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**Investigational Drug Service (IDS) Review Form:**

**Drug/Biologic Management Plan**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **SECTION 1** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| The Study Protocol, Investigator’s Brochure, and Preparation Procedures/Pharmacy Manual (if applicable) should be provided as part of the IDS Submission. The IDS Coordinator will review the project for safety, feasibility, and assess any request for IDS support. The Investigator should adequately budget for all IDS services, including the IDS Review and any other requested services. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| \*Protocol Title: | | | | | | Click here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| \*Principal Investigator (PI): | | | | | | Click here to enter text. | | | | | | | | | | | | | | | | | | \*PI’s Life Number: | | | | | | Click here to enter text. | | | | | | | | | PI’s life number is required to utilize Sinai Central for billing. | | | | | | | | | | |
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| Co-Investigator(s) with Prescriptive Authority (MDs, NPs, etc.): | | | | | | | | | | | | | Click here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| \*Primary Contact Name: | | | | | | Click here to enter text. | | | | | | | | | | | | | | | | | | Contact Info (Phone/Email): | | | | | | | | | | | | Click here to enter text. | | | | | | | | | | | | | |
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| Project Number(s) | | | | | | IF#: | | | | Click here to enter text. | | | | | | | | | | | | | | | GCO#: | | | | | | | | | | | Click here to enter text. | | | | | | | | | | | | | |
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| \*Study Sponsor: | | | | | | Click here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| \*Sponsor Type: | | | | | | Choose an item. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| If Other, specify: | | | | | | | | | | | | | Click here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |
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| \*Funding Source: | | | | | | Choose an item. | | | | | | | | | | | | | | | | | | IDS Maintenance Fees applies to Non-Federally funded studies only. | | | | | | | | | | | | | | | | | | | | | | | | | |
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| \*\*Study Fund Account | | | | | | Click here to enter text. | | | | | | | | | | | | | | | | \*\***Fund Number is Required** for IDS Pharmacy Review. If a Study Fund is not yet available, provide an alternate Fund (ex. Departmental Fund). IDS will delay billing for 6 months to the alternate Fund while awaiting the Study Team to provide the Study Fund number to IDS. | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| If Study Fund is not yet established, provide alternate Fund account: | | | | | | | | | | | | | | Click here to enter text. | | | | | | | |
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| **SECTION 2** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Complete **Section 2** for EACH Drug/Biologic† specified in the protocol, including Drug/Biologics supplied by or paid for by the Sponsor, and any FDA-approved Drug/Biologics not used under routine medical care.   * Section 2 is NOT required for FDA-approved Drug/Biologics 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. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 1.) \***Drug/Biologic Generic Name**, Form/Strength, & Manufacturer: | | | | | | | | | | | | | Click here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 1. **\*Is the use of this product considered Standard of Care?** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | | |  | | | | |
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| 1. **\*Controlled Substance?** | | | | | | | | | | | | | Choose an item. | | | | | | | | | | | | | | | ‡Schedule II to V Controlled Substances should be stored in the IDS Pharmacy under an institutional Research License when available. Contact IDS coordinator for details. | | | | | | | | | | | | | | | | | | | | | |
|  | | If Yes, Schedule?‡ | | | | | | | | | | | Choose an item. | | | | | | | | | | | | | | |
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| 1. **\*Supplied by:** | | | | | | | | | | | | | Choose an item. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
| If Other, specify: | | | | | | | | | | | | | Click here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
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| 1. **\*Will placebo be used?** | | | | | | | | | | | | | Choose an item. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
| If Yes, supplied by: | | | | | | | | | | | | | Choose an item. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
| If prepared by IDS Pharmacy, is special compounding required? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | | |  | | | | |
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| 1. **\*IDS Services Requested:** | | | | | | | | | | | | | Protocol Review | | | | | | | | | | | | | | | | | | | Storage | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | Dispensation/Preparation | | | | | | | | | | | | | | | | | | | Monitoring/Site Visits | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | Randomization | | | | | | | | | | | | | | | | | | | Destruction | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | Shipment to other sites as Coordinating Center | | | | | | | | | | | | | | | | | | | Other, specify: | | | | | | Click here to enter text. | | | | | | | | | | |  |
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| 1. **\*Administered at:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Mount Sinai Hospital | | | | | | | | | | | | | | Area: | | Choose an item. | | | | | | | | | | | | | Site PI: | | | | | | Click here to enter text. | | | | | | | |  | | | | |
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|  | | Mount Sinai Beth Israel | | | | | | | | | | | | | | Area: | | Choose an item. | | | | | | | | | | | | | Site PI: | | | | | | Click here to enter text. | | | | | | | |  | | | | |
|  | | | | | | | | | | | | | | | | Phillips Ambulatory Care Center (PACC)  Comprehensive Cancer Center – West Campus (BICCC-WC)  Petrie Campus / Downtown BI Hospital | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | | Mount Sinai West | | | | | | | | | | | | | | Area: | | Choose an item. | | | | | | | | | | | | | Site PI: | | | | | | Click here to enter text. | | | | | | | |  | | | | |
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|  | | Mount Sinai St. Luke’s | | | | | | | | | | | | | | Area: | | Choose an item. | | | | | | | | | | | | | Site PI: | | | | | | Click here to enter text. | | | | | | | |  | | | | |
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|  | | Mount Sinai Queens | | | | | | | | | | | | | | Area: | | Choose an item. | | | | | | | | | | | | | Site PI: | | | | | | Click here to enter text. | | | | | | | |  | | | | |
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|  | | NYEE | | | | | | | | | | | | | | Area: | | Choose an item. | | | | | | | | | | | | | Site PI: | | | | | | Click here to enter text. | | | | | | | |  | | | | |
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|  | | ISMMS | | | | | | | | | | | | | | Specify location(s): | | | | | | | | | | | | Click here to enter text. | | | | | | | | | | | | | | | | |  | | | | |
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|  | | Faculty Practice/ Private Office | | | | | | | | | | | | | | Specify location(s): | | | | | | | | | | | | Click here to enter text. | | | | | | | | | | | | | | | | |  | | | | |
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|  | | Other | | | | | | | | | | | | | | Specify location(s): | | | | | | | | | | | | Click here to enter text. | | | | | | | | | | | | | | | | |  | | | | |
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| 1. **\*Storage Temperatures:** | | | | | | | | | | | | | Choose an item. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
| If Other, specify: | | | | | | | | | | | | | | | | | | | | | | | | | | | | Click here to enter text. | | | | | | | | | | | | | | | | |  | | | | |
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| 1. **\*Stored at:** | | | | | | | | | | | | | Choose an item. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
| If Other, specify: | | | | | | | | | | | | | | | | | | | | | | | | | | | | Click here to enter text. | | | | | | | | | | | | | | | | |  | | | | |
|  | **Skip Question #10** if agents are NOT stored by PI and his/her authorized personnel (ie. stored at IDS Pharmacy, Hospital/Clinic Pharmacy, Patient’s Own Supply, or Vaccine Cell Therapy Lab.) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |
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| 1. \*\*If stored by **PI and his/her authorized personnel**, please provide information on the plan for storage and distribution: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
|  | | | | Yes | | | | No | | | Storage area is well-maintained, provides adequate lighting, ventilation, sanitation, space, and security. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
|  | | | | Yes | | | | No | | | Temperature in Storage Area is controlled and monitored using calibrated monitoring devices. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
|  | | | | Yes | | | | No | | | Temperature Monitoring System has sensors for continuous monitoring and alarms set at the points of temperature extremes. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
|  | | | | Yes | | | | No | | | Records of Temperatures and Alarms are maintained. Excursions outside of the labeled storage conditions are appropriately investigated and reported to Sponsor. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
|  | | | | If No is selected above, explain: | | | | | | | | | | | | | | | Click here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
|  | | | | Yes | | | | No | | | Investigator will not dispense Investigational Drug/Biologic to any person not authorized under the protocol to receive it. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
|  | | | | Yes | | | | No | | | Investigational Drug/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 | | | Investigator will maintain adequate Records for the Receipt, Storage, and Disposition of the Drug/Biologic, including dates, quantity, and use by subjects. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
|  | | | | Yes | | | | No | | | Investigational Drug/Biologic will be stored in a secure area with access restricted to authorized personnel only. All associated records will be locked and/or stored in a restricted area. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
|  | | | | Yes | | | | No | | | Investigator will label the immediate package of the Investigational Drug/Biologic with the FDA-required statement "Caution: New Drug--Limited by Federal (or US) law to investigational use.” | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
|  | | | | If No is selected above, specify plan: | | | | | | | | | | | | | | | | Click here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
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| Comments to IDS Reviewer: | | | | Click here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
| I assure that the plan for the control of research drug/biologics involved in human research is accurately described and appropriate. I will conduct the study in accordance with this plan, as well as with applicable regulations and institutional policies and procedures. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Click here to enter text. | | | | | | |  | |  | | | | | | | | | | | |  | | Click here to enter text. | | | | | | | |  | | | Click here to enter text. | | | | | | |  | | Click here to enter text. | | | | |  | |
| PI Printed Name | | | | | | |  | | PI Signature | | | | | | | | | | | |  | | Date | | | | | | | |  | | | Department | | | | | | |  | | Division  (if applicable) | | | | |  | |
| |  | | --- | | **SECTION 3 – To be completed by IDS Reviewer** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Funding Source:  Federal  Non-Federal | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **IDS Services** | | | | | | | | | | | | **Fee** | | | | | | | | | | | | | |  | **Comments** | | | | | | | | | | | | | | | | | | | | | |  |
| Study Review (once per study) | | | | | | | | | | | |  | | | | | | | | | | | | | |  | Choose an item. | | | | | | | | | | | | | | | | | | | | | |  |
| Study Initiation (once per study) | | | | | | | | | | | |  | | | | | | | | | | | | | |  | Choose an item. | | | | | | | | | | | | | | | | | | | | | |  |
| Dispensation | | | | | | | | | | | |  | | | | | | | | | | | | | |  | Choose an item. | | | | | | | | | | | | | | | | | | | | | |  |
| Compounding | | | | | | | | | | | |  | | | | | | | | | | | | | |  | Choose an item. | | | | | | | | | | | | | | | | | | | | | |  |
| Shipments/Coordinating Center | | | | | | | | | | | |  | | | | | | | | | | | | | |  | Choose an item. | | | | | | | | | | | | | | | | | | | | | |  |
| Maintenance/Storage Fee (monthly) | | | | | | | | | | | |  | | | | | | | | | | | | | |  | Choose an item. | | | | | | | | | | | | | | | | | | | | | |  |
| Close-out Fee (once per study) | | | | | | | | | | | |  | | | | | | | | | | | | | |  | Choose an item. | | | | | | | | | | | | | | | | | | | | | |  |
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| *Note*: IDS services at Mount Sinai Hospital will be charged to the Study Fund on a monthly basis. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Approved by: | | |  | |  | | | | | | | | | |  | |  | | | | | | | | | | | |  | | | |  | | | | | | |  | |  | | | | |  | | |
|  | | |  | | Name | | | | | | | | | |  | | Signature | | | | | | | | | | | |  | | | | Date | | | | | | |  | | Site/Hospital | | | | |  | | |