IWK Research Ethics
Standard Operating Procedures

Document # **RE 1.101**	Title: **Introduction**	Effective Date: **February 1, 2023**
Pages**: 2**	Responsibility of: **Research Ethics Board**	Date Approved: **February 1, 2023**

The mandate of the IWK Research Ethics Board (REB) is to protect the rights and welfare of human participants who take part in research conducted under the auspices of the IWK. The REB will assess, sanction and monitor the ethical aspects of all human subject research, including pilot studies, conducted under IWK's jurisdiction, both prior to inception and during execution.

The REB will ensure that research involving human participation meets current scientific and ethical standards for the protection of participants. These include but are not limited to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd edition (TCPS 2); the International Conference on Harmonization (ICH) Good Clinical Practice Consolidated Guideline; Health Canada's Food & Drug Regulations; Nova Scotia Personal Health Information Act (PHIA); and where applicable, U.S. federal regulations. The REB also operates under applicable laws and regulations of the Province of Nova Scotia and of Canada.

In the context of the TCPS-2, the REB subscribes to the following core ethical principles that are held and valued by diverse research disciplines:

- Respect for persons
    - Respect for human dignity
    - Respect for free and informed consent
    - Respect for vulnerable persons
    - Respect for privacy and confidentiality
- Concern for welfare
    - Balancing harms and benefits
- Justice
    - Respect for justice and inclusiveness

The REB will independently approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants or human materials conducted at the IWK or by its employees or staff. The Board will review all human-subject research involving patients, staff, resources

or data before the research may begin. Human-subject research includes all research involving human participants, human biological materials of any type including human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This also applies to materials derived from both living and deceased persons. REB approval is required for all research, involving humans, carried out under the auspices of the Health Centre or by its Staff, regardless of where the research is conducted. In the event that an investigator cannot determine whether an intended investigation constitutes research (for instance, quality assurance studies do not constitute research), the investigator should contact the Ethics Office for assistance.

Forms/Records:

Form #	Form/Record Name
SOP 101	Introduction

Revision History:

Revision	Date	Description of changes
0.0	April 1, 2017	Initial Release
1.0	September 9, 2022	Additions to comply with TCPS2-2018
1.1	February 1, 2023	Updated logo