

AI in Supported Human Subjects Research

PURPOSE: This information sheet is for individuals utilizing AI within human subjects research. Documented application of the DoW Ethical Principles for Artificial Intelligence is required at the time of protocol submission.

BACKGROUND

DOWI 3216.02_DAFI 40-402, Section 3.19, requires all DAF-conducted or -supported human subjects research (HSR) involving Artificial Intelligence (AI) enabled tools or capabilities to comply with DoW Ethical Principles for AI.

Specifically:

Research proposals must “describe provisions to meet each of the DoW Ethical Principles for AI.”

Scientific merit reviews must document consideration of whether the DoW Ethical Principles for AI are appropriately implemented for non-exempt HSR. This can be outlined in the IRB protocol, a separate memo, or an approval letter.

DOWI 3216.02_DAFI 40-402 points to the following definition of AI: “The ability of machines to perform tasks that normally require human intelligence (e.g., recognizing patterns, learning from experience, drawing conclusions, making predictions, or taking action) whether digitally or as the smart software behind autonomous physical systems.” (2018 DoW AI Strategy)

Using AI in research does not alleviate or alter the researchers’ level of responsibility. This guidance is provided to help researchers consider factors they may have otherwise overlooked.

Quick tip: Avoid using buzz words, which may needlessly increase protocol requirements. This includes the term “AI.” Only use the term if AI is actually employed in the study.

DOW ETHICAL PRINCIPLES FOR AI

Responsible: Exercise appropriate levels of judgment and care, while remaining responsible for the development, deployment, and use of AI capabilities.

Equitable: Take deliberate steps to minimize unintended bias in AI capabilities.

Traceable: Develop and deploy AI such that relevant personnel possess an appropriate understanding of the technology, development processes, and operational methods, including with transparent and auditable methodologies, data sources and design procedures, and documentation.

Reliable: Ensure AI capabilities have explicit, well-defined uses, and the safety, security and effectiveness of such capabilities will be subject to testing and assurance within those defined uses across their entire life cycles.

Governable: Use AI systems only for their intended function. Detect and deactivate systems demonstrating unintended behavior.



HOW TO DOCUMENT THE ETHICAL PRINCIPLES FOR AI

Below is an **example** of how you might address these principles. Note: Your responses should be specific to your procedures; therefore, adjust your responses accordingly.

Background: The machine learning employed in the protocol is primarily a robust statistical analysis tool, used under human supervision for all subsequent knowledge products. The AI interface is not intended to provide automated, autonomous output to decision-makers. Nevertheless, every effort will be made to ensure that this protocol adheres to implementing the DoW Ethical Principles for AI.

Responsible: The human researchers will oversee every aspect of data collection and data analysis, to include the statistical parameters used to define the predictive modelling and a review of the results of the machine learning analysis.

Equitable: The machine learning analyses will examine physiological patterns associated with medical risk across demographics. Inclusion is open to all military veterans to ensure equitable representation, and any outcomes that differ across a demographic category will be noted for future scientific study to clarify whether unintended error or bias was contributory.

Traceable: The methods of machine learning will be clearly recorded and the de-identified database will be available to future, IRB-approved research programs to ensure that the results are replicable and auditable.

Reliable: The machine learning processes in this study are limited to the role of report probabilistic data patterns and models of physiological signals that are associated with medical risk. The machine learning in this study will not render diagnostic or prognostic decisions.

Governable: The machine learning analyses in this protocol are intended only to identify patterns of wearable signals that are common around the time of various retrospective medical contacts. The deliverable product is a knowledge product only, and no autonomous action or decisions will be made by the computational system.

Tips on using AI to write protocol documents:

1. You are responsible for the content of all documents submitted for review. The IRB/ Ethics Committee and HRPO review is based on the submitted procedures; be sure that the written documents match your intended procedure/process. Audits and post approval compliance monitoring compare your actions against your written approved procedures.
2. When using AI to help write your protocol, expect multiple iterations to get the best set of procedures.
 - a. Start with a fairly detailed rough draft/outline of the intended procedures.
 - b. Use multiple prompts to provide best quality documents. Prompts can assist with:
 - i. Conciseness: creating clear and direct language in fewer words
 - ii. Clarity: creating documents that are transparent and understandable
 - iii. Efficiency: using AI inputs to reduce your time, energy, and efforts
 - c. Revise section by section, rather than revising the whole document at once.