Title	Guidelines for Email Communication in Research
Original Issue Date:	10-Oct-2019
Revised:	22-August-2022
Approved By:	REB Chair

1.0 PURPOSE

This document is to provide guidance on the use of email to communicate with potential participants and enrolled participants.

2.0 POLICY STATEMENT

Email communication in research may be used to send consent forms, appointment reminders, distributing online surveys, or invitations to participate in research studies. Researchers must also abide by the Osler institutional policy for email communication.

3.0 PROCEDURES

When appropriate, email communication should be optional to the participant by providing an alternative method of communication that is more secure (i.e., phone).

Emailing Informed Consent Forms to potential study participants:
It is possible to send ICFs via email to potential study participants for informational purposes only. REB approval is not required for this. However, the following process should be followed:

1. A person who is part of the individual's circle of care or someone the patient knows should make the initial contact. A person's circle of care includes any member of the health care team who provides direct care to the patient or assists with providing the care required.
2. Permission to be contacted by a research team is obtained and documented.
3. Study team member emails a copy of the encrypted or password-protected study consent form.
4. Include the body of the email the following information *(see What to include in emails to participants* section below*)* as well as inform the research participant that they should NOT communicate any questions related to the consent document back to the researchers via email.
5. Follow REB-approved informed consent procedures/ process in person, by telephone or remote.

Consent to communicate via email for research purposes <u>after</u> written study consent is obtained:

- Email addresses recorded in clinical documentation does **not** imply consent for research purposes; permission for use for research must still be obtained and documented. REB approval to include communicating by email **is required**.
- Please see Research Participant Consent to Communicate by Email (Appendix 1) to collect the participants consent.

What to include in Emails to participants:

For all studies where email is used, the following should be provided:

- Clearly state why they are being contacted.
- If this is the first communication, clearly state how their contact information was obtained.
- Provide how often they will be contacted via email (i.e., you will receive XX reminder emails).
- Provide an opt-out option from receiving future email communication.
- Research staff must include the following disclaimers in all email communication:
    - ***"This e-mail message (and any attachments) may contain confidential and/or privileged information for the sole use of the intended recipient. Any review or distribution by anyone other than the person for whom it was originally intended is strictly prohibited. If you have received this e-mail in error, please contact the sender and delete all copies. Opinions, conclusions or other information contained in this e-mail may not be that of the organization."***
    - ***"Email is generally not a secure way to communicate sensitive or health-related information as there are many ways for unauthorized users to access email."***

What NOT to include in emails to participants:

- Do not include multiple participants on an email. Participants should not see the names of other participants in the email.

Personal Health Information (PHI) within Emails:

1. Keep the use of Personal health information (PHI) in research-related emails to a minimum (i.e., name)
    a. The email address of the potential participant combined with PHI can indirectly identify the participant and their health condition.
    b. If PHI needs to be discussed, such as eligibility criteria involving medical history and or diagnosis, choose a more secure approach such as a phone or in-person clinic visit.
2. Be extra careful handling sensitive health information, such as communicable disease status, sensitive lab test results, etc.
3. Consent forms inherently contain PHI as they discuss the medical condition of the

study population. Make sure it is shared using a secure method and with consent.
4. Include “Private and Confidential” in the subject line of all emails.

Consent Forms:

- Consent forms must outline the risks of using email to communicate, for example:

There are common risks of using email to communicate:
- *Information travels electronically and its security cannot be guaranteed.*
- *If someone sees these emails they may know that you are a participant in this study or see the health information included in the email.*
- *Emails may be read or saved by your internet or phone provider (i.e. cloud)*
- *Copies of an email may continue to exist, even after efforts to delete the email have been made.*
- *You must not use email for medical emergencies. If you require immediate help, call your clinic or care provider, or visit your nearest emergency department.*
- Consent forms must be encrypted or password protected.

Recruitment materials (Study Posters):

- Outline the risks of contacting the researchers via email. For example: *Please note, email is not a secure method of communication.*

Information to include in REB submissions:

Protocol/Appendix:

1. Description of why unsecure email communication is needed for your study.
2. Who will be communicating with the participant by email?
3. What kind of emails are expected for participation (i.e., reminder of appointment);
4. How emails will be handled, tracked and documented.
5. **Planned** email communication templates such as appointment reminders should be submitted for REB review and approval.

Reporting email related privacy incidents to the REB:

- If you suspect there has been a privacy breach via email, report the incident(s) as soon as possible to the REB and privacy office.

4.0 REVISION HISTORY

Effective Date	Summary of Changes
10-Oct-2019	Original version
22-August-2022	See tracked copy for changes

William Osler Health System

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. William Osler Health System (Osler) tries 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 Osler email addresses, such as jsmith@williamoslerhs.ca. If you do get emails from someone who claims to work for Osler that seem unusual, you should report it to Osler study team.
- ☐ 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.
- ☐ Osler 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:

You may receive emails regarding scheduling study visits, questionnaires, consent forms or information letters.

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 Osler 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: _____/____/___

Participant Email Address: _____