Research Road Map

April 2017 **Pharmacy Services Issue**

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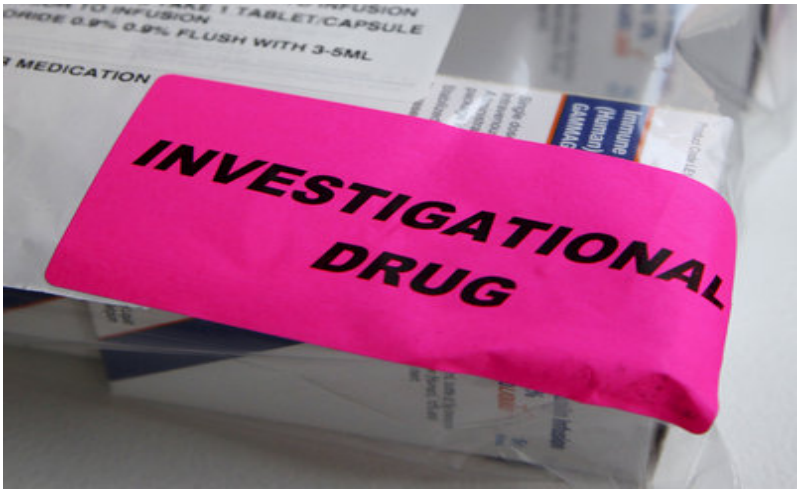

Pharmacy Services for Research:

KHSC Pharmacy Services provides support to researchers for their clinical drug trials through the Investigational Drug Service (IDS) team. Research protocols are reviewed, blinding and randomization protocols are followed, and investigational drugs are received, stored, and prepared for research purposes within the hospital, if the service is required. The IDS team consists of highly specialized pharmacy technicians and pharmacists who take every effort to ensure that drug trial protocols are stringently followed to support all of the Principal Investigator's (PI) and Sponsor's needs. Prior to any services being provided for your drug trial, all certifications (i.e. human ethics, animal care, biohazards) and hospital approvals must be in place using the Queen's University Research Services' TRAQ DSS FORM.

STUDY REQUEST FORM AND TRAQ DSS FORM

PIs need to submit a "*KHSC Pharmacy Services Study Request Form*". The completed form must be **ATTACHED** to your TRAQ DSS FORM prior to submission to ensure that your drug trial is processed in a timely manner and to minimize any delays in initiating your drug trial once all approvals have been obtained. Please remember to check off "*KHSC-Pharmacy*" on the Approvals Tab of your TRAQ DSS FORM so that KHSC Pharmacy Services

can sign off on your TRAQ DSS FORM. We strongly encourage PIs to contact KHSC Pharmacy Services in the early stages of their protocol and budget development to ensure that their studies are set up properly and PIs are aware of any pharmacy costs associated with their research. PIs are responsible for covering all pharmacy costs associated with their drug trial above and beyond the standard of care. Please refer to the fee guide for more information.

The "*KHSC Pharmacy Services Study Request Form*" can be found here: http://www.kgh.on.ca/research/researchers-staff-trainees.

Once your TRAQ DSS FORM is submitted, the KHSC Pharmacy Services will be automatically notified of your TRAQ DSS FORM and the Pharmacist Coordinator of the IDS team (Michelle Tryon) and Hospital Operational Director (Veronique Briggs) will review your documents and either approve "as is" or reach out to you for further clarification, if required. To contact KHSC Pharmacy Services regarding your TRAQ DSS FORM, please reach out Michelle Tryon at KGH Site ext. 6893 or tryonm@kgh.kari.net and/or Veronique Briggs at KGH Site ext. 4334 or briggsv@kgh.kari.net.

MANAGEMENT OF INVESTIGATIONAL DRUGS

Receipt and Inventory**:**

The IDS team reviews protocol procedures for receiving investigational products, reviews all shipping documentation, documents quantity and records any damages and/or discrepancies. Shipments with identified excursions require the Sponsor's approval prior to using the investigational product. The IDS team will complete and return any acknowledgment receipt required by the Distributor. The IDS team documents the date, quantity and lot numbers of all investigational products received from the Sponsor in the Sponsor's "*Drug Accountability Log*" and enters all investigational products into the clinical trial inventory.

Interactive Voice Response System (IVRS)/Online Enrollment and Randomization:

If the randomization and blinding is delegated to the IDS team by the Sponsor or PI, the IDS team follows the randomization procedures as described in the protocol and ensures that the randomization code is only broken in accordance with the protocol. If IVRS or online enrollment is required, each IDS staff member will obtain a password and follow randomization procedures as specified. Randomization outside of regular operating hours (Monday to Friday 8:00 am-4:00 pm) can be arranged and is associated with an additional cost. Please refer to the fee guide for more information.

Drug Preparation, Labelling and Relabeling:

The manufacturing, labeling, packaging and shipping of investigational products is the responsibility of the Sponsor, Distributor or PI. If the contents of the label do not meet KHSC Pharmacy Services' or Health Canada's standards, then the IDS team ensures that the investigational product label meets or exceeds the requirements. If an additional label is required (e.g. subject name), the IDS team will supply an additional label. If the drug trial involves manipulation of the investigational product (e.g. for IV administration or repackaging) then the IDS team will prepare the product according to protocol and label according to the PI. The investigational product is only dispensed upon the receipt of a prescription or physician order form from the PI or delegate (i.e. Sub-Investigator). The IDS team maintains an accountability log to document assignment of investigational products to specific study subjects. The accountability log includes the amount dispensed, lot number, date, and initials of the person dispensing the investigational product.

Drug Returns/Destructions:

All returned investigational drugs are recorded in the accountability log. At the conclusion of the study, the IDS team ensures that all documentation regarding receipt, storage, dispensing, return of used containers, and accountability is complete and accurate. The IDS team returns investigational products after study completion to the Sponsor, Distributor or PI and follows the instructions in the protocol. The IDS team destroys defective, returned or unused investigational products using the appropriate procedures if written authorization from the Sponsor or PI has been obtained. Upon completion of the study, provided all investigational products have either been returned or destroyed, the study files are returned to the PI for storage/archiving.

Drug Storage:

Pharmacy storage includes a facility for room temperature (18-25 ºC), refrigerated (2-8 ºC) and freezer (-15°C to -25°C) storage of investigational products. All investigational products are stored in a 24-hour secure, locked area with controlled access restricted to authorized personnel and the investigational products are kept separate from all other medications at KHSC.

Maintenance/calibration records for storage equipment are available upon request. Minimum and maximum storage temperatures of refrigerated and room temperature investigational products are monitored on a daily basis on temperature logs. The IDS team ensures the storage of investigational products, including storage temperatures, acceptable temperature ranges and humidity levels are kept within the Sponsor's requirements. The controlled area has a traceable, certified thermometer with alarm notifications to ensure temperatures are monitored 24 hours per day. Temperature or humidity records are stored in a central log and are available upon request by the Sponsor or PI. Unauthorized personnel are only allowed accompanied access for monitoring and auditing of drug trials in these areas.

PHARMACY STANDARD OPERATING PROCEDURES

All investigational products are received and accounted for according to Standard Operating Procedures for Clinical Research (SOP) set forth by the Network of Networks (N2). The IDS team has adopted the N2 SOPs. The IDS team is bound by confidentiality to N2 and cannot allow copies to be distributed outside of this institution. Sponsors are encouraged to review the SOPs on-site, if needed. Please note that tools and templates used in the conduct of drug trials are not part of the SOPs and as such do not require formal N2 approval to disseminate to Sponsors. Tools and templates are reviewed and updated by the IDS team, as required.

IDS TEAM QUALIFICATIONS

The IDS team is certified in Good Clinical Practice (GCP) and Health Canada Division 5. Training logs, updated CVs, and signature logs are available on request for all IDS team members. Trial specific training will be completed if required by Sponsor or PI. The formal GCP training program provided to the IDS team through KHSC is N2's "*CITI-Canada GCP Online Education Program*". As per KHSC-KGH Site's policy, GCP refresher training is required once every five (5) years or earlier at the discretion of the PI, institution (KHSC-KGH Site) and/or Sponsor. Complete retraining may be required at the request of the PI and/or institution after changes in GCP guidelines have occurred, after long periods of absence from the clinical research practice (>1yr) and/or when significant non-compliance issues have been identified on monitoring, auditing and/or inspection visits to research sites. Sponsor-specific GCP training will not be required to be completed by the PI and IDS/research team at KHSC-KGH Site unless the Sponsor has evaluated N2's "*CITI-Canada GCP Online Education Program*" and has deemed the program unacceptable with written justification provided to the PI and institution that will be kept on file at site.

PHARMACY HOURS FOR DRUG TRIALS

The IDS team is available for drug trials during regular business hours, excluding holidays, Monday to Friday 8:00 am-4:00 pm. Requests for on-call (after hours) service must be made in advance to ensure that an IDS team member is available. Requests for on-call service should be made at the time of your TRAQ DSS FORM submission and must be agreed upon by both the IDS team and PI at the beginning of the drug trial set-up. Additional fees apply for on-call service. Please refer to the fee guide for more information.

An on-call pharmacist is available 24/7 for PIs and research staff at KHSC-KGH Site (no fee required) for emergency situations that arise related to your drug trial. For emergencies, please call 613-548-3232.

FEE GUIDE FOR DRUG TRIALS

Pharmacy Investigational Drug Service Fee		KHSC 2015-2016 (in $)	
Study Initiation Fee (Formerly Protocol Review and Administrative Fee) (Paid at start-up)		1500.00 industry sponsored 750.00 non-industry sponsored	
Sponsor Training Requirements (standard GCP and division 5 training included in initiation fee)		44.35/hr. for Technicians	
Technician/Assistant Call-back ($ per call-back)		266.10	
Pharmacist Call-back ($ per call-back)		491.04	
IDS On-Call/ Standby Fee (new)	1600hrs - 0800 on Mondays through Thursday (56h X 3.96)	221.76	475.20/week
	1600 Friday to 0800 Monday (64h X 3.96)	253.44	
Dispensing Fee ($)	Inpatient Oral (Unit Dose)	13.25 / day	
	Outpatient Oral (Ambulatory)	17.50 / Rx	
	Intravenous Admixture	25.00/dose	
Compounding Fee	Any study medication requiring more than 20 minutes per dose in prep. Time intravenous or oral.	0.85/minute	
Study Closure ($ per study) packaging, shipping, freight costs are not included		Included in Study Initiation Fee	
IMP Disposal (per 6 gal container)		72.50	
Patient enrolment fee ($/patient) IVRS, CORE etc.		32.50	
Drug shipment receipt ($ per shipment)		30.00	
Pharmacist or Technician time outside 0800 to 1600 Mon to Fri		1.5 times the regular rate	
Protocol revisions (minor) * Major revisions = > 2.5 hours IDS time		Included in Study Initiation Fee	
• Pharmacist Time Mon to Fri 0800 to 1600 • Technician Time Mon to Fri 0800 to 1600		81.84 / hour 44.35 / hour	
Monthly Administration fee ($) ** Starting 01 April 2014, all clinical trials must pay a monthly administration fee regardless of study status. Fee will be applicable from the SIV to the COV. Includes storage of IP.		37.50	
Site visits ($ per visit)		81.84/hour, 1hr minimum	

ARCHIVING OF PHARMACY STUDY FILES

All study documents are returned to the PI for proper storage/retention following the closure of the drug trial. The IDS team will not store study documents for the PI. It is the responsibility of the PI to ensure that their study budgets negotiated with Sponsors include archiving costs.