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

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Introduction

Email can be an effective method for recruitment and communication between research teams and study participants; however, institutional policies must be followed to ensure the privacy and confidentiality of potential/existing participants is maintained.

On December 7, 2022, The Ottawa Hospital and University of Ottawa Heart Institute implemented a new procedure at registration to collect and document consent to use patient emails for clinical purposes and/or other communication purposes, including research.

This document provides guidance on the use of email with potential/existing research participants as well as information on what to include in your REB application. Initial Contact/Recruitment via Email

TOH and/or UOHI Patients

When email is used to make initial contact with **TOH and/or UOHI patients**, the following must be confirmed by the research team **prior to** contact:

1. The patient has agreed to be contacted for research purposes (i.e.: permission to contact (PTC) is documented in EPIC).

2. The patient has agreed to be contacted by email (i.e.: email is listed as a patient's communication preference in EPIC, or email is listed as preferred method of contact under "Other Communications" in the patient's MyChart)
    - For instructions on how to check a patient's communication preferences in EPIC/MyChart, please see *'Use of Patient Email in Clinical Research: Researcher FAQs and Answers.'*

3. The REB has approved the email recruitment plan and email templates for use. **All applicants requesting to use email as a recruitment strategy must review the guidance documents for using patient email in their study prior to completing the REB application.**

Note the following regarding initial email contact with **TOH and/or UOHI patients**:

- Initial contact by email should only be used when other, more secure methods (e.g.: in person, MyChart, FortiMail (UOHI only), etc.) are not practical, available, or sufficient for the research or patient population.

- If personal health information (PHI) is communicated to patients via email, it must be done via a secure link within the email (Microsoft 365 SharePoint /OneDrive, Methods Centre Electronic Data Capture System, FortiMail (UOHI only), etc.) .
    - Alternatively, PHI may be communicated to participants in an encrypted/password protected document attached to the email, with the password relayed to the potential/existing participant over the phone not via email. At UOHI, the use of FortiMail for secure transfer of documents is best practice and should be used whenever possible.

- The REB will typically only approve a maximum of 3 recruitment emails (1 initial contact and 2 reminders); if no contact has been established after 3 email attempts, then the potential participant

should be deemed as having refused to be part of the study. If more than 3 recruitment emails are required, strong justification must be provided for the REB to assess.

- Do NOT send mass emails; CC or BCC options are **not** permitted. **Each patient must be sent an individual email.**

Non-Patients (e.g.: TOH and/or UOHI staff, society members, etc.):

When email is used for initial contact with **non-patients**, the following must be confirmed by the research team **prior to** contact:

1. The sender of the email must already have access to the email addresses via their regular duties *or* email addresses are publicly available. Email addresses cannot be circulated/passed around without consent.

2. The sender of the email is known to the recipients or is someone from whom they would expect to receive an email.

3. The sender of the email is not in a position of power or authority over the recipients.
    - For example, a Department Head should not send a recruitment email to those who directly report to them, as the recipients may feel obligated to participate. The Department Head's administrative assistant should send the email on the Department Head's behalf and, if possible, the Department Head should not be aware of who has agreed or declined to participate.

4. The REB has approved the email recruitment plan and email templates for use.

Note the following regarding initial contact with **non- patients** via email:

- Mass emails are acceptable; however, the BCC field must be used.

- Typically, email attachments (e.g.: Information Sheet or Consent Form) for research involving **non-patients** do not include personal health information. If that is the case, email attachments are acceptable.

- The REB will typically only approve a maximum of 3 recruitment emails (1 initial contact and 2 reminders); if no contact has been established after 3 email attempts, then the potential participant should be deemed as having refused to be part of the study. If more than 3 recruitment emails are required, strong justification must be provided for the REB to assess.

Ongoing Correspondence via Email

TOH and/or UOHI Patient Participants

When email is used for ongoing correspondence with **TOH and/or UOHI patient participants** (e.g.: consent discussion/documentation, survey links, visit reminders, etc.), the following must be confirmed by the research team **prior to** contact:

1. The patient has agreed to be contacted for research purposes by email. This can be done in one to two ways:
    - ✓ Email is listed as the patient's communication preference in EPIC, or under "Other Communications" in their MyChart. For instructions on how to check a patient's communication preferences in MyChart, please see *'Use of Patient Email in Clinical Research: Researcher FAQs and Answers.'*

- ✓ You have obtained explicit verbal or written consent from the patient participant to communicate via email and the consent has been documented in the study file, either in a note in EPIC or via the '*Research Participant Consent to Communicate by Email*' form.

2. The email contact, as well as all email templates, have been approved by the REB office.

Non-Patient Participants (e.g.: TOH and/or UOHI staff, society members, etc.):

When email is used for ongoing correspondence with **non-patient participants** (e.g.: consent discussion/documentation, survey links, visit reminders, etc.), the following must be confirmed by the research team **prior to** contact:

1. The participant has agreed to be contacted via email.

2. The email contact, as well as all email templates, have been approved by the REB office.

Obtaining and Documenting TOH/UOHI Patient Consent to Communicate via Email for Research

There are several ways to obtain and document patient consent to communicate by email:

- ✓ **EPIC/My Chart (gold standard)**
  - If email is listed as a patient's communication preference in EPIC, it is assumed they have consented to communicate by email, including for research purposes (unless they indicate otherwise).

  - On December 7, 2022, The Ottawa Hospital and University of Ottawa Heart Institute implemented a new procedure at registration to collect and document consent to use patient email for clinical purposes and/or other communication purposes, including research.
    - When interacting with patients, registration clerks read a script that requests their verbal permission to be contacted via email for various purposes, including research. The patient's response is documented in Epic and available in MyChart.
    - Patients may update their communication preferences (including those for research) themselves in MyChart.

  - For instructions on how to check a patient's communication preferences for research in EPIC/MyChart, please see *'Use of Patient Email in Clinical Research: Researcher FAQs and Answers.'*

- ✓ **<u>Verbally</u> via a study note in EPIC *or* the *"Research Participant Consent to Communicate by Email"* form**
  - Research teams may obtain verbal consent to communicate via email from the patient.

  - The verbal conversation must be documented by the research team, in the study file, in a note in EPIC *or* on the *"Research Participant Consent to Communicate by Email"* form.

  - For more information on the *"Research Participant Consent to Communicate by Email*" form, please see the following documents available on IRISGuide:

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

✓ **In <u>writing</u> via the *"Research Participant Consent to Communicate by Email"* form**

- Research teams may obtain written consent to communicate via email from the patient.

- Written consent must be documented on the *"Research Participant Consent to Communicate by Email"* email. The signed form should be uploaded into EPIC as a media file under the name "Consent for Email" to ensure that it is available for all Atlas Alliance Partners.

- For more information, please see the following documents available on IRISGuide:
  - ✓ Guidance Document for Obtaining Participant Consent Using the *"Research Participant Consent to Communicate by Email"* Form
  - ✓ English Research Participant Consent to Communicate by Email Form
  - ✓ French Research Participant Consent to Communicate by Email Form

Email Accounts

1. Only email from a corporate TOH/OHRI and UOHI/OHIRC email account can be used. Personal email addresses or email addresses associated with other institutions (e.g.: University of Ottawa) **cannot** be used.

2. To ensure active monitoring of the account and cross-coverage in an absence, use of shared email accounts for your research team (e.g.: REBAdministration@ohri.ca) are suggested for studies that will enroll many participants or involve frequent communication with participants.

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

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

   - ➢ 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.

Email Disclaimer

Emails 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 include default disclaimer text into emails sent externally from the institutions. The following is an example of 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)

Personal health information (PHI) is information about an individual, whether in oral or recorded form, that identifies the individual or could enable such identification and that relates to the individual's health, medical history or past or future medical treatment (e.g. a patient's physical or mental health or personal or family history; the provision of healthcare to a patient; the identity of a patient's healthcare provider or substitute decision-maker; payments or eligibility for healthcare or healthcare coverage; donation by any individual of any body part or bodily substance; a patient's health number).

PHI includes, but is not limited to:

- ✓ Consent forms, information sheets, other documents, and/or links to surveys/questionnaires that mention a disease or condition.

- ✓ Discussing eligibility criteria involving medical history, diagnosis, or follow-up outcomes.

Initial Contact/Recruitment via Email:

- PHI should be communicated to patients via secure link rather than as an attachment to an email.

- Email should only be used when other more secure methods are not practical, available, or sufficient for the research or patient population.

Ongoing Correspondence via Email:

- Ongoing research correspondence with potential/existing participants may involve some disclosure of PHI as visit reminders may provide testing/imaging information, questionnaires or surveys are often shared, and the study consent form reveals disease conditions or procedures; therefore, caution is required.
- It is recommended that PHI be discussed with the participant in person, over the phone, be sent to the participant via mail, MyChart, FortiMail (UOHI only) or secure link. When these gold standard methods are not practical, available, or sufficient for the research, PHI should be linked or attached to an email as an encrypted/password protected document rather than having the PHI in the body of the email. The password to the encrypted document must be provided to the participant by phone, not via 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.

General Email Requirements:

- Use a "private," "confidential," or similar flag.
- The **subject line** of the email should:
    - Include "Private and Confidential" to alert the potential/existing participants.

    - 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*").
- The **email body** should inform the potential/existing participant of the following, as applicable:
    - The source of the email addresses/list (e.g.: "You are receiving this email because you have agreed to be contacted about research opportunities.")
    - The purpose of the email (e.g.: "You are being asked to participate in a research study we are conducting.").
    - What they are expected to do upon receipt of the email.
    - How many more times they may receive the email and for what purpose.
    - How they can remove themselves from receiving further emails.
    - Who they should contact for questions.

- If sending **mass emails** to non-patients (note: mass emails to patients are not allowed), potential/existing 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.

- 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.

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

Methods of Secure File Transfer Preferred Before Use of Email

Details about the research study, and study documents such as consent forms, can be shared with participants via email with their consent; however, upon review, the REB may request a more secure method of document transfer. To uphold the principles of TCPS2, researchers must protect personal health information to the best of their ability, while considering software availability and participant capabilities.

The following methods of secure file transfer are preferred and should be considered prior to use of email:

- EPIC/MyChart (only available for TOH and UOHI patients) **(preferred)**
    - Note, this is for sending documents only. Patients cannot return documents via MyChart; however, this could be combined with the "request file" feature in OneDrive.
- At UOHI, the use of FortiMail for secure transfer of documents is best practice and should be used whenever possible.
- TOH and UOHI Corporate Microsoft SharePoint (to send) & OneDrive (to receive)
- TOH Methods Centre Electronic Data Capture (EDC) system
- Registered Mail
- For sending and receiving surveys/questionnaires: One of the institutionally approved survey/questionnaire platforms:
    - For TOH: Microsoft Forms (for non-patient research only), LimeSurvey, REDCap
    - For UOHI: Heart Survey, REDCap under the direction of UOHI's CRMC

Email should only be used when the preferred methods of secure file transfer listed above are not practical for the research or patient population. Note the following when using email:

- Use of detailed PHI in the email body is highly discouraged; general descriptions can be used to convey the relevancy to the patient.

- The consent form (and any other documents containing sensitive information) should be included as a secure link or attached in PDF format as an encrypted/password protected attachment. TOH policy states that the password must be provided to the email recipient by telephone not via email.
  - 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.

Regardless of the method of secure file transfer being used, potential/existing participants should be informed of the following:

- What they are to do with the document (e.g.: sign and return the consent form, fill out the electronic survey, respond via email, no action, etc.)

- If they are to return a document to the research team, how they are to do so (e.g.: sign in ink and mail the consent form using the pre-paid and stamped envelope, scan, and fax to TOH, email with password protected attachment, upload into a link provided in the email, etc.)

REB Approval for Use of Email in Research

Do I need REB approval to email potential/existing participants?

Yes, prior to emailing potential/existing participants, you must ensure you have REB approval to do so. The REB must review and approve all aspects of communicating with potential/existing participants via email (e.g.: for initial contact/recruitment purposes, consenting purposes, study procedures, follow up, etc.). Note, some communications may not be appropriate to be made via email and the REB may request a more secure method of communication.

New Studies (not yet approved by REB):

- Use of email must be explained in the initial REB application.

Ongoing Studies (already approved by REB):

- If your study has approval to use email but only for ongoing correspondence and you now wish to use email as a means of initial contact/recruitment, an Amendment Form must be submitted to REB to amend the study's recruitment plan.

- If your study has approval to use email but only as a means of initial contact/recruitment and you now wish to use email for ongoing correspondence, an Amendment Form must be submitted to REB.

- If your study does **not** have REB approval to email potential/existing participants, and you now wish to use email as a means of initial contact/recruitment and/or for ongoing communication, an amendment form must be submitted to the REB.

What **information** do I need to include in an initial REB application or Amendment Form?

- ✓ Reason for use of email (e.g.: for initial contact/recruitment, for sending the consent form, for sending study surveys, for visit reminders, etc.).

- ✓ The targeted population of the emails (e.g.: TOH or UOHI patients, TOH/OHRI or UOHI/OHIRC staff, members of a professional body or society, etc.).

- ✓ The source of the emails (e.g.: individual patient emails in EPIC/MyChart, society membership lists, etc.).

- ✓ The sender of the emails (e.g.: circle of care, research team member, the research team's email will be forwarded by an individual or organization that holds all the email addresses, etc.).
    - o If the research team will send the email, specify if their employee specific institutional email account will be used, or if a shared/common email account will be used. If shared, provide the email address (e.g.: REBAdministration@ohri.ca).

- ✓ Frequency and the total number of emails that will be sent to potential participants.
    - o **Note:** The REB will only approve a maximum of 3 recruitment emails to be sent (1 initial + 2 follow up); if no contact has been established after 3 email attempts, then the potential participant is deemed as having refused to be part of the study.

- ✓ Method for how individuals who do not wish to receive any more emails can unsubscribe or be removed from the mailing list.
    - o Note, this is a requirement from the Canadian Anti-Spam Legislation (CASL). For more information on the CASL compliant tool, please contact the TOH or UOHI Privacy Office.

- ✓ If using email for **initial contact/recruitment purposes with <u>TOH or UOHI patients</u>**, confirm that it will only be used when:
    - ✓ The patient has agreed to be contacted <u>for research purposes</u> (i.e.: permission to contact (PTC) is documented in EPIC).
    - ✓ The patient has agreed to be contacted by <u>email</u> (i.e.: email is included as a communication preference in EPIC or as a preferred method of contact under "Other Communications" in MyChart)

What **documents** do I need to include in an initial REB application or Amendment Form?

- ✓ All emails that will be sent to potential/existing participants (e.g.: recruitment email, reminder recruitment email, appointment reminder, survey/questionnaire reminder, sending ICF (Informed Consent Form) to potential participant, follow up email, etc.).
    - o **Use the OHSN-REB's Email Templates when creating emails for your study**

- ✓ Depending on the magnitude of the email plan, email use may need to be described in the Consent Form. For example, to explain:

- ✓ Why the participant will be emailed.
- ✓ What the participant is expected to do upon receipt of the email.
- ✓ Frequency of email contacts
- ✓ If the participant no longer wishes to receive emails, how they can remove themselves from receiving any further emails

Consequences:

Staff of The Ottawa Hospital/Ottawa Hospital Research Institute (TOH/OHRI) and University of Ottawa Heart Institute/Ottawa Heart Institute Research Corporation (UOHI/OHIRC) must comply with institutional privacy policies and be accountable for ensuring personal health information is always protected. As per institutional privacy policies, there are serious consequences for privacy breaches.

This document is meant to assist you in developing your own process to ensure that potential/existing participants have consented to be contacted via email for research purposes and to ensure that 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.

What if there is a problem?

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

- If you suspect there has been a privacy breach via email, ensure you report to the privacy office via the online Safety Learning System (SLS). For UOHI studies, privacy incidents must also be reported to the Office of Clinical Research and via the UOHI Issue Management Form. Further reporting to the REB may be required for both OHRI/UOHI studies.
    - E.g.: the wrong participant email address was used

References

- TOH Corporate Policy C-SOP II 350: Secure Transfer of Sensitive Information
- TOH Email of November 23, 2022, from Emily Sharples, with subject line "IMPORTANT Change to Registration Workflow"
- OHRI Addendum to N2 SOP 019 – Confidentiality and Privacy
- OHRI Clinical Research Privacy Tools – Email Encryption:
  IRISGuide → Research Administration → Clinical Research Support → Privacy
- OHSN-REB Email Templates:
  IRISGuide → Research Administration/Human Research Ethics/Templates, Forms, Guidelines
- UOHI How to Use FortiMail to Send Secure Email in Outlook (refer to Heart Hub)