Title	4.07 Management of Migrated Protocols
Version	1.0
Effective Date	June 1, 2025

Purpose

This standard operating procedure (SOP) describes the management of Protocols migrated into the Research Administration System (RAS).

Scope

This SOP pertains to Protocols submitted to any of the Fort Garry Research Ethics Boards (REB) before the online Research Administration System (RAS) was implemented in July 2021 designated by an HS number (Migrated Protocols).

Rationale

The REB must make an informed decision about the continuing ethical acceptability of research involving human participants. This work is complicated when the forms used in Migrated Protocols and the information contained in them are no longer up to date with current TCPS2 expectations and University policies and procedures. As a result, the ethical acceptability of amendments and continuing review more generally are increasingly difficult for the REB to manage.

Responsibilities

All REB members, Office of Human Research Ethics (OHRE) Personnel and Researchers are responsible for ensuring that the requirements of this SOP are met.

The Researcher is responsible for submitting information to the REB regarding any changes to and ongoing review of their Protocols.

The REB Chair or designee is responsible for undertaking continuing ethical review of all active Protocols.

Procedure

Renewals

When a renewal request is received by OHRE Personnel, the following question will be asked of the Researcher:

1. Are you still interacting with research participants?
    a. If yes, at what stage are you (ex. recruiting, consenting, data collection, preparing summary of results)?
    b. If no, provide a rationale for renewing the study.

The Protocol will then be sent to the REB Chair for review. The REB Chair will review the documentation and make one of the following determinations:

1. The Protocol can remain open for another year on the condition that no changes to study can be made and no amendments can be submitted. A renewal application or Protocol closure will be required before the Protocol's next expiry date.
2. A new Protocol may be requested where new engagement with participants and/or new secondary use of data is contemplated. The currently submitted Renewal Request is approved, and the original Protocol must be closed before the next expiry date.
3. The Protocol must be closed as there is no longer any active interaction with study participants. A new Protocol must be submitted if engagement with participants and/or secondary use of data is contemplated in the future.
4. Continuing review is approved and there are no restrictions on further amendments or continuing review at this time.

Amendments

When an amendment is received by OHRE Personnel, it will be sent to the REB Chair for review. The REB Chair will review the amendment and make one of the following determinations:

1. The amendment is approved and there are no restrictions on further amendments or continuing review at this time.
2. The amendment is approved but no future amendments or continuing review applications will be considered. To ensure ethical compliance, a new Protocol must be submitted to the OHRE as soon as possible (at least 4 months before the current protocol expires). The original Protocol must still be closed before the next expiry date.
3. The amendment is not approved. A new Protocol must be submitted to the OHRE as soon as possible to continue the study before any further research activities can take place. The original Protocol may be closed once the new Protocol is approved or at the next renewal date if all communication with previous participants is complete.

Revision History

Version	Effective Date	Summary of Changes