**Research Product Management Plan (RPMP) - Devices**

*Please note: The RPMP is password protected, and only specified fields can be edited and checkboxes can be checked.*

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**Study Information**

|  |  |
| --- | --- |
| **COMIRB number**  | Click or tap here to enter text. |
| **Protocol Title:**  | Click or tap here to enter text. |
| **Principal Investigator:** | Click or tap here to enter text. |
|  |  |

Institutions involved in managing this product:

**Indicate specific UCHealth Region(s) Where Study Will Take Place (must match Portal Form):**[ ]  Metro Denver

[ ]  University of Colorado/CU Medicine/CU Anschutz

[ ]  Other: specify Click or tap here to enter text.

 **Review Information**

|  |  |
| --- | --- |
| **Version of RPMP:**  | [x]  Original [ ]  Revision |
| **Approver Name:**  |  |
| **Approval:** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***Signature of RPRC Delegate Date* |
|  | ***Routing instructions for UCHealth:****For products only managed at UCHealth Metro Denver: UCHealth RPRC delegate will approve and sign RPMP.* |
|  |  |

***Study Description***

1. **How many products are involved in this study**: Click or tap here to enter text.

*If more than one product is involved, you will need to add additional forms until all products have been represented. Use of a research product and a comparator is considered two products. Matching placebo for a research product is entered as one product.*

1. **Describe in a succinct way the FDA IDE status, and how the research device(s) used in this study will be obtained and managed. Please also include source of device supply (i.e. sponsor/manufacturer or PI designed and manufactured (***e.g. all devices used in this study are FDA-approved and commercially available***)**

Click or tap here to enter text.

1. **For randomized studies: Briefly describe the process / system that will be used to assign study subjects to a specific study treatment (e.g. IRT, randomization table created by study team etc.)**

Click or tap here to enter text.

1. **Describe how use of the device on a participant is going to be documented (i.e. – research record):**

Click or tap here to enter text.

***Source and Labeling - Product #1***

1. **Name of the product and ancillary supplies:** Click or tap here to enter text.
2. **Name of supplier of the product (***i.e. where you get the product from. E.G. this may be the manufacturer, a lead site***):**Click or tap here to enter text.
3. **If the device is investigator manufactured, please provide additional details regarding the manufacturing process, prior testing in animals or humans, and safety information:**Click or tap here to enter text.
4. **Please provide sample product labels you plan to use:**

(required for all studies: COMIRB number, PI name, Study Title, Contact Number)
Click or tap here to enter text.

1. **Select the options that apply to research device**

[ ] Research product will be provided already labeled and pre-packaged for each study subject or subject’s visit. Study team will also add local labeling

[ ]  Research product will be provided, but study team will label and package for each study subject or subject’s visit.

[ ]  Investigator obtains research product through commercial source, study team will label and package for each study subject’s visit.

[ ]  Research product manufactured by investigator

[ ]  Other, specify: Click or tap here to enter text.

1. **Please provide product inventory logs you plan to use.**(If using industry sponsor documents and not yet received, please indicate below)

Click or tap here to enter text.

1. **Please provide drafts of individual patient accountability logs you plan to use.** [ ]  Yes [ ]  N/A(If not yet received from industry sponsor, please indicate below)

Click or tap here to enter text.

1. **Provide any Standard Operating Procedures related to product management
(drafts are acceptable)**

**If none, checkbox here:** [ ]

Click or tap here to enter text.

***Storage - Product #1***

1. **Storage Location (*must include each building, room #, and location in the room)***

|  |  |
| --- | --- |
|  | **Product Storage Location\***  |
| **1** | Click or tap here to enter text. |
| **2** | Click or tap here to enter text. |
| **3** | Click or tap here to enter text. |
| **4** | Click or tap here to enter text. |

1. **Describe the building and storage area security:**Click or tap here to enter text.
2. **Describe the storage unit security (e.g. cabinet, closet, etc.):** Click or tap here to enter text.
3. **Storage Temperature Requirements**

**A. Will temperate monitoring be required for this product?** [ ]  Yes [ ]  No
If yes, please indicate in the box below.
If no, please indicate why: Click or tap here to enter text.

|  |  |
| --- | --- |
| Allowable Temperature Range | Click or tap here to enter text. |
| Max Duration of Allowed Temp Excursion | Click or tap here to enter text. |
| Describe how temp will be monitored | Click or tap here to enter text. |
| Frequency of temp monitoring | Click or tap here to enter text. |
| Describe how temp will be documented | Click or tap here to enter text. |
| Will an alarm be used for temp excursions? If yes . . .  | [ ]  Yes [ ]  No |
|  Who will be notified by alarm? | Click or tap here to enter text. |
|  What is the alarm’s sensitivity?  | Click or tap here to enter text. |

1. **If facilities is not providing temperature monitoring, how the temperature calibration expiration date will be tracked:**

Click or tap here to enter text.

1. **Will a new thermometer be purchased prior to the calibration expiration date?** [ ]  Yes [ ]  No

Click or tap here to enter text.

1. **Describe any other storage requirements, how the study team will manage them and how they are documented.**

Click or tap here to enter text.

1. **Is the research device single-use per patient?** [ ]  Yes [ ]  No
2. **If multi-use, provide the disinfection SOP (provide manufacturer cleaning documentation if available):
Cleaning log will be required, please reach out to RPRC coordinator**

Click or tap here to enter text.

1. **Describe any specialized handling for this product (i.e. – hazardous material).**

Click or tap here to enter text.

1. **Please describe device preparation, set-up, programming and/or adjustment and removal procedure**

Click or tap here to enter text.

**Product Manipulation and Administration - Product #1**

1. **Describe the product administration/distribution:**

[ ] On-site by a study team member

 **If checked, specify:**

* The location, including building, floor and if possible room, where the product administration will take place: Click or tap here to enter text.
* Training, licensing, and work experience of the staff member(s) who will administer the product: Click or tap here to enter text.
* Name and degree of the person who will provide medical supervision and oversight over the administration of the product: Click or tap here to enter text.

[ ]  Self-administered/self-use by the patient at home

 If checked, provide details about patient education in the “Personnel” Section

[ ]  Other / Notes: Click or tap here to enter text.

1. **Describe the process used to transport the study device between the supplier, storage or preparation location or distribution to the study subject**
	1. How will the product be transported: Click or tap here to enter text.
	2. How will the chain of custody of the product be documented: Click or tap here to enter text.
	3. How will the temperature be maintained at the recommended range during the transport: Click or tap here to enter text.
	4. How will transportation back to storage location be handled: Click or tap here to enter text.

***Product Disposal - Product #1***

1. **Is the device disposed of on campus or returned to the sponsor/kept for an additional future study?**(green tagging process should be followed if disposed on campus)Click or tap here to enter text.
2. **Describe your plan for disposal or return of expired or unused product, and how disposal of the product will be documented in the research records. If kept for future research, please indicate below.**

Click or tap here to enter text.

**(if only one product will be managed, please skip to the Personnel section)**

***Source and Labeling - Product #2***

1. **Name of the product and ancillary supplies:** Click or tap here to enter text.
2. **Name of supplier of the product (***i.e. where you get the product from. E.G. this may be the manufacturer, a lead site***):**Click or tap here to enter text.
3. **If the device is investigator manufactured, please provide additional details regarding the manufacturing process, prior testing in animals or humans, and safety information:**Click or tap here to enter text.
4. **Please provide sample product labels you plan to use:**

(required for all studies: COMIRB number, PI name, Study Title, Contact Number)
Click or tap here to enter text.

1. **Select the options that apply to research device**

[ ] Research product will be provided already labeled and pre-packaged for each study subject or subject’s visit. Study team will also add local labeling

[ ]  Research product will be provided, but study team will label and package for each study subject or subject’s visit.

[ ]  Investigator obtains research product through commercial source, study team will label and package for each study subject’s visit.

[ ]  Research product manufactured by investigator

[ ]  Other, specify: Click or tap here to enter text.

1. **Please provide product inventory logs you plan to use.**(If using industry sponsor documents and not yet received, please indicate below)

Click or tap here to enter text.

1. **Please provide drafts of individual patient accountability logs you plan to use.** [ ]  Yes [ ]  N/A(If not yet received from industry sponsor, please indicate below)

Click or tap here to enter text.

1. **Provide any Standard Operating Procedures related to product management
(drafts are acceptable)**

**If none, checkbox here:** [ ]

Click or tap here to enter text.

***Storage - Product #2***

1. **Storage Location (*must include each building, room #, and location in the room)***

|  |  |
| --- | --- |
|  | **Product Storage Location\***  |
| **1** | Click or tap here to enter text. |
| **2** | Click or tap here to enter text. |
| **3** | Click or tap here to enter text. |
| **4** | Click or tap here to enter text. |

1. **Describe the building and storage area security:**Click or tap here to enter text.
2. **Describe the storage unit security (e.g. cabinet, closet, etc.):**Click or tap here to enter text.
3. **Storage Temperature Requirements**

**A. Will temperate monitoring be required for this product?** [ ]  Yes [ ]  No
If yes, please indicate in the box below.
If no, please indicate why: Click or tap here to enter text.

|  |  |
| --- | --- |
| Allowable Temperature Range | Click or tap here to enter text. |
| Max Duration of Allowed Temp Excursion | Click or tap here to enter text. |
| Describe how temp will be monitored | Click or tap here to enter text. |
| Frequency of temp monitoring | Click or tap here to enter text. |
| Describe how temp will be documented | Click or tap here to enter text. |
| Will an alarm be used for temp excursions? If yes . . .  | [ ]  Yes [ ]  No |
|  Who will be notified by alarm? | Click or tap here to enter text. |
|  What is the alarm’s sensitivity?  | Click or tap here to enter text. |

1. **If facilities is not providing temperature monitoring, how the temperature calibration expiration date will be tracked:**

Click or tap here to enter text.

1. **Will a new thermometer be purchased prior to the calibration expiration date?** [ ]  Yes [ ]  No

Click or tap here to enter text.

1. **Describe any other storage requirements, how the study team will manage them and how they are documented.**

Click or tap here to enter text.

1. **Is the research device single-use per patient?** [ ]  Yes [ ]  No
2. **If multi-use, provide the disinfection SOP (provide manufacturer cleaning documentation if available):
Cleaning log will be required, please reach out to RPRC coordinator**

Click or tap here to enter text.

1. **Describe any specialized handling for this product (i.e. – hazardous material).**

Click or tap here to enter text.

1. **Please describe device preparation, set-up, programming and/or adjustment and removal procedure**

Click or tap here to enter text.

 **Product Manipulation and Administration - Product #2**

1. **Describe the product administration/distribution:**

[ ] On-site by a study team member

 **If checked, specify:**

* The location, including building, floor and if possible room, where the product administration will take place: Click or tap here to enter text.
* Training, licensing, and work experience of the staff member(s) who will administer the product: Click or tap here to enter text.
* Name and degree of the person who will provide medical supervision and oversight over the administration of the product: Click or tap here to enter text.

[ ]  Self-administered/self-use by the patient at home

 If checked, provide details about patient education in the “Personnel” Section

[ ]  Other / Notes: Click or tap here to enter text.

1. **Describe the process used to transport the study device between the supplier, storage or preparation location or distribution to the study subject**
	1. How will the product be transported: Click or tap here to enter text.
	2. How will the chain of custody of the product be documented: Click or tap here to enter text.
	3. How will the temperature be maintained at the recommended range during the transport: Click or tap here to enter text.
	4. How will transportation back to storage location be handled: Click or tap here to enter text.

 ***Product Disposal - Product #2***

1. **Is the device disposed of on campus or returned to the sponsor/kept for an additional future study?**(green tagging process should be followed if disposed on campus)Click or tap here to enter text.
2. **Describe your plan for disposal or return of expired or unused product, and how disposal of the product will be documented in the research records. If kept for future research, please indicate below.**

Click or tap here to enter text.

**Personnel**

1. **Check which tasks apply to this study and describe which roles will perform them:**
	1. Orders the research product from supplier [ ]  Yes [ ]  No
		* + If Yes, list the role of the person performing this task (e.g. PRA): Click or tap here to enter text.
	2. Manages proper storage of the product(s) [ ]  Yes [ ]  No
		* + If Yes, list the role of the person performing this task (e.g. PRA): Click or tap here to enter text.
	3. Dispenses the product(s) [ ]  Yes [ ]  No

 (*Dispensing means receiving and reviewing a request for the research product from a licensed practitioner (i.e. an order or equivalent), selecting the appropriate product, preparing, packaging, labeling, and/or record keeping as described in the RPMP*)

* + - * If Yes, list the role of the person performing this task (e.g. PRA): Click or tap here to enter text.
	1. Administers the product(s) [ ]  Yes [ ]  No

 (*Administration means the direct application of a device to a research subject by injection, inhalation, ingestion or any other method. Administration is limited to individuals with appropriate training and licensure, see* [*here*](https://thesource.uchealth.org/Departments/ResearchAdmin/Pages/Investigational-Product.aspx) *for guidance*):

* + - * If Yes, list the role of the person performing this task: Click or tap here to enter text.
	1. Distributes the product(s) to the study subject(s). [ ]  Yes [ ]  No

*(Distributes means transfer of the research product to the end user following the chain of custody plan described in this section*)

* + - * If Yes, list the role of the person performing this task (e.g. PRA): Click or tap here to enter text.
	1. Completes the individual patient’s product accountability log(s) [ ]  Yes [ ]  No
		+ - If Yes, list the role of the person performing this task (e.g. PRA): Click or tap here to enter text.
	2. Completes required inventory logs [ ]  Yes [ ]  No
	(check yes if not yet received from sponsor)
		+ - If Yes, list the role of the person performing this task (e.g. PRA): Click or tap here to enter text.
	3. Tracks product expiration dates [ ]  Yes [ ]  No
		+ - If Yes, list the role of the person performing this task (e.g. PRA): Click or tap here to enter text.
	4. Documents receipt of research product shipment(s) as required [ ]  Yes [ ]  No
		+ - If Yes, list the role of the person performing this task (e.g. PRA): Click or tap here to enter text.
	5. Manages disposal process for the product(s) [ ]  Yes [ ]  No
		+ - If Yes, list the role of the person performing this task (e.g. PRA): Click or tap here to enter text.
	6. Provides patient education about the use of the research product [ ]  Yes [ ]  No
		+ - If Yes, list the role of the person performing this task (e.g. PRA): Click or tap here to enter text.
	7. Cleaning of multi-use products [ ]  Yes [ ]  No
		+ - If Yes, list the role of the person performing this task (e.g. PRA): Click or tap here to enter text.

1. **What training will be provided to anyone responsible for managing of the product?**

Click or tap here to enter text.

1. **Who will provide the training?**

Click or tap here to enter text.

*If you have any questions, please contact the Clinical Research Support Center*

*clinicalresearchspportcenter@ucdenver.edu*