MARKHAM STOUFFVILLE HOSPITAL CORPORATION	**210.914.914.010 Informed Consent Requirements and Documentation**
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PURPOSE AND SCOPE:
The purpose of the 'Informed Consent Requirements and Documentation' policy is to describe the process for obtaining and documenting information consent for research purposes at Markham Stouffville Hospital (MSH).

This policy applies to members of the Research Ethics Board (REB), office of research, staff, students or external persons intending to participate in or conduct research at and/or in collaboration with MSH.

The Principle Investigator (PI) will provide the REB with detailed consent documents; outline the consent process and recruitment methods.

The PI and sponsor (if applicable) will ensure that all the required elements are clearly included in the consent form (see MSH REB ICF Template and MSH ICF Checklist).

The PI will provide translated consent documentation if required.

The REB will determine the applicability of exemptions and waivers to informed consent.

POLICY STATEMENT(S):
Consent is a cornerstone of ethical research involving human participants. The Research Ethics Board (REB) reviews consent documents and procedures to ensure compliance with current scientific, regulatory and ethical standards. Unless the REB has granted a waiver, the PI or designate is responsible for obtaining informed consent from potential research participants or their authorized third party before conducting any research-related procedures.

PROCEDURE:
1. **Required elements of informed consent**
    i. The office of research will distribute consent documentation to REB members for review;
    ii. REB members will review consent documentation utilizing the MSH ICF Checklist and template in order to assure that all requirements have been met;
    iii. The REB will approve or request changed to the ICF documents and the office of research will log these required changes;

iv. The REB Chair or designate will approve the required changes to the ICF documentation requested as a result of review.

2. **Translation**
   i. The process of informed consent should occur in a language that is understandable to the potential participant or authorized third party;
   ii. When a potential study participant does not speak and/or understand English, one of the two following methods may be used for obtaining informed consent:
      - Written translation of the ICF documents: The REB approved English version of the ICF is translated to the potential subject's native language;
      - Oral consent of the ICF documents: A translator fluent in English and the potential participants' native language will translate the REB approved English version of the ICF. The translator should be impartial and if the study involves clinical interventions the translator should be a member of the RHPA;
   iii. Translated material must be submitted to the REB via delegated review for approval prior to use if English documents have been previously approved. An attestation certificate of the translator is required;
   iv. The translator will sign and date the ICF indicating that the information was accurately translated and understood by the potential participant.

3. **Re-Consenting Participants**
   i. The PI or designate will inform research participants or authorized third party of any new information that might affect their willingness to continue to participate in research;
   ii. In situations where there is a significant change to the protocol or an increase in risk to the participant, the PI will obtain consent from the participant or authorized third party to continue participation in the study. This consent will be documented via an REB approved amended ICF.

4. **Recruitment Materials**
   i. The REB will review recruitment materials as part of the study review process. Recruitment materials (advertisements, letters, notices, emails) will be free from coercive or influential tone and the information included will be consistent with the study protocol;
   ii. Information on recruitment materials will be limited to only the information a potential participant needs to make an informed decision on whether or not they are interested in participating in research. Information that should be readily available to the potential participant includes:
      - Full Study Title
      - MSH Logo
      - The name of the PI(s)
      - Contact information of a person knowledgeable in research ethics
      - Purpose of the study
      - Summary of what will be done and participant's responsibilities

- Number of participants needed
- Duration of study and duration each participant will be involved
- Where the study will take place
- Payments/costs of participating
- Participant's rights

5. **Documentation of Informed Consent**
   i. Unless otherwise approved, informed consent will be documented by the PI or designate on an REB approved ICF;
   ii. The ICF will be version dated and will be signed and dated by the participant and/or their authorized third party, and by the person obtaining consent;
   iii. A copy of the signed and dated ICF will be provided to the participant
   iv. The PI is responsible for maintaining the signed and dated ICF in a secure location and may be asked to produce them, if required by the REB.

6. **Waivers or Alterations of Informed Consent**
   i. In certain circumstances, the REB may grant a waiver of the consent process or allow an alteration of the informed consent process. This typically occurs when;
      - The research involves no more than minimal risk to participants;
      - The lack of the participant's consent is unlikely to adversely affect the rights and welfare of the participants;
      - It is impossible or impracticable to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required;
      - The nature and extent of any proposed alteration is defined;

   i. If appropriate and possible, the participant will be provided with information regarding their involvement after the fact;
   ii. The REB will document justifications for waivers or alterations in their meeting minutes.

DEFINITION(S):
Consent: An indication of agreement by an individual to become a participant in a research project. Throughout this Policy, the term "consent" means "free (also referred to as voluntary), informed and ongoing consent."

Authorized third party: (also known as "authorized third party decision makers") refers to any person with the necessary legal authority to make decisions on behalf of an individual who lacks the capacity to decide whether or not to participate or to continue to participate in a particular research project.

REFERENCE(S):
1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. www.pre.ethics.gc.ca

2. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use: Guideline for Good Clinical Practice. www.ich.org
3. The Personal Health Information Protection Act. www.ipc.on.ca

RELATED DOCUMENTS:
Not Applicable.

RESPONSIBILITY:

Required Endorsements	Sponsor	Approval Authority
	Manager, Office of Research	Research Ethics Board (REB)

DOCUMENT HISTORY:

Type	Individual/Committee	Date	Outcome
Draft		01/03/1994	New Document
Revise		11/09/2012	
Revise	Research Ethics Board	23/07/2018	Major Revision of policy 201.914.914.010; Approved

APPENDICES:
Not Applicable.