UM | Human Research Ethics & Contract Compliance

403-4 Administration Building
66 Chancellors Circle
Winnipeg, MB R3T 2N2
T: (204) 599-8300
Marion.Kiprop@umanitoba.ca

September 10, 2024

ROUTINE[1] AUDIT – INITIAL REPORT (TEMPLATE)

Project Title:
Ethics Protocol No.:
Principal Investigator (PI):
Faculty/Department:
Research Location:
Audit No.:
Auditor:
Audit Period:[2]

BACKGROUND[3]

This protocol (HE0000) was selected for a Routine Audit as part of the University of Manitoba Human Research Ethics Audit Program. Protocols are selected for routine audits based on specified criteria including those that are more than minimal risk, involve current/active participant engagement, conducted by a PI with multiple active protocols, are multi-year/longitudinal, and involve research agreement. This protocol was selected for audit because it involves a research agreement.

AUDIT OBJECTIVES

1. To assess compliance with
   - the approved research protocol and protocol-referenced documents,
   - Good Clinical Practice: International Council for Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use.

[1] Other types of audits conducted are directed audits and data management audits.
[2] Audit dates start when the first email initiating the audit is sent to the PI and end when the final audit report is distributed.
[3] Background information will vary depending on the type of audit.

- Health Canada Food and Drug Regulations. Part C Division 5,
- the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2 (2022),
- the Personal Health Information Act (PHIA) and the Personal Health Information Regulation 245/97,
- the University of Manitoba Ethics of Research Involving Humans Policy and Procedure,
- the University of Manitoba Responsible Conduct of Research Policy, Responsible Conduct of Research - Code of Research Ethics Policy, and Responsible Conduct of Research - Investigation Procedure, and
- the University of Manitoba Research Agreements Policy and Procedure.

2. To identify requirements for change and/or improvement based on audit observations.[4]

AUDIT SCOPE

In this section, the Research Compliance Specialist will outline the areas reviewed during the audit. The scope of an audit usually varies and is tailored to the complexity of the study.

AUDIT METHODS

In this section, the Research Compliance Specialist will outline the methods used during the audit including review of project-related materials and interviews with research staff.

AUDIT NOTES

In this section, the Research Compliance Specialist will describe the complete study narrative from research personnel, recruitment and screening, informed consent, data collection, participant compensation, dissemination, and data management.

[4] An audit observation is a finding of a deviation from the approved protocol and protocol referenced documents, or a failure to comply in some way with one or more activities as outlined in the approved protocol and protocol referenced documents, the University of Manitoba (UM) policies and procedures, other applicable regulatory frameworks, and with contractual obligations.

AUDIT OBSERVATIONS

In this section, the Research Compliance Specialist will list audit observations and the criteria for determining said observations. Here are a few examples.

#	OBSERVATION	CRITERIA FOR EVALUATION
1	Failing to obtain REB approval prior to commencing research activities.	The University of Manitoba Responsible Conduct of Research - Code of Research Ethics Policy, Article 2.3(a): “Non-Compliance: Failure to obtain all necessary approvals or conduct the Research in accordance with the University's policies (including research ethics approvals), the requirements of Funding Agencies, the rules of professional governing bodies, and all relevant laws.”
2	Failing to obtain informed consent from participants.	TCPS 2 (2022), Article 3.2: “Researchers shall provide to prospective participants, or authorized third parties, full disclosure of all information necessary for making an informed decision to participate in a research project.”
3	Failing to disseminate research findings.	TCPS 2 (2022), Article 4.8: “Researchers shall disseminate, through publication or otherwise, the analysis of data and interpretation of

#	OBSERVATION	CRITERIA FOR EVALUATION
		research results, including those that do not support the research hypotheses. The dissemination shall take place in a timely manner without undue restriction."

AUDIT CONCLUSIONS

In this section, the Research Compliance Specialist concludes by listing what the study team has breached in the conduct of research including breaches of the protocol, policies, procedures, other legislative and regulatory frameworks, and with contractual obligations as applicable.

DIRECTED AUDIT– RESEARCHER RESPONSE[5]

Below is a list of the observations following the audit of your study. These observations are based on the information reviewed and interactions with research staff at the time of the audit.

Researchers are required to respond to each observation, addressing:

- The validity of the observation. (If you have new evidence or information refuting the observation, state as such and provide supporting documentation as applicable.)

- Any corrective and preventive actions you propose to take.

[5] In this section, the researcher is required to respond to any observations outlined in the initial audit report. This may include providing any clarifications, additional information, feedback, or proposals for corrective action.

The final audit report will be based on both initial observation(s) and any additional information provided by the researcher in response. Please include your comments in the boxes under “Researcher Response (REQUIRED).”

Observation 1
Failing to obtain REB approval prior to commencing research activities.
Researcher Response (REQUIRED)
Observation 2
Failing to obtain informed consent from participants.
Researcher Response (REQUIRED)

Observation 3
Failing to disseminate research findings.
Researcher Response (REQUIRED)
Additional Researcher Comments (OPTIONAL) *(If you have any other remarks or insights about the audit, please add them here.)*

Marion Kiprop
Research Compliance Specialist
Research Ethics and Compliance
403-4 Administration Building
Email: Marion.Kiprop@umanitoba.ca
Phone: (204) 599-8300