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|  | Research Investigator Qualifications and Responsibilities |
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PURPOSE AND SCOPE:

The purpose of this policy is to describe the qualifications and responsibilities of investigators carrying out research at or in collaboration with Markham Stouffville Hospital (MSH).

This policy pertains to all staff, faculty, students or external persons intending to participate in or carry out research at and/or in collaboration with MSH.

POLICY STATEMENT(S):

Individuals carrying out research at or in collaboration with MSH must be appropriately qualified in terms of their education, training and experience to assume the responsibilities associated with the role.

Principle Investigators (PI) will carry out research at MSH in such a way that the research meets current scientific, regulatory and ethical standards while maintaining alignment with MSH's corporate policies, vision, mission and values.

PROCEDURE:

1. PI Qualifications

- 1.1 A current CV will be held on file and may be reviewed by the REB at any time
- 1.2 The Chair/Department Head will be made aware of, consider feasibility and support the proposed study being carried out by the PI
- 1.3 The PI must have the authority, based on their role and/or professional qualifications to conduct the study within MSH
- 1.4 The PI must complete the Tri-Council Policy Statement 2 Core online tutorial (<https://tcps2core.ca/welcome>) and submit the certificate of completion to the Office of Research, in addition to other documentation, as outlined by the Office of Research.

2. PI Responsibilities

- 2.1 All research staff members are appropriately qualified and able to assume the responsibilities associated with carrying out research with human subjects
- 2.2 All research staff members have completed the TCPS2 online tutorial on ethical conduct for research involving humans and submitted the certificate of completion to the Office of Research

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- 2.3 Research staff members have appropriate resources necessary to carry out their research projects
- 2.4 All research staff members adhere to the MSH Code of Conduct
- 2.5 REB approval has been obtained
- 2.6 The study is carried out in accordance to all applicable regulations and guidelines and follows the approved protocol
- 2.7 All changes, amendments, notifications are submitted to the REB for approval before being applied to the study
- 2.8 The REB and Office of Research is notified of any unexpected and/or unanticipated and/or serious problems and/or findings associated with the study
- 2.9 Accurate and complete records are kept and are easily accessible
- 2.10 All required reports are submitted on time to the Office of Research

DEFINITION(S):

Principle Investigator (PI) - The 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

REFERENCE(S):

1. Tri-Council Policy Statement (TCPS 2). Ethical Conduct for Research Involving Humans, Medical research Council of Canada 2014.
2. ICH Harmonized Tripartite Guideline. Good Clinical Practice: Consolidated Guideline (E6)1996.
3. World Health Organization (WHO). Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011
4. Health Canada (Division 5, Part C) Food and Drug Act 2001.

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 | Research Ethics Board | 13/08/2018 | New Document; Approved |

APPENDICES:

Not Applicable.

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