# Description of TelEMA System for University Institutional Review Boards (IRBs)

*Extracted from the IRB-approved protocol for the TelEMA pilot study*

**Provide a detailed description in sequential order of the study procedures following the consent process.**
**DESCRIBE:**
**What participants will be asked to do/what happens in the study (in sequential order)**
*** The time period over which procedures will occur**
*** The time commitment for the participant for individual visits/procedures**
*** Long-term followup and how it occurs**

The experimenter will begin by providing the participant with a tutorial in which he/she instructs the participant on how the automated EMA system works.

Confirmation of participant's ability to complete EMA: The experimenter will then ask the participant if he or she has regular access to a telephone, and if he or she is willing to complete four surveys per day, for a total participation time of roughly 1.5 hours. If the participant is willing and able to complete the EMA portion of the study, the experimenter will proceed to the tutorial. Otherwise, the participant will be instructed that, if he or she wishes to continue participating in the study, he or she will be asked to fill out a comprehensive set of retrospective questionnaires during the second lab session approximately one week in the future. The retrospective questionnaires will take approximately one hour. If the participant declines to participate in the EMA portion of the study, the experimenter will schedule the second session with the participant and the first session is concluded.

Next, the experimenter will obtain telephone contact information for the participant. This contact information primarily consists of a list of phone numbers at which the participant wishes to be reached for the EMA surveys, in order of preference. The participant will also specify the interval at which the automated EMA system should call back if the participant does not answer the phone for a survey, the maximum number of times they wish to be called back per survey, and the earliest and latest times of day they wish to be called. Finally, the participant will choose a personal identification number (PIN) to authenticate themselves with the automated EMA system, and enter their PIN into a computer in the laboratory. If a participant does not have regular access to a phone or does not wish to complete the EMA portion of the study, they will be given the option to instead complete a comprehensive set of retrospective surveys during their second session.

After entering their contact and authentication information, the participant will complete a test survey using the automated EMA system, in order to make sure they know how to complete the surveys and can ask the experimenter to clarify any part of the survey or EMA process. Once the test survey is complete, the participant and experimenter will schedule a second session in the laboratory for approximately one week after the first session. The total time for the first question is estimated at 45 minutes.

For the first 7 days after the first session, the automated EMA system will call the participant four times per day, according to the contact information and preferences specified by the participant. Each survey should last 3-4 minutes, for a total survey time of approximately 1.5 hours for the week. The four calls per day will be timed in the following manner: the participant specifies the earliest and latest call times, and that time interval is split into four equal parts. One call will be placed at a random time within each of the four intervals, with the additional constraint that, as long as the participant has

specified a window of at least eight hours, no two calls should be less than two hours apart. This minimizes burden on the participant.

Authentication: It is important that no identifying information about the participant or the nature of the study is disclosed to any third party during outgoing or incoming calls. For this reason, we require varying degrees of authentication on the part of the participant. For outgoing calls, TelEMA knows which participant is involved a priori, so in most cases the participant only needs to enter their PIN. If multiple participants specify the same phone number, the participant will be asked to enter their participant ID before entering their PIN. For incoming calls, the participant will be asked to enter the participant ID and PIN before completing the survey.

If TelEMA requires multiple pieces of information to authenticate (e.g., a participant ID and PIN), all information will be entered first. Then, if any piece of information is invalid, TelEMA will inform the participant "I'm sorry, the information you have entered is not valid. Please try again."

Call flow: Once the participant has authenticated, they will be given an EMA survey, which consists of single-digit, multi-digit, and voice response questions. The participant will be instructed to press the star key ("*") at any time to return to the previous question, if they did not hear the question or if they mis-entered their response. In order to minimize cognitive load on the participant, all questions of the same nature (e.g., using the same set of instructions) will be given together in a block. However, the ordering of such questions within a block and the ordering of the blocks themselves will be randomized for each survey.

We now give examples of three question types: single-digit, multi-digit, and voice response.

Single-digit:
TelEMA: How do you feel about your social life over the last four hours? Please enter a number between 1 and 7, where 1 is "very negatively", 4 is "neither positively nor negatively", and 7 is "very positively."
<Wait 10 seconds for keypress>
If user presses a number between 1 and 7:
<Proceed to next question.>
If user presses 0,8,9, or pound:
TelEMA: I'm sorry, you have pressed an invalid key.
<Repeat question>
If user doesn't press a key within 10 seconds:
<Repeat question>

Multi-digit:
TelEMA: How many people have you spoken to in the last hour? Please enter a number, followed by the pound sign.
<Wait 15 seconds for keypress>
If user doesn't press a key within 15 seconds:
<Repeat question>
If user enters a number outside of experimenter-specified expected range (e.g., 1000):
TelEMA: You have entered 1000. Is this correct? Press 1 for yes. Press 2 for no.
<Wait 5 seconds for keypress>
If user doesn't press a key within 5 seconds:
<Repeat "Is this correct?" prompt>

If user presses 1:
<Proceed to next question>
If user presses 2:
<Repeat question>
If user enters a number inside experimenter-specified expected range:
<Proceed to next question>
If user enters a number with the star key inside it (e.g., "35*7#"):
TelEMA: "I'm sorry, the number you have entered is invalid."
<Repeat question>

Voice response:
TelEMA: Describe your last social encounter. Record your answer after the beep. When you are finished recording, press pound.
<Record voice for up to experimenter-specified time limit>
If time limit expired:
TelEMA: Your time limit expired. Would you like to re-record? Press 1 for yes. Press 2 for no.
<Wait 5 seconds for keypress>
If user doesn't press a key within 5 seconds:
<Repeat "Would you like to re-record?" prompt>
If user presses 1:
<Repeat question>
If user presses 2:
<Proceed to next question>
If time limit did not expire:
<Proceed to next question>

Second Session:
In the second session, participants will be asked to complete a single questionnaire delineating their experience with the TelEMA system. Participants will also give general verbal feedback about their experience with the automated EMA system. The second session should take approximately 10-15 minutes.

**Privacy & Confidentiality**

**Describe your plans to protect the privacy interests of the participants during the conduct of the study including:**
*** How will you provide a private setting during the recruitment process**
*** How will you provide a private setting for the consent process including an opportunity for the participant to ask questions privately**
*** Describe how interventions occur in a private setting and/or how information will be collected using methods that protect the participant's privacy.**

The participant will be instructed during the first session to ensure they are in a private setting before completing the EMA surveys. If the participant is not in a private setting when the EMA system calls, they can call back once they are in a private setting. The EMA system is not made aware of the person's name, demographic information, or other identifying information, and thus will not disclose it at any time during a survey. The EMA system will not begin a survey, or even disclose that a survey or any kind of assessment is taking place, until after the participant has authenticated using their PIN. Each call from the EMA system will begin with the following script:

EMA System: Please enter your PIN, followed by the pound sign.
<Participant enters incorrect PIN, followed by the pound sign.>
EMA System: I'm sorry, that PIN is incorrect. Please enter your PIN, followed by the pound sign.
<Participant enters correct PIN, followed by the pound sign.>
EMA System: Welcome to TelEMA.
<EMA System begins survey>

The participant's responses will always be transmitted in encrypted form, preventing their disclosure to an unauthorized third party. The EMA system will never replay a participant's response during any call, preventing the accidental disclosure of a response to a third party near the phone or if a participant's PIN is compromised.

Participants will be informed during the first laboratory session that they may skip any EMA survey question that makes them uncomfortable from a privacy perspective.

***How will information/data be collected and stored for this study:***

The automated EMA system will contain participant ID numbers, phone numbers, contact preferences, and EMA survey responses. The EMA system will never store a participant's name, demographics, or other identifying information. Survey responses can be either a sequence of telephone keypresses, or a short voice recording. The EMA system is operated on a server in a datacenter in Dallas, Texas. The datacenter implements numerous physical and electronic security measures. At the server level, we use several layers of electronic security to protect the server itself, the database containing participant survey responses and contact information, and the web administration interface. The web administration interface is only accessible by study personnel. Each person with access to the web interface has their own username and password, which can be revoked upon termination of their involvement with the study. Study personnel other than the faculty sponsor, PI, and EMA system developer have limited access to the administration interface; they can only add participants to the database and enter participant contact information and preferences. Only the faculty sponsor, PI, and EMA system developer may view participant contact information and survey responses, download response data for further analysis, delete participants, change participant contact information, or add or modify EMA surveys. All access to the administration interface must be done from a pre-approved list of computers, over an encrypted connection. The EMA system uses a third-party service provider to complete telephone calls. All communication between the EMA system and service provider is encrypted. The third-party provider never receives any participant information other than the phone number to call and their ID number. The EMA system automatically instructs the third-party service provider to delete all voice recordings, so the recordings are only stored on the server controlled and secured by the experimenters. The voice recordings can only be downloaded from the EMA system by the faculty sponsor and PI, and will only be listened to by study personnel using headphones.