Saskatchewan Health Authority

Privacy Guidelines: Recruiting Patients for Research within the Saskatchewan Health Authority (SHA)

These guidelines apply to SHA-affiliated researchers, clinicians, and research personnel conducting studies involving SHA patients or resources. External researchers working cand collaborating with SHA are also required to follow them.

The guidelines are designed to ensure that the recruitment of patients for research within the Saskatchewan Health Authority (SHA) is conducted ethically, transparently, and in full compliance with all applicable privacy legislation, including *The Health Information Protection Act (HIPA)*, its Regulations and SHA policies.

1. Core Principles

Principle	Practical Meaning
Necessity	Access only the minimum amount of personal health information (PHI) necessary for recruitment
Permission	Obtain informed and voluntary permission from patients before accessing their PHI to determine study eligibility
Privacy	Only clinicians actively involved in patient care are authorized to access patient health records without the patient's explicit permission, unless there is REB approval for a waiver of consent allowing study team members access.
Accountability	Researchers and SHA staff must adhere to these guidelines and all applicable privacy legislation.

2. Approvals Required *Before* Recruitment

2.1 Research Ethics Board (REB) Approval:

All studies recruiting SHA patients must have full REB approval (or formal exemption) from a recognized Saskatchewan REB (e.g., SHA, University of Saskatchewan Biomedical or Behavioural, or University of Regina).

Please contact the REB Office to inquire about the expected timelines for obtaining REB approval.

2.2 SHA Operational Approval (OA):

OA is required for any study that uses SHA resources (e.g., staff time, facilities, data). SHA facilitated resources (eHealth eViewer, PIP, Panorama), where the steward of the data is not SHA, **are not to be used for research**. All recruitment materials posted or distributed within SHA facilities (posters, flyers, brochures, emails, patient-portal notices, etc.) are subject to review.

2.3 Privacy Review

- If PHI will be accessed without patient consent, there must be ethics approval in place for this waiver of consent.
- If the project is exempt from research ethics review, SHA Privacy must confirm legislative authority under HIPA section 27 before any data access occurs.
  NOTE: REB-exempt projects still require SHA Privacy review for any data release.

Please reach out to the SHA Privacy Office to confirm the anticipated timelines for the review process.

Tip: Recommend confirming with the REB whether your project qualifies as "research" or is exempt from REB review (e.g., Quality Improvement, Quality Assurance or Program Evaluation) — this affects the type of review and authorization required.

3. Patient Identification and Initial Contact

3.1 SHA-Stewarded PHI

Patient recruitment should be **clinician-mediated and conducted exclusively during active care to ensure** privacy and ethical access to health records. Clinicians (e.g., physician, nurse, medical office assistants) can follow these steps:

- During the course of routine care, identify potential participants using the study's inclusion/exclusion criteria.
- Provide the patient with study information, including researchers' contact information, enabling the patient to initiate direct contact to discuss potential participation.
- Share the patient's contact information with the research team only after confirming the patient's interest in being contacted and having received their explicit consent.

Please note: Clinicians cannot contact patients using SHA-stewarded PHI solely for research recruitment, even if they are the patients are under their care. All recruitment using SHA-stewarded PHI must **only** occur in the context of delivery healthcare.

3.2 Non-SHA Stewarded PHI

Follow the same clinician-mediated process but ensure the non-SHA trustee's privacy rules are also met.

3.3 Prohibited Practices

- Research staff who do not have an established care relationship with the patients are strictly prohibited from accessing health databases for the purpose of generating recruitment lists. In these cases, they must work with authorized SHA staff (e.g., Health Records staff or clinical staff member) to provide the list in accordance with privacy requirements.
- Clinicians must not disclose patient contact information to research teams without obtaining the patient's explicit and informed consent.

- The use of bulk or group messaging to contact patients is strictly prohibited, including the use of blind carbon copy (BCC) features; all initial approach must be individualized.

4. Passive Recruitment

- Public advertisements (e.g., posters in clinics, flyers, public website listings) are permitted and rely on self-referral.
- OA approval is required for any material posted or circulated in SHA spaces.
- Avoid language implying SHA endorsement and avoid practices revealing diagnoses in public areas.

5. SHA Clinical Support in Recruitment

- SHA clinical personnel may assist in identifying or contacting participants only if the REB-approved protocol authorizes their role.
- If participants (or their designated decision makers) consent to be approached, then a member of research team can connect with them to share study information and obtain informed study consent.
- Recruitment communications may be scripted or templated and approved by the REB.

Best practice: Include a "Letter of Initial Contact" template in your REB submission.

6. Conducting Recruitment Activities in SHA Facilities

- Hold consent conversations in private locations such as closed consultation rooms, not public waiting areas.
- Respect a patient's right to decline, no coercion.
- Do not publicize participant status.

7. Training & Compliance

All research team members must:

- Complete training for the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) and the Hamilton Integrated Research Ethics Board (HiREB) Chart Review Tutorial.
- Understand and comply with **SHA's Research Policy and Research Procedure Handbook**.
- Follow REB and OA conditions throughout the study lifecycle.

8. Accountability and Oversight

- **Principal Investigator (PI) Responsibility**:

  The PI is responsible for ensuring compliance with these guidelines, REB and OA approvals, and all applicable privacy legislation, even for responsibilities delegated to others.

- **SHA Oversight:**

  The SHA is responsible to have oversight of all research conducted within its facilities ensuring it adheres to research ethics and privacy principles. This may include:

  - Reviewing research protocols.
  - Monitoring compliance with data access.
  - Investigating any privacy breaches.

- **Privacy Breach:**

  In the event of a privacy incident, the SHA's privacy breach protocol must be immediately followed, including using the Privacy Incident Report Form to notify the SHA Privacy Office. Note there may also be potential notification to the Office of the Saskatchewan Information and Privacy Commissioner (OPIC), if required.

9. Support Contacts

- **SHA Research Ethics Office:** researchethics@saskhealthauthority.ca
- **SHA Operational Approval:**
  - Regina: researchapprovalregina@saskhealthauthority.ca
  - Saskatoon: researchapproval.saskatoon@saskhealthauthority.ca
- **SHA Privacy Office:** privacy@saskhealthauthority.ca

These guidelines serve as a framework. Researchers and SHA staff must also refer the most current SHA policies, HIPA, and REB requirements for definitive guidance and approval on recruitment activities. Research teams are expected to regularly review these guidelines, including any changes in legislation, institutional regulations, and best practices.

Frequently Asked Questions

1) What is the authority that the SHA and its units, such as Privacy, have over health information maintained or stewarded by physicians?

SHA has authority over health information collected, stored, or managed within its facilities, systems, or programs. If a physician-researcher provides care within SHA (e.g., clinics, hospitals), any health records generated within the scope of that care fall under SHA's stewardship and HIPA governance.

If the physician-researcher is self-employed (e.g., in private practice), and the health records are not generated or stored within SHA systems, SHA does **not** have authority over the document/data within the physician-researcher's own system. However, if the research involves data derived from SHA sources (e.g., SCM or PACS), SHA remains a data steward of the data/document within the SHA system.

2) When does a physician *not* belong to the SHA?

A physician may not be considered part of SHA if:

- They operate exclusively in **private practice**, with **no affiliation** to an SHA-operated facility.
- They are **independently contracted** and do not use SHA clinical systems.
- Their work is governed under another entity (e.g., **Saskatchewan Cancer Agency**, **University of Saskatchewan** faculty only roles).

3) When is the SHA *not* the steward of health data?

SHA is not the steward when:

- Data is collected in **private clinics**, **academic studies** independent of clinical care, or by **third parties** not under SHA's data stewardship.
- The data is hosted in **University-owned systems** or external platforms without SHA involvement.
- The health record originates in a **federal or other provincial jurisdiction** (e.g., federal corrections, or other provincial health authorities).
- The procedure/assessment is performed, and data is collected specifically for research purposes where it is not recorded within SHA systems.

4) **Can research team members review PHI to identify patients for recruitment?**

Only if **ALL** conditions are met:

- ✓ They are **SHA-affiliated healthcare providers** (e.g., Principal Investigator, sub-Investigator) **with a care-based need-to-know**.
- ✓ They are **actively involved in the patient's care**, or their defined role justifies ongoing access to data (e.g., follow-up care or oversight).
- ✓ The study has **REB approval** and **SHA Operational Approval** permitting access to records for recruitment purposes.

⚠️ If there is no active care relationship following need-to-know privacy principles and no legal authorization (like consent), access may breach HIPA.