PATIENT NAME AND HISTORY NUMBER

**Instructions**

**In accordance with the policy on investigational new drugs (INDs), a member of the study team must scan a completed IDDS into the Media tab of the participant’s Epic chart whenever a participant is first enrolled in the study and when an amendment to the IDDS is approved through the IRB. (For Department of Oncology studies, a completed copy of the IDDS must also be posted to the Protocol Library).**

**A separate IDDS must be submitted for each site at which the IND-related product will be dispensed.**

**Questions about the description or contents of this form or other matters regarding INDs or medication use in clinical studies should be directed to the P&T representative of the assigned IRB.**

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IRB Protocol Number: Click or tap here to enter text.

Protocol Title: Click or tap here to enter text.

(For Oncology): Study number Click or tap here to enter text.

Hopkins Principal Investigator: Click or tap here to enter text.

Office Phone: Click or tap here to enter text.

Emergency Contact Information: Pager, Cell Phone or Home Phone: Click or tap here to enter text.

Please indicate at which site this IDDS will be used (a separate IDDS must be submitted for each site). Click below to choose your site:

Click or tap here to select a site

If other please specify: Click or tap here to enter text.

Site Primary Investigator: Click or tap here to enter text.

Office Phone: Click or tap here to enter text.

Emergency Contact Information: Pager, Cell Phone, or Home Phone: Click or tap here to enter text.

Authorized Prescribers at this site [**Only IRB-approved study team members may serve as Authorized Prescribers**]: Click or tap here to enter text.

Person/Pharmacy responsible for storing and dispensing drug at this site:Click or tap here to enter text.

Person/Pharmacy:Click or tap here to enter text.

Phone Number:Click or tap here to enter text.

Pharmacy Storage Location:Click or tap here to enter text.

Dispensing location: Click or tap here to enter text.

Brief Study Background and Primary Objective(s): [Please limit to no more than a brief paragraph- 2-3 sentences]

Click or tap here to enter text.

Expected Therapeutic Effects (if known or applicable):Click or tap here to enter text.

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Drug Information

1.  Drug Name (Name to be used in prescribing and labeling): Click or tap here to enter text.

2.  Drug Synonyms: Click or tap here to enter text.

3.  Final Dosage Form and Strength Administered to the Participants in This Study: (e.g., tablets, capsules, injections and mg content of each tablet or mg content and volume of diluent for infusions): Click or tap here to enter text.

4. Drug Regimen for This Study (drug, dose, route, frequency) including Schema (if desired): Click or tap here to enter text.

5. Possible Adverse Effects: See example of table that could be used to present AE information- Table may

be deleted if an alternate format is used (e.g. listing events by frequency).

|  |  |
| --- | --- |
| SYSTEM | DESCRIPTIONS/EVENTS |
| Allergy/immune | Click or tap here to enter text. |
| Heme | Click or tap here to enter text. |
| Neuro/Psych | Click or tap here to enter text. |
| Cardiac | Click or tap here to enter text. |
| Pulmonary | Click or tap here to enter text. |
| GI | Click or tap here to enter text. |
| GU | Click or tap here to enter text. |
| Skin/musculoskeletal | Click or tap here to enter text. |
| Other | Click or tap here to enter text. |

6. Directions for Administering Drug(s) (e.g., duration of timed infusion or “take with 240 mL water”, etc.): Click or tap here to enter text.

7. Person(s) administering the study drug to the participants at this site after dispensing (e.g., patient, home caregiver, nurse, authorized prescriber):Choose an item.

8.  Other Nursing Information: (e.g. flush requirements, EKGs, vitals, monitoring requirements)

For hazardous drugs, can drug be infused through a closed system transfer device (CSTD)? Select a response from the drop down.

Vesicant properties if known? Click or tap here to enter text.

9. Special instructions for managing the drug after dispensing (e.g., tubing, filters, light exposure, storage outside of the pharmacy): Click or tap here to enter text.

10. Describe, in detail, any special precautions required for the person(s) handling the drug after dispensing, related to teratogenicity, carcinogenicity, mutagenicity and reproductive toxicity, based on data from the sponsor of the IND or institutional standards:

Click or tap here to enter text.

11. Instructions for disposal of used or unused medications and containers/bags after dispensing:

Click or tap here to enter text.

Prepared by: Date:

Updated by: Date:

Submission of this form implies endorsement of its contents by the Principal Investigator, even if the Principal Investigator is not the one who prepared it.