Mass General Brigham Human IRB Office

FAQ's about email communication with research subjects

What's the best way to communicate with subjects by email?
Patient Gateway is strongly preferred whenever possible. However, many patients are not "on" Patient Gateway, research subjects who are not also patients cannot join it, and study staff who are not nurses or other providers with clinical roles do not have access to Gateway. When Gateway cannot be used, "Send Secure" is the next preferred option

We understand that "Send Secure" is cumbersome and may deter participation. As a final option, non-secure email may be used to communicate with research subjects, but only if they have been informed of, and agree to accept the associated risks. The preferred current language to obtain a subject's agreement follows.

How do I get and document someone's agreement to communicate by non-secure email?
Individuals may read or have read to them the following information, and then can agree by signing or verbally acknowledging that they agree to receive un-secured email. Researchers are required to document this agreement, including the date of the agreement, by noting it in research records, or retaining the participant's a signature.

Required Warning Language: Before sending or responding to an unencrypted email message to an individual, the individual must acknowledge understanding of, and agreement to accept the risks as communicated to them via the following language (this language must be copied into an email response to an individual, or may be read over the phone to the individual, or an individual could agree by reading this in person and signing this or simply agreeing verbally):

"The Mass General Brigham standard is to send email securely. This requires you to initially set up and activate an account witha password. You can then use the password to access secure emails sent to you from Mass General Brigham. If you prefer, we can send you "unencrypted" email that is not secure and could result in the unauthorized use or disclosure of your information. If you want to receive communications by unencrypted email despite these risks, Mass General Brigham will not be held responsible. Your preference to receive unencrypted email will apply to emails sent from this research group/study only."

Can I use or copy my gmail account?
No. Hospital business should be conducted using institutional email addresses only.

Can I communicate with subjects over Facebook or other social media?
No. This is not secure. IRB-approved advertisements may be posted on Facebook or other sites.

Can I send recruitment letters by email, if I can access a potential participant's email address in the hospital records system?
No. We are not currently allowing researchers to send unsolicited emails for recruitment. Recruitment letters through Patient Gateway are possible, but you need to work with the Mass General Brigham Epic team/research council.

Can I send more information by email, if I spoke with a subject on the phone and they asked me to do so?
Yes. You should try to use Patient Gateway, or Send Secure, or obtain and document the person's agreement to use non-secure email as discussed above.

What if a participant was in my prior study, and agreed to hear about new studies and wanted to be contacted by email?

This is OK. We'd prefer you use Patient Gateway, or Send Secure, but if the person requested non-secure email and you have documentation of that in your research files you could send un-secured email.

What if a participant responds to my posting a recruitment flier on the T, or elsewhere, which has an email address?
You should see if Patient Gateway, or Send Secure can be used. If not, obtain permission to communicate by un-secured email. Please note you should MINIMIZE the amount of PHI (protected health information) sent electronically.

Do I need IRB approval to switch from paper to email?
Yes. The IRB needs to review and approve all aspects of recruiting, including the specific methodologies used, and the text of recruitment letters or emails. Some communications may not be appropriate for non-secure email communication, *e.g.,* "*We are recruiting patients who recently were treated for a sexually transmitted infection in our clinic.*"

Can I send confirmatory information about research appointments by email without formal IRB approval of that communication and process?
Yes. 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 me and Dr Smith on January 2, 2018 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. You should be sure that your IRB protocol describes electronic communication if you are attaching consent forms or other study information which imply or state diagnoses.

Can I send TEXTS with the information above?
Yes. Minimize the PHI sent. Others may read or see text messages.

I want to search for patients with a specific diagnosis in EPIC and generate an automatic email to go out via Patient Gateway. Can I do that?
Maybe. This would first require IRB review and approval and the agreement of the pEC Research group. You'll need to pay the EPIC research team to do the programming for you. Contact Sri Emani or Holly Barr-Vermilya.

If a patient has agreed to direct contact by researchers "RODY yes" noted in RPDR, can I send them a direct email? (RODY = Research Opportunities Direct to You).
Only if the IRB has reviewed and approved your email communication AND you have ascertained that the person has indicated "RODY yes." We would still strongly recommend communication via Patient Gateway, or Send Secure methodologies. **PLEASE NOTE:** RPDR search algorithms are not perfect. You should not be sending letters that specifically indicate sensitive or distressing diagnoses (metastatic cancer, HIV infection, sexually transmitted infections, serious mental illness) unless you are certain they are accurate AND the IRB has approved your contact methodologies and documents. Think about what it would be like to receive a letter if you

were receiving it and you do not actually have the diagnosis. This degrades confidence in the entire research enterprise.

Is there specific information that CANNOT be sent by unsecured email?
Yes. Social Security numbers (SSN's), financial account numbers (credit card numbers or account numbers) CANNOT be sent by unsecured email per 201 CMR 17.00, even if a subject requests this. The IRB would likely not allow communication about some diagnoses or behaviors by email (STI's, HIV, illicit drug use, illegal or abusive behaviors). Mental health conditions are a judgment call by the investigators and IRB.

Do I need to use "Send Secure**" when communicating by email with staff at other Mass General Brigham entities?**
NO. These are "behind the firewall"

What about other Boston hospitals?
There are secure email tunnels to certain Boston entities. See the list here:
http://ccmu.massgeneral.org/emaildomain/default.aspx

Isn't email sent through REDCap secure?
No! It is not secure unless you insert "Send Secure" in the subject line or use REDCap's Survey Login Feature. Survey links sent though REDCap to a patient ARE secured once accessed, but the email itself is not.

For Send Secure: The subject will need to register in the Send Secure system, create a password, etc.

For the Survey Login Feature: The subject 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.