

RESEARCH SUPPORT PHARMACY (RSP)-
Review and Approval Process for Research Studies Involving
Drugs/Biologics or Natural Health Products (NHP)

RSP will require a full copy of the version dated protocol and an Investigator's Brochure (IB) if the product is not marketed in Canada or a Full Product Monograph if it is. The Principal Investigator/Study Coordinator must contact the RSP (x6705, Room 3717) for guidance on study requirements and the services provided by RSP **for ALL studies which involve use of a drug/biologic or Natural Health Product.**

The RSP pharmacist will determine the level of review and/or ongoing pharmacy involvement required for each study on a case by case basis (see guidance next page for levels of review) according to SickKids and Health Canada policies and regulations.

- a. If an RSP review is not required prior to SRB/REB review, the RSP will sign and date the Investigational Drug Study Cost Finder (page 13 of REB Application), indicating "Not Applicable".
- b. If an RSP review is required prior to SRB/REB review, [regardless of whether there will be any ongoing support from pharmacy], a minimum of 2 weeks will be required to complete the review. Additional time may be required to assess the feasibility of manufacturing blinded capsules, placebos etc.

REB application timelines should be taken into account when planning a submission to RSP.

The RSP pharmacist will fill out pages 13 (Clinical Investigational Drug Information Form), 14 (Investigational Drug Study Cost Finder) and 12 (Utilization of Diagnostic Services-Pharmacy) of the REB application form.

A hard copy of these 3 pharmacy forms/sections of the REB application, with original signatures of the RSP pharmacist and/or Director of Pharmacy, will be given to the study coordinator or PI. These hard copies with original signatures must replace the templates in the REB application package. If an electronic copy is required without original signatures, a specific request must be made.

The PI is responsible for ensuring that all information and assumptions used in the preparation of the pharmacy forms are accurate.

Pharmacy services are provided on a cost recovery basis.

The cost provided in the Investigational Drug Study Cost Finder is only an estimate and is valid only for 6 months. Costs are subject to change depending on the final study procedures, design, patient enrollment and pharmacy staffing availability at the time the study is initiated.

Investigators who require an Investigational Drug Study Cost Estimate for budget and/or grant submission purposes only should consult the RSP pharmacist.

If any changes are made to the study protocol prior to or after final REB approval, the RSP should be kept updated with the final version and all approved amendments to the protocol.

LEVELS OF PHARMACY REVIEW and/or ONGOING INVOLVEMENT
for RESEARCH STUDIES - GUIDELINES

ALL studies which involve use of a drug/biological/food or Natural Health Product (NPH) for which SickKids is the Sponsor or a study site require a pharmacy consultation to determine the Pharmacy Review Level.

<u>Pharmacy Review Level</u>	<u>Fee Range</u>
<p>1. Pre-REB Review Required, Ongoing Pharmacy Support Required:</p> <ul style="list-style-type: none"> • The use of a marketed or non-marketed study drug where the study will provide the drug supply. The drug(s) may be a free supply provided by a company/coordinating centre or a supply purchased through the RSP for use in the study. • There is no study drug involved but there are other supportive drugs (either for testing purposes or supportive care) that the study fund will be paying for or that are not commercially available in Canada 	<ul style="list-style-type: none"> • Review Fee: \$100 to \$500 (depending on complexity and issues raised) • Dispensing Procedures and Set Up: \$300 to \$2000 • Monthly Maintenance Fee: \$20 to \$120/month • Per Use or Per Patient Fees: Drug Acquisition Costs, Manufacturing Costs, Dispensing Fees, Study Closure Fees etc. See Cost Finder or consult RSP for details.
<p>2. Pre-REB Review Required, No Ongoing Pharmacy Support Required:</p> <ul style="list-style-type: none"> • The use of a marketed study drug(s) where the study fund will <u>not</u> be providing the drug free of charge (ie. families purchase the study drug at a pharmacy of their choice or the Division agrees to pay for the cost of the drug as per Standard of Care). • The PI is a SickKids staff member but the study is being conducted at other site(s). 	<ul style="list-style-type: none"> • Review Fee: \$100 to \$500 (depending on complexity and issues raised)
<p>3. No Pre-REB Pharmacy Review Required:</p> <ul style="list-style-type: none"> • The use, safety, efficacy or pharmacokinetics of the drug is not part of the primary or secondary objectives of the study (ie an observational study) and where the marketed drug is used under generally accepted Standard of Care in doses routinely used at SickKids • The use of a “medical device” or “food” as defined by Health Canada when there is no other pharmacy service required such as randomization, dispensing or blinding. • The use of a drug for “animal” studies (drug may be purchased through pharmacy by using an interdepartmental requisition) • Retrospective chart review involving a drug • In all of the above cases it is assumed that the PI understands how to comply with and agrees to abide by all Health Canada Clinical Trial Regulations for conduct of Clinical Trials (Division 5 GCP and ICH E6 Guidelines) with respect to the study drug handling distribution, destruction & record keeping. 	<ul style="list-style-type: none"> • Mandatory Review Fee: no charge (the RSS pharmacy will sign and date the Investigational Drug Study Cost Finder [page 14 of REB Application], indicating “Not Applicable”)
<p>* RSS Pharmacy services are provided on a “Cost Recovery” basis.</p>	