New version of Investigational Product Management Plan (IPMP)

This revised version of the IPMP is required for studies that initiate the HSR Portal process on or after 1/1/2018.

Changes to the form include questions about randomization procedures, process for documenting the “order” for the investigational product, and additional details and definitions in the Personnel section.

The revised IPMP is password protected, and only specified fields can be edited and checkboxes can be checked. To edit the document, open the file in WORD, go to “View” in the menubar and select “Edit document” from the picklist. If you have more than two products that need to be managed differently from each other, please contact clinicalresearchsupportcenter@ucdenver.edu to get additional sections added to the form. Send a quick note to the same email address if you have problems with the revised form.



**Investigational Product Management Plan (IPMP)**

**Study Information**

|  |  |
| --- | --- |
| **IRB Protocol 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:

[ ]  UCH

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

[ ]  Denver Metro

[ ]  Colorado Springs

[ ]  University of Colorado

[ ]  Children’s Hospital of Colorado

[ ]  Denver Health

[ ]  VA

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

**Review Information**

|  |  |
| --- | --- |
| **Version of IPMP:**  | [ ]  Original [ ]  Revision |
| **Approver Name:**  |  |
| **Approval:** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***Signature of IPRC Delegate Date* |
| **Approval Contingent On:**  | ***Routing instructions for UCHealth:****For products only managed at UCHealth Metro Denver: UCHealth IPRC delegate will approve and sign IPMP.**For products only managed at UCHealth North and/or South: Both Regional pharmacist and UCHealth System Director of Research Admin will approve and sign IPMP.*  |
|  |  |

***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 an investigational product and a comparator is considered two products. Matching placebo for an investigational product is entered as one product.*

1. **Will a comparison product be used in this study?**  [ ]  Yes [ ]  No

*If yes, please complete the information for this product separate from the investigational product*

1. **Which kind of product(s) is involved in this study:** Click or tap here to enter text.
* **Drug/biologic/nutritional supplement or similar substance:** [ ]

*(check if the product achieves its primary intended purposes through chemical action within or on the body, and is dependent upon being metabolized for the achievement of any of its primary intended purposes.)*

* **Device:**[ ]

*(check if the product is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article which does not achieve its primary intended purposes through chemical action within or on the body, and is not dependent upon being metabolized for the achievement of any of its primary intended purposes.)*

* **Both drug(s) and device(s):** [ ]
1. **Describe in a succinct way the FDA status, and how each/all of the products used in this study will be obtained and managed. Provide separate brief descriptions if needed. Include all products that will be used as part of this study, not just investigational products. (***e.g. all drugs used in this study are FDA-approved and commercially available. PI will purchase all products in bulk from the UCHealth outpatient pharmacy, and PI’s study team will store and manage all products in a storage location in AO1***)**

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. IWRS, randomization table created by study team etc)**

Click or tap here to enter text.

1. **Describe how the PI will document that he/she requests the study product (“orders” it) for a study subject (e.g. research note in Medical Record system, paper prescription in research record etc)**

Click or tap here to enter text.

***Source and Labeling - Product # \_1\_\_ (enter sequential number for each product used)***

1. **Name of the product:** 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, or a retail pharmacy***):** Click or tap here to enter text.
3. **Role of this product in Study:** [ ] Investigational product

 [ ]  Supplemental product stored by study team

1. **Is this product a DEA-controlled substance?** [ ]  Yes [ ]  No

*You can check to see if your drug is classified on* [*this website*](http://www.dea.gov/druginfo/ds.shtml)*, which has a link to a complete listing at the bottom. Please note that marijuana is classified as a Schedule I drug.*

1. **Will a placebo be used for this product?** [ ]  Yes [ ]  No
2. Do you have drafts of product labels you plan to use**?** [ ]  Yes [ ]  No

If yes, please provide

Click or tap here to enter text.

**Describe who will provide the label(s):**

Click or tap here to enter text.

1. **Select the options that apply to product and/or placebo preparation**

[ ] Investigational product and/or matching placebo will be provided already labeled and pre-packaged for each study subject or subject’s visit.

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

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

[ ]  If placebo is obtained from a different source than the investigational product, provide:

* + - Name of supplier: Click or tap here to enter text.
		- Ingredients: Click or tap here to enter text.

**Select the options that applies:**

[ ]  Placebo will be provided already labeled and pre-packaged for each study subject’s visit.

[ ]  Placebo will be provided in bulk, study team will label and package for each study subject’s visit.

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

1. Do you have drafts of product inventory logs you plan to use**?** [ ]  Yes [ ]  No

If Yes, please provide

Click or tap here to enter text.

1. Do you have drafts of individual patient product accountability logs you plan to use**?** [ ]  Yes [ ]  No

If Yes, please provide

Click or tap here to enter text.

1. Do you have Standard Operating Procedures related to product management that apply**?** [ ]  Yes [ ]  No

If Yes, please provide

Click or tap here to enter text.

***Storage - Product #\_\_\_(enter sequential number for each product used)***

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. |
| **5** | Click or tap here to enter text. |

1. **Storage Temperature Requirements**

|  |  |
| --- | --- |
| 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. **Describe 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 and how the study team will comply with them.**

*Example: Humidity range*

Click or tap here to enter text.

1. **Describe any specialized handling and/or shipping instructions for this product.**

*Example: dry ice, infectious substance, biological product etc*

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, freezer etc):** Click or tap here to enter text.

Click or tap here to enter text.

***Product Manipulation and Administration - Product #\_\_\_(enter sequential number for each product used)***

1. **Does the product need to be manipulated between receipt by the investigator and administration?** [ ]  Yes [ ]  No

**If Yes, describe:**

* + Required preparation procedures (including dose calculations and dose preparation procedures): Click or tap here to enter text.
	+ Procedures for minimizing staff exposure to the product: Click or tap here to enter text.
	+ Any Quality Assurance procedures used: Click or tap here to enter text.
	+ How the above listed procedures will be documented in the research files: Click or tap here to enter text.
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 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. **Does the product need to be transported between the supplier, storage or preparation location or distribution to the study subject?**

 [ ]  Yes [ ]  No

**If Yes, describe:**

* + How will the product be transported: Click or tap here to enter text.
	+ How will the chain of custody of the product be documented: Click or tap here to enter text.
	+ How will the temperature be maintained at the recommended range during the transport: Click or tap here to enter text.

***Product Disposal - Product #\_\_\_(enter sequential number for each product used)***

1. **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.**

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\_\_ (enter sequential number for each product used)***

1. **Name of the product:** 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, or a retail pharmacy***)::** Click or tap here to enter text.
3. **Role of this product in Study:** [ ] Investigational product

 [ ]  Supplemental product stored by study team

1. **Is this product a DEA-controlled substance?** [ ]  Yes [ ]  No

*You can check to see if your drug is classified on* [*this website*](http://www.dea.gov/druginfo/ds.shtml)*, which has a link to a complete listing at the bottom. Please note that marijuana is classified as a Schedule I drug.*

1. **Will a placebo be used for this product?** [ ]  Yes [ ]  No
2. Do you have drafts of product labels you plan to use**?** [ ]  Yes [ ]  No

If yes, please provide

Click or tap here to enter text.

**Describe who will provide the label(s) :**

Click or tap here to enter text.

1. **Select the options that apply to product and/or placebo preparation**

[ ] Investigational product and/or matching placebo will be provided already labeled and pre-packaged for each study subject or subject’s visit.

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

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

[ ]  If placebo is obtained from a different source than the investigational product, provide:

* + - Name of supplier: Click or tap here to enter text.
		- Ingredients: Click or tap here to enter text.

**Select the options that applies:**

[ ]  Placebo will be provided already labeled and pre-packaged for each study subject’s visit.

[ ]  Placebo will be provided in bulk, study team will label and package for each study subject’s visit.

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

1. Do you have drafts of product inventory logs you plan to use**?** [ ]  Yes [ ]  No

If Yes, please provide

Click or tap here to enter text.

1. Do you have drafts of individual patient product accountability logs you plan to use**?** [ ]  Yes [ ]  No

If Yes, please provide

Click or tap here to enter text.

1. Do you have Standard Operating Procedures related to product management that apply**?** [ ]  Yes [ ]  No

If Yes, please provide

Click or tap here to enter text.

***Storage - Product #\_\_\_(enter sequential number for each product used)***

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. |
| **5** | Click or tap here to enter text. |

1. **Storage Temperature Requirements**

|  |  |
| --- | --- |
| 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. **Describe 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 and how the study team will comply with them.**

*Example: Humidity range*

Click or tap here to enter text.

1. **Describe any specialized handling and/or shipping instructions for this product.**

*Example: dry ice, infectious substance, biological product etc*

Click or tap here to enter text.

1. **Describe the building and storage area security:**

Click or tap here to enter text.

1. **Describe the storage unit security (e.g. cabinet, freezer etc):**

Click or tap here to enter text.

***Product Manipulation and Administration - Product #\_\_\_(enter sequential number for each product used)***

1. **Does the product need to be manipulated between receipt by the investigator and administration?** [ ]  Yes [ ]  No

**If Yes, describe:**

* + Required preparation procedures (including dose calculations and dose preparation procedures): Click or tap here to enter text.
	+ Procedures for minimizing staff exposure to the product: Click or tap here to enter text.
	+ Any Quality Assurance procedures used: Click or tap here to enter text.
	+ How the above listed procedures will be documented in the research files: Click or tap here to enter text.
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 where 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 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.

**Does the product need to be transported between the supplier, storage or preparation location or distribution to the study subject?**  [ ]  Yes [ ]  No

**If Yes, describe:**

* + How will the product be transported: Click or tap here to enter text.
	+ How will the chain of custody of the product be documented: Click or tap here to enter text.
	+ How will the temperature be maintained at the recommended range during the transport: Click or tap here to enter text.

***Product Disposal - Product #\_\_\_(enter sequential number for each product used)***

1. **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.**

Click or tap here to enter text.

**(if you have more than two products that need to be managed, please Contact clinicalresearchsupportcenter@ucdenver.edu)**

**Personnel**

1. **Check which tasks apply to this study and describe which roles will perform them:**
	* Orders the investigational 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.
	* 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.
	* Compounds and/or repackages the product(s) [ ]  Yes [ ]  No
		+ - If Yes, list the role of the person performing this task (e.g. IDS Pharmacist): Click or tap here to enter text.
	* Dispenses the product(s) [ ]  Yes [ ]  No

 (*Dispensing means receiving and reviewing a request for the investigational 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 IPMP*)

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

 (*Administration means the direct application of a drug or 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.
	+ Distributes the product(s) to the study subject(s). [ ]  Yes [ ]  No

*(Distributes means transfer of the investigational 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.
	+ 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.
	+ Documents receipt of investigational 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.
	+ Completes required inventory logs [ ]  Yes [ ]  No
		- * If Yes, list the role of the person performing this task (e.g. PRA): Click or tap here to enter text.
	+ 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.
	+ 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.
	+ Provides patient education about the use of the investigational product [ ]  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 or 303.724.1111*

*Once this is prepared, it must be attached to the Human Subject Research Portal submission.*