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01-2-2 Standard Study Information - Continued

Hide Help

1* Is the research using "AI technology" in any of the following ways?
Select all that apply.

AI Usage

No use of AI technology, or use limited to supporting tasks

This selection DOES NOT activate any further questions.

Examples of supporting tasks:

- [ ]
  - AI helps a PI write a study protocol section
  - AI suggests research questions or summarizes literature
  - Transcription or translation of study team meetings where no sensitive or identifiable participant information is discussed

Interact and/or intervene with research participants

This and all selections below activate all following questions.

Examples:

- [ ]
  - Participants enter data into AI agent, which may provide feedback
  - Clinical decision tools provide treatment suggestions to clinicians
  - Assigning participants to study treatment arms based on prior data
  - Assessing effectiveness of an AI tool in teaching specific courses

Analyze or use information and/or biospecimens

Examples:

- [x]
  - Training a new model intended eventually to assist in a clinical, educational, or other "real-world" setting
  - Data collection tool reads and interprets scanned documents and extracts fields
  - Transcription or translation of participant-specific data or audiovisual interactions
  - FDA-regulated device (such as clinical decision software) with AI component
  - AI assesses historical patient data to predict which patients would respond best to certain treatments

- [ ] **Other uses to support research**

"AI technology" means an engineered or machine-based system or functionality,which is designed, for a given set of objectives,

- to generate outputs such as text, images, predictions, or
- to make recommendations or decisions influencing human action, or real or virtual environments.

Examples include:

- AI-assisted transcription or translation such as by natural language processing (NLP)
- Use of large language models (LLM) or chatbots as part of a social behavioral intervention
- Development of novel AI algorithms to analyze human subjects research
- Generation of content used in an intervention
- Agentic workflows (AI use without human oversight or review)

1.1* List the AI technology that you will use for interaction, intervention and/or analysis.
Include the kind of technology (e.g., Natural Language Processing (NLP), Deep Learning, chatbot, etc.) and when applicable the model and version numbers.

REMINDER: Ensure that any/each use of AI technology is described in sufficient detail in your human research protocol or research design section of the application to allow the IRB to evaluate the impact on human participants and/or their identifiable private information. Consult the guidance linked in the help text for factors to include.

HRPP guidance on describing AI technology in research protocol/research design

1.2* How is the AI technology made available to the study team?

U-M AI Tools is an ITS-managed set of generative AI tools.

Using U-M GPT at Michigan Medicine

Commercial/public availability can include UM-licensed commercial services (e.g. Google Gemini) as well as fully publicly available tools.

AI Source
☐ U-M AI Tools
☐ Commercial/public product
☐ Other (research team/academic)

1.3* Are any of the AI systems used "adaptive"?

"Adaptive" means the AI system updates its model based on new data, user feedback, or ongoing interactions. Most free online platforms like ChatGPT are "adaptive."
"Static" or "locked," in contrast to "adaptive," means the AI system operates as originally designed, and does not change its behavior or update its knowledge after deployment.

◯ Yes ◯ No Clear

1.4* Is the AI technology approved for use with data at this level of sensitivity?

AI tools cannot be considered approved without IA (Information Assurance) consultation. For information on approval of software tools and data sensitivity levels consult ITS AI resources linked in the helptext.

◯ Yes ◯ No Clear

Third-party AI services: ITS SafeComputing Artificial Intelligence and U-M Institutional Data

ITS AI Services: Sensitive Data Guide and list of tools

Michigan Medicine: Trusted Service Provider (TSP) Resources