BC Children's Hospital
An agency of the Provincial Health Services Authority

4480 Oak St, Vancouver, BC V6H 3N1
t 604.875.2345 | tf 1.888.663.3088
bcchildrens.ca

MEDICAL DAY UNIT

Program Utilization Form

This form must be completed if access to Medical Day Unit (MDU) space is required. Please complete this form and send along with requested attachments to MDUresearch@cw.bc.ca. A completed signed MDU PU Form AND a copy of your REB approval certificate is required before **ANY** clinical research studies can begin in the MDU.

A. Study Information:

Project Title: _____

REB #:_____

Principal Investigator: _____

Department/Division: _____

Does the PI have medical appointment with BCCH? ☐*Yes* ☐*No*

If no, please name co-investigator with medical appointment at BCCH:

Primary Contact: _____

Telephone:_____ **Email:** _____

Name of Funder: _____

Funding Source:

☐ *Industry Sponsored* ☐ *Grant-Funded*

☐ *Unfunded* ☐ *Other*

Anticipated Study Start Date:_____**Anticipated Study End Date:** _____

B. Study Details

1a. Participant visit details:

a. Total number of participants expected: _____
b. Number of visits to MDU **per** participant:_____
c. More than one participant possible per day? _____
d. Age range of participant in study: _____

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1b. Please detail participant visit schedule (to MDU only) below, or attach summary separately.

2. Please detail the procedures required for this study (point form okay), including any support that will be required from MDU in terms of scheduling visits, nursing requirements, allied health, or other services needed.

3. Are there any constraints to the visits that MDU needs to be aware of, includingfrequency of visits within a specific date range, restrictions to date or time of visits, etc.

4. Will patients be receiving clinical care in addition to their study visit?
   ☐ Yes ☐ No, *If yes, please detail:*

5. Are any of the study participants coming from outside of the Province of B.C.?
   (Note: Some items/ services that may be a benefit in B.C. for B.C. residents may not be covered for study participants coming from outside the Province)

   ☐ Yes ☐ No, *If yes, please detail:*

It is the Investigator's responsibility to orient staff that will be involved in this study. As part of the Program's impact assessment, the MDU Coordinator and Research Nurse will work with the Investigator todetermine the best strategy for how Hospital employees in this program can be oriented to the study.

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The following documents should be attached with your submission:

☐ Copy of study protocol
☐ Copy of detailed patient visit schedule (relevant only to visits occurring in MDU, if not included in protocol)

Approval:

_____ Date	_____ Principal Investigator (Name and Signature Required)
_____ Date	_____ Program Manager, Ambulatory (Name and Signature Required)
_____ Date	_____ Medical Director, Ambulatory Care
_____ Date	_____ Senior Director, Ambulatory Care

Please submit the request to:

Attention: MDU Research Coordinator, Ambulatory Care Services
MDUresearch@cw.bc.ca

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OPERATIONAL WORKFLOW (Study Submission/Review/ Approval Process)

	Study Team	MDU Research Team
Study Request Package Submission	Submits the following documents to MDUresearch@cw.bc.ca: • A completed MDU PU Form • A copy of study protocol • MDU specific patient visit schedule	• Reviews and intakes study request • May contact study team to confirm any details • Arranges a mandatory OIA meeting with the study team
CST PowerPlan Build 1-2 weeks post submission	• Connects with Clinical Informatics Specialist to initiate CST Power Plan Build (Sunita Minhas, RTT Clinical Informatics Specialist: Research & Clinical Trials @ email: Sunita.minhas@phsa.ca **NOTE: CST PowerPlan must be completed in order for a Study to receive Operational Approval to commence study visits in MDU.**	• Connects with Clinical Informatics Specialist to confirm CST PowerPlan build has been initiated
Operational Impact Assessment (OIA) Meeting 1-2 weeks post submission	• Attends OIA meeting • Reviews and completes MDU operational impact assessment with MDU Research Team	• Attends OIA meeting • Reviews MDU operational impact and costing estimate with the study team • Shares OIA findings with the MDU Leadership/ Signing Authority
Senior Leadership Input	No action required	• Provides input based on OIA meeting findings

Decision Notice
3-4 weeks post submission* (***Study Visits in MDU may commence only upon Completion of CST Power Plan Build**)
	Study team receives notice of decision via:
	• Approved:
	  ○ A signed PU form,
	  ○ Letter ofapproval (Confirmation Letter)
	• Rejected: Letter of Rejection
		• Sends notice of decision to study team

Study Preparation 4-6 weeks prior to study start	• Send *REB Certificate of Approval* to MDUresearch@cw.bc.ca. • Liaise with MDU CNC to finalize study specific orders • Liaise with MDU CNC to coordinate study-specific education with MDU staff	• Facilitates study onboarding in the MDU • Confirms completion of CST PowerPlan • Ensures study- specific education has been provided and all related documentation is on file

PLEASE NOTE:

Study Start

- In order to accommodate the timelines outlined above, study teams are advised to allow at least 2 months from the submission of the request to the first planned participant visit.
- Study teams will be invoiced quarterly by MDU. All invoices will be marked with the REB#, which will serve as the MDU reference # for any given study. If you require a cost estimate in advance of this program review, please contact MDUresearch@cw.bc.ca**.**
- Study team to ensure Child Life has been arranged for study participants as required.
- For Lab requirements, Study team to connect with Lab directly (LabResearch@cw.bc.ca)

Mid- Year Study Requirements Review

- Program Coordinator will reach out to Study team to review requirements and re-confirm study status/end date.
- Costing is effective for two years after Operational approval and may be adjusted as required, based on the current FY BCNU nursing rates

Study Close-Out/ Knowledge Translation

- Program Coordinator will reach out to Study team to arrange a Knowledge Translation Session with the MDU Nursing Team. These are 15-20 minute informal information sessions (1 per study) geared to gather information on study/patient outcomes for process improvement, knowledge sustainment and best practices.