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 Obtaining Participant Consent Using the "Research Participant Consent to Communicate by Email" Form

Note, this instruction document and the new Research Participant Consent to Communicate by Email form applies when the study population involves TOH and/or UOHI patients. When the study includes other populations external to TOH and/or UOHI, other institutions' policies regarding email use must be followed.

General

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

Working remotely has forced review of the institution's privacy policies around communicating via email with participants. TOH and UOHI privacy policies state that patients must be informed of the potential risks associated with the use of email correspondence; therefore, participant consent to communicate via email must be **obtained** and **documented (for each study and in the participant's study record and/or EPIC) prior to contacting them via email**.

It is recognized that some disclosure of PHI/PII may be included in documents attached to email. Caution is required; these documents should be sent as an encrypted or password protected document where possible and then the password shared with the individual by phone.

In review with The Ottawa Hospital (TOH) and University of Ottawa Heart Institute (UOHI) Privacy Offices, it was determined that email addresses recorded in a patient's EPIC medical record have been collected for specific use (only to be used by the Foundation, Alumni and Patient Experience Survey), and not for research purposes. Even if the Permission to Contact (PTC) for research purposes is on file in EPIC, contacting patients for research by email is not permitted without "Research Participant Consent to Communicate by Email".

How do I obtain consent to communicate by email and document in the study record in order to communicate with the participant via email?

1. Initial patient contact must be done either in-person, telephone or regular mail, followed by the consent discussion for use of email. The discussion must be well documented in either EPIC and/or in the research records. (See #3 below for details on documentation.)

2. Use the "**Research Participant Consent to Communicate by Email**" (Appendix 1) form to collect the patient's consent. Patient consent must be obtained prior to sending emails to them. A French version of the form is available on the OHSN-REB website.

    - As per the **OHRI Clinical Research Memo circulated on October 16, 2020**, you may proceed to use the new "Research participant consent to communicate by email" form. **UOHI research staff** should review the communication via the Clinical Research Compliance and Support Office.

- A Note to File must be created in the study record to document that a new process to collect consent to communicate via email must be implemented immediately. Researchers should note the official date the new process was implemented into their study.

- For REB approved studies, the researcher can determine whether the "Research participant consent to communicate by email" should be obtained verbally or in writing; the decision must consider the sensitivity and nature of the project. If there is any uncertainty, the researcher should contact the REB office for consultation.
- For new studies and amendments submitted to the REB for review, the documentation of verbal or written consent from the participant will be at the discretion of the REB on a study-by-study basis.

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

   Evidence of "Research Participant Consent to Communicate by Email" must be retained with your research records. An EPIC S*martphrase* has been created and is available to facilitate documentation within EPIC. For studies documented outside of EPIC, you must document in the study record.

Existing or potential participant's consent to communicate via email may be obtained in the following 3 ways:

1. **In-person**:

   Provide the "Research Participant Consent to Communicate by Email" consent form to the existing/potential participant and obtain signature when they are onsite for a visit.

   a. If there is a potential risk related to COVID, verbal consent to communicate via email from the existing/potential participant will be acceptable. The verbal consent process must be documented on the Research Participant -Consent to Communicate by Email form itself, in EPIC and/or in the study record.

2. **Over the phone**:

   Read the "Research Participant Consent to Communicate by Email" consent form to the existing/potential participant over the phone and obtain verbal consent. Consent of the participant can be captured in any of the following 3 ways:

   a. The patient **only** provides verbal consent over the phone. The consent form is used as a verbal script to explain and obtain patient's consent to be contacted via email. The research staff document on the "Research Participant Consent to Communicate by Email" consent form itself, as well as document in EPIC and/or research record.

   b. After verbal consent is obtained over the phone, the form is mailed to the patient along with a pre-paid and addressed envelope. The patient signs the form and returns via mail or in-person at an upcoming appointment onsite.

c. After verbal consent is obtained over the phone, the form is emailed to the patient, they sign the form and returned by mail, scan/fax, or email, or in-person at an upcoming appointment – however they prefer.

Please review the **new** "Remote Recruitment and Consent" tab on the OHSN-REB website for guidance on mailing, scan/faxing or emailing documents to participants.

3. Mail to the participant:

The "Research Participant Consent to Communicate by Email" form is mailed to the participant along with a pre-paid and addressed envelope. If mail is the recruitment method of initial contact for study, this form should be enclosed with the other REB approved documents introducing the study to the participants if there is a plan to communicate via email in the study. The patient signs the form and returns via mail.

Does the use of the "Research Participant Consent to Communicate by Email" form require a REB amendment submission?

No. The "Research Participant Consent to Communicate by Email" form to obtain participant consent to communicate via email itself **does not** need to be submitted to the REB for approval. This is a standard document that has been approved by TOH and UOHI Privacy Offices and OHSN-REB and should not be altered. It is an institution policy to obtain consent from a research participant to communicate via email.

References

TOH Corporate Policy ADM II 260: Patient Privacy

TOH Policy (01654): Secure Transfer of Sensitive Information Orally, and by phone, fax, email

For Heart Institute policy and procedures, please refer to the Heart Hub

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APPENDIX 1: RESEARCH PARTICIPANT CONSENT TO COMMUNICATE BY EMAIL

Patient (or SDM, if applicable) Name: _____

Please check each box to indicate each item below has been read:

- ☐ Email is not secure. The Ottawa Hospital (TOH) and the University of Ottawa Heart Institute (UOHI) try to protect the emails they send and receive. They cannot guarantee that email messages will be secure.
- ☐ Since email is sent across the Internet it could be read by someone else. This could happen due to computer problems, emails sent to the wrong address or outside computers that are not secure.
- ☐ You should only reply to emails from TOH, OHRI or UOHI email addresses, such as jsmith@toh.ca, jsmith@ohri.ca or jsmith@ottawaheart.ca. If you do get emails from someone who claims to work for TOH, OHRI or UOHI that seem unusual, you should report it to The Ottawa Hospital's Information and Privacy Office at infoprivacyoffice@toh.ca.
- ☐ You should only send emails from a personal account. Employers may be allowed to read any emails sent from a work email account.
- ☐ Email should not be used in emergencies or for anything that needs a quick answer.
- ☐ TOH, OHRI or UOHI may save or print your emails and put them in the research record. Other staff who are part of the study team will have access to the emails.
- ☐ Study team members may forward or send emails to other staff who take care of you.
- ☐ Study team members will not forward emails to others, such as family members, without your written consent unless required by law.

Other information:

- If you want to change any of your contact information you will need to let the study team know. This may include changes to your email address, phone number, or other contact information.
- If you decide later that you do not want to communicate with the study team by email, you just need to tell them.
- The study team can also decide at any time to stop using email to connect with you. They will let you know if they decide to do this.

Consenting to communication by email means:

- You have had a chance to ask questions about this consent. All your questions were answered.
- You understand and accept the risks of using email.
- **You understand that TOH/OHRI/UOHI will not be liable to you for any harm caused by using email or failing to respond to your emails.**

Discussed on: _____/____/____ Time: _____ hours □ Phone or □ other: _____

Consenting Process completed by: _____ Date: _____/____/____

Participant Signature, if available: _____ Date: _____/____/____