Mass General Brigham

HUMAN RESEARCH AFFAIRS

COMMUNICATING WITH RESEARCH PARTICIPANTS

All communication methods used with research participants must be approved by the IRB.

Use of Email with Research Participants

Send Secure is the preferred option when communicating with participants by email. For Send Secure: The participant may need to register in the Send Secure system, create a password, and login to access their messages, depending on their email address/server. Non-secure email may be used to communicate with research participants, but only if they have been informed of and agree to accept the associated risks. Refer to the MGB IS policy *Requests to Receive Unencrypted Email* on Archer for information about institutional requirements that govern the use of Send Secure and how research participants can indicate their agreement to non-secure emails (Partners HealthCare GRC).

Mass General Brigham business must be conducted using institutional email addresses only. Non-institutional domains (e.g., Gmail) must not be used for research communications.

Confirmatory information about research appointments can be sent by email without formal IRB approval of that communication and process**.** A short email lacking medical information, or diagnoses may be sent without formal IRB approval, as exemplified below:

> Thank you for your interest in our research study. I'm writing to confirm your appointment with Dr. Smith on January 2, 20xx on the 6th Floor of the COX building at 2 pm. Please call me if you have questions or cannot make it.
>
> Jim Jones, Study Coordinator
> Cardiology Division, Massachusetts General Hospital. Phone number, email.

Please include the minimum necessary information in such communications. If research consent forms or other study information which imply or state diagnoses will be attached in emails, the approved IRB protocol must describe this.

Specific information such as Social Security numbers (SSN's), financial account numbers (credit card numbers or account numbers) cannot be sent by unsecured email even if it is requested by a participant.

Email sent through REDCap is not secure unless you insert "Send Secure" in the subject line or use REDCap's Survey Login Feature as described below. Survey links sent though REDCap to a participant are secured once accessed, but the email itself is not.

For the Survey Login Feature: Remove all medical content, diagnoses, study descriptors, medical questions, or any other PHI from the REDCap email survey invite. Move all this information into the REDCap survey itself. The participant will need to authenticate (Log in) to the survey before they can view and complete the survey. The respondent will log in to the survey by entering one or more known

values for fields in the project (up to three) – e.g., last name, date of birth. These values must already be saved in the respondent's record in the project. Those values may have been entered or uploaded by a project user/admin or may have been entered on a previous survey by the respondents themselves.

Use of Texts with Research Participants

Texting with research participants is permitted but must be prospectively approved by the IRB and RISO and participants must agree to the risks of texting.

The following language must be added to the research study informed consent. When the IRB waives informed consent documentation, the following language must be added to the Information/Fact Sheet.

> Text messages by mobile/cell phones are a common form of communication. The _____ (*insert study name*) research study involves sending you text messages that are relevant to the research study. Texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier.
>
> Below are some important points about texting in this research study.
>
> - Text messages are not encrypted, and therefore carry security risks. This research study and Mass General Brigham are not responsible for any interception of messages sent through unencrypted text message communications.
>
> - You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and Mass General Brigham are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts *(Include language if participants are paid/given stipends to cover potential charges).*
>
> - Text messages will only be read [*Insert information specific to the research study, e.g. text messages will only be read during regular business hours. Texts sent on nights or weekends will not be read until _____].*
>
> - Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.
>
> - You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number a text message that says "Stop Research Text."
>
> - Your agreement applies to this research study only. Agreeing to other texts from Mass General Brigham, for example appointment reminders, is a separate process. Opting out of other texts from Mass General Brigham is a separate process as well.

- It is your responsibility to update your mobile/cell phone number with this research study in the event of a change.

I have had the chance to ask questions about texting with staff associated with this research study. I have been informed of the risks and other information covered above and consent to the use of unencrypted text communications associated with this research study.

Obtain participant's signature and date if a written Informed Consent Form is being used. If an Information/Fact Sheet is used, record the participant's response, name, and date in the study files.

Patient Gateway

Use of Patient Gateway for research must be limited to sending Research Invitations or Targeted Research Announcements to recruit potential participants. It should not be used to communicate with research participants or send other study-related documents. Patient Gateway is primarily used for clinical purposes.

Rally Secure Messaging

Investigators can communicate securely with potential participants ages 18 and older using Rally secure messaging. Only an investigator can initiate messaging with a potential participant. Rally secure messaging is not 21 CFR Part 11 compliant. It may be used for things like scheduling screening visits or answering questions prior to enrollment.

If Rally advertisement and use of email was approved by the IRB, investigators may begin using Rally secure messaging without additional IRB approval. At next Continuing Review or Amendment, investigators should update their protocol to describe using Rally secure messaging.

If studies do not currently have IRB approval to use email communications, investigators will need to submit an amendment to use Rally secure messaging.

Studies approved by an external IRB should seek approval from the external reviewing IRB.

Other Communication Methods

Social Media

Study team members cannot communicate with participants via social media platforms as this is not secure. IRB-approved advertisements may be posted on social media platforms if the use of social media is approved by the IRB. The advertisements should include contact information for the study team so that potential participants can contact the study team directly rather than via social media. Commenting and messaging functionalities on these websites must be turned off wherever possible. Social media posts must also comply with MGB Social Media policy (search Social Media in Archer).

Other Electronic Communication

To inquire about the use of other forms of electronic communication, contact the Research Information Security Office at riso@partners.org.

Virtual Visits

There are also several resources available for virtual visits.