

Electronic Communication with Research Participants

Purpose

This document provides guidance on how to communicate with research participants electronically. There are two types of electronic communication: one-on-one directed personal communication and general non-directed research recruitment activities. This guidance document focuses specifically on directed personal communication, which may include email, text messages, and social media.

General, non-directed research recruitment activities, such as placing ads and banners on websites, are discussed in more detail in the Spectrum Health IRB guidance document entitled, "Recruitment Advertising."

Regulatory Guidance

- The HIPAA Privacy and Security, 45 CFR Parts 160 and 164
- DHHS Protection of Human Subjects, 45 CFR Part 46
- FDA Protection of Human Subjects, 45 CFR Part 50
- Electronic Messaging Appropriate Use policy, Spectrum Health policy reference #55
- Social Media Policy, Spectrum Health policy reference #2333

Discussion

When the IRB is deliberating whether to approve a research study, two of the approval criteria that must be met are (1) risks to research participants must be reasonable in relation to anticipated benefits and (2) there must be adequate provisions to protect the privacy of participants and to maintain the confidentiality of data. In addition, the HIPAA regulations require that patient information be kept both private and secure¹. The HIPAA regulations are also very specific on what health information can be shared electronically. One of the ways the IRB assesses the approval criteria is to consider how the research team will communicate with participants.

Electronic communication may include use of email, texts, and social media websites such as Facebook. This communication can range from sending simple appointment reminders, to sharing tips on healthy living, to following up of research test results. The HIPAA Privacy and Security Rules offer the most comprehensive guidance on sharing patient information electronically for research-related purposes. If the information being shared constitutes protected health information, then additional measures need to be in place to protect the transmission of these messages.

¹ The Spectrum Health IRB also serves as spectrum Health's Privacy Board for purposes of ensuring compliance with HIPAA regulations relevant to research.

EMAIL

MyChart

Spectrum Health has created MyChart to allow for secure, HIPAA-compliant electronic messages to be exchanged between patients and providers. A provider can send a message to the patient in MyChart, and the patient receives an email from MyChart letting him or her know there is a secure message waiting in MyChart. The patient can then log into the secure website and read and respond to this message. This is the preferred method for electronic communication when the patient is also a research participant. You may send attachments to patients using the In Basket function. This feature is only available for Adult participants at this time.

Encrypted

Not all research participants are patients of the researchers. Also, not all researchers are Spectrum Health providers. In these cases, MyChart may not be an option for communication. An alternative is to send encrypted emails to research participants by placing *[secure]* in the subject line of the email or marking the sensitivity of the email as “confidential.” As with MyChart, the participant will receive an email letting him or her know there is a secure message waiting and a link will be provided. Upon selecting the link, the participant will log into the secure website and can then read and respond to the message.

TEXT MESSAGES

This guidance is specifically concerned with text messages sent by Spectrum Health research team members; this document is not providing guidance on third-party organizations that are providing contracted services to send texts to research participants. The contract between the sponsor and the organization delineates acceptable text message activity and is outside the purview of this guidance.

Text messages are problematic because they may not be a secure form of communication. Only generic information should be sent via text message. If the research involves using text messages as the research intervention, the text messages should be as generic as possible. For example, instead of saying, “Remember to take your Metformin,” it is preferable to say, “Taking medications when your doctor prescribes them may help you feel better.”

SOCIAL MEDIA

Using Facebook, Google+, or other social media websites to communicate personally with research participants is generally not appropriate. Sending private messages through a social media website is not a secure form of communication and Spectrum Health policy strongly discourages use of social media to communicate with patients. If a research study plans to utilize a social media platform for research communication and/or research interventions, the research team will need to complete training through the System Communications and Marketing social media team of Spectrum Health. In addition, communicating with participants via social media requires IRB approval. If this was not originally approved during the initial IRB review, then a modification must be submitted to the IRB prior to initiating any communication with participants through social media.

Institutional Review Board

Conclusions

- Utilize MyChart to send secure electronic communication to research participants.
- If MyChart is not an option, send encrypted emails to research participants by placing [secure] in the subject line of the email or marking the sensitivity of the email as “confidential.”
- Text messages must contain generic information.
- Social media websites such as Facebook cannot be used to communicate with research participants.