**Non-JHH/JHU Sites Investigational Drug Data Sheet (IDDS)**

*For use in JHSPH Drug studies occurring outside JHU*

Personnel Involved and Contact Information

Site Name:

|  |  |  |
| --- | --- | --- |
| **Role in Study** | **Name** | **Contact and Location Information** |
| Site Principal Investigator |  | Office:  Pager:  Cell:  Email:  Home: |
| Site Co-Investigator |  | Office:  Pager:  Cell:  Email:  Home: |
| Authorized Prescribers at Site |  | Office:  Pager:  Cell:  Email:  Home: |
| Person/Pharmacy Responsible for storage/dispensing at site |  | Phone:  Storage Location:  Dispensing Location: |
| Person(s) administering drug to site participants (e.g., prescriber, nurse, patient, home caregiver, etc.) |  | Contact info: |

­­­­­­­­­­­­­­­­­­­­­­Drug Information

1.  Drug Name (Name to be used in prescribing and labeling):

2.  Drug Synonyms:

3.  Dosage Form (e.g., tablets, capsules, injection) and Strength (e.g., mg content of each tablet) Administered to the Participants in This Study:

4. Dosing Regimen for This Study (drug, dose, route, frequency):

5. Directions for Administering Drug:

6. Expected Therapeutic Effects:

7. Possible Adverse Effects:

8. Describe, in detail, any special precautions required for the person(s) handling the drug according to the sponsor of the IND, based on teratogenicity, carcinogenicity, mutagenicity, and reproductive toxicity data:

9.  Special instructions for managing the drug after dispensing: (e.g., storage, disposal of used or unused medications and containers/bags):

Prepared 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.