

**Brown University**

**Appendix E. Prescription Drug/Medication Management**

**Protocol Title:**

**Principal Investigator (PI):**

**IRB Protocol # (if amendment):**

**Date of submission:** Click here to enter a date.

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| **This Appendix must be completed by the PI and included with:****1) All new Full Board / Expedited IRB Applications the involve providing prescription medications / drugs to study participants; and****2) Any amendment to an approved IRB protocol when adding a new drug/medication****Please fill out this Appendix for EACH study drug. Please see** [**Management of Human Research Studies Involving Drugs & Medications**](https://www.brown.edu/research/sites/research/files/Guidance%20for%20Investigators-The%20Management%20of%20Human%20Research%20Studies%20Invo.pdf) **for guidance.**  |
| 1. Drug name:  |
| **PROCUREMENT** |
| 2. Who provides the study drug? | [ ]  Pharmacy. Please name: [ ]  Manufacturer. Please name: |
| 3. Does the study involve the use of a placebo? | [ ]  Yes [ ]  NoIf “Yes,” who provides the study placebo?[ ]  Pharmacy. Please name: [ ]  Manufacturer. Please name: |
| **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. |
| 4. A licensed prescriber provides a separate prescription for each participant in which the participant is identified by name. | [ ]  Confirmed. Name of prescriber:[ ]  N/A. Drug provided by manufacturer. |
| **OBTAINING** |
| 5. Please describe how the study drugs/prescriptions are obtained/received by the study team (e.g., once filled, study prescriptions are shipped to the study PI): |
| **ADMINISTERING** |
| 6. Please confirm that the study ensures medication is properly checked (a drug utilization review is conducted[[1]](#footnote-1)) by a licensed individual, such as the study MD, prior to the medication being given to a study participant:[ ]  I confirm that a drug utilization review will be conducted and documented.[ ]  I confirmed that the drug utilization review will be conducted by a licensed clinician.  |
| **STORAGE & CONTROL** |
| 7. Please describe procedures for storage and control of the study drugs: |
| **DISPOSAL** |
| 8. Please describe procedures for disposal of the study drug: |
| **RECORDS MANAGEMENT** |
| 9. 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.[ ]  I affirm that I understand my responsibilities as the PI for the study to adhere to the record-keeping responsibilities stated above. |

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)