INVESTIGATIONAL DRUG SERVICE AUTHORIZATION FORM

The IDS requests a copy of the sponsor's protocol, Investigator's Brochure and the PPHS protocol summary and consent form. The IDS Coordinator will review the project for safety and feasibility, and assess IDS requirements and support. Investigators will be charged for resources utilized on a fee per service basis. The investigator should adequately budget for all pharmacy costs. This form is required for ***each*** *of the agents listed on IRB form HRP211, and if they are specifically stated in the protocol/informed consent form, whether it is an investigational agent or standard of care (i.e. anaphylaxis, supportive care, commercially available, etc.).*

Protocol Title: _____

_____

Protocol Sponsor: _____ GCO #: _____ IF#: _____

☐ Federal ☐ Non-Federal

Principal Investigator: _____ Principal Investigator's Life Number: _____

Primary Contact Name: _____ Primary Contact Phone: _____

Study Fund Account*: _____ Alternate departmental /fund account, if study fund is not yet established: _____

***A fund number is required before the IDS will sign off on any forms or initiate any procedures. For those studies which an alternate departmental fund number is provided, IDS will delay billing by 6 months.**

1. Is The Mount Sinai School of Medicine the Coordinating Center? No ☐ Yes ☐ If yes, our role: _____

2. Agent Description (Manufacturer/Generic Name/Form/Strength): _____

3. Controlled Substance? No ☐ Yes ☐ If Yes, Schedule _____ and NYS **Research** license # _____and DEA **Research** #_____
   Copies of Valid NYS Controlled Drug License and DEA Research license MUST be provided in order for Controlled Drugs for research to be dispensed. Signature of PI acknowledging this requirement _____

4. Is the use of this product in the trial considered standard of care? No ☐ Yes ☐

5. Requested IDS services:
   ☐Dispensation ☐Storage ☐Randomization ☐Preparation ☐Destruction ☐Site Visits ☐Repack ☐Label

   ☐ N/A (standard of care) ☐Other → Specify:

6. The agent will be supplied by:
   Sponsor ☐ IDS (purchased by study funds) ☐ Commercially Available/Sourced by Hospital ☐ Patients own supply ☐ Other ☐ Specify: Other requirements may apply

7. The placebo will be supplied by:
   N/A ☐ Sponsor ☐ IDS ☐ If supplied by the IDS, is compounding required? (paid for by study funds) No ☐ Yes ☐

8. The agent will be administered:
   Inpatient Hospital ☐
   Outpatient Clinic ☐
   Outpatient FPA ☐
   Private Office (MSSM or offsite location) ☐ → Specify:

9. Indicate the storage requirements of the agent:
   Controlled Room Temperature 15 - 30°C ☐
   Refrigerated 2-8°C ☐
   Frozen -20°C ☐
   Deep Freeze -80°C ☐

10. Indicate where the agent will be stored:
    The IDS Pharmacy ☐ If checked, please skip questions 11, 12.
    Patient's own supply ☐ If checked, please skip questions 11, 12.
    Sourced by Hospital ☐ If checked, please skip questions 11, 12.
    The PI and his/her authorized personnel ☐ If checked, please complete questions 11, 12.

11. Please comment on the following questions regarding storage of the agent:

11a. The storage area is well maintained, provides adequate lighting, ventilation, sanitation, space and security.	Yes ☐ No ☐
11b. The temperature in the storage area is controlled and monitored using calibrated monitoring devices.	Yes ☐ No ☐
11c. The temperature monitoring system has sensors for continuous monitoring and alarms set at the points representing the temperature extremes.	Yes ☐ No ☐
11d. Records of temperatures and alarms are maintained and all excursions outside the labeled storage conditions are appropriately investigated and reported to the sponsor.	Yes ☐ No ☐

If answered no for any part of question 11, please explain: _____

12. Please comment on the plan to control the distribution of the agents. Attach other materials as necessary.

12a. The investigator will not dispense the investigational agent to any person not authorized under the protocol to receive it.	Yes ☐ No ☐
12b. The drug, agent, biologic may only be used in subjects under the investigator's personal supervision or under the supervision of a physician who is directly responsible to the investigator.	Yes ☐ No ☐
12c. The investigator will maintain adequate records for the receipt, storage, and disposition of the drug, including dates, quantity, and use by subjects.	Yes ☐ No ☐
12d. The investigational agents will be stored in a secure area and in such a way to restrict access to authorized personnel only as defined in the protocol. Additionally, all associated records will be stored in a restricted area and/or locked.	Yes ☐ No ☐

If answered no for any part of question 12, please explain: _____

I assure that the plan for the control of the research drugs and biologics involved in this Human Research is accurately described and appropriate. I will conduct the Human Research in accordance with this plan, as well as with applicable regulations and organizational policies and procedures.

Principal Investigator Printed Name	**Department:**	**Division (if applicable):**
Principal Investigator Signature	**Date**	

IDS Coordinator to complete:

SERVICES	**FEE ($)**	**COMMENTS:**
Initiation	_____	_____
Dispensing		
Simple	_____	_____
Moderate	_____	_____
Complex	_____	_____
Compounding	_____	_____
Coordinating Center Role	_____	_____
Administrative	_____	_____
Close-out	_____	_____

Fees will be assessed quarterly, or as study needs dictate.
Invoices will be generated by Sinai Central.

Approved by: _____

IDS coordinator Date

GUIDANCE TO FILLING OUT THE INVESTIGATIONAL DRUG SERVICE AUTHORIZATION FORM

- A form is required for **EACH** drug/biologic whose use is specifically prescribed in the research protocol, as per HRP211. The form does not need to be completed for approved agents whose use is up to the discretion of the physician as part of routine medical care.

- Funds for pharmacy review must be provided **at the time of form submission**. The IDS will not sign off on any forms or initiate any procedures until a fund number has been provided. The investigator may provide an alternate departmental fund account, if a study specific fund is not yet established. For those studies which an alternate departmental fund number is provided, IDS will **delay billing by 6 months, and the charge would then be included in the subsequent quarter's billing**. It is the responsibility of the study team to update IDS with the study specific fund number prior to quarter-end processing, or the departmental fund number will be charged, and your department will be responsible for the fund transfer.

- The principal investigator's life number is required to utilize Sinai Central for billing.

- Non-federal trials: industry-sponsored and investigator-initiated; Federal trials include those supported by Cooperative Groups

Question 1:
To be a coordinating center, the Mount Sinai investigator is the Principal Investigator for multi-site participation in the trial. Currently, IDS supports some trials as the coordinating center. We are working towards expanding this service to more investigators at Mount Sinai. Please contact an IDS coordinator to discuss further details. See expanded definition below.

Question 2:
Please indicate the manufacturer of the agent, generic name, form of the agent that the subject will be receiving (i.e. tablet, capsule, injection, solution, suspension, etc.), and the strength of the agent that will be supplied (i.e. 20mg/mL injection, 10 mL vial, 50mg tablet, etc; the dose that the subject will be receiving is not necessary).

Question 3:
Public Health Law requires any person acting as a manufacturer, distributor, importer, exporter, institutional dispenser or institutional dispenser limited of controlled substances, or conducting research, instructional activities or chemical analysis with controlled substances in New York State to obtain a license from the Department of Health. Individuals conducting human subjects research that involves controlled substances must do so in accordance with the relevant policies and processes of the research pharmacy and other applicable policies.

Any individual who uses or synthesizes controlled substances for research under the auspices of the Medical Center must be: (a) licensed with NYS DOH, and registered with the US DEA (a "Licensed Individual") to conduct such research; or (b) authorized under the license of a Licensed Individual with respect to such research. **The Medical Center does not hold an "institutional license" for use of controlled substances in research.** Even if an individual already has a clinical license and DEA registration for treatment of patients with controlled substances, if he or she will also be conducting laboratory or non-therapeutic research involving controlled substances, a separate research license from NYS DOH is required. In addition, for research with Schedule I drugs, a separate registration (Class 7) with the DEA is required. (refer to www.health.state.ny.us/professionals/narcotic and http://www.firstclinical.com/journal/2011/1112_DEA.pdf for more information). **A copy of both the NYS research and DEA research licenses must be supplied to IDS at the time of submission for documentation in the study folder.**

Questions 6 and 7:
Please identify the source of each test article listed on PPHS form HRP211. This will help determine the role of the IDS. Hospital supplies should not be used to support research activities.

Question 8:
The Joint Commission of Accreditation of Health Care Organizations requires that when a hospital operates a pharmacy, the pharmacy must control the storage, dispensing, labeling and distribution of investigational medication. Research taking place in hospital areas **MUST** use the Investigational Drug Service (IDS) to control the agent.

Hospital Areas: Inpatient, GCRC, Clinics → MUST USE IDS
Non-Hospital Areas: Outpatient FPA, Private Offices, School of Medicine
→If you choose not to utilize the IDS, please provide a description of your plan to store, handle, and control the distribution of the agent to ensure that the agent will be dispensed by only authorized investigators and the agent will be used in subjects that have agreed to take part in the research.

Questions 9, 10, and 11:
IDS requires proper documentation on how each test article will be controlled and stored. If IDS is storing the test article, numbers 11 and 12 do not have to be filled out; the IDS will maintain this documentation. The IRB requires the IDS to review the plan for control and storage of all test articles to ensure patient safety and drug integrity.

Storage of Investigational Agents

- All investigational agents should be stored according to conditions described on labels or within investigator brochures.
- When specified on the label, controls for humidity, light, etc should be in place.
- If no storage requirements are established, the investigational agent may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.
- Used investigational agents must be stored separately from unused investigational agents and accurate records maintained.

FDA defined storage parameters are as follows:

Storage conditions	Celsius	Fahrenheit
Controlled room temperature (Excursions permitted)	20 to 25 °C (15 to 30 °C)	68 to 77 °F (59 to 86)°F
Cool Storage	8 to 15 °C	46 to 59 °F
Refrigerater Storage	2 to 8 °C	36 to 46 °F
Freezer storage	-25 to -10 °C	-13 to 14°F

Question 12:
Acceptable plans to control the distribution of the investigational agents.

- The investigator may not dispense the investigational agent to any person not authorized under the protocol to receive it.
- The drug, agent, biologic may only be used in subjects under the investigator's personal supervision or under the supervision of a physician who is directly responsible to the investigator.
- The investigator is required to maintain adequate records for the receipt, storage, and disposition of the drug, including dates, quantity, and use by subjects.
- The investigational agents must be stored in a secure area and in such a way to restrict access to authorized personnel only as defined in the protocol. Additionally, all associated records must also be stored in a restricted area and/or locked.

Fee Breakdown:
The fees to utilize the IDS are itemized below. Utilize these fees in your budget negotiations with industry sponsors and when preparing federally sponsored grant budgets.

	FEDERAL SPONSORS	**NON-FEDERAL SPONSORS**
Initiation Fee	$1500/study	$1500/study
Dispensing Fee		
Simple	$50/dispensation	$50/dispensation
Moderate	$80/dispensation	$80/dispensation
Complex	$150/dispensation	$150/dispensation
Special Compounding	$90/hour	$90/hour
Administrative Fee	N/A	$750/annually (billed as $62.50/month)
Close-out Fee	$500/study	$500/study
Coordinating Center Services	TBD/contact IDS coordinator	TBD/contact IDS coordinator

Initiation fee: One-time cost incurred **regardless** of study enrollment broken out into $750 for protocol review and $750 for the remaining set-up (preparing procedures, initiation meetings, staff in-services, and set-up of computer order entry screens).

Dispensing Fees
Simple: Does not require manipulation of dosage form, including oral dosage forms & blinded kits

Moderate: IV preparations with minimal effort; Controlled substances, Oral chemotherapy

Complex: Labor intensive and/or hazardous IV preparations, including chemotherapy, gene therapy, antibodies, virus vectors; IVRS required; Advance notice not possible, including STAT preparations &poor stability preparations

Administrative Fee: Includes quality assurance; Compliance with Hospital, JCAHO, state and federal standards; Site visits; Audits; Storage of study materials (inventory, recordkeeping, refrigerator, room temperature, freezer and temperature monitoring software); Drug destruction; Overall maintenance

Close-Out Fee: Includes return or destruction of all remaining study materials; Copies of records returned as appropriate

Coordinating Center Services (for multi-site trials): Includes but is not limited to randomizing for other sites, managing drug supply for all sites, shipping drug to participating sites, etc