HREB Monitoring Policy	**HREA-REB04**
Issuing Authority	Health Research Ethics Authority
Signature of Administrative Authority Chairperson, HREA	Regina Coady
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Original Approval Date	December 15, 2021
Review Date	December 15, 2024

Background: The Health Research Ethics Authority (HREA) was established by the HREA Act and came into effect on July 1, 2011. The HREA Act mandates that all research approved by the Health Research Ethics Board (HREB) will be monitored to ensure it is conducted ethically and in compliance with applicable policy, guidelines, regulations and legislation.

Purpose: The purpose of this policy is to:

1. Promote responsible research conduct and review
2. Support Researcher compliance with applicable guidelines, regulations and legislation related to health research.
3. Specify the process for monitoring for compliance to ensure the ethical conduct of health research.

Scope: All HREB members, Research Ethics Office (REO) Personnel and Researchers are responsible for ensuring that the requirements of this policy are met.

Policy Statements:

1. The Principal Investigator is responsible for ensuring that their research study is conducted in compliance with the HREB approved application, as well as applicable policies, guidelines, legislation and regulations.

2. The HREB will conduct routine, as well as, for-cause inspections of HREB approved research. Inspections will be conducted by designated REO Personnel.

3. Inspection findings will be measured against established policies and procedures and applicable ethical, legal and regulatory requirements. When areas for improvement are identified, corrective action will be taken. Findings of non-compliance will be reported to the applicable persons, in compliance with applicable ethical, legal and regulatory requirements.

4. Reports of non-compliance related to health research will be investigated by REO Personnel. An inspection will be conducted on all credible allegations of non-compliance.

5. The HREB is subject to applicable external regulatory inspections/audits and will follow applicable approved procedures when participating in an inspection/audit.

Related Documents:

Standard Operating Procedure 901: **Monitoring HREB Approved Research**

Standard Operating Procedure 902: **External Inspections or Audits**

Standard Operating Procedure 903: **Non-Compliance**

Health Research Ethics Authority Act: An act to establish a health research ethics authority for the province. (2011). Retrieved from: SNL2006 CHAPTER H-1.2 - HEALTH RESEARCH ETHICS AUTHORITY ACT (assembly.nl.ca)

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. Retrieved from: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2

Health Canada Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects (Schedule 1024): Guidance Document: Part C, Division 5 of the Food and Drug Regulations "Drugs for Clinical Trials Involving Human Subjects" (GUI-0100) - Summary - Canada.ca

Health Canada Guidance for Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6(R2), Notice - Interim Implementation of International Council for Harmonisation (ICH) Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) - Canada.ca

U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46): 2018 Requirements (2018 Common Rule) | HHS.gov

U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56):https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart