Kingston Health Sciences Centre Pharmacy Services
Investigational Drug Service (IDS)
COST ESTIMATE REQUEST FORM
Version May 2020

Please complete the KHSC Pharmacy Services Study Request Form and **ATTACH the Form to your TRAQ DSS FORM prior to submission**. If you forgot to attach the Form to your TRAQ DSS FORM prior to submission, please send it along separately, with a copy of your study protocol/proposal and pharmacy manual/investigational brochure/product monograph (if applicable) to:

Investigational Drug Service
kghphids@KingstonHSC.ca or 613-548-1386 (fax)

Contact Information:

Principal Investigator:

NAME:		TELEPHONE:	
EMAIL:		FAX:	

Research Coordinator:

NAME:		TELEPHONE:	
EMAIL:		FAX:	

Study Title:

1. Do you need KHSC IDS to supply/purchase/receive the clinical trial medication(s)?
   ◯ Yes ◯ No

   If No, who will be supplying the medication(s)?

2. Do you need KHSC IDS to mix, label or manipulate the clinical trial medication(s) in any way? ◯ Yes ◯ No

****IF YOU ANSWERED NO TO #1 AND #2 STOP HERE****

****IF YOU ANSWERED YES TO #1 AND/OR #2 PLEASE CONTINUE ANSWERING THE QUESTIONS ON THE FORM BELOW****

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Kingston Health Sciences Centre
Centre des sciences de la santé de Kingston

Study Information:

Has Project been submitted to HSREB/OCREB/CTO? ◯ Yes ◯ No

If YES, HSREB/OCREB/CTO # _____

Anticipated Study Start Date: _____ Approximate duration of Study: _____

Estimated number of Study Participants: _____

Study Description: (check all that apply) ☐ Inpatient ☐ Outpatient ☐ Single-Centre ☐ Multi-center

Funding Source: check all that apply

☐ Industry-Sponsored ☐ Non-Industry-Sponsored (i.e. grant(s)) ☐ Non-Funded

If Industry-Sponsored, please provide the following information:

SPONSOR NAME: _____ SPONSOR PROTOCOL #: _____

SPONSOR'S CONTACT NAME: _____ EMAIL: _____

TELEPHONE: _____ FAX: _____

Pharmacy Services Requested:

Dispense: (check all that apply)

☐ Capsules/Tablet ☐ Patient Kit ☐ IV Product ☐ Pre-filled Syringes

☐ Ointment/Cream ☐ Other (please specify): _____

Please specify dispensing intervals: _____

Do you require a placebo to be prepared? ◯ Yes ◯ No

On-Call Study*? ◯ Yes ◯ No Weekend and/or Holiday dispensing? ◯ Yes ◯ No

A study is considered on-call if there is a possibility for dispensing outside of normal business hours (M-F 8AM-4PM). There is an additional fee for this service and it must be pre-arranged.

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Delivery:

Are deliveries within Kingston Health Sciences Centre required? ◯ Yes ◯ No

If YES, please specify delivery to which location(s): ☐ KGH Site ☐ HDH Site

(Building, Floor, Room): _____

Where will Study Participants be seen (Clinic location)? _____

Is temperature monitoring required during transit? ◯ Yes ◯ No

If YES, please specify (_____ °C to _____ °C)

Will chain of custody signatures be required? ◯ Yes ◯ No

Drug Returns: (*Principal Investigator, if unsure, check with study Sponsor*):

◯ No drug returns to IDS, Principal Investigator will oversee drug return and destruction

◯ Used drug supplies will be returned to IDS for immediate destruction

◯ Used drug supplies will be returned to IDS for storage and reconciliation by study monitor, and then destruction or return to sponsor

◯ Used drug supplies generated in the pharmacy must be stored in the IDS for reconciliation by study monitor, and then destruction or return to sponsor

Randomization: (*Principal Investigator, if unsure, check with study Sponsor*):

◯ There is no randomization

◯ Randomization will be managed by the Principal Investigator and the IDS will be notified of treatment assignment in writing on drug order or via separate FAX

◯ Randomization will be managed by the IDS via IWRS or IVRS

◯ Randomization will be generated by the Sponsor or Principal Investigator and treatment assignment will be managed by the IDS via paper copy, email, or IWRS

◯ Randomization will be generated by the Sponsor or Principal Investigator and treatment assignment will be managed by the IDS via paper copy, email or IWRS and will require online confirmation of randomization by IDS

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Inventory:

◯ Inventory will be handled by the IDS using standard GCP and Division 5 compliant methods and IDS produced forms

◯ Inventory will be handled by the IDS using Sponsor specific inventory forms

◯ Inventory will be handled by the IDS using Sponsor specific inventory forms and IVRS or IWRS

Drug Description: ***Anti-Neoplastic/hazardous Agent(s)?*** ◯ Yes ◯ No

Study Drugs: (include both investigational agents, FDA approved products and standard of care)

Study drug provider: | |

Formulation: (check all that apply)

☐ Capsules ☐ Tablet ☐ Vials ☐ Pre-Packaged For Dispensing
☐ Bulk (Requires Packaging/Labeling/Dispensing)

KHSC Drug Product Ordering? ◯ Yes ◯ No

Storage Requirements: (check all that apply)
☐ 2°C to 8°C ☐ 15°C to 25°C ☐ -15°C to -25°C ☐ < -25°C

☐ Other | |

Additional Items/Equipment Required*:*

Items/equipment provider: | |

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Monitoring*:*

◯ Investigator will monitor IDS function directly without outside monitoring

◯ Sponsor will not monitor IDS function

◯ Sponsor will monitor IDS function

MONITORING COMPANIES NAME/DIVISION: _____

MONITOR'S NAME: _____ EMAIL: _____

TELEPHONE: _____ FAX: _____

Number of outside monitoring visits expected each year: _____

Training*:*

Are there specific training requirements for pharmacy staff? ◯ ***Yes*** ◯ ***No***

If YES, please specify:

_____

NOTE 1: **Invoices will be mailed to the Principal Investigator by the KHSC Finance Department within 45 days of inception and with each fiscal quarter there after. IDS fee for service guide is updated yearly. All IDS staff are certified in Division 5 and GCP. Signed curriculum vitae for staff available upon request.**

NOTE 2: **IDS will not provide services until the signed cost estimate and HSREB/OCREB/CTO ethical clearance letter have been received.**

NOTE 3: **When you are ready to initiate the study, please notify IDS. Please give sufficient notice (2 weeks) to IDS prior to the first research participant being enrolled into the Study.**

Thank you.