Data and Safety Monitoring Plan

This Data and Safety Monitoring Plan (DSMP) is designed for a low-risk, single-site feasibility study with behavioral conversational sessions. A Data and Safety Monitoring Board (DSMB) is not planned for this study design. Monitoring will be conducted by a multi-person team led by the Program Director/Principal Investigator (PI), with operational support from the program manager and designated study coordinator. The PI is responsible for overall study monitoring decisions and for advising the appointing institution on study continuation, protocol modification, or temporary pause when safety concerns arise.

The monitoring framework integrates automated and human review. Real-time guardrails in the conversational system monitor protocol drift and safety signals, including negative affect, suicidal language, misinformation, and financial risk content. Study staff review safety alerts, weekly check-in findings, session adherence patterns, participant complaints, and technology incidents. The team also monitors confidentiality events, data security issues, and any event that may increase risk to participants.

Monitoring occurs continuously at the session level through real-time guardrails and through regular staff review of accumulated safety and protocol data. Weekly participant check-ins provide an additional safety layer outside session time. Because this project is a feasibility study and does not test efficacy outcomes, no formal interim efficacy analysis is planned. Stopping guidance is risk-based: if new or worsening safety concerns are identified, the PI may pause affected sessions or broader study activities pending review and corrective action.

Adverse Events (AEs), Serious Adverse Events (SAEs), and Unanticipated Problems (UPs) will be documented in the study records, reviewed by the PI, and managed under the approved protocol and institutional policy. Events that require expedited reporting will be reported to the IRB, the National Institutes of Health (NIH) awarding Institute or Center (IC), and the monitoring entity within required timelines. Food and Drug Administration (FDA) reporting is not expected for this behavioral study; if reporting requirements apply, reporting will follow all applicable federal and institutional requirements.