1.0 ORGANIZATIONAL SCOPE:

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 the Michener Institute.

2.0 PURPOSE:

The purpose of this policy is to describe the qualifications and responsibilities of investigators carrying out research at or in collaboration with the Michener Institute.

3.0 POLICY:

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

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

RESPONSIBILITY:

This Policy applies to research investigators, REB Chair and Research Office Staff. The Principal Investigator (PI) is responsible for ensuring that:

- All staff members are appropriately qualified and able to assume the responsibilities associated with carrying out research with human subjects;
- All staff members have completed the TCPS online tutorial on ethical conduct for research involving humans accessible at: http://tcps2core.ca/welcome;
- Staff members have appropriate resources necessary to carry out their research projects;
- All staff members adhere to the Michener Research Code of Conduct;
- All staff members protect the rights and welfare of participants;
- REB approval has been obtained prior to enrolling participants;
- Any real or potential conflicts of interest have been declared;
- The study is carried out in accordance with all applicable regulations and guidelines and follows the prescribed protocol;
- All changes, amendments, notifications are submitted to the REB for approval before being applied to the study;
- The REB and research office is notified of any unexpected and/or unanticipated findings and/or serious problems and/or new research knowledge associated with the study;

- The process of informed consent has been appropriately applied;
- Accurate and complete records are kept and are easily accessible;
- All required reports are submitted on time to the research office;
- The REB is notified when the study is completed.

3.1 Investigator Qualifications

3.1.1 A current CV will be held on file (usually held in Human Resources) and may be reviewed by the REB at any time;

3.1.2 The Chair/Department Head will be made aware of, consider feasibility and support the proposed study being carried out by the PI;

3.1.3 The Investigator must have the authority, based on his role and/or professional qualifications to conduct the study within the Michener Institute;

3.1.4 The Investigator must have completed the appropriate online tutorial and any additional qualifications necessary to carry out the research study.

4.0 REFERENCES:

1. Tri-Council Policy Statement (TCPS 2). Ethical Conduct for Research Involving Humans, Medical research Council of Canada 2010. http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/
2. Tri-Council Policy Statement (TCPS 2-CORE). Online Tutorial. http://tcps2core.ca/welcome
3. ICH Harmonized Tripartite Guideline. Good Clinical Practice: Consolidated Guideline (E6)1996. http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php
4. World Health Organization (WHO). Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011. http://whqlibdoc.who.int/publications/2011/9789241502948_eng.pdf
5. Interagency Advisory Panel on Research-Introductory Tutorial for the Tricouncil Policy Statement-Ethical Conduct for Research Involving Humans (TCPS) http://www.pre.ethics.gc.ca/english/tutorial/
6. Health Canada (Division 5, Part C) Food and Drug Act 2001. http://laws.justice.gc.ca/en/showdoc/cr/C.R.C.-c.870/bo-ga:l_C-gb:l_5//en#anchorbo-ga:l_C-gb:l_5
7. Ontario Personal Health Information Protection Act (PHIPA) 2004. http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm
8. Part 4 of the Natural Health Products Regulations 2003

http://laws.justice.gc.ca/en/showdoc/cr/SOR-2003-196/bo-ga:l_4//en#anchorbo-ga:l_4

9. Part 3 of the Medical Devices Regulations 1998 http://laws.justice.gc.ca/en/showdoc/cr/SOR-98-282/bo-ga:l_3//en#anchorbo-ga:l_3
10. CIHR Best Practices for Protecting Privacy in Health Research (2005) http://www.cihr-irsc.gc.ca/e/29072.html

5.0 ASSOCIATED DOCUMENTATION:

- Research Code of Conduct

6.0 REVISION HISTORY – TO BE COMPLETED AT EVERY REVISION

This information is required for review as well as for each new version of this document.

PLEASE NOTE - To ensure accuracy, policies should only be housed in the following locations:

Internal – Y/Shareit/Michener Policies and Procedures
http://my.michener.ca/policies/index.php

External – www.michener.ca/About/Policies (TO BE CONFIRMED)

DATE	REVIEWER	CHANGE(S) MADE	POLICY LOCATION(S) (i.e. internet, intranet, academic handbook)