Ottawa Health Science Network Research Ethics Board (OHSN-REB) /
Conseil d'éthique de la recherche du réseau de science de la santé d'Ottawa (CÉR-RSSO)

Guidance for Use of Email in Clinical Research

Table of Contents

General

The use of email can be an effective method of communication between the research team and research study participants; however, guidance and policies need to be followed to ensure the privacy and confidentiality of potential/existing participants.

This document provides guidance on how to use email to communicate with potential/existing participants. Also, it includes information on what to include in your REB application and documents to be submitted for review.

Email may be used for consent documentation exchanges as well as for recruitment and study-related purposes, with appropriate REB approval and provided that prior consent to communicate by email has been obtained from the potential/existing participants and documented.

Although email may be used to correspond with potential/existing participants and to exchange encrypted (password protected) study documents, the following secure options should be considered and may be less cumbersome for participants as methods of communication:

- MyChart (for sending documents only, cannot receive documents from participants; this could be combined with the "request file" feature in OneDrive).
- For TOH/OHRI research staff only:
    - Corporate Microsoft SharePoint/OneDrive
    - The Ottawa Methods Centre Electronic Data Capture (EDCS)

TOH and UOHI policy states that patients must be informed of the potential risks associated with the use of email correspondence; therefore, consent to use email for research purposes must be obtained and documented from potential/existing participants prior to contacting them via email.

- Initial patient contact must be done either in-person, telephone or regular mail.

- The consent to communicate via email should be documented by a research team member in a way that a colleague, new research team member or auditor could review and understand the process.

- Even if the potential/existing participant's email has already been collected and included in EPIC for clinical purposes, permission for use for research purposes must still be obtained and documented.

What should be discussed with the potential/existing participant when obtaining consent to use email?

- To obtain consent from the participant to communicate via email, please use the following documents (can also be found on the OHSN-REB website):

    - ✓ English Research Participant Consent to Communicate by Email Form
    - ✓ French Research Participant Consent to Communicate by Email Form
    - ✓ Guidance Document for Obtaining Participant Consent Using the 'Research Participant Consent to Communicate by Email' Form

- Explain how email will be used during the research study. For example, emailing recruitment poster/brochure, consent forms, scheduling study visits, sharing of online / electronic questionnaire(s) that are to be completed by study participants.
  - ✓ Confirm the type of sensitive information they wish to receive (or not receive) by email.

- Inform them that they do not need to share an email address in order to take part in a research study, unless the study activities cannot be carried out without access to email. In this case, use of email will need to be part of the study inclusion criteria in the REB application.

- Inform them that if they decide at any time throughout the duration of the study that they no longer want to communicate via email they may withdraw their email contact information. This must be documented immediately in the study record and/or EPIC.

  - ✓ Note, TOH privacy office states that patients must be reminded that email can be insecure, and that staff must provide their patients with advice to help safeguard sensitive information they receive via email. The policy also encourages that patients use MyChart instead of communicating via email wherever possible.

Email Accounts

1. Only secure corporate (e.g., TOH, OHRI, UOHI) email accounts can be used by staff. Personal email accounts such as gmail.com, **cannot** be used.

2. Use of shared email accounts for your study team (e.g., REBAdministration@toh.ca) are suggested for studies that will enroll many participants or involve frequent communication with participants.

   - ➢ The name of the sender must be indicated in the body of the email when using a shared email address.

   - ➢ This is preferred, over providing contact information for a single member of the study team, in order to ensure active monitoring of the account and cross-coverage in an absence.

   - ➢ When out of the office for longer than one workday, auto-reply messages should be set to ensure potential/existing participants are aware that the inbox will not be monitored. Consider providing alternate contacts in case of urgent/emergent issues.

3. Email addresses that include health-related information should not be used. This includes addresses that directly or indirectly reference health status (e.g., CancerCentre@toh.ca).

Email Disclaimer

Email sent to potential/existing participants must have a disclaimer to instruct what to do if the person receiving the email is not the intended recipient. TOH and UOHI already default disclaimer text into emails sent externally from the institutions. The following is the disclaimer from TOH:

- ➢ *Confidentiality Statement - The contents of this email, as well as what's attached, are to be used only by the person meant to receive it. The email may contain private or privileged information. If you are not the person meant to receive it, by law you cannot read, use, disclose, copy, or send this email or any of its contents. If you received this email by mistake, let the sender know right away, and delete the email and what's attached, as well as any copies you have. Also, if you think the email is spam or is sales-like and you don't*

want to receive any more, let the sender know right away. You may also report the email to the Information and Privacy Office (infoprivacyoffice@toh.ca). Thank you.

Emails Containing Personal Health Information (PHI)

Research correspondence with participants generally involves some disclosure of PHI as visit reminders may provide testing/imaging information, questionnaires or surveys are often shared, and the study ICF reveals disease conditions or procedures; therefore, caution is required. It is recommended that Personal health information (PHI) be discussed with the participant over the phone or include a password protected document containing PHI (such as disease names, procedures) as an attachment to the email, not in the body of the email. The document should be encrypted with a password, that password should be provided to the patient by phone not email.

To uphold the principles of TCPS2, you should protect PHI to the best of your ability, while considering software availability and participant's capabilities. In limited circumstances, some participant populations may require accommodation and decline receiving password protected documents and accept the risk related to email; this must be well documented. The email address of the participant combined with the information contained in a consent form can link a diagnosis/health condition to an individual, making it indirectly identifying health information of the participant.

1. If items related to PHI , such as eligibility criteria involving medical history, diagnosis, or follow-up outcomes need to be discussed, it is preferred that this is done via a phone call, during an in-person clinic visit, or by sending potential participants a link in an email with questions they can answer on a more secure platform and/or attached document with encryption. The body of the email should not reference the health condition.
2. Use a "private", "confidential", or similar flag. Also ensure to include "Private and Confidential" in the subject line of the email to alert the potential/existing participants. The subject line of the email should also **not** reference the health condition or pending procedure.
    - For example, if email is being sent to a specific disease group, subject line should read "*Seeking participants for a TOH/UOHI Research Study*" and **not** "*Seeking participants for Lupus Study*".
3. Potential/existing participants should not be asked to provide sensitive health information such as status of communicable diseases, sensitive lab test results, or other stigmatizing health information via email.
4. Links to online / electronic questionnaires and surveys can be sent via email.

Sending Informed Consent Forms (or other attachments) via Email

Details about the research study and study documents such as consent forms can be shared via email with potential/existing participants. However, upon review, the REB may request a more secure document transfer method. To uphold the principles of TCPS2, you should protect PHI to the best of your ability, while considering software availability and participant's capabilities.

Although email may be used to correspond with potential/existing participants and to exchange encrypted (password protected) study documents, the following secure options should be considered and may be less cumbersome for participants as methods of communication:

- MyChart (for sending documents only, cannot receive documents from participants; this could be combined with the "request file" feature in OneDrive)
- For TOH/OHRI research staff only:
    - Corporate Microsoft SharePoint/OneDrive
    - Methods Centre Electronic Data Capture (EDC) system

The following are examples of secure document transfer methods:

- **MyChart** (only available for TOH and UOHI patients) (instructions coming soon)

- **Emailing a link:** Research teams can email a link to potential/existing participants to read the consent form, or other study documents.

    - **Preferred link methods** (only available to TOH/OHRI Research Staff):
        - Corporate Microsoft 365 SharePoint and OneDrive (see instructions here)
        - The Ottawa Methods Centre Electronic Data Capture system (EDCS) (instructions coming soon)

    - **Other link methods:**
        - REDCap, DocuSign or Adobe Sign. Note, signature cannot be received via external REDCap for regulated trials (non-validated process). DocuSign and Adobe Sign will have additional costs which you must consider when creating your study budget.

- **Emailing an attachment:** Use of PHI in the email body is highly discouraged; PHI should be put into a password protected attachment.

    - Attach the consent form (and any other documents containing sensitive information) in PDF format as a password protected attachment. TOH policy states that the password to the protected document must be provided by telephone.
        - For OHRI research staff:
          Tip Sheet – Protecting Consent Forms and other documents containing PHI/PI to send via email to Study Participants
        - For UOHI research staff, please visit the Heart Hub

Participants should be informed of the following:

- Clear expectations of what the potential/existing participant is to do with the email (e.g.: sign and return the consent form, fill out the electronic survey, respond via email, no action, etc.)
- Clear instructions on how potential/existing participants should return the signed consent form or completed document to research team (for example, mail signed consent form, scan and fax to TOH, email with password protected attachment, upload into the link provided in the email, etc.)

Do I need REB approval to use email in the study?

The answer is 'Yes'. The REB needs to review and approve all aspects of communicating with potential/existing participants via email (i.e. for recruitment purposes, consenting purposes, study procedures, sending the completed ICF, survey emails etc.). 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*."

Clarification for studies using email to communicate with participants during the pandemic:

For approved studies that already have approval for use of email in their study:

You do not need to communicate to the REB if your study **already has approval to use email.** However, you must proceed to use the ***new*** "Research participant consent to communicate by email" form, as required by the OHRI memo dated October 16, 2020. UOHI research staff should review the communication via the Clinical Research Compliance and Support Office. Please review the guidance document to obtain participant consent to communicate via email referenced on page 2 of this document.

For approved studies that do not have approval for use of email in their study:

An Amendment Form is required if email communication was not previously approved by the REB and was implemented for use in response to the pandemic and the study will continue after January 31st, 2021. Although email was acceptable to be covered with a Note to File (NTF) process in the early stages of the pandemic, it is no longer considered temporary. You may continue with your changed plan while awaiting amendment approval.

Information to include in a new REB application or amendment:

- Justification for use of email (i.e. for recruitment, consent, study procedures, etc.)

- If using email for recruitment purposes:
    - Identify of the sender of the email (i.e. someone will email on behalf of the researcher or the research team's email will be forwarded by an individual or organization that holds all the email addresses)
    - The source of the email list
    - The targeted population of the emails
    - Frequency and the total number of emails that will be sent to potential participants
    - Method for how individuals who do not wish to receive any more emails will be unsubscribed or removed. Note this is a requirement from the Canadian Anti-Spam Legislation (CASL). For more information on the CASL compliant tool, please contact the TOH Privacy Office.

Documents to include in a new REB application or amendment submission:

- Email messages that will be sent to potential/existing participants. Please visit the OHSN-REB website for templates provided (i.e., recruitment, follow-up, appointment reminders)
- Depending on the magnitude of the email plan, email use may need to be included in the Protocol and in the Consent Form, if applicable.
  For Examples:
    - Why the participant is being emailed without discussing detailed personal health information

- What the participant is expected to do upon receiving the email
- How many more times they may receive the email and for what purpose?
- How they remove themselves from receiving the emails

The following details should be included for studies planning to use email as a recruitment method (for studies that involve mass emails for completion of survey):

- Specify who the senders of the email will be (for example, one of the research coordinators who have been delegated this task, do not list out individual names of staff but positions instead). Also specify if the emails will be sent from a shared email account (and provide the email address), or from employee specific institutional email accounts.

- The subject line should clearly state that the email is regarding a research study. E.g. "*Seeking participants for a research study,*" "*Information about a Research Opportunity*" or "*Research appointment reminder*"

- Participants should not see the email addresses of the other email recipients; use the BCC field if sending to multiple participants. Always re-check to ensure all the fields are correctly completed to avoid errors that may lead to a privacy breach.

- The email body should include the following details, as applicable (note: "they" is referring to participants):
  - The source of the email addresses/list "*You are receiving this email because …*"
  - Why they are being emailed without discussing detailed personal health information
  - What they are expected to do upon receiving the email
  - How many more times they may receive the email and for what purpose
  - How they remove themselves from receiving the emails
  - Who they should contact for questions?

After sending or receiving emails, remove any sensitive information and store it in the appropriate, secure repository on TOH/UOHI network. This is, do not permanently store sensitive information in email.

Consequences:

The Ottawa Hospital (TOH/OHRI) and University of Ottawa Heart Institute (UOHI) staff must comply with Institutional Privacy Policies and be accountable for ensuring Personal Health Information is always protected. As per the policies, there are serious consequences for privacy breaches (e.g.: emailing potential/existing participants without consent or sharing health information without consent).

This document is meant to assist you in developing your own process to ensure that use of email in research is fully consented and the privacy of participants is protected. The Ottawa Health Science Network Research Ethics Board, TOH Privacy Office and/or UOHI Privacy Office are available to help guide researchers in this process.

When in doubt about the security of online platforms or methodologies, consult with TOH IT servicenow@toh.ca or UOHI IT services and then discuss with the REB about the change in process, if different from initially approved.

What if there's a problem?

- If the research team receives complaints from the recipient of an email, the complaint should be reported to the REB via the Reportable Event Form.

- If you suspect there has been a privacy breach via email, ensure you report to the REB **and** the OHRI privacy office via the online Safety Learning System (SLS) for OHRI studies or the Clinical Research Compliance and Support office via the Issue Management Form for UOHI studies.
    - E.g. the wrong participant email address was used

References

- TOH Corporate Policy (ADM II 260): Patient Privacy
- TOH Policy (01654): Secure Transfer of Sensitive Information Orally, and by phone, fax, email
- Please see the OHSN-REB website for Email Templates (e.g., Recruitment Email, Reminder Recruitment Email, Appointment Reminder, etc.)
- http://www.ohri.ca/extranet/clinical_research/documents/email%20encryption.docx
- repositoryhttp://www.ohri.ca/extranet/clinical_research/documents/Password%20Protecting%20Documents.doc