

Purpose

To provide guidance to help researchers meet ethical review requirements for AI-related projects submitted to a Bellberry HREC.

AI refers to intelligent technologies and algorithms that can support decision-making by identifying patterns in data.

Classification

AI-related projects may be classified as a medical device if they meet the regulatory criteria or not classified as a medical device if they fall outside the medical-device definition.

Medical device

AI is classed as a medical device if it is intended to be used for:

- diagnosis, prevention, monitoring, prediction, prognosis, or treatment of a disease, injury, or disability or
- alleviation of, or compensation for, an injury or disability or
- investigation of the anatomy or of a physiological process or
- control or support of conception.

AI that meets any of these criteria is regulated as a medical device, regardless of its form. This includes any app, website, software program, internet-based service or software package. It may operate on a watch, phone, tablet, laptop, or other computer, be embedded in medical-device hardware, or function as part of a cloud-based ecosystem or as a standalone product.

Software incorporating generative AI—such as large language models (LLMs), text-generation systems, or multimodal generative-AI tools—is also regulated as a medical device if it performs a function that meets the above criteria.

Not classified as a medical device

Other AI products submitted for HREC review may not meet the definition of a medical device because they do not diagnose, treat, or inform clinical care. These tools typically support social, behavioural, or operational research without influencing health-related decisions.

Examples include:

- AI chatbots used for simulated interviews in social-science studies
- Behavioural-science simulation tools that model social scenarios
- Tools identifying common procrastination patterns among university students
- Models forecasting public-transport usage

Application guidance

Researchers should provide clear information about the nature, purpose, and use of AI tools to support accurate classification and ethical review. The HREC will consider the intended purpose, risk profile, data governance, and participant impacts when evaluating applications.

Internal - Administration

Researchers developing AI tools should ensure their application provides the following:

Project description

- A clear explanation of what the AI tool does
- The purpose of the tool (research, educational, operational, or clinical)
- Whether the intended use meets medical device criteria

Data sources and handling

- Description of training, validation, and test datasets
- Whether any personal or sensitive information is used
- Data governance arrangements (collection, storage, retention, destruction)
- Any de-identification or anonymisation processes

Model development and functionality

- Overview of the AI model type (e.g., machine learning, LLM, predictive model)
- How the model will be trained, fine-tuned, or modified
- Any third-party platforms, cloud services, or APIs used

Risk assessment

- Potential participant risks (data breaches, algorithmic bias, misclassification)
- Measures to mitigate these risks
- Any limitations in model accuracy and how these are communicated

Participant information and consent

- Whether participants will interact with the AI tool directly
- What participants will be told about the AI system and its limitations
- Any opt-out or withdrawal processes
- Explanation of any transfer of information across borders or storage of information in another jurisdiction (Refer Bellberry documents BA G11 Researcher Data Storage & Retention Guidance and BA F11.1.1 Confidentiality & Privacy Standard Clauses).

Ongoing oversight and governance

- Monitoring processes for model performance and safety
- Procedures for handling errors, unexpected outputs, or adverse events
- Responsibilities of the research team and any external collaborators

References

BA G11 Researcher Data Storage & Retention Guidance

BA F11.1.1 Confidentiality & Privacy Standard Clauses

[NHMRC Guide for assessing research involving Artificial Intelligence, Machine Learning, and Large Language model Technology \(collectively “AI”\)](#)