

Institutional Review Board (IRB) Policies & Procedures Manual



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Use of Non-secure Email and Texting in Research

Purpose

This policy applies to all investigators at Boston Children's Hospital who conduct research at Boston Children's Hospital.

When sending health information or communicating electronically with Boston Children's patients and families, it is required by federal and state law to use secure messaging systems. To ensure compliance in our current environment, our policies prohibit non-secure email or texting to communicate with patients and families.

Currently, Boston Children's does not have a secure texting system for communicating with patients and families. Any organization-wide texting programs—such as the appointment reminders sent by Boston Children's—have been carefully assessed and approved by Information Security and Compliance.

In all other cases, the MyChildren's Portal should be used whenever you communicate electronically with patients and families. If a patient/family does not have access to the portal, using Boston Children's email with #secure# in the subject heading is acceptable for sending patient information.

This includes when a generic email identifies the sending department, because patient diagnosis, condition, or other confidential information may be inferred from the department name.

Many Principal Investigators and their clinical research staff have reported that the MyChildren's Portal and #secure# are cumbersome or not accessible for research subjects and deters participation. For example, research subjects who are not Boston Children's patients do not have access to the Portal, as well as certain research staff who are not clinical providers may not have access to the Portal.

This can also raise issues of health equity/justice in that available secure communication options may present barriers for non-English speaking participants or participants who do not have access to the technology required.

As set forth below, non-secure email or texting may be used to communicate with research subjects, but only if they have been informed of, and agree to accept the associated risks.

Non-secure email or texting is not appropriate for treatment-related or non-research communications; secure options should continue to be used to communicate this type of information with patients and families.

Policy

PRIOR APPROVAL

A research protocol must specify if the research team intends to follow an individual's preference to communicate via non-secure email or text. Plans to utilize non secure email or text must be described in the CHERP application submitted for IRB review.

The ability to include non-secure email and texting after obtaining consent is initially limited to new submissions only. After a trial period of several months it will be extended to approved existing protocols through submission of an amendment. There will be future communications and guidance when amendments may be submitted

Requests will be evaluated on a case-by-case basis. Certain studies may not be appropriate for non-secure email or text communications, e.g., certain mental health conditions, sexually transmitted disease, HIV, illicit drug use, illegal or abusive behaviors.

Templated consent language is included below. Any process or language outside of the template informed consent language below will be subject to review and approval by the Compliance/Privacy Office

This policy does not apply to texting or emailing unsolicited information to prospective enrollees for recruitment purposes.

INFORMED CONSENT

A research team requesting approval to send non-secure email or texts must have a method to document and follow each individual's preference whether to receive non-secure communications.

Before sending or responding to a non-secure email message or text, the research subject must acknowledge an understanding of an agreement to accept the risks as communicated to them as well as any applicable charges

Template language that may be used in consents is as follows:

Email only:

The Boston Children's Hospital standard is to send emails securely by encryption. If you prefer, we can send you regular non-encrypted emails Unencrypted emails are sent directly to and can be opened from your personal email account. There is a

potential risk of loss of confidentiality when using unencrypted e-mail, as your email account is hosted by a third-party. Please be aware that e-mail communication can be intercepted in transmission or misdirected.

You acknowledge that you have been informed and understand that we cannot guarantee that regular non-encrypted email will be confidential. Please check below if you wish to receive non-encrypted emails.

_____ I wish to receive regular non-encrypted emails from the study team.

If, at any point, you no longer wish to receive unencrypted emails from us, you may indicate this by sending an email to [studyemail@childrens.harvard.edu] or calling this number [xxx-xxx-xxxx], and we will return to communicating via encrypted email.

Text message only:

We would like to offer you the option of receiving study information and updates via SMS text message. Text messages are sent directly to the personal phone number you have provided. Text messages are sent from study-related Boston Children’s Hospital phone numbers.

There is a potential risk of loss of confidentiality when using SMS text messages, as text messaging is hosted by a third-party. Please be aware that text messages can be intercepted in transmission or misdirected.

You acknowledge that you have been informed and understand that we cannot guarantee that text messages will be confidential. Please check below if you wish to receive text messages.

_____ I wish to receive text messages from the study team.

If, at any point, you no longer wish to receive text messages from us, you may indicate this by replying STOP to a study text message, sending an email to [studyemail@childrens.harvard.edu], or calling this number [xxx-xxx-xxxx], and we will no longer send you text messages.

Email and text messages:

The Boston Children’s Hospital standard is to send emails securely by encryption. If you prefer, we can send you regular non-encrypted emails. Unencrypted emails are sent directly to and can be opened from your personal email account.

We would also like to offer you the option of receiving study information and updates via SMS text message. Text messages are sent directly to the personal phone number you have provided. Text messages are sent from study-related Boston Children’s Hospital phone numbers.

There is a potential risk of loss of confidentiality when using unencrypted e-mail and text messaging, as both are hosted by a third-party. Please be aware that these communications can be intercepted in transmission or misdirected.

You acknowledge that you have been informed and understand that we cannot guarantee that regular non-encrypted email or text messages will be confidential. Please check below if you wish to receive non-encrypted emails or text messages.

- _____ I wish to receive regular non-encrypted emails from the study team.
_____ I wish to receive text messages from the study team.

If, at any point, you no longer wish to receive unencrypted emails from us, you may indicate this by sending an email to [studyemail@childrens.harvard.edu] or calling this number [xxx-xxx-xxxx], and we will return to communicating via encrypted email. If you no longer wish to receive text messages from us, you may also reply STOP to a study text message and we will no longer send study text messages.

This language may be included in informed consent documentation or an addendum to consent documents. The study team must propose a method to document and follow subject preference as well as tracking if subject changes their preference.

It is recommended the research team remind individuals at the time of enrollment and periodically throughout the study that non-secure email or texting should not be used to obtain medical or other emergency help or clinical care.

Approval of non-secure email or texts for research communication will be considered on a protocol-by-protocol basis.

Procedure

- When a research subject consents to receive non-secure email or texts, common identifiers such as names do not need to be excluded from messages. However, research teams must minimize the amount of protected health information sent electronically.
- Some communications may not be appropriate for non-secure email or texting, such as e.g., certain mental health conditions, sexually transmitted disease, HIV, illicit drug use illegal or abusive behaviors.
- Even if requested by an individual, certain specific information must never be sent via non-secure email or text, including Social Security numbers (SSN), credit card numbers, or other financial account numbers.
- Emails or texts must not be addressed / sent to more than one patient/research subject at a time, in order to safeguard the confidentiality of recipients.

- Emails must be sent using Boston Children’s email credentials only, not personal or non-BCH email addresses (i.e., research teams will not use Yahoo, G-Mail, etc.)
- Texts must be sent using Boston Children’s devices only, not personal devices. Texting is appropriate only for certain limited types of messages, e.g., short confirmatory messages about appointments, reminders to complete activities, requests to call a study team member.
- Research teams will not use unapproved third-party applications for texting, e.g., Doximity, Facebook Messenger, WhatsApp, Slack.
- For longer-term studies, it is recommended that research teams periodically re-confirm the accuracy of contact information for participants who have consented to receive non-secure email or texts.
- Researchers need to provide a plan for text communication which will include how people can opt out of receiving research text messages should they change their mind. This must include how the study will track and immediately honor each opt-out. The method to opt out must be described in each initial message sent (e.g. reply STOP if you no longer wish to receive these messages).

Email or text must not be used to send unsolicited information to prospective enrollees for recruitment. Research teams interested in non-secure alternatives to communicate with prospective enrollees should contact the Chief Compliance Officer to discuss options.

Violation of this policy may result in disciplinary or other remedial action, including termination of employment and removal from office.

Related Content

PHI Manual

[Minimum Necessary Requirements When Using or Disclosing PHI](#)
[Use of Secure Text Messaging Among Employees](#)

Information Security Program

[Acceptable Use of Computer and Network Resources](#)
[Email Policy](#)

Document Attributes

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