nova scotia health	**Obtaining Informed Consent for Clinical Research from a Mature Minor.**	Effective Date: February 18, 2021
Clinical Trials Standard Operating Procedures		Version: V1.0
Page # 1-5		Next Review Date: February 2023
SOP Owner: Research Quality		

1. **Purpose:**
   This Standard Operating Procedure (SOP) describes the process of assessing capacity and obtaining informed consent for participation in clinical research when the potential study participant is a Mature Minor.

2. **Ethical Considerations:**

   The Nova Scotia Age of Majority Act states that 'every person attains the age of majority, and ceases to be a minor, on attaining the age of nineteen years."

   In Nova Scotia, there is no designated age of consent. The Principal Investigator is responsible for determining if the minor is a Mature Minor based on the child's ability to understand and appreciate the nature and consequences of their participation in the clinical research.

   Obtaining informed consent from prospective study participants is embedded in all ethical principles, statements and guidelines of research involving human subjects. Examples include**:**

   - Tri-Council Policy Statement (TCPS2)
   - ICH-GCP E6(R2)
   - Declaration of Helsinki
   - The Belmont Report

   The method of obtaining informed consent must be fully approved by the Nova Scotia Health Research Ethics Board prior to obtaining consent from any study participant, regardless of the modality to be used.

3. **Definitions:**

Decision-making Capacity: The ability of prospective or actual participants to understand relevant information presented (e.g. purpose of the research, foreseeable risks, and potential benefits), and to appreciate the potential consequences of their decision to participate or not to participate.

Co-Investigator: An individual who makes significant contributions to a clinical research study, but does not have the overall responsibility and authority for the study. This term is associated with clinical research that does not fall under ICH-GCP guidance.

Good Clinical Practice (commonly referred to ICH-GCP): an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects in drug, natural health products, or medical device trials.

Healthcare Professional: an individual who is appropriately qualified and allowed by a regulatory body to provide health care treatment and advice.

Informed Consent: A process by which a subject voluntarily confirms their willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate.

Mature Minor: an individual under the age of maturity according to the Nova Scotia Age of Maturity Act who demonstrates adequate understanding and Decision-making Capacity.

Principal Investigator/Investigator: the person responsible for the conduct of the study or clinical trial at a site. If a study or trial is conducted by a team of individuals at a site, the investigator is the responsible leader of a research team who is responsible for the conduct of the research, and for the actions of any member of the research team (also known as "Qualified Investigator" or "Researcher").

Research Ethics Board: a body of researchers, community members, and others with specific expertise established by an institution to review the ethical acceptability of all research involving humans conducted within the institution's jurisdiction or under its auspices.

Sub-Investigator: an individual member of the clinical trial team designated and supervised by the Investigator at a clinical trial site to perform critical trial-related procedures and/or to make important trial related decisions. This is the accepted terminology for clinical research that incorporates ICH-GCP Guidelines

Tri-Council Policy Statement: Statement document that is the foundation of ethical conduct of all research involving humans in Canada.

4. **Procedure:**

4.1

Confirm there is an REB approved method of contact prior to approaching the potential study participant.

4.2

Confirm age by date of birth for determination of minor status.

4.3

The appropriately qualified healthcare professional within, or associated with, the research team, determines if the minor has the capacity to make independent decisions regarding clinical research participation.

4.4

The appropriately qualified healthcare professional documents the discussion and decision of capacity determination, and Mature Minor status.

4.5

If the potential study participant is deemed to be a Mature Minor, the informed consent discussion is initiated by the Investigator, Co/Sub-Investigator, or study team member assigned the responsibility of obtaining informed consent.

4.6

The content of the REB and Sponsor approved informed consent form is reviewed together by the person obtaining informed consent and the Mature Minor allowing and encouraging questions or clarifications during the consent review.

4.7

Allow time at the end of the consent discussion for questions, clarifications, concerns, and independent decision making from the potential study participant.

4.7.1

To confirm that the participant is informed and understands what is asked of them, ask the following questions throughout the consent discussion and document the responses:

- What is the purpose of the study?
- Do you think you are volunteering for the study?
- What are the risks?
- What are the benefits?

4.8

If confirmation of informed consent cannot be determined, ask for futher clarifications and/or involve the physican that determined capacity.

4.9

Obtain the study participant informed consent to participate in the clinical research.

4.10

Document the consenting process:

- How and when did you obtain their name
- How/when/here were you introduced to the patient
- Document details of the introduction discussion including date and time of first contact,
- When and how was the ICF offered to the potential study participant

- What consent version was provided
- What instructions were provided
- Follow-up details after ICF was provided
- Date, time, and location of informed consent discussion.
- Who was present and their role.
- List any questions asked by the participant and answers that were provided and by whom.
- Record the answers to the 4 questions from section 4.7.1 to confirm that the study participant is informed.
- The participant is aware that their involvement in the study is voluntary and if they had an opportunity to speak to the PI if required before signing the consent.Date and time of informed consent
- Provide copy of signed consent to study participant.

References:

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice E6(R2). Published 09 November 2016. Retrieved 10 February 2021 <https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf>

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2018. Retrieved 10 February 2021 <https://ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf> chapter 4, Article 4.4 and Chapter 3, Section C

NSHA Research Ethics Board Glossary of Terms, 2017. Retrieved 10 February 2021 <http://www.cdha.nshealth.ca/system/files/sites/391/documents/nsha-glossary-terms.pdf>

Nova Scotia Age of Majority Chapter 4
https://nslegislature.ca/sites/default/files/legc/statutes/agemajor.htm

CDHA-CH 30-045 Policy: Consent to Treatment, July 2014. Retrieved 10 February 2021 <http://policy.nshealth.ca/Site_Published/DHA9/policy_details.aspx?policyDetails.QueryId.Id=50984>

NSH-REB-SOP-7-001 Informed Consent Requirements and Documentation, 2017. Retrieved 10 February 2021 < https://www.cdha.nshealth.ca/standard-operating-procedures-sops>

World Medical Association. (2001). World Medical Association Declaration of Helsinki. Ethical principles for medical research involving human subjects.. Bulletin of the World Health Organization, 79 (4), 373 - 374. World Health Organization

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1978). The Belmont report: Ethical principles and guidelines for the protection of human subjects of research. [Bethesda, Md.]: The Commission

Version History

Version:	Effective:	Approved by:	What's changed:
Original	2021-02-18	M.Chappell Dr. C MacKnight R. Stabile	N/A
[Revised / Reaffirmed]	YYYY-MM-DD	[Sponsor or Issuing Authority	[Brief description]