

Tips on the Remote Consent Process

Contributing Authors:

NC TraCS Regulatory and Recruitment Programs, UNC ITS, UNC OHRE, and SOM CRSO

Please note: Guidance and regulations are subject to change

There are multiple methods that can be employed to obtain consent from research participants when the research team is unable to have an in-person meeting. Methods may range from mailing consent documents to potential participants and discussing the study and consent document via phone or secure web meeting, using an electronic consent platform, or waiving the requirement for signatures on the consent form. The type of research and risk level (e.g., greater than minimal risk/minimal risk, FDA-regulated), the unique situation of the participant, as well as your ability to fulfill the requirements to obtain informed consent will need to be considered when choosing a remote consenting method. As always, the method(s) chosen for consenting participants must be described in the IRB application and approved by the IRB before employed. If the method utilized is a change from what was initially approved by the IRB, it may require a modification.

For the purposes of this Tip Sheet, we use the term “Remote Consenting” to describe the various methods that can be used to obtain consent outside of an in-person meeting. Below we describe the most commonly used methods of remote consenting and provide guidance on how and when they can be utilized.

Telephone or Video Conferencing with a Paper Consent Form

This method involves the study team sending a participant consent documents, meeting with the participant by telephone or other audio/video conferencing platform (see below HIPAA-approved platforms), conducting the consent discussion, and having the participant sign and return the documents. This consent process is similar to how a participant is consented in-person, except the process is conducted using a format that allows for a conversation to be held remotely. This process can be used for any study in which the research can be adequately explained and understanding of the participant ensured via remote discussion. It should be noted that for participants who are hearing impaired, use of telephone consent may not be appropriate. If use of telephone consent has not previously been described in the IRB application, an IRB modification to approve the new method will be required.

The USPS is the preferred method to send consent forms to and from participants. Use of email for this purpose is only permissible if sent via a secured mechanism. Your unit’s IT data security liaison should be consulted to determine appropriate means of sharing documents and communicating with your participants.

HIPAA-approved video conferencing platforms

UNC Health and UNC IT Security have business associate agreements (BAAs) with the below platforms which permit sharing of PHI. The approved video conferencing platforms that are HIPAA-compliant include the sub-accounts of Zoom listed below, the UNC instance of Microsoft Office 365 Teams, the SOM account for WebEx, and UNC@Epic combined with American Well. The UNC data security designation provided by the IRB informs which platform can be used. **Consult your unit’s IT data security personnel to verify if the platform chosen is appropriate for your study.**

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- **SOM WebEx** – Preferred program for tier 3 data security designated studies or those collecting PHI.
- **UNC Instance of Office 365 Teams** – Can be used for tier 3 data security designated studies or to conduct video visits with UNC Health patients.
- **UNC@Epic combined with American Well** – Can be used for tier 3 data security designated studies or to conduct video visits with UNC Health patients.
- **Zoom HIPAA configured sub-account from UNC** – Can be used for tier 2 or tier 3 data security designated studies involving sensitive information or PHI if using one of the following sub-accounts:
 - School of Medicine
 - School of Dentistry
 - School of Nursing
 - Student Affairs Campus Health
 - College of Arts and Sciences

Please note: If PHI may be involved, the Zoom user creating the invitation needs to be in a HIPAA configured sub-account. Each sub account is managed by the School/Department IT unit. Contact the IT unit in your department to discuss how to be added to the sub-account. If you do not see a sub account that you would belong to, please have your IT unit contact UNC IT Security Office to assist in creating a HIPAA-configured sub account.

Note: UNC does not have a BAA with Doximity, thus it is not considered a HIPAA-compliant video conferencing platform and is not recommend for communicating with patients or research participants.

Remote Consenting and Re-Consenting by Phone or Web Meeting, Step by Step Process:

- Get approval from the IRB to obtain consent remotely by telephone using the IRB-approved paper consent documents. Describe the process in the consent procedures section of the IRB application, including whether physical copies of documents will be returned, how phone consent will be documented, and when in the process these will occur in relation to starting research activities.
- A witness may not be necessary, but if required by IRB regulations or best practice standards (e.g., when using an LAR), be sure the approved ICF includes a signature and date line for the witness (do not draw additional signatures lines on the ICF).
- Contact participant for potential recruitment in manner approved by IRB.
- If participant potentially agrees to hear more (review consent), send two copies of all consent documents (main, HIPAA, stored samples, etc.) to the subject by mail with a self-addressed, stamped return envelope.
- Call participant by telephone at agreed-upon time to discuss informed consent documents (ask that they read it ahead of time). Go through consent forms over phone or via appropriate videoconferencing platform in same manner as would be done in person (section by section, asking if there are questions, etc.).
- If a witness to the consent process is required, make sure the witness has been present during the entire consent discussion.
- The study team will document the consent discussion and any questions asked/answered in a progress note.
- If the participant agrees to participate, he/she is asked to sign and date one copy of the consent form. If a witness is also required, they too sign and date consent form on the appropriate lines.
- The participant returns by mail the signed copy of the consent documents to the research site in a self-addressed envelope and the blank versions are retained by the participant.

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- When the signed consent documents are received at the research site, the person who consented the participant signs and dates the forms, using the current date. The date difference is explained in the progress notes.
- The research can begin once the signed consent forms are received by the study team, unless otherwise approved by the IRB to begin prior to receiving a signed consent (dependent upon risk level and FDA regulations).
- Copies of the signed consent forms (by participant and study team) are then sent to participant.

Additional Considerations:

- When using a telephone or other video conferencing platform to conduct study calls or visits from your home or other off-campus location, please be sure to deactivate any in-home smart technology (such as Alexa or Google Home), as these devices may inadvertently capture or record private information.
- The use of an office phone to call participants is recommended, whenever possible; however, when not possible and study personnel must work from home, it is permissible to use a personal cell or home phone. It is also permissible for study teams to provide participants with their office number and forward those calls to their personal phones. Study teams may also choose to purchase a dedicated study cell phone.

Electronic Consent (e-Consent)

Electronic consent is another method for researchers to conduct the consent process with potential participants who are not physically present during the consenting process. With this process, an electronic consent platform (e.g., REDCap or other online application) displays the consent document(s) to the potential participant and signatures are obtained electronically (e-signature). When electronic consent is utilized, the consent process itself should still be designed to ensure that participants are adequately informed about the research, can easily ask questions and receive answers, and recognize that participation in the research is voluntary.

There are a number of ways in which an electronic signature (e-signature) might be documented and a variety of electronic platforms that can be used to obtain an e-signature. Examples include:

- Attaching a scanned handwritten signature or using an e-signature service;
- Typing one's name with an accompanying check box and statement of "By checking this box and typing my name below, I am electronically signing this consent form"; or
- Signing with a stylus or finger in an electronic platform

Federal regulations allow electronic signatures to document informed consent, so long as electronic signatures are legally valid within the jurisdiction where the research is being conducted. The research team must comply with all other consent requirements and participants must still be provided with a printed or downloadable version of the consent form to retain for their records. If properly obtained, an electronic signature can be considered 'original' for the purposes of recordkeeping (satisfy requirements in case of an audit). For FDA-regulated research of greater than minimal risk, the e-Consent platform utilized to obtain the subject's signature must be 21 CFR Part-11 compliant. **FDA-regulated research typically includes any study run under an IND or IDE, considered IND or IDE exempt, or in which an NSR determination was made for the device.**

It is strongly recommended to consult your unit's IT data security liaison to verify if the platform chosen for electronic consent is appropriate for your study from a HIPAA data

security perspective, 21 CFR Part-11 compliance requirement, and to confirm that UNC has a BAA in place with the specific vendor (as applicable).

Below are a few platforms used at UNC for electronic consent:

- **REDCap:** See <https://tracs.unc.edu/index.php/services/informatics-and-data-science/redcap>. For minimal risk studies in which no interaction with the study team is required (e.g., survey), REDCap can be used to convey the consent document and allow the participant to check a box that they agree to participate but no signature is obtained. Once the participant clicks on "I agree", the platform populates with the research activities such as a survey. In this situation, the study team must request the IRB waive the requirement for a participant signature.

For minimal risk studies in which the IRB requires a signature by the participant, **REDCap's eConsent Framework** can be used. With the eConsent Framework, the consent document populates for review by the potential participant, they click through checkboxes and/or radio buttons, and then e-sign by drawing their signature with their computer mouse or stylus. A best practice is to use Zoom along with the eConsent Framework. This allows the study team to talk to the participant and answer any questions prior to the participant signing electronically. When the participant is ready to sign the consent document, the study team member gives the participant control of the mouse to sign the form. The study team member then takes control of the mouse and signs the form immediately after the participant. Once both signatures are on the consent forms, a copy can be downloaded and/or printed. **As, REDCap is HIPAA compliant, it can be used to collect PHI in a tier 3 data security designated studies.**

UNC's version of REDCap is not certified as 21 CFR Part-11 compliant and thus it cannot be used for FDA-regulated studies of greater than minimal risk. If REDCap is used for an FDA-regulated study, you will need to print the eConsent document from the online consent platform and have the study participant sign and date it with a wet signature.

- **Qualtrics** (<https://software.sites.unc.edu/qualtrics/>): Qualtrics is a powerful [online survey tool](#) available to all UNC Chapel Hill faculty, staff, and students, for UNC-related projects. It allows you to build complex surveys that fulfill a variety of research needs. You can use this tool to build surveys, distribute surveys and analyze responses, all from one convenient online location. Qualtrics can be used to obtain consent in minimal risk studies that do not require interaction with the study team or when the requirement for a participant's signature is waived. UNC Healthcare is not covered by the UNC Chapel Hill Qualtrics license. **UNC's version of Qualtrics is HIPAA compliant.** Qualtrics is not certified as 21 CFR Part 11 compliant and cannot be used for FDA-regulated research that is greater than minimal risk.

*Please note, use of email to send consent forms to and from the participant is only permissible if sent via a secure mechanism. Your unit's IT data security liaison should be consulted to determine if email is an appropriate means of sharing documents and communicating with your participants. For your unit's IT data security liaison, see <https://safecomputing.unc.edu/data/information-security-liaisons/isl-list/>.

FDA-Regulated Studies of Greater than Minimal Risk

If a fully electronic (online) consent platform will be utilized to obtain consent in an FDA-regulated study of greater than minimal risk, the platform must be certified as 21 CFR Part-11 compliant. An alternative, if the online consent platform is not 21 CFR Part-11 compliant or considered acceptable for regulatory or legal reasons, is to print the eConsent document from the online

consent platform and have the study participant sign/date with a wet signature. **FDA-regulated research generally includes any study run under an IND or IDE, considered IND or IDE exempt, or in which an NSR determination was made for the device.**

A platform that is 21 CFR Part-11 compliant for use in FDA-regulated research is not currently available at UNC for broad use. The School of Medicine is currently working to purchase and implement a tool that can be used to obtain signatures for FDA-regulated studies requiring Part-11 compliance. If you are working on studies conducted outside the School of Medicine and would like to explore options for obtaining electronic signatures that are compliant with CFR Part-11, please contact your IT Data Security Liaison to discuss.

Before an online platform can be used at UNC, a risk assessment must be completed by the UNC Information Security Office (ISO) and Privacy Office to determine if it meets UNC's security and privacy policies. A contract and BAA with the company may also be required. Please contact the UNC ISO and UNC Privacy Office prior to choosing to use an online platform.

Consent Process for Subjects in Isolation Areas and FDA-Regulated Research

The UNC OHRE has worked with the Office of Clinical Trials and the Clinical Trial Quality Assurance (CTQA) program to develop an algorithm or decision tree that can be used to determine what consent processes are available to participants who are in isolation and being offered participation in research that is greater than minimal risk and FDA-regulated. The algorithm and consent form checklist may be viewed at <https://research.unc.edu/2020/03/10/ohre-irb-covid-19-update/>.

UNC Consent Process for Isolation Areas

When a signed informed consent document cannot be safely collected from the participant's location and included in the study records (e.g., a COVID patient's isolation room), it may be possible to use an attestation checklist to document the consent process. This consent process is permissible for all studies including FDA-regulated ([FDA March 2020 Guidance updated July 2 2020](#)) for the duration of the public health emergency in relation to COVID-19. A modification to utilize this process does not need to be submitted to the IRB. However, the OHRE does recommend utilization of the UNC attestation checklist (see Appendix 2) to document that the proper steps are followed.

In utilizing this method to obtain informed consent, an observer/witness who is physically present with the participant must be included in the consent process. The observer/witness is ideally an independent individual not associated with the study, but if not feasible, it can be a study staff member different than the individual conducting the consent process. The observer/witness brings a paper consent document, HIPAA Authorization form and ink pen into participant's room. The study staff or investigator obtaining informed consent do not need to be physically in contact with the subject and can use a phone, FaceTime, WebEx or other IT-approved mechanism to discuss the consent forms and HIPAA authorization and answer questions from the participant. An attestation checklist is used to document the consent process, including: versions of the forms reviewed and signed, the time of informed consent, and signatures of the witness and study team member obtaining consent. The subject signs the consent document(s) and HIPAA forms and retains a copy in the isolation room. A separate consent form located outside the participant's room is signed by the study staff that obtained consent and the witness. For the step by step process, see <https://research.unc.edu/files/2020/03/UNC-Consent-Process-for-Isolation.pdf> and the guidance below titled **UNC Consent Process for Isolation Areas** (Appendix 1).

Hints for completing the UNC IRB application section on consent:

- If mailing consent forms to review the study over the phone and have the participant sign and return them to the study site, describe this in section D.1 (section about consent process).
- If doing electronic consent, in section D.2 (waiver of written documentation of informed consent), check YES for “waiver of any aspect of written (signed) documentation” and choose the approach you will use in the list that populates. The list includes “online CF with electronic agreement.”
- Clearly describe the consenting process in the consent procedures section of the IRB application, including if physical copies will be returned, how phone consent will be documented, and when in the process these will occur in relation to starting research activities. If using an electronic platform, provide information about the platform and how you will ensure subject understanding and answer questions.

Appendix 1



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UNC Consent Process for Isolation Areas

This checklist and form are meant to serve as an aide when alternate consent documentation processes are required for studies when a signed informed consent document cannot be collected from the subject's location and included in the study records (e.g., a COVID patient's isolation room). This consent process is permissible for all studies including FDA-regulated ([FDA March 2020 Guidance](#)) for the duration of the public health emergency in relation to COVID-19. A modification to utilize this process does not need to be submitted to the IRB. However, the OHRE does recommend utilization of the checklist and that the documentation steps below are followed.

Please note, utilizing this process is never to be considered the standard consent process and an adequate reason for utilization (e.g. spread of COVID in COVID patient's room) must be documented in the utilization checklist below.

Individuals Involved:

- Subject/Legal Authorized Representative- If the subject is unable to appropriately participate or is incapable of providing consent and a LAR is not available please refer to alternate emergency consent procedures (Consent Process Algorithm for In-Patient Subjects and FDA Regulated Research).
- Study Staff-Individual obtaining consent- **does not need to be physically located with the subject.**
- Observer/witness (e.g. ideally an independent individual not associated with the study, but if not feasible a study staff member different than the individual conducting ICF process)- **does need to be physically present with the subject.**

Documentation Needed

- Signed Consent Form and HIPAA authorization forms that stay with the subject and documented in Attestation/Research Record.
- Attestation filled out below completely and placed in research record.
- Consent signed by study staff that obtained consent and witness for research record

The following **attestation checklist** will be completed by the study staff member conducting the ICF process.

Appendix 2

Attestation Checklist		
IRB #:		
Study title:		
Subject ID:		
Witness/Observer Name:		
Study Staff/Consenter Name:		
Reason for Utilizing Process _____		
Y	N	Consenting Process
<input type="checkbox"/>	<input type="checkbox"/>	1. Observer/witness brought paper ICF, HIPAA Authorization & ink pen into subject’s room.
<input type="checkbox"/>	<input type="checkbox"/>	2. Observer/witness provided their full name, and confirmation to the study staff member that they understand their role as a witness/observer of the ICF process .
<input type="checkbox"/>	<input type="checkbox"/>	3. Observer/witness confirmed to study staff member via phone, Zoom, FaceTime, WebEx or other IT approved mechanism (circle utilized mechanism) the version of ICF being used, version noted by study staff and the HIPAA Authorization form is present. <ul style="list-style-type: none"> • ICF Version/date: _____ HIPAA Auth. Form: _____
<input type="checkbox"/>	<input type="checkbox"/>	4. Investigator discussed consent forms with the subject and answered all of the subject’s questions. <ul style="list-style-type: none"> • Noted by study staff: _____
<input type="checkbox"/>	<input type="checkbox"/>	5. Investigator discussed consent forms with the subject and answered all of the subject’s questions. <ul style="list-style-type: none"> • Noted by observer/witness: _____
<input type="checkbox"/>	<input type="checkbox"/>	6. Subject signed the informed consent form, confirm same ICF Version as #3 and HIPAA Authorization Form. <ul style="list-style-type: none"> • ICF Version/date: _____ HIPAA Auth. Form: _____
		• Time consent obtained: __: __ : __ (24-hour)
<input type="checkbox"/>	<input type="checkbox"/>	7. Investigator obtained written informed consent before any study procedures took place.
<input type="checkbox"/>	<input type="checkbox"/>	8. Subject retained copy of signed informed consent form and HIPAA Authorization form.

Checklist complete. Informed consent for participation in research obtained. Signatures to be added below. Completed checklist and ICF and HIPAA Authorization signed by witness as well as study staff who obtained consent to be filed in subject’s research record.

Signature of **study staff who obtained consent**

Date

Signature of **observer/witness**

Date

*The checklist is adapted from multiple sources including NIAD and Advarra.