

Title	Guideline on the Use and Disclosure of Generative Artificial Intelligence in Submissions to the Osler REB
Original Issue Date:	31 October 2025
Approved By:	REB Chair

1.0 PURPOSE

The purpose of this guideline is to promote transparency, accountability, and integrity in the use of generative Artificial Intelligence (AI) technologies in **submissions** to the Osler Research Ethics Board. It provides clear procedures for the disclosure and review of AI-generated content to uphold ethical and scientific standards in human participant research.

As the AI landscape continues to evolve rapidly, we acknowledge that guidance and best practices may change. We remain committed to adhering to updated standards as they become available and will revise our practices accordingly.

2.0 SCOPE

This guideline applies to submission types, including initial applications, amendments, renewals, and reportable events, and all individuals preparing submissions for REB review at Osler, including:

- Principal Investigators
- Research Coordinators
- Research Staff
- Students

Note: This guideline does not address the ethical review of studies involving the design, testing, or deployment of artificial intelligence or machine learning (AI/ML) systems.

3.0 Definitions

Artificial Intelligence System: A machine-based system that, for explicit or implicit objectives, infers from the input it receives in order to generate outputs such as predictions, content, recommendations or decisions that can influence physical or virtual environments (*Enhancing Digital Security and Trust Act, 2024*)

AI-generated content: Any material produced by generative AI technologies, including text, images, data analysis, and figures.

Generative Artificial Intelligence: Artificial intelligence systems capable of generating text, images, or other content based on input data (ex. ChatGPT, Microsoft Copilot)

Disclosure: A formal statement within an REB submission that specifies whether generative AI tools were used in the creation of the submission, and if so, the purpose and extent of such use.

REB Submission: Any document provided to the Research Ethics Board for review, including protocols, consent forms, applications, amendments, renewals, and reports.

Research: Research is defined as an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation. For the purposes of this guideline, “research” refers to activities that require ethics review and approval by an REB before the research commences: (a) Research involving living human participants, (b) Research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

4.0 PRINCIPLES

Transparency: Any use of generative AI must be disclosed.

Accountability: The Principal Investigator retains responsibility for the accuracy, appropriateness, and originality of all submission materials.

Privacy and Confidentiality: Identifiable, sensitive, or confidential information about research participants, collaborators, or institutions must not be entered into generative AI systems. Personal health information, personal health information and corporate confidential information as defined in Osler’s *Artificial Intelligence (AI) Acceptable Use Policy* is considered confidential and sensitive information.

Integrity: Generative AI use must not compromise the ethical, scientific, or regulatory quality of submissions.

5.0 DISCLOSURE REQUIREMENT PROCEDURE FOR SUBMISSIONS

This section outlines the procedures for disclosing the use of generative AI tools in submissions to ensure transparency, accountability, and adherence to research ethics standards.

Researchers are required to maintain human oversight and control over all AI-generated content. Any AI-generated content must be carefully reviewed, verified and edited by the researcher.

When submitting a study for REB review, researchers must disclose the use of generative AI in the development of any study materials. This includes, but is not limited to:

- Study protocols, including literature reviews to help generate background and/or methodology sections
- Consent forms
- Participant-facing materials
- Survey questionnaires
- Data collection tools

Disclosure of AI use in the study protocols and other study materials is **mandatory**. A statement regarding the use of AI must appear in the applicable study materials. This includes disclosure of which AI systems were used. It also includes disclosure if used for writing assistance and/or literature reviews.

Example disclosure statement:

ChatGPT was used to support grammar editing and formatting of this submission. Open Evidence was used to ensure completeness of a literature review after a standard review approach was utilized; any new references were verified not to be hallucinations. All content has been reviewed and verified by the research team.

Researchers must confirm responsibility for the accuracy, integrity, and ethical use of AI-assisted content. Details of AI use should be included in the relevant section of the eREB application and submission documents.

If AI was used for data collection, statistical analysis, figure generation, or similar tasks, this must be described in:

- The Methods section of the study protocol
- The relevant section of the eREB system

Researchers must ensure that AI-generated content does not contain plagiarized text or images. All quoted or referenced material must be properly attributed with full citations.

eREB System Disclosure

The eREB submission system will prompt researchers to disclose whether they used generative AI, large language models, machine learning, or similar technologies to create or assist with content.

Researchers who answer “Yes” must provide a clear description of the AI-generated content, including:

- The name of the AI tool,
- The version number and/or extension identifiers, and
- The manufacturer/ developer or provider of the tool.

eREB Attestation for AI Use

As part of the eREB submission process, researchers who indicate that generative AI was used will be required to complete an attestation confirming responsible and ethical use.

A checkbox prompt will appear in the system, and researchers must confirm that:

1. AI-generated content, including consent materials, has been reviewed to ensure correctness, completeness, and absence of biased or misleading information.
2. Researchers are fully knowledgeable about the study protocol and procedures and are accountable for the accuracy and integrity of AI-generated content.
3. No plagiarism of text or images exists in AI-generated materials.

Compliance with Institutional Policy

In addition to REB disclosure, researchers must comply with the [Osler Artificial Intelligence \(AI\) Acceptable Use Policy](#), including rules regarding confidentiality, privacy, and appropriate use of institutional resources. Researchers must also comply with the Osler Responsible Conduct of Research Policy. Failure to disclose or appropriately manage AI use may constitute a breach of the [Osler Responsible Conduct of Research Policy](#).

7.0 REVISION HISTORY

Effective Date	Summary of Changes
31 October 2025	Original version

8.0 REFERENCES

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NEJM AI. (2024). *Editorial policies*. NEJM AI. <https://www.nejm.ai/editorial-policies>

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