**Instruction Page**

**The principal investigator** will ensure the Pharmacists of Record receives the following documents prior to dispensing drugs.

1. Copy of protocol and any amendments
2. Copy of FDA 1572
3. IRB approval letter
4. Copy of consents
5. Investigator’s brochure
6. Notification of Investigational Drug Service (IDS)
7. Investigational Drug Services Financial Agreement Form

**The Pharmacist of Record checklist**

* Study drugs appropriately secured and stored
* Order files are setup in physician order entry system (if inpatient study)
* Copy of pre-printed outpatient prescription (where applicable)
* Dedicated pharmacy binder that includes enrollment logs, drug accountability logs, patient worksheets (if applicable), and protocol procedures
* Drug inventory/ compliance monitoring
* Dispensing according to protocol

Pharmacist of Record is required answer the questions on the following page. Upon completion return the drug service form to the investigator in charge of this study.

**KEEP THIS PAGE FOR YOUR RECORDS**

**Pharmacist / Medical Research Representative**

**Complete this form**

**Study Title**

1. **Enter name of physician In charge of study:**
2. **Enter name person other than doctor who is responsible for this study:**
3. **Enter drug sponsor/company:**
4. **List name(s) of assigned Pharmacist of Record *(primary individual who is expected to develop and maintain investigational product control system.)***

|  |  |  |
| --- | --- | --- |
| **Enter name of pharmacist(s) of record for this trial** | **Contact number** | **Assigned (A)**  **Back-up (B) Pharmacist** |
|  |  | A  B |
|  |  | A  B |
|  |  | A  B |

1. **List name(s) of Medical Representatives other than a licensed pharmacist who will be responsible for storing, dispensing, and record keeping.**

|  |  |  |
| --- | --- | --- |
| **Enter names of Medical Research Representatives (*other than a licensed pharmacist)*** | **Contact number** | **Assigned (A)**  **Back-up (B)**  **Staff** |
|  |  | A  B |
|  |  | A  B |
|  |  | A  B |

1. **Where will study medication(s) be dispensed?** (check all that apply)
2. **Pharmacy Unit:**  **Inpatient**  **Outpatient. Indicated the pharmacy unit/ hospital name:**
3. **Clinical Research Site:** **Enter site name:**

|  |  |  |  |
| --- | --- | --- | --- |
| **List FDA non-approved investigational drug** | **Drug supplied by:** | **List FDA approved commercial drug for this investigation**  ***(new indication)*** | **Cost of Agents**  ***if supplied by Department of Pharmacy*** |
|  | Pharmacy  Sponsor |  |  |
|  | Pharmacy  Sponsor |  |  |
|  | Pharmacy  Sponsor |  |  |
|  | Pharmacy  Sponsor |  |  |
|  | Pharmacy  Sponsor |  |  |
|  | Pharmacy  Sponsor |  |  |

1. If the investigational agents will be supplied by the Department of Pharmacy *(i.e., FDA approved agents, comparative agents, or standard of care)*, who will be responsible for reimbursement of the medication costs to the Department of Pharmacy / Broward Health? If the cost will not be reimbursed? Please explain.

1. Provide shipping address where the study products are to be shipped.

1. How will the Pharmacist of Record / Medical Representative be informed of the IRB approval of this protocol?

1. How will the Pharmacist of Record / Medical Representative verify that she/he is working with the current IRB approved version of a protocol?

1. How will authorized prescribing be identified for this protocol to prevent the unauthorized prescribing of investigational products?

1. Will the Pharmacist of Record / Medical Representative be involved in participant consultation/ counseling?

1. Will the Pharmacist of Record / Medical Representative be involved in the research site initiation?

1. Other than the Pharmacist of Record / Medical Representative, who has access to study products and storage areas?
2. What temperature range is the storage area(s) maintained?
3. Is there documentation of temperature monitoring of the refrigerator? Yes  No
4. How often is the refrigerator monitored for temperature control?
5. Does the Pharmacy Unit have a separate refrigerator and storage area clearly identifying investigational product(s)? Yes  No
6. **Refrigerated Storage in the Clinic**: ifstudy products that require refrigeration are prepared in advance for a participant’s collection (pick up) at the clinic, will refrigeration be available in the clinic?

Yes  No

1. What mechanisms are in place to notify the Pharmacist of Record / Medical Representative of any temperature deviations in the storage areas, when staff is not present?

**Pharmacist of Record Agreement**

Pharmacist of Record identified below has accepted the responsibility for conducting the investigational drug services for this protocol.

**Department of Pharmacy Acknowledgement:**

The Clinical Coordinator of the Department of Pharmacy has acknowledged and received all pertinent information and documentation related to the investigational drug protocol.

**For studies requiring a Pharmacist of Record:**

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Print Pharmacist of Record Name Signature Date

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Print Alternate Pharmacist Name Signature Date

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

Print Operational Pharmacy Supervisor / Signature Date

Pharmacy Manager Name

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**For studies with a Medical Representative:**

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Print Medical Representative Name Signature Date

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Print Alternate Medical Representative Name Signature Date

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Print Research Manager / Signature Date

Principal Investigator Name

*A copy of this completed form should be kept on file in the pharmacy binder.*