IRB Materials Packet

Generated 2026-06-17 by SecureMedAssist · For IRB submission — contains every patient-facing material verbatim.

1. Study

Study (internal)	Patient Depression Analysis
Name patients see	Patient Depression Analysis
Protocol #	—
Survey instrument	PHQ-9 Depression Screening (Baseline) — 10 questions
Languages	English, Spanish

2. Contact sequence

- Step 1 (at enrollment): email invitation.
- Step 2 (next business day if no response): reminder email plus one text message.
- Step 3 (next business day if still no response): one AI-assisted phone call (max 2 dial attempts).
- All outreach stops immediately when the patient completes the survey or opts out (STOP reply, email link, or telling the caller).
- Sending windows: email 7 AM-6 PM, texts and calls 9 AM-6 PM (patient's local quiet-hours rules applied), business days only.

3. Patient-facing messages (verbatim)

Invitation email — subject: We'd like your feedback — Patient Depression Analysis

Hi [Patient first name],

You are receiving this survey as part of a research study. Your responses are confidential and help improve patient care.

PHQ-9 Depression Screening

Take the Survey: https://securemedassist.com/s/...individual-link...

This email was sent by Patient Depression Analysis as part of a research study. Your responses are confidential and protected under HIPAA. If you received this email in error, you can simply ignore it. https://securemedassist.com/terms.html#patient-privacy

Reminder email — subject: Reminder: We'd like your feedback — Patient Depression Analysis

Hi [Patient first name],

This is a friendly reminder — we noticed you haven't had a chance to complete the "PHQ-9 Depression Screening" survey yet. It only takes a few minutes.

PHQ-9 Depression Screening

Take the Survey: https://securemedassist.com/s/...individual-link...

This email was sent by Patient Depression Analysis as part of a research study. Your responses are confidential and protected under HIPAA. If you received this email in error, you can simply ignore it. https://securemedassist.com/terms.html#patient-privacy

Text message

Hi Sarah, Patient Depression Analysis asks you to complete a survey: https://patient.securemedassist.com/s/Ab3kZq Reply STOP to opt out.

AI phone call (step 3)

Opening line: Hi, may I please speak with [Patient first name]?

Agent behavior commitments:

- The AI agent identifies itself as an automated assistant calling on behalf of the study team.
- It verifies it is speaking with the named patient before any survey content.
- If someone other than the patient answers and confirms they are the patient's caretaker or representative, the agent may, with their verbal consent, administer the survey on the patient's behalf. It records the proxy's first name and relationship to the patient and asks every question in the third person about the patient.

- It reads each survey question verbatim and records only the structured answers.
- It never gives medical advice, never discusses the patient's condition or care, and cannot access any clinical data.
- The patient may decline any question. If they refuse, the agent asks once more, then moves on and never re-asks it; a declined required question ends the call as an honest partial response, never a fabricated completion.
- If the patient expresses distress or a safety concern, the agent provides 911/988 guidance, the call is flagged for the research team's review, and outreach stops.
- If the patient asks not to be called again, all further contact stops across every channel and the opt-out is recorded (with its date and channel) for the study team's reporting.
- Calls are limited to 2 dial attempts. No audio recordings or full call transcripts are stored — only call dispositions and the survey answers. For non-text answers (rating scales, choice questions), the patient's per-answer spoken phrase is stored alongside the recorded value so the study team can verify the AI interpreted it correctly.

4. Consent page (shown before any questions)

Research Participation Consent

> You are invited to take part in a research study at [Institution Name], led by [Principal Investigator Name].
>
> What this is: A short survey ([X] questions, about [X] minutes) about [topic, e.g., your recent hospital visit].
>
> Your choice: Taking part is voluntary. You can skip questions or stop at any time. This will not affect your care in any way.
>
> Your privacy: Your answers are confidential and stored securely under HIPAA regulations. Only the research team will see individual responses. Published results will never identify you.
>
> Questions? Contact [Name] at [email or phone]. For questions about your rights as a participant, contact the IRB office at [phone or email].
>
> IRB Protocol: [Number] - Approved: [Date]

Agree button: **I have read the above and agree to participate** · Decline button: **I decline to participate**

Shown on decline: Thank you for considering participation. You may close this page.

Proxy / caretaker respondents

This survey permits a proxy (a caretaker, family member, or authorized representative) to complete the survey on the patient's behalf when the patient is unable to respond directly.

- On the web survey, after consent the respondent is asked whether they are the patient or are completing the survey on the patient's behalf. A proxy provides their name and relationship to the patient (parent, spouse, guardian, adult child, or other).
- On AI phone calls, if the person who answers states they are not the patient but are the patient's caretaker or representative, the agent asks whether they can answer on the patient's behalf and obtains their verbal consent to continue with the recorded call before any survey question is asked.
- The proxy's name and relationship to the patient are recorded on the response and included in the study's results export, so the research team can distinguish patient-reported from proxy-reported answers.
- The study team should ensure the consent language above addresses proxy completion where the protocol permits it (the consent text is editable per survey).

5. Thank-you page

Thank you for your feedback!

Your responses have been recorded and will be used to improve patient care. You may now close this page.

6. Survey questions

#	Question	Type	Answer options / range	Required
1	Little interest or pleasure in doing things	Multiple choice	Not at all / Several days / More than half the days / Nearly every day	Yes
2	Feeling down, depressed, or hopeless	Multiple choice	Not at all / Several days / More than half the days /	Yes

			Nearly every day	
3	Trouble falling or staying asleep, or sleeping too much	Multiple choice	Not at all / Several days / More than half the days / Nearly every day	Yes
4	Feeling tired or having little energy	Multiple choice	Not at all / Several days / More than half the days / Nearly every day	Yes
5	Poor appetite or overeating	Multiple choice	Not at all / Several days / More than half the days / Nearly every day	Yes
6	Feeling bad about yourself — or that you are a failure or have let yourself or your family down	Multiple choice	Not at all / Several days / More than half the days / Nearly every day	Yes
7	Trouble concentrating on things, such as reading the newspaper or watching television	Multiple choice	Not at all / Several days / More than half the days / Nearly every day	Yes
8	Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	Multiple choice	Not at all / Several days / More than half the days / Nearly every day	Yes
9	Thoughts that you would be better off dead or of hurting yourself in some way *Safety alert: selecting "Several days" or "More than half the days" or "Nearly every day"*	Multiple choice	Not at all / Several days / More than half the days / Nearly every day	Yes
10	If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	Multiple choice	Not difficult at all / Somewhat difficult / Very difficult / Extremely difficult	No

7. Participant safety monitoring (question-level alerts)

The study team has configured automatic safety escalation on the following question(s):

Question	Alert trigger
Thoughts that you would be better off dead or of hurting yourself in some way	selecting "Several days" or "More than half the days" or "Nearly every day"

Escalation protocol:

- When a response meets a trigger, the platform immediately emails the study's designated safety contact(s), configured by the study team in advance.
- The alert identifies the study, the participant's study identifier, the flagged question, the answer given, and a link to the response in the study dashboard. It never contains contact information or other PHI.
- Alerts fire for web responses and AI-call responses alike, including partial (in-progress) responses, so a flagged answer is escalated even if the participant never finishes the survey.
- Every alert is logged with recipient, time sent, and delivery status, and the study team records acknowledgment in the dashboard -- an audit trail available for continuing review.

8. Data handling & security

- All systems holding identifiable data operate inside Microsoft Azure services covered by a HIPAA Business Associate Agreement.
- Patient contact lists are uploaded over TLS, stored encrypted at rest, and are visible only to the study team's authenticated accounts.
- Outreach messages contain only the patient's first name, the study's patient-facing name, and an opaque survey link — never clinical information.
- Survey links use random, unguessable identifiers; responses are stored keyed to internal IDs, not contact details.
- Identifiable contact information (name, email, phone) is permanently deleted as soon as each participant's outreach is complete. Remaining study data is deleted when the research team closes the study, or automatically after 365 days of inactivity. Researchers are reminded to export their dataset before closing.