freezer supported by a generator or back-up power source? Yes 🞎 No 🞎
3. What range can the -70**°**C freezer temperature be maintained? \_\_\_°C and \_\_\_°C

**-70°C FREEZER STORAGE-**

**Additional -70°C Freezer Storage**

1. Is there additional -70**°**C freezer storage? Yes 🞎 No 🞎 (If ‘No’, skip to *‘-70°C Freezer- Primary Continuous Temperature Monitoring and Recording Device’* section.)
2. The additional type of -70**°**C freezer is:

* Scientific grade -70**°**C freezer
* Walk-in -70**°**C freezer
* Other:

1. Is the additional -70**°**C freezer located in the research pharmacy? Yes 🞎 No 🞎

If ‘No’, describe the location:

1. Is the additional -70**°**C freezer supported by a generator or back-up power source? Yes 🞎 No 🞎
2. What range can the additional -70**°**C freezer temperature be maintained? \_\_\_°C and \_\_\_°C
3. Is the additional -70**°**C freezer a cycling (frost-free) or non-cycling freezer? Cycling 🞎 Non-cycling 🞎

**-70°C FREEZER STORAGE-**

**Primary Continuous Temperature Monitoring and Recording Device**

1. The primary device used to continuously monitor and record the temperature of the -70**°**C freezer is a:

* Chart recorder
* Data logger
* USB data logger
* Integrated facility system
* Other: \_\_\_\_\_\_\_\_\_\_
* None

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

* Hard-wired
* Battery Operated
* Plugged-in to a power supply
* Other: \_\_\_\_\_\_\_\_\_

1. The interval at which the temperature is recorded is: every \_\_\_\_\_minutes
2. For data captured electronically, what is the frequency which the Site Research Pharmacist *prints* and *reviews* the temperature documentation for the primary device?
   * Daily
   * Weekly
   * Monthly
   * Never
   * Other: \_\_\_\_\_\_\_\_\_\_
   * N/A
3. For chart recorded data, what is the frequency which the Site Research Pharmacist *reviews* the temperature documentation for the primary device?
   * Daily
   * Weekly
   * Monthly
   * Never
   * Other: \_\_\_\_\_\_\_\_\_\_
   * N/A
4. For chart recorded data, what is the frequency which the Site Research Pharmacist *replaces* the chart paper for the primary device?
   * Daily
   * Weekly
   * Monthly
   * Never
   * Other: \_\_\_\_\_\_\_\_\_\_
   * N/A

**-70°C FREEZER STORAGE-**

**Secondary/Back-Up Temperature Monitoring and Review**

1. Is manual documentation of temperatures conducted on a daily basis? Yes 🞎 No 🞎
2. From which of the following secondary/back-up devices are temperatures manually recorded?
   * Chart recorder
   * Data logger
   * USB data logger
   * Integrated facility system
   * Digital min/max thermometer
   * Mercury min/max thermometer
   * Other: \_\_\_\_\_\_\_\_\_\_
   * None
3. On which days are temperatures reviewed and manually documented? (check all that apply)

* Monday
* Tuesday
* Wednesday
* Thursday
* Friday
* Saturday
* Sunday
* Official Holidays

**NOTIFICATION SYSTEM- ALL STUDY PRODUCT STORAGE AREAS AND EQUIPMENT**

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

* Audible Alarm
* Auto Dialer Alarm
* Integrated facility alert system
* Other: \_\_\_\_\_\_\_\_\_\_
* None

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):
   * Text message to mobile phone or pager
   * Audible phone message
   * Email
   * Audible alarm within pharmacy
   * Audible alarm within the pharmacy storage area
   * Audible alarm outside of the pharmacy
   * Other: \_\_\_\_\_\_\_\_\_\_
   * None
     1. How soon after the deviation is the Site Research Pharmacist contacted?

* within 1 – 15 minutes
* within 16 – 30 minutes
* within 31 – 45 minutes
* within 46 – 60 minutes
* more than 60 minutes
* Never

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):
   * Text message to mobile phone or pager
   * Audible phone or pager message
   * Email
   * Audible ringing within pharmacy
   * Audible ringing within the pharmacy storage area
   * Audible ringing outside of the pharmacy
   * Other: \_\_\_\_\_\_\_\_\_\_
   * None
     1. How soon after the deviation is the Site Research Pharmacist contacted?

* within 1 – 15 minutes
* within 16 – 30 minutes
* within 31 – 45 minutes
* within 46 – 60 minutes
* more than 60 minutes
* Never

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**BIOSAFETY CABINET/ISOLATOR-**

**Primary biosafety cabinet/isolator**

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

* Class II…..Type:
* Class III
* Isolator ……..Type:
* Other:
* None (If ‘None’, skip to *‘Transportation/ Chain of Custody’* section.)

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

If ‘No’, describe the location:

1. Is access to the Biological Cabinet or Isolator limited to pharmacy staff only? Yes 🞎 No 🞎
2. Is the Biological Cabinet or Isolator supported by a generator or back-up power source? Yes 🞎 No 🞎
3. Is the Biological Cabinet or Isolator in good working order? Yes 🞎 No 🞎

If ‘No’, provide additional information:

**ADDITIONAL BIOLOGICAL CABINET/ISOLATOR**

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

* Class II………Type:
* Class III
* Isolator…….Type:
* Other:

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

If ‘No’, describe the location:

# Transportation/Chain of Custody

1. Will pharmacist-dispensed study products be transported from the pharmacy to a clinic or other location? Yes 🞎 No 🞎 (If ‘Yes’, continue completing this section. If ‘No’, stop here.)
2. Who transports the pharmacist-dispensed study products from the pharmacy to the clinic?

* Pharmacist
* Pharmacy staff
* Clinic staff
* Courier
* Other: \_\_\_\_\_\_\_\_\_\_

1. Are the pharmacist-dispensed study products transported in a container that enables the appropriate storage conditions to be maintained? Yes 🞎 No 🞎
2. 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’, skip to question #5)
   1. Is the temperature documented at the time of departure from the pharmacy? Yes 🞎 No 🞎
   2. Is the temperature documented upon arrival at the clinic or other location? Yes 🞎 No 🞎
3. Is there a *Transport/* *Chain of Custody* SOP? Yes 🞎 No 🞎
4. Is there a chain of custody document? Yes 🞎 No 🞎
5. Is there a *Cold Chain Management* SOP? Yes 🞎 No 🞎
6. Does the Site Research Pharmacist receive confirmation that the pharmacist-dispensed study products was delivered intact, and at the appropriate temperature? Yes 🞏 No 🞏
7. 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? Yes 🞎 No 🞎
    2. Are temperatures documented immediately prior to being given to a participant? Yes 🞎 No 🞎
    3. Is access limited to pharmacy staff and study clinicians? Yes 🞎 No 🞎
    4. Are there sufficient security measures in place to ensure limited access? Yes 🞎 No 🞎

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

# VTEU contract Specific requirements

**Quality Management**

1. Describe Pharmacy QM Processes (systematic process for quality management and problem-solving activities)

**Double Check/ Second Check Process**

1. Describe the Double Check Process

*Double-check Process Requirement Description:*

*Upon dispensing of study product by the site Research Pharmacist to the clinic or location where study product administration will occur and prior to study product administration, a “double-check” of the dispensed study product must be performed.    The ‘double-check’ required for VTEU clinical research trials is performed by an individual licensed to administer drugs before the study product is administered.  This individual must also be appropriately qualified by training, licensure and registration to perform this function.*

*This ‘double-check’ is exemplified as follows:*

1. *In the instance where no further manipulations or dose preparation after dispensing is required, after receipt of the dispensed study product, the individual licensed to administrator study product verifies that the study product corresponds with the protocol-assigned treatment (e.g., treatment assignment, product name (if unblinded), strength/concentration, dose, route, and frequency).*
2. *In the instance where, after dispensing by the site Research Pharmacist, the study product requires additional manipulation or dose preparation prior to administration (e.g., withdrawal of a single-dose from a multi-dose vial or single-step dilution of a vaccine for immediate administration), the individual performing the additional manipulation verifies study product corresponds with the protocol-assigned treatment (e.g., treatment assignment, product name (if unblinded), strength/concentration, dose, route, and frequency).  A “double-check” by a second individual (again, licensed to administer drugs) must also occur during and/or after manipulation or dose preparation and prior to administration of the product.*