

EVALUATION OF RISK
ST. MICHAEL'S HOSPITAL (SMH) RESEARCH ETHICS BOARD (REB)

FRAMEWORK

TYPE OF STUDY	INTERVENTIONAL RISK	INFORMATIONAL RISK	PATIENT CONDITION	REGULATORY/OTHER
Device	Device	Disclosing PHI/personal information (PI) internally	High risk patients where standard of care (SOC) treatment is available	Importing (drug, device, NHP)
Drug	Drug	Disclosing PHI/PI to Canadian organizations	High risk patients where no SOC treatment is available	Good manufacturing practices (GMP)
Natural Health Product (NHP)	Natural Health Product	Disclosing PHI/PI to US	Low risk patients with high risk intervention	Investigator initiated studies – meeting regulatory and other Sponsor obligations
Community	Combination of the above	Disclosing PHI/PI internationally		
Collaboration (medical)	Procedure	Collecting highly sensitive information (e.g. SIN, OHIP, genetic profile, etc.)		
Genetic / Biomarker/ Unspecified Research		Aggregating substantial volumes of information		
Material Transfer		Ownership (information, samples, patents, intellectual property – IP, publication)		
Qualitative		Conflicts of Interest		
Investigator Initiated		Collecting from other sources (do those others have permission to disclose, do you have permission to access)		
Database / Registry				

The columns in the table above are independent of each other; that is, a type of study (e.g. Investigator initiated) can have multiple matches in the remaining columns (i.e. be a drug & device study, have multiple informational risks and regulatory concerns, etc.).

Furthermore, the table is not entirely comprehensive; concerns such as liability insurance, indemnification, compensation, publication/IP, and other contract clauses/questions derive from some of the risk categories described above.