

Protection of Human Subjects

1. Risks to Human Subjects

a. *Human Subjects involvement, characteristics, and design.* This project includes voluntary participation of older adults with limited social interaction, age 75 years or older, with mild cognitive impairment (MCI) or normal cognition (NC). Participants will be recruited from the Memory Division at Massachusetts General Brigham (MGB) and the Massachusetts Alzheimer's Disease Research Center (MADRC). The study is a feasibility study of Conversational Artificial Intelligence with Multimodal Interaction (AIMI-CONECT), with four 15-minute sessions per week for six weeks and weekly staff check-in calls. The intervention is behavioral and conversational, with no drug administration and no invasive procedures.

b. *Study procedures, materials, and potential risks.* Study procedures include conversational sessions with AIMI-CONECT, brief weekly check-ins, and collection of study data including conversation audio and video records, de-identified transcripts, derived language features, survey responses, and system logs. The main risks are expected to be low and include emotional discomfort during conversations, fatigue or frustration from repeated sessions, exposure to unsafe or inaccurate model-generated content, technology burden, and loss of confidentiality if identifiable data are improperly disclosed.

c. *Protections against risks.* The protocol includes real-time safety guardrails that monitor for critical situations such as negative affect, suicidal language, misinformation, and financial risk content, with immediate alerts to study staff for follow-up. Staff will conduct weekly check-ins to assess emotional status, potential risks, and technical barriers, and participants may pause or stop sessions at any time. Data protection includes informed consent, minimization of personally identifiable information, de-identification for analysis, encrypted storage and transfer, and access control within Health Insurance Portability and Accountability Act (HIPAA)-compliant MGB systems. All study procedures will start only after Institutional Review Board (IRB) approval, and all key personnel will complete required human-subject and privacy training.

2. Adequacy of Protection Against Risks

a. *Recruitment and informed consent.* Eligible participants will be identified using the study inclusion and exclusion criteria defined in the research strategy. The study team will review the consent form in plain language, explain study purpose, procedures, risks, data use, and alternatives, and allow adequate time for questions before any research procedures begin. Written informed consent will be obtained before participation. Only participants with the ability to provide informed consent will be enrolled.

b. *Risk management and confidentiality safeguards.* Safety monitoring combines automated in-conversation monitoring with staff review and follow-up. Any event that suggests participant distress, safety concern, or technology-related burden will be documented, assessed, and managed by the study team under the approved protocol. Confidentiality will be protected through role-based data access, secure storage, and separation of direct identifiers from analytic datasets. Results will be reported in aggregate form, and no participant-identifying information will be disclosed in publications.

3. Potential Benefits of the Proposed Research to Human Subjects and Others

Participants may benefit from structured conversational engagement, increased opportunities for social interaction, and a low-burden interface designed for older adults. The study may also provide practical insight into how to design safer and more acceptable artificial intelligence tools for older adults with limited social interaction.

4. Importance of Knowledge to be Gained

The proposed research will generate evidence on the feasibility, acceptability, and implementation safety of an artificial intelligence-delivered conversational intervention adapted from the Internet-based Conversational Engagement Clinical Trial (I-CONECT). This knowledge is important for developing scalable, accessible approaches to support older adults who have limited access to frequent human-delivered conversational engagement.