

CENTRE FOR INNOVATIVE MEDICINE (CIM)

Ethics team – Expertise in submissions to Research Ethics Board (REB)

Initial Submission

MUHC Single or Lead site

Reception of documents	ICF preparation	Submission	Approval Authorization	Reception of documents 1 st submission	ICF preparation	2 nd submission	Authorization
 □ Verification of complete package. □ Study creation in NAGANO □ PI and Head of department. 	☐ ICF preparation ICF review by CRC ☐ ICF review by Sponsor/CRO	1. Ethics review: □ Submission in NAGANO □ REB Review/Conditional approval □ Answers to REB □ French translation 2. Feasibility review: □ Contract □ Budget □ Pharmacy □ DPS □ Lab/Technical platform □ Nursingetc	□ REB Final approval □ MUHC PM Authorization	 □ Verification of complete package □ Study creation in NAGANO □ PI and Head of department signatures. 1st submission in NAGANO for Feasibility review: □ Contract □ Budget □ Pharmacy □ DPS □ Lab/Technical platform □ Nursingetc 	Following reception of Lead REB approval: □ ICF preparation □ ICF review by CRC □ ICF review by Sponsor/CRO	□ Submission in NAGANO.	□ MUHC PM Authorization

MUHC Single site: Ethics review done by MUHC REB for our site only. No other participating sites in Québec.

MUHC Lead site: Ethics review done by MUHC REB for all participating sites in Québec.

MUHC Participating site: Ethics review done by another REB for all participating sites in Québec, including MUHC.

MUHC Participating site



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Amendments

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Reception of documents ICF preparation Submission **Approval** Verification of If ICF is updated: 1. Ethics review **REB Final** complete approval ☐ Submission in package preparation NAGANO ☐ ICF review by ☐ REB CRC Review/Condition ☐ ICF review by al approval ☐ Answers to REB Sponsor/CRO ☐ French translation If no ICF updates: 2. Feasibility review: Go directly to (If applicable) Submission step. Contract Budget Pharmacy DPS ☐ Lab/Technical platform

MUHC Participating site

Reception of documen	ts ICF preparation	Submission	Acknowledgment
☐ Verification of complete package ☐ Confirm if Protocol amendment impact on Feasibility review.	Following reception of Lead REB approval: If ICF updated: ICF preparation ICF review by CRC ICF review by Sponsor/CRO If no ICF updates: Go directly to Submission step.	□ Submission of ICFs in NAGANO (Delivery channel or F1-MEO) □ PM validation Feasibility review: (If applicable) Submit F1-MEO □ Contract □ Budget □ Pharmacy □ DPS □ Lab/Technical platform □ Nursingetc	□ MUHC PM Acknowledgment

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□ Nursing....etc

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