IDS Budget Request Form

Date: ________________________________
Sponsor(s): ________________________________
Study Title: ________________________________
Protocol Number: ________________________________
Drug Name(s): ________________________________
Funding Type: ________________________________
Primary Investigator (PI): ________________________________
Contact Person & Tel #: ________________________________
Study Phase (if known): ________________________________

Documents Supplied:
☐ Protocol (required)  ☐ Investigator’s Brochure (IB)  ☐ Pharmacy Manual
☐ Drug Package Insert  ☐ Other: ________________________________

Study Type:
☐ Investigator-Initiated and Funded  ☐ Industry Funded  ☐ Government Funded

Drug delivery route:
☐ By mouth (PO)  ☐ Subcutaneous (SC)  ☐ Intradermal
☐ Intramuscular (IM)  ☐ Intravenous (IV)  ☐ Suppository (PR)
☐ Inhaled  ☐ Sublingual (SL)  ☐ Intranasal
☐ Other: ________________________________  ☐ Topical  ☐ Intraventricular

General Information
If available, refer to the study’s Protocol, Investigator’s Brochure, and Pharmacy Manual for information needed for the following questions.

Will a Medical Device be part of this study? ☐ Yes ☐ No

Will IDS be compounding any sterile products (IV admixtures, syringe preparation)? ☐ Yes ☐ No

Will any drugs need to be purchased by IDS? ☐ Yes ☐ No
If yes, please provide below information:

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Strength</th>
<th>Dosage Form</th>
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Will any supplies (filters, tubing sets, sharps containers, etc.) need to be purchased by IDS? ☐ Yes ☐ No
If yes, please specify: ________________________________

Dispensing outside of normal IDS Pharmacy hours (08:00-16:30 weekdays)? ☐ Yes ☐ No
Will any Investigational Product (IP) need to be weighed at dispense or return? ☐ Yes ☐ No

Are there any special compounding requirements such as: producing capsules, preparing test batches, filling applicators? ☐ Yes ☐ No If yes, please explain and indicate quantity if known.

Will an automated system (IXRS) be used by the Pharmacy for:
☐ Drug receipt, return, or destruction?
☐ Obtaining randomization or kit assignments?

**Storage Requirements**

Is room temperature (20-25°C) storage required? ☐ Yes ☐ No

Is refrigerated (2-8°C) storage required? ☐ Yes ☐ No

Is freezer storage required?
-20° C ☐ Yes ☐ No
-80° C ☐ Yes ☐ No

**Enrollment**

Number of subjects expected to enroll at Duke: __________________________

Will subjects be:
☐ In-patient? ☐ Out-patient? ☐ Both ☐ DCRU

**Dispensing Requirements**

**Ancillary Supplies:**
Will the IDS Pharmacy be storing tote bags, cooling packs, auto-injector, syringes, infusion sets, or similar materials? ☐ Yes ☐ No

Will any medical devices (nebulizer, dispensers, etc.) be stored the IDS Pharmacy? ☐ Yes ☐ No

Specify: ___________________________________________________________________________

**Controlled Substances:**
Are any items controlled substances? ☐ Yes ☐ No If yes, schedule (C2, C3, etc.) ______________

If schedule C1 or C2:
Study Team will pick up locked transport container? ☐ Yes ☐ No
IDS will deliver to automated dispensing cabinet (Omnicell)? ☐ Yes ☐ No

**Kits:**
Will IDS Pharmacy be creating kits for dispensing? For example, packaging IP and/or placebo together in a blinded or un-blinded package for dispensing at initial or subsequent visits? ☐ Yes ☐ No

If kits are supplied by sponsor, will IDS need to open packaging to add, remove, assemble, or label items before dispensing? ☐ Yes ☐ No

*Email completed form and documents to Pharmacy-Grp_IDS [Pharmacy-Grp_IDS@dm.duke.edu]*

*Include “ESTIMATE REQUEST” in the subject line.*