

SHA REB Guidelines: Using Generative AI (GenAI) in Research Involving Human Participants

These guidelines apply to SHA-affiliated researchers, clinicians, and research personnel conducting studies involving SHA patients or resources under the jurisdiction of the Saskatchewan Health Authority Research Ethics Board (SHA REB). External researchers will need to consult with their own REBs and ensure alignment with SHA requirements where applicable.

The guidelines are designed to help researchers applying for SHA REB approval for studies that include the use of generative AI for research within the SHA. They are informed by, and must be read in conjunction with, the [SHA Policy: Artificial Intelligence \(AI\) Acceptable Use](#). Researchers should familiarize themselves with this policy. In the event of any contradiction between the policy and these guidelines, defer to the policy. All uses of GenAI must also comply with applicable legislation, including but not limited to *The Health Information Protection Act (HIPA)*, and other relevant federal and provincial privacy and health information laws. These guidelines are applicable both to new tools, but also to existing tools that add or have added GenAI capabilities.

Given the rapid evolution of generative AI technologies, a principle-based approach is required for their safe and ethical inclusion into research with human participants. Specific instructions are likely to become obsolete as these tools and their use change. Ensuring that the use of GenAI in research with human participants follows the core principles of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)*, Respect for Persons, Concern for Welfare, Justice, is the most appropriate way to support the ethical use of these tools.

This guide will help you understand your responsibilities to the SHA REB and your participants regarding the use of GenAI.

1. Background Use

* These uses include the development of the study itself (e.g., the research question, methodology) and the drafting and refinement of documents (e.g., grammar, clarity, structure, summarization of researcher-authored text).

* Researchers retain full responsibility for the accuracy and completeness of all content and documents submitted to the SHA REB. Do not treat GenAI outputs as authoritative. Review, verify, and critically edit all material. The SHA does not endorse or warrant any specific GenAI tools. Researchers are solely responsible for ensuring that their use of such tools complies with applicable laws, professional standards, and institutional policies.

2. Interaction with Participant Data

2.1 Mandatory Disclosure:

* You must disclose to the SHA REB any intended interaction between participant data and GenAI in your study. This includes identifying the specific GenAI tool(s) you intend to use, whether the tool(s) have been approved by the SHA Artificial Intelligence Governance Committee (AIGC), and the purpose for their use, e.g., transcription, data analysis.

* Be prepared to provide a clear rationale for its use and to describe mitigation strategies for any associated risks, including privacy, confidentiality, and data governance considerations.

 **Tip:** Be sure to identify the specific GenAI tool(s) you intend to use consistently across all study materials, including in the REB application and relevant consent form(s).

2.2 Approvable Tools:

* The REB expects the use of institutionally approved GenAI tools with clearly defined data governance, security safeguards, and privacy policies. The SHA AIGC will be responsible for approving AI tools, not the SHA REB. Researchers should include in their application evidence that AIGC approval process has been completed or initiated. Where available, researchers should consult any SHA-maintained list of approved [tools](#).

* The REB will not approve the use of public, general-purpose GenAI tools (e.g., ChatGPT, Gemini) for any interaction with participant data. Use of such tools presents a high risk of confidentiality and privacy breaches by exposing participant data to third parties, which may violate the participant's informed consent requirements, SHA policies, and applicable legislations.

 **Please note:** Both the REB and the participants are unlikely to be familiar with the privacy policies of specific GenAI tools. It is the researcher's responsibility to explain these practices and inform both the REB and participants in a way that they can readily understand.

3. Privacy, Confidentiality, and Data Security

3.1 Prohibition on Uploading Sensitive Data

*The REB will **not** approve the entry, uploading, or processing of patient health information (PHI) or other sensitive data into any GenAI tool, even if the data is de-identified, unless the AIGC has approved it for use with PHI, such as AI Scribe.

3.2 Internal and External Uses

*The REB may not approve the use of a GenAI tool that retains for its own purposes uploaded information beyond the function requested by the research team. Examples include training or refining of the tool itself. The SHA REB's decision will depend on the sensitivity of the data, the vulnerability of the participants, and contractual guarantees regarding retention, training, and data residency.

* Researchers should include in both the application and the consent form whether any uploaded data will be stored or processed outside Canada. Cross-border data transfers must be explicitly disclosed, justified, and approved by the REB, with associated risk assessment.

*The REB will **not** approve the use of GenAI tools that share, sell, or otherwise disclose, uploaded information to third parties.



Best practice: Researchers must be fully aware of how the GenAI(s) tool will handle and use the participant data both internally and externally. The best places to find this out are the tools' privacy policies, End User Licensing Agreements, and Terms of Use. It is advisable to keep copies of these documents for your own records.

3.3 Privacy Breach Management

*In the event of a privacy incident, the SHA's [Privacy Breach Protocol](#) must be immediately followed, including submission of the [Privacy Incident Report Form](#) to notify the SHA Privacy Office. Note the Office of the Saskatchewan Information and Privacy Commissioner (OPIC) may also be notified, if required, in accordance with applicable legislation and SHA policies and procedures.

4. Informed Consent

* When GenAI is used to transcribe, process, analyze, or support the interpretation of participant data, the informed consent process should explicitly disclose the following, using simple, non-technical language:

- the use of GenAI;
- the specific tool(s) being used;
- the purpose of the GenAI use; and
- any specific measures taken to protect the participants' privacy and confidentiality.

*The consent form should also describe any of the tool's internal or external uses of the data, where applicable.

* For research involving Indigenous communities, permission from the relevant Indigenous Nation, organization, or governing body may be required for the use of their data or knowledge in GenAI

systems, consistent with **TCPS 2 Chapter 9** and applicable Indigenous data governance principles.

5. Bias, Accuracy, and Human Oversight

* GenAI models are trained on vast datasets that may reflect, and can even amplify, systemic and societal biases, inequities, and stereotypes.

* Researchers should include in their application a description of how they intend to critically review and evaluate GenAI-generated analysis and outputs for unfair, discriminatory, or misleading biases and interpretations, particularly where findings concern equity-deserving populations. Practical steps to ensure this include documentation of human review, validation steps, and acknowledgment of known limitations of the tool(s) used.

*Where appropriate, collaboration and consultation with community representatives should be incorporated into the interpretation and validation processes.

6. Support Contacts

- **SHA Research Ethics Office:** researchethics@saskhealthauthority.ca
- **SHA Privacy Office:** privacy@saskhealthauthority.ca

These guidelines serve as a principles-based framework. Researchers and SHA staff must also refer to the most current SHA policies, the Health Information Protection Act (HIPA), and SHA REB requirements for definitive guidance and approval on the use of GenAI. Research teams are expected to regularly review these guidelines, including any changes in legislation, institutional regulations, and best practice developments.

7. Compliance and Accountability

Researchers are accountable for:

- ✓ compliance with SHA policies,
- ✓ compliance with applicable laws including HIPA,
- ✓ ensuring ethical use consistent with TCPS 2,
- ✓ and proper documentation of all GenAI-related processes.

8. References

- SHA Policy: Artificial Intelligence (AI) Acceptable Use (SHA-07-008)
- The Health Information Protection Act (HIPA)
- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) (2022)
- First Nations Information Governance Centre: Ownership, Control, Access, and Possession (OCAP®) Principles