Agenda

1. Guidance on Communicating with Research Participants through Email or Text
2. IRBIS Updates related to Communicating with Research Participants through Email or Text
3. Other IRBIS Updates
4. CIRTification for community partners
5. PI Departure Form
Housekeeping

- Slides will be available on the OHRE website

- Recording will be available on OHRE website

- Please send questions through the Q&A box and we will answer as many questions as we can at the end of that topic
Communications with research participants through text or email
Objectives for Communications with research participants through text or email

• Review the revised “Communications with research participants through text or email” including the exception to the standard for unencrypted communication.

• Identify how requests for utilization of unencrypted communication can be made for human subject research

• Answer questions
How comfortable are you with the guidance around Unencrypted Communications from 2020?

Not at all 20%
Somewhat 54%
Very 26%
Have you used the Unencrypted Communications language in the consent or the Unencrypted Communications addendum to the consent form for any studies?

- Yes: 63%
- No: 18%
- Unsure: 19%
Transmission of Sensitive Information Standard

Standard

• Protected Health Information (PHI) and other Sensitive Information (SI) (data classified as Tier 2 or Tier 3 in the UNC-Chapel Hill Information Classification Standard) that is transmitted on behalf of the University by any Constituent must be encrypted in accordance with this Standard. This means either a secure connection (VPN, HTTPS, SFTP, etc.) between each endpoint or encryption of the file/information, unless an exception applies.
Transmission of Sensitive Information is exempted from this Standard if documented consent is obtained from the participant or someone with authority to consent on their behalf (e.g. patient or research subject consent). Other security controls, IRB or other research requirements, or privacy requirements may apply in your specific situation. This Standard does not take the place of guidance from those authorities.
## Examples of Encrypted vs Unencrypted communication

<table>
<thead>
<tr>
<th>Encrypted</th>
<th>Unencrypted</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-mails using the “Secure” functionality</td>
<td>E-mails not using the “Secure” functionality</td>
</tr>
<tr>
<td>“Messages” through an encrypted/secure platform approved by ITS</td>
<td>Direct SMS messages, e.g. cell phone to cell phone</td>
</tr>
<tr>
<td>Response</td>
<td>Percentage</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>------------</td>
</tr>
<tr>
<td>Yes</td>
<td>67%</td>
</tr>
<tr>
<td>No</td>
<td>8%</td>
</tr>
<tr>
<td>Mix of covered and not covered</td>
<td>17%</td>
</tr>
<tr>
<td>Unsure</td>
<td>8%</td>
</tr>
</tbody>
</table>
Is the study covered under HIPAA?

HIPAA's requirements apply to records of individually identifiable health information in the control of health care clearing houses, health plans, and health care providers that transmit any health information electronically to carry out financial or administrative transactions related to health care or health insurance. The individually identifiable health information in these records is called Protected Health Information ("PHI").
HIPAA covered studies

When communications must contain PHI

• Study team may communicate through unencrypted means AFTER the study participant has consented to such communication by executing the University’s template Consent for Unencrypted Communication.

When communications will NOT contain PHI

• Study team may communicate through unencrypted means without participants signing the Consent for Unencrypted Communication, including text and email for appointment reminders and general study reminders.
  • Communications must not include PHI or information about the participant’s health status and must include only the minimal amount of information necessary.
Non-HIPAA covered studies

Study team is permitted to communicate with study participants through unencrypted means (e.g. text, email) without the need for the Unencrypted Communication language.

Study team must limit the content of the communication to the minimum amount of information necessary to accomplish the intended purpose of the communication.

Study team should inform the participant that the communications are not encrypted and that there is the risk of loss of confidentiality for this communication method.

Participants should be given the option to receive encrypted communications throughout the life study (either in the consent form or verbally).
Researchers may use text and email for study recruitment. When texting or emailing unsolicited information to prospective enrollees for recruitment purpose, communications must not include information about the prospective enrollees’ health, PHI, PII, and must include only the minimal amount of information necessary.

Consent language for Unencrypted Communication is not needed for this purpose.

Note: Names and email or phone number are considered “minimally necessary” for recruitment.
Studies involving minors

When study communications DO NOT involve PHI, unencrypted communication with the minor is permitted once the parent/guardian agrees to this through the parental permission form and the minor agrees to this through the assent form.

When study communications MAY involve PHI, unencrypted communication with the minor is permitted once the study participant and their parent/guardian has consented to such communication by executing the University’s template Consent Language for Unencrypted Communication.
What can I text or email...

...through unencrypted communication prior to consent (non-HIPAA covered) or prior to Unencrypted Communications consent language (HIPAA covered)?

Simple Appointment Reminders
(ex: Reminder for your study appointment Monday at 2 pm)

Requests/Reminders to Complete Study Activities
(ex: Please complete your study diary tonight.)

Requests for participants to contact study team members.
(ex: Please call the study team at xxx-xxx-xxxx)
What can I NOT text or email...

...through unencrypted communication prior to consent (non-HIPAA covered) or prior to Unencrypted Communications consent language (HIPAA covered)?

- Results of testing or clinical outcomes
- Messages that contain disease status (or other sensitive information)
- Communications with minors prior to the parental permission and assent
- Other messaging that is not considered “minimally necessary”
Additional Info (FAQs)

• If texting or emailing **patients**, regardless of where their contact information originates from, researchers must request a partial HIPAA waiver in IRBIS.

• Initial contact through text or email should seek to establish a connection with the participant. (Ex:...There is a study you may be interested in. Please let me know a good time to contact you).

• Researchers should limit their recruitment contacts to a max of three attempts if no response.

• Researchers should not immediately send an attached consent form via email or text without a confirmation from the potential participant to do so.

• Recruitment emails and texts must be provided to IRB. The messages can contain patient name but should not contain any other PHI or PII such as DOB, address, diagnosis, etc.

• Participants must be able to request **encrypted** communications and still participate in the research.
Quick recap - If your study is covered under HIPAA

- Request a **partial HIPAA Waiver** in the IRBIS IRB application for screening purposes.
- If sending text messages or emails for recruitment purposes, ensure your initial recruitment messages do not contain any PHI, or other sensitive information that could link the person to a disease state or specific provider (such as PI name, name of medical department, study title, etc).
- Ensure the recruitment message contains a method for the individual to **opt out** of future contact for the study.
- If the individual responds favorably, **schedule a phone call** to discuss the study and only send the consent form once you have their **permission**.
Quick recap - If your study is covered under HIPAA

- If the individual agrees to participate and if there is the intent to email or text PHI or other sensitive information throughout the course of the study, the individual must sign a consent with the Unencrypted Communications language.
- The Unencrypted Communications is not needed if the communications through the study are limited to appointment reminders or reminders to complete study activities and will not contain PHI or other sensitive or identifiable data, but the methods of communications must be disclosed in the consent form.
- If a third-party communication platform is being used, the consent must reference the platform’s Terms of Service, and a security risk assessment may be needed.
- Participants may provide a new cell phone number or email address without the participant signing a new consent addendum, as long as the participant has given verbal permission and the researcher documents the verbal permission in the research record.
Quick recap - If your study is NOT covered under HIPAA

• If sending text messages or emails for recruitment purposes or after initial contact from the individual, do not include information that could link the person to a disease state or specific provider (such as PI name, name of medical department, study title, etc).
• Ask the individual if you can send them information about the study or **schedule a phone call** to discuss the study and only send the consent form once you have their **permission**.
• If the individual agrees to participate and if there is the intent to email personal information throughout the course of the study, the **consent form must state the risk** associated with this method of communication.
• If a third-party communication platform is being used, the consent must reference the platform’s Terms of Service, and a security risk assessment may be needed.
• Participants must be given the option to receive encrypted communications.

Note: The Unencrypted Communications language is not needed.
Communicating with Research Participants through Email or Text

It is the responsibility of all researchers and staff to be familiar with and to comply with the UNC-Chapel Hill Privacy of Protected Health Information Policy and Transmission of Sensitive Information Standard.

All communication methods used with research participants must first be approved by the IRB. To determine the applicability of this guidance, research teams must determine whether the study in question is regulated under the HIPAA Privacy Rule or if the study is not regulated under HIPAA. This is a study-by-study determination.

Guidance for HIPAA Covered Studies

HIPAA covered studies include studies that require access to patient/participant’s protected health information (PHI) through their medical record.

For studies in which there is access to the medical record for reviewing or recording of data but the study does NOT involve interaction or intervention with research participants (often referred to as secondary data studies or retrospective studies) or studies where study teams receive a full waiver of the HIPAA authorization and waiver of the informed consent process from the IRB, this guidance does NOT apply.
Do you find the new guidance to be clear?

- Yes: 65%
- No: 0%
- Unsure - need to read and think about: 35%
Questions?
IRBIS Updates Pertaining to Unsecure Communications
Section B.3: Subject Contact

- Moved Unsecure Communication from Section A.4 to B.3
- Added new question to collect information about use of email and text for ongoing communication during study participation
Non-sensitive information vs sensitive information/PHI

• Selection of communications will populate the appropriate template language to the consent builder
• This language will be in all consent templates:
  – Adult Consent, Parental Permission, Consent Addendum*, and Assents

*Note: There is no longer a separate Consent Addendum for Unencrypted Communication.
Messing with Minors

- Unsecure email and text messaging with minors is allowed after obtaining Parental Permission and assent of the minor.

**Please select one of the following:**

- I intend to text or email minor participants. Parent permission and minor assent are required prior to communicating directly with the minor participant.
- I do not intend to text or email minor participants.
Section B.1: Methods of Recruiting

- Updated methods to separate listserv announcements and email
- Added text messaging
- Free text response to describe how email and text will be used for recruitment
Other IRBIS Updates
New Submission Type: Protocol Exception

- Separate submission to collect Single Subject Exception and Continuation of study activities during lapse of approval
- Questions are the same as the Word form, but now they are tailored for the specific request
- These submissions can be submitted at any time regardless of whether there is another submission in progress.
The PI can designate a Co-investigator to certify on their behalf.

Alleviates delays that are caused by conferences, vacations, or other hurdles PI’s experience.
COI Pending Status

• New submission status
• OHRE review of the submission is complete and there is a COI determination that is pending review for Initial or Renewal submissions
• Once the COI determination is final, submission returns to analyst for action
  • Expedited, both Initial submissions and Renewals: IRB review is complete with COI review pending. Once COI determination is complete, analyst reviews determination and any requirements prior to final approval.
  • Full Board, Initial submissions: Pre-review is complete with COI review pending. Once COI determination is final, analyst reviews determination and any requirements, then places the study on meeting agenda. If the COI management plan requires a change of PI or other requirements, the submission may be returned for updating.
  • Full Board, Continuing Review submissions: Renewal submission will be reviewed by the Full Board. If COI review is still pending after board review AND there are not any pending stipulations, the study will be placed in “COI Pending Review”. Once determination is complete, analyst reviews determination and any requirements prior to final approval.
• Indication of COI Pending status on Investigator study view will be forthcoming
Website Update

• “Card” design on the main page and subsequent pages for easier navigation

• Links on the left side of page remain once a card is opened
For Researchers

This page is a collection of quick links most commonly used by researchers when navigating the research review process at UNC.

IRBIS
Online Submissions

CITI Program
Required Training

IRB Schedule
Sample Consent Forms

Reliance Agreements
The Review Process

Other Useful Resources

IRBIS Online Submission Guide: "how to" guides for navigating the IRBIS interface.
IRBIS Online Submission FAQ: answers to the most frequently asked questions about submitting studies through IRBIS.
Review Process FAQ: provides guidance on how to determine whether research requires IRB review; what first steps to take in preparing to the IRB; and the basic issues that must be addressed in the IRB.
CIRTification HSR Training
- IRBIS
  Online Submissions
  Sample Consent Forms

- CITI Program
  Required Training
  Standard Operating Procedures

Get Started

- For Researchers
- For Participants
- For Community Partners
- For IRB Members
CIRTification training does not replace CITI training for UNC-CH faculty, staff, and students.

**Overview**

CIRTification course covers a wide range of topics, including:

- **Introduction to Research**: The basic terminology, activities, and people involved in research and various ethical considerations.
- **The Institutional Review Board (IRB)**: The purpose of an IRB, people on the IRB, the process of submitting to the IRB, and the criteria that IRBs apply to the review of research.
- **Research History**: Past research abuses and the rules we have now to prevent future abuse. This module also introduces the goals of community engagement in research and the important responsibilities shared by community research partners.
- **Eligibility & Recruitment**: The importance of adhering to study inclusion/exclusion criteria and best practices identifying and recruiting research participants.
- **Informed Consent**: The key components of informed consent, the kinds of information included in the consent form, how to respond to participants’ questions about enrollment and withdrawal, and discussion of practical challenges and good practices.
CIRTification: Community Involvement in Research Training

https://training.ccts.uic.edu/course/CourseDetails.aspx?CourseID=3
Do you collaborate with any community partners that could benefit from the CIRTification HSR training?

(A) Yes 23%
(B) No 50%
(C) Unsure 27%
PI Separation Checklist

Meant for principal investigators (PIs) who are leaving or retiring from UNC and plan to:

- Close their study;
- Transfer their study to a new PI;
- Transfer their study to a new institution.

A departing PI should complete the PI Separation Checklist and email it to irb_questions@unc.edu at least 45 days before departure.
PI Separation Checklist

For Researchers

IRBIS
- Online Submissions
- IRB Schedule

CITI Program
- Required Training
- Reliance Agreements
- The Review Process

IRB and the Office of Human Research Ethics
- Contact Us
- About CHRE and the IRBs
- IRB Meeting Schedule
- IRBIS Online Submission
- Reliance Agreements
- SOPs and Guidance

Additional Documents and Forms
- Additional Documents and Forms: a collection of helpful documents and forms to use through:

New PI Separation Checklist!

CHRE and the IRB have created a new form for principal investigators (PIs) who are:
- Closing their study
- Transferring their study to a new PI
- Transferring their study to a new institution

A departing PI should complete the PI Separation Checklist and email it to irb_questions@unc.edu at least 45 days before departure.
Principal Investigator Separation Request form for IRB/OHRE

Email this form to irb_questions@unc.edu at least 45 days before departure

<table>
<thead>
<tr>
<th>SEPARATING EMPLOYEE INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI Name and Title:</td>
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<tr>
<td>Department/School:</td>
</tr>
<tr>
<td>Dept Chair Name:</td>
</tr>
<tr>
<td>Dept Admin Name:</td>
</tr>
<tr>
<td>PI New Contact Information:</td>
</tr>
<tr>
<td>Institution:</td>
</tr>
<tr>
<td>Email:</td>
</tr>
<tr>
<td>Phone:</td>
</tr>
<tr>
<td>Separation Date:</td>
</tr>
<tr>
<td>Last UNC-Ch day worked:</td>
</tr>
<tr>
<td>Date starting at new institution:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IRB Number, Title, and Sponsor</th>
<th>Study Status</th>
<th>Request</th>
<th>Action</th>
<th>IRB Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB#</td>
<td></td>
<td></td>
<td>□ Active – recruitment ongoing</td>
<td>□ Submit study closure via IRBIS</td>
</tr>
<tr>
<td>IRB Study Title:</td>
<td></td>
<td></td>
<td>□ Recruitment completed - data collection ongoing.</td>
<td>□ If there are active subjects on the protocol – include plan for orderly completion of research activities.</td>
</tr>
<tr>
<td>Study Sponsor:</td>
<td>□ Recruitment completed - data collection completed, data analysis ongoing.</td>
<td>□ Close study</td>
<td>□ Transfer to new UNC-CH PI</td>
<td>□ Identify new UNC-CH PI</td>
</tr>
<tr>
<td></td>
<td>□ Study completed.</td>
<td></td>
<td>□ Transfer to New Institution</td>
<td>□ Seek sponsor approval for new PI, if applicable.</td>
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<td></td>
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<td>□ Name of new PI:</td>
<td>□ Submit revised consent document, if applicable.</td>
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<td>□ Transfer to New Institution</td>
<td>□ Submit modification for PI change via IRBIS</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>□ Name of new PI:</td>
<td>□ Request a reliance agreement if will continue involvement at new institution</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>□ Complete new institution’s IRB requirements.</td>
<td>□ Submit study closure via IRBIS</td>
</tr>
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<td></td>
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Version 3.5.24.2014
Office for Human Research Ethics - UNC Chapel Hill
Contact Information

• Carley Emerson, Director: carley_emerson@unc.edu
• Celeste Cantrell, Associate Director of Operations: cdc@unc.edu
• General Questions: irb_questions@unc.edu, 919-966-3113
• Contact Information page: https://research.unc.edu/human-research-ethics/about/staff/
Resources

- https://research.unc.edu/human-research-ethics/standard-operating-procedures-sops/communicating-with-research-participants-through-email-or-text/
- Transmission of Sensitive Information Standard
- https://research.unc.edu/human-research-ethics/training-and-education-resources/cirtification/
- https://research.unc.edu/human-research-ethics/additional-forms/