Research Improvement Through
Harmonization in Manitoba
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Policy Title	**RITHIM Harmony Signature Authority**
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Review Date	
Responsible Officer	Director, RITHIM

1 PURPOSE

This policy defines the appropriate use, limitations, and governance of the **Signature Authority (SA)** role within the Harmony system. It ensures that Principal Investigators (PIs) retain accountability while allowing limited delegation under clearly defined circumstances.

2 SCOPE

This policy applies to:

- all research projects submitted through RITHIM Harmony
- Principal Investigators (PIs)
- Individuals acting as Signature Authorities (SAs)
- Research personnel involved in submission and follow-on activities

3 DEFINITIONS

3.1 **Principal Investigator (PI):** The individual with ultimate responsibility for the conduct of the health research project.

3.2 **Signature Authority (SA):** A research team member who submits certain items in Harmony on behalf of the PI under approved circumstances.

3.3 **Follow-on Submissions:** Includes amendments, renewals, adverse events, protocol deviations, reportable events, and project completions.

4 POLICY

4.1 The PI is ultimately responsible for all research activities and submissions within RITHIM Harmony. The use of Signature Authority is **exception-based**, limited, and must be justified. It is **not intended for convenience or workload management**.

4.2 The SA must be a member of the Research Personnel listed in Section 2.2 of the RITHIM Application Form.

4.3 The SA must have a complete and valid Personal Profile form.

4.4 For regulated projects (Health Canada, FDA, etc.), the SA must be a Co-Investigator who meets the eligibility criteria to act as a PI

4.5 **Initial Applications**

4.5.1 The initial project application, plus all re-submissions up to the point of initial approval must be signed by the PI. The SA cannot sign initial applications under any circumstances.

4.6 **Follow-On Submissions**

4.6.1 Follow-on submissions may be submitted by the PI (standard expectation), or a SA **with appropriate justification**

4.6.2 Follow-on submissions include

- Local Unanticipated Problems (Initial or Follow-up)
- Amendments
- Project Renewals
- Major Protocol Deviations
- Reportable Events
- Material Incidental Findings
- Project Completions

4.7 **Acceptable Use Circumstances**

4.7.1 Signature Authority may only be used when the PI is **unable** to sign submissions due to:

- Short-term absence (e.g. travel, vacation)
- Short-term medical leave due to Illness or injury
- Death of the PI

4.8 **Unacceptable Use Circumstances**

4.8.1 Signature Authority may **not** be used:

- For PI convenience or workload delegation
- When the PI is **available but busy**
- During long-term absences such as extended medical leaves or sabbaticals (requires an amendment for a formal PI change).
- Without detailed justification

4.8.2 When determining if a formal PI change is required, consideration will be given to the level of risk, project activities underway, and the level of oversight required.

4.9 A **mandatory justification** must accompany all SA signatures. Submissions lacking appropriate justification will be returned for correction.

4.10 The **PI retains full responsibility and accountability** for all submissions, all project conduct, all actions taken by the SA on their behalf.

4.11 All correspondence remains in the **name of the PI**, regardless of SA use.

4.12 All SA actions are logged and auditable within Harmony.