Managing Research Deviations and Non-Compliance

(*Including Operational, Contractual, and Funding Obligations*)

1. Introduction

This document serves as a comprehensive guide to identifying, documenting, and reporting deviations and non-compliance issues associated with research projects authorized to occur in the Saskatchewan Health Authority (SHA). This includes projects occurring within SHA-operated facilities and those that involve SHA patients, clients, staff, data, systems, or resources, regardless of whether activities take place in a physical SHA facility.

It is intended to support Principal Investigators (PIs) and their teams in meeting the ethical, legal, contractual, and financial obligations required to comply with: The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)*

- *The Health Information Protection Act (HIPA)*
- SHA policies and procedures
- Funding agreements, contracts, and sponsor requirements

PIs are ultimately responsible for ensuring compliance across all aspects of their research, including Research Ethics Board (REB) approvals, operational approvals, data use agreements, contracts, and funding terms.

2. Scope

This guidance applies to all individuals involved in projects involving human participants or data at SHA, whether the activity is:

- REB-approved or REB-exempt
- Funded or unfunded
- Internally or externally sponsored

and includes projects conducted:

- Within SHA facilities
- Using SHA resources, data, or systems
- Involving SHA staff or patients (whether as team members or participants)
- Under research contracts, data sharing agreements, or funding agreements administered by or involving SHA

3. Key Definitions

3.1 Deviation: Any departure from an approved or authorized plan, requirement, or process.

- For REB-approved research: a deviation is a departure from the REB-approved protocol, consent, or related procedures.
- For REB-exempt activities (e.g., QI/QA/Program Evaluation): a deviation is a departure from the approved project plan, operational approval, Letter of Authorization (LOA), data use parameters, or other documented requirements.

Note: Deviations may be minor or major depending on risk and impact (see Section 4).

3.2 Major Deviation (Violation): A deviation that increases risk to participants or others, compromises rights, safety, or welfare, materially affects data integrity, or represents a repeated or willful failure to follow required processes.

3.3 Non-Compliance: Any failure to comply with applicable ethical, legal, regulatory, operational, contractual, privacy/security, or funding requirements.

- Relationship to "Deviation": A deviation is often a specific instance of non-compliance with an approved plan. Non-compliance is a broader umbrella that also covers issues not tied to a single protocol step (e.g., using funds for ineligible expenses, breaching a data-sharing restriction, missing required insurance or reporting).
- Non-compliance may be isolated, recurrent, or systemic.

3.4 Categories of Non-Compliance

a. Contractual Non-Compliance: Failure to meet obligations outlined in a research contract or agreement, including but not limited to unauthorized data sharing, conducting activities outside the scope of the agreement, or failure to meet reporting or insurance requirements.

b. Funding Non-Compliance: Failure to meet funder requirements, including use of funds for ineligible expenses, missed financial or progress reporting deadlines, or failure to meet project milestones and deliverables.

c. Privacy Breach (or Incident): Any unauthorized **access, use, disclosure, alteration, loss, or destruction** of personal health information or confidential institutional information, including failures to follow HIPA-aligned safeguards and data-use agreements.

d. Unanticipated Problem: An unexpected incident, experience, or outcome related to project activities that increase risk to participants or others and was not previously described in the approved protocol or plan (applies to research and, as relevant, to QI/QA).

4. Assessing Severity and Impact

Severity levels guide notification, documentation, and escalation. Classify based on actual or potential risk, data integrity, rights and welfare, and recurrence/intent.

Level	Description	Example
Minor	Minimal/no risk; limited impact; isolated; promptly corrected	Follow-up missed by 1–2 days; template version discrepancy caught and corrected; administrative form omission.
Moderate	May affect data integrity or policy adherence	Unapproved consent form used once; data field exported beyond LOA scope and deleted upon discovery.

Major	Increases risk to participants/others; compromises rights or data integrity; repeated	Unauthorized EMR access; unapproved data disclosure to third party; repeated activity outside contract scope; missed report causing material funding risk.

Decision cues include**:**

- **Risk:** Did the event increase risk to participants, staff, or the public?
- **Integrity:** Did it compromise scientific or analytic integrity?
- **Rights & Privacy:** Did it affect consent, privacy, or confidentiality?
- **Recurrence/Intent:** Is it repeated, systemic, or willful?
- **Obligation:** Does it breach REB approval, operational approval/LOA, contract, funder term, or privacy/security requirement?

5. Documentation and Reporting

All deviations must be documented contemporaneously in a Protocol Deviation Log (or equivalent project record).

Reporting Requirements

- **Research Ethics Boards:**
  Reporting expectations may vary by REB. PIs must follow the specific reporting requirements of the REB of record, which may require reporting of all deviations, including minor deviations, or may distinguish between minor, moderate, and major events. When requirements are unclear, a conservative approach should be taken, and clarification should be sought from the REB.
- **SHA Operational Approvals:**
  Deviations and non-compliance issues that may affect operational approvals, Letters of Authorization, patient or staff involvement, data access, or use of SHA systems must be reported to the SHA Operational Approvals team in accordance with internal guidance.
- **Financial and Contractual Matters:**
  Any deviations or non-compliance related to funding, financial management, or contractual obligations must be reported promptly and accurately to the Research Funding and Contracts team.

6. Corrective and Preventive Actions

Corrective and Preventive Actions (CAPA) refers to a structured process used to address identified deviations, non-compliance, privacy breaches, or unanticipated problems, with the aim of correcting the immediate issue and preventing recurrence. CAPA is typically required when an issue is classified as moderate or major, or when repeated or systemic issues are identified, as determined in Section 4 (Severity and Impact).

When CAPA is required, the Principal Investigator (delegate) is expected to:

- Identify and describe the issue
- Determine the root cause (i.e., why the issue occurred)
- Implement corrective actions to resolve the immediate issue (e.g., stopping the activity, correcting data entry errors, retraining of research personnel, notifying REB and sponsor/funder, as applicable)
- Implement preventative measures to reduce recurrence (e.g., updating site specific operating procedures, adding checklists, revising workflows, additional training)
- Assign responsibility and timelines for completion
- Document actions taken and outcomes

CAPA actions must be documented in the project file and/or deviation log, and provided to relevant oversight or regulatory bodies as applicable (e.g., REB, sponsor, funder).

7. Examples of Deviation vs. Non-Compliance

Situation	Classification	Action Required
Missed visit window (by 2 days)	Deviation (Minor)	Document in deviation log; report to REB if required by the REB of record or if a pattern emerges
Accessed EMR without being listed or authorized	Non-Compliance	Notify REB; report through applicable incident process
Expired consent form used once	Deviation (Moderate)	Document and report to REB in accordance with REB requirements
Recruitment initiated prior to REB approval	Non-Compliance (Major)	Notify REB immediately; cease affected activities and follow REB direction
Data shared outside scope of approved agreement or Letter of Authorization	Contractual Non-Compliance	Notify REB, OA, Privacy, and Research Contracts,
Ineligible expense charged to grant or research account	Funding Non-Compliance	Notify Research Funding and Contracts; notify funder if required by funding terms
Late submission of required financial report	Funding Non-Compliance	Document and notify Research Funding and

	Contracts; remediate per funder requirements

8. Preventive Measures

The following preventive measures are intended to reduce the risk of deviations and non-compliance across research and project-related activities conducted under SHA authority or oversight:

1. Conduct regular team training on:
    - Research ethics and applicable approvals
    - Data access and privacy requirements
    - Project specific contractual obligations and awarded funding conditions
2. Use checklists and tools for recruitment and eligibility, consent, and data access
3. Review REB approval letters, conditions, and amendments on a regular basis to ensure continued compliance.
4. Ensure all required Operational Approvals are in place prior to initiating project activities or accessing SHA data, systems, or resources.
5. Monitor financial expenditures against funding award letter, approved study budgets, and sponsor or funder requirements.
6. Conduct periodic audits or reviews of project documentation, contracts and agreements, as well as financial and funding records.

9. Roles and Responsibilities

Principal Investigator or Project Lead

The Principal Investigator for research projects, or the Project Lead for REB-exempt activities (e.g., quality improvement, quality assurance, or program evaluation), holds ultimate accountability for:

- Ethical conduct of the project and protection of participants or data subjects
- Compliance with:
    - REB approvals (as applicable)
    - SHA policies and procedures
    - Operational approvals and Letters of Authorization
    - Contractual and funding requirements
- Oversight and supervision of all project personnel
- Timely identification, documentation, and reporting of deviations and non-compliance

Project Personnel

All individuals involved in project activities must:

- Follow approved protocols, project plans, agreements, and conditions
- Comply with applicable privacy, security, and data-use requirements
- Promptly report concerns, deviations, or potential non-compliance issues to the PI or Project Lead

10. Key Contacts

- **SHA Research Ethics Office**: ResearchEthics@saskhealthauthority.ca
- **SHA Privacy Office**: privacy@saskhealthauthority.ca
- **SHA Operational Approval Team**:
  - Regina: researchapprovalregina@saskhealthauthority.ca
  - Saskatoon: researchapproval.saskatoon@saskhealthauthority.ca
- SHA Research Funding and Contracts Team: ResearchContracts@saskhealthauthority.ca
- **SHA REB Forms & Templates:** https://www.saskhealthauthority.ca/our-organization/our-direction/research/research-forms

11. References

- **Tri-Council Policy Statement:** Ethical Conduct for Research Involving Humans – TCPS2 (2022)
- **HIPA**: Health Information Protection Act, H-0.021
- **SHA Research Policy** (SHA-02-006) **and Procedure Handbook** (SHA-02-006P1)