SECTION I. USE OF DRUGS OR BIOLOGICAL AGENTS

All IRB-approved protocols that involve the administration of FDA-approved medications and/or investigational medications **MUST** utilize the NYPH Investigational Pharmacy to dispense the medications specified in the research protocol. Prior to submission of a new IRB application, investigators must make arrangements with the Investigational Pharmacy and must have the Use of Drugs and Biological Agents Form signed by an authorized member of the Department of Pharmacy. This will ensure that all medications are accounted for and that studies budget properly for the utilization of the Investigational Pharmacy.

To be completed by the study team:

IRB#:

Protocol ID/Study Title:

PI:

Complete the table below for each medication being administered as part of the protocol

Medication Name	Status of Medication:		
	*Investigational**	*Off-label Use of FDA-approved Medication**	*Used According to FDA Labeling*
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐

Submit copies (as applicable) of each of the following materials to the Investigational Pharmacy at pharmacysectioni@med.cornell.edu:

☐ IRB Protocol Submission ☐ Protocol ☐ Investigator's Brochure or Package Insert

☐ FDA 1572 ☐ Pharmacy Manual

Select sponsor type (select only one):

☐ Industry Sponsored/Non-NYPH/WC Affiliated ☐ Grant/Federal Funding (NCI, NIH, NIAID, etc.)

☐ Investigator-Initiated/COOP Group ☐ SIND/EIND

CONROLLED SUBSTANCES: COMPLETE THIS SECTION ONLY IF THE REFERENCED STUDY UTILIZES SCHEDULE II-V CONTROLLED SUBSTANCES

Schedule of Controlled Substance: ☐ II ☐ III ☐ IV ☐ V

Updated: 16JUL2018

When submitting this document to Investigational Pharmacy, please include the following additional documents for studies utilizing controlled substances:

- IRB Approval Letter
- Current IRB Roster(s)
- New York State Controlled Substance License of the distributor or manufacturer providing the substances (note the certificate must be specific to the schedule of the relevant controlled substance (II-V)
- Drug Enforcement Administration Controlled Substance Registration Certificate of the distributor or manufacturer providing the substances (note the certificate must be specific to the schedule of the relevant controlled substance (II-V)
- Drug Enforcement Administration Controlled Substance Registration Certificate of the researcher(s) ordering the substances

***The Investigational Pharmacy does not manage studies involving the use of Schedule I controlled substances**

To be completed by pharmacy:

Service(s) required from the Investigational Pharmacy:

Maintenance:

☐ Drug Storage/Inventory/Accountability x ____ Drugs

☐ Supply Storage/Inventory/Accountability x ____ Supplies

Dispensing:

☐ Low Complexity ☐ Moderate Complexity

☐ High Complexity – Non-Hazardous ☐ High Complexity – Hazardous

☐ High Complexity – Viral Vectors

Randomization:

☐ Design Randomization Schema

Miscellaneous:

☐ Controlled Substance Licensing

☐ 24/7 Enrollment/Dispensing

☐ Other _____

If any medications will be administered and/or dispensed as part of this protocol, please obtain approval from the Department of Pharmacy. The signature of NYP Pharmacy Management on this document indicates only the Hospital's acknowledgement that the Department of Pharmacy will provide facilities, services and other operational resources in connection with the clinical services required by this study, as per Dr. Forese letter dated 2/23/2010

Cindy Ippoliti

_____	_____	_____
Department of Pharmacy (Print Name)	**Signature**	**Date**

Updated: 16JUL2018