

Kingston Health Sciences Centre Pharmacy Services
Investigational Drug Service (IDS)
COST ESTIMATE REQUEST FORM
Version July 2017



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, you will need to 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@kgh.kari.net or 613-548-1386 (fax)

Contact Information:

Principal Investigator:

NAME:	<input type="text"/>	TELEPHONE:	<input type="text"/>
EMAIL:	<input type="text"/>	FAX:	<input type="text"/>

Research Coordinator:

NAME:	<input type="text"/>	TELEPHONE:	<input type="text"/>
EMAIL:	<input type="text"/>	FAX:	<input type="text"/>

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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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 managed by the IDS via paper copy, email, or IWRS

Randomization code will be generated by the IDS and managed within the 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 thereafter. 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.