Icahn School of Medicine at Mount Sinai | Mount Sinai Hospital | Mount Sinai Beth Israel | Mount Sinai St. Luke's | Mount Sinai West | New York Eye and Ear Infirmary of Mount Sinai

Investigational Drug Service (IDS) Review Form: Drug/Biologic Management Plan

GUIDANCE ON COMPLETING THE INVESTIGATIONAL DRUG SERVICE (IDS) REVIEW FORM

- †IDS Review form is required for **EACH** drug/biologic whose use is specified in the research protocol.
    - It is required for each of the agent listed on IRB form HRP211 Appendix B (e.g. investigational and/or FDA-approved drugs/biologics specified in the protocol and not used under routine medical care). This form does not need to be completed for FDA-approved agents whose use is determined by the investigator's discretion as part of routine medical care (eg. supportive care) and supplied by a hospital or commercial pharmacy in the US.
    - Dietary supplements, nutraceuticals, and other compounds, when intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease (including studies for that purpose) are considered drugs. Drugs also include "articles (other than food) intended to affect the structure or any function of the body of man or other animals" including endogenous compounds used to provoke or blunt a physiologic response.
    - Live organisms/vaccines may be both a biological product and a drug.
- Funds for Pharmacy Review must be provided **at the time of IDS Review 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 fund account (e.g. Departmental Fund) if a study-specific fund is not yet established. For studies which an alternate fund number is provided, IDS will **delay billing by 6 months**. The Study Team is responsible for providing IDS with the study-specific fund number before the end of the 6 months to avoid the alternate fund number being charged and for any necessary fund transfers.
- Principal Investigator's Life number is required to utilize Sinai Central for billing.
- Non-federal trials include industry-sponsored and investigator-initiated trials. Federal trials include those supported by NIH, NCI, and Cooperative Groups.

Question 1:
Please indicate the manufacturer of the agent, generic name, dosage form of the agent (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). It is not necessary to include the dose that the subjects will be receiving.

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 (NYS) to obtain a license from the Department of Health (DOH). Individuals conducting human subject research that involves controlled substances must do so in accordance with the relevant policies and processes of the research pharmacy and other applicable institutional 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. **When available at the member site, the "institutional license" for scheduled II to V controlled substances in research may be used. Contact an IDS coordinator to discuss details**. Refer to www.health.state.ny.us/professionals/narcotic and http://www.firstclinical.com/journal/2011/1112_DEA.pdf for more information..

- Even if an individual already has a clinical license and DEA registration for treatment of patients with controlled substances, a separate research license from NYS DOH is required for conducting laboratory or non-therapeutic research involving controlled substances.
- For research with Schedule I drugs, a separate registration (Class 7) with the DEA is required.

Question 4: Identify the source of each agent listed on PPHS form HRP211 Appendix B. Hospital resources should not be used to support research activities.

Question 6: IDS provides support for drug shipments to other participating sites in a multi-center clinical trial. Contact an IDS coordinator to discuss further details.

Question 7:
The Joint Commission requires that when a hospital operates a pharmacy, the pharmacy must control the storage, dispensing, labeling and distribution of investigational medications. Research taking place in hospital areas **MUST** use the Investigational Drug Service (IDS) to control the agent.

- Hospital Areas: Inpatient, Clinical Research Unit, Hospital-based Clinics → MUST USE IDS
- Non-Hospital Areas: Faculty Practice, Icahn School of Medicine at Mount Sinai, Private Offices →If you choose not to utilize the IDS, please provide a description of the plan to store, handle, and control the distribution of the agent to ensure that the agent will be dispensed by authorized investigators and the agent will only be used in subjects who have agreed to take part in the research. Refer to Question #10.

Questions 8, 9, 10:
IDS requires proper documentation on how each agent will be controlled and stored. If IDS is storing the agent, question 10 does not need to be completed as IDS will maintain all required documentation. The IRB requires the IDS to review the plan for the control and storage of all agents to ensure patient safety and drug integrity.

Storage of Investigational Agents:

- All investigational agents should be stored according to the 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 its integrity, strength, quality, and purity are not adversely affected.
- Used investigational agents must be stored separately from unused investigational agents and accurate records maintained.
- USP-defined temperature storage conditions 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
Refrigerator Storage	2 to 8 °C	36 to 46 °F
Freezer storage	-25 to -10 °C	-13 to 14°F

Question 10:
Acceptable plans to control the distribution of the investigational agents:

- Investigator may not dispense the investigational agent to any person not authorized under the protocol to receive it.
- 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.
- Investigator is required to maintain adequate records for the receipt, storage, and disposition of the drug, including dates, quantity, and use by subjects.
- Investigational agents must be stored in a secure area with access restricted to authorized personnel only. Additionally, all associated records must also be locked and/or stored in a restricted area.

IDS Fee Schedule:
The fees to utilize the IDS are itemized below. Utilize these fees in your budget negotiations with sponsors and when allocating funds based upon grants awarded to investigators and the institution.

	Non-Federal Sponsors	Federal Sponsor for Mount Sinai Hospital only**
Initiation Fee	$750 Review* + $750 Initiation	$750 Review* + $750 Initiation
	Dispensation	**Dispensation**
Simple	$50/dispensation	$50/dispensation
Moderate	$80/dispensation	$80/dispensation
Complex	$150/dispensation	$150/dispensation
Special Compounding	$90/hour	$90/hour

Storage/Maintenance Fee	$750 annually (billed as $62.50 /month)	Exempted
Close-Out Fee	$500/ study	$500/ study
Coordinating Center Services	TBD/Contact IDS coordinator	TBD/Contact IDS coordinator

**For Federal Fees at other member sites, contact the IDS Coordinator at that site.

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 study procedure, attending initiation meetings, providing staff in-services, and set-up of electronic order entry records). ***For clinical trials involving more than 1 member site, a $750 Initiation Fee applies to <u>each</u> participating site, but a single Review Fee will apply for the entire Health-System.**
Dispensing Fees	
Simple	Does not require manipulation of dosage form, including oral dosage forms and blinded kits
Moderate	IV preparations with low to moderate labor intensity; Controlled substances, Oral chemotherapy
Complex	Labor intensive and/or hazardous IV preparations, including chemotherapy, biologics, antibodies, immunotherapy, virus/bacterial vectors; IVRS required; Advance notice not possible, including STAT preparations and poor stability preparations
Storage/ Maintenance Fee	Includes storage of study materials (e.g., inventory, recordkeeping, refrigerator, room temperature, freezer, temperature monitoring software); quality assurance; compliance with Hospital, Joint Commission, state and federal standards; site visits; audits; drug destruction; and overall maintenance
Close-Out Fee	Includes return or destruction of all remaining study materials; copies of records returned as appropriate
Coordinating Center Services	Includes but is not limited to randomization for other sites, managing drug supply for all sites, shipping drug to participating sites, etc.