



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:

PI name:

Date:

(Complete a separate form for each study drug)

Drug name: _____

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 information for IRB review, (based on protocol submission and checklist) by noting with your initials and the date confirmed.

Procurement:

Who provides the study drug?

Pharmacy

Name:

Manufacturer

Name:

Does the study involve the use of a placebo?

YES NO

If YES, Who provides the study placebo?

Pharmacy

Name:

Manufacturer

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.

confirmed

N/A
(check only if drug is provided by manufacturer)



	<p>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).</p>	
	<p>Administering: Please confirm that the study ensures that the medication is properly checked (a drug utilization review*¹ is conducted) by a licensed individual, such as the study MD, prior to the medication being given to a study participant.</p>	<p><input type="checkbox"/> confirmed</p>
	<p>Storage and control: Please describe the procedures for the storage and control of the study drugs here.</p>	
	<p>Disposal: Please describe the procedures for the disposal of the study drugs here.</p>	
<p>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.</p>		

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.