|  |
| --- |
| **Prescription Drug/Medication Management Addendum****(This form must be completed by the PI and included with the IRB submission packet for all new protocols that involve drugs/medications or existing protocols that add a new drug/medication).** |
| **Protocol Title:** Click or tap here to enter text. |
| **Protocol Number:**Click or tap here to enter text. |
| **PI Name:** Click or tap here to enter text. | **Date:**Click or tap here to enter text. |
|  | **(Complete a separate form for each study drug)****Drug Name:** Click or tap here to enter text.**If your research involves providing prescription medication/drugs to study participants, this checklist must be completed and submitted to the HRPP with IRB Form 1 and all other required submission materials. Completion of this form provides information for the IRB in assessing adequate compliance with the RI Board of Pharmacy regulations and Brown University Policies regarding the appropriate procurement, prescribing, dispensing, administering, storing, controlling and disposal of study drugs. You may attach any additional relevant information if more space is needed in any section.**  | **HRPP USE ONLY:**Confirm informationfor IRB review,(based on protocolsubmission andchecklist) by noting with your initials and the date confirmed. |
|  | **Procurement:** Who provides the study drug?  | [ ]  PharmacyName:Click or tap here to enter text. | [ ]  ManufacturerName:Click or tap here to enter text. | Click or tap here to enter text. |
|  | Does the study involve the use of a placebo? [ ]  YES [ ]  NOIf YES, who provides the study placebo?Click or tap here to enter text. | [ ]  PharmacyName:Click or tap here to enter text. | [ ]  ManufacturerName:Click or tap here to enter text. | Click or tap here to enter text. |
|  | **Dispensing:** If a **pharmacy** provides and/or prepares the study drug and/or placebo, please confirm that a licensed individual (e.g., study MD) provides the pharmacy with a separate prescription for each study participant and that each prescription is identified by the participant’s name.  | [ ]  Confirmed | [ ]  N/A(check only if drug is provided by manufacturer) | Click or tap here to enter text. |
|  | **Obtaining:**Please describe how the drugs/prescriptions are obtained/received by the study here. (e.g., once filled, study prescriptions are shipped to the study PI or coordinator).Click or tap here to enter text. | Click or tap here to enter text. |
|  | **Administering:**Please confirm that the study ensures that the medication is properly checked (a drug utilization review\*[[1]](#footnote-1) is conducted) by a licensed individual, such as the study MD, prior to the medication being given to a study participant.  | [ ]  Confirmed | Click or tap here to enter text. |
|  | **Storage and control:**Please describe the procedures for the storage and control of the study drugs here. Click or tap here to enter text. | Click or tap here to enter text. |
|  | **Disposal:** Please describe the procedures for the disposal of the study drugs here. Click or tap here to enter text. | Click or tap here to enter text. |
|  | **All activities related to medication management must be documented by the study team. This documentation includes records and inventories of all of drug procurement, dispensing, administering, storage and control, and disposal procedures.** |
|  |

1. Per RI Board of Pharmacy regulations, a drug utilization review must be performed in settings where an institution or the practitioner does not hold an institutional pharmacy license. This review requires that a licensed individual, such as medical doctor, perform a review/validation check of the medication prior to the medication being provided to a study participant. This review may take place several days in advance of the participant’s appointment at which he/she will receive the study medication. Once the review takes place, a trained and designated, non-licensed study staff person (e.g., an RA) may provide the medication to the study participant. Documentation of the drug utilization review process must be maintained by the study team. [↑](#footnote-ref-1)