Conducting Research Remotely:

Ensuring Participant Privacy, Confidentiality, and Other Considerations for Adapting Research During COVID-19

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Overview

- Current ORARC COVID-19 Research Operations
- Remote Research Procedures
- Remote Informed Consent
Current ORARC COVID-19 Research Operations


- Requesting priority for COVID-19 Research
- Modifications to Existing Research
- International Research
- Remote Research Technology
  - https://security.harvard.edu/collaboration-tools-matrix
- Tips/Resources
- Etc.
Converting In-Person to Remote Research Procedures

• Face-to-face Interviews
  – Zoom
  – Phone Calls

• Home Visits
  – Zoom
  – Logs/Journals

• In person questionnaires/surveys
  – Online (e.g., Qualtrics, RedCap, etc.)
  – Zoom interview
Converting In-Person to Remote Research Procedures

• Non-invasive specimen collection
  – Self-specimen collection (e.g., urine, stool, hair, nail, saliva, etc.)

• Observational clinical visits
  – Zoom, etc.

• Measurements
  – Self-measurements via Zoom, etc.
Remote Informed Consent

*When is remote consent more appropriate and/or efficient than an in-person consent process?*

- When conducting an online survey
- To expand enrollment and sample selection
- When the researchers and participants are in different physical locations
- Where it is safer or more convenient to the participant
Remote Informed Consent

✓ Remote consent is allowable by the federal regulations!

What are the regulatory requirements?

• Consent to participate in research **must be obtained from participants** by the investigator.

• The consent form **must include all elements** of informed consent required by HHS and/or FDA regulations. (e.g. purpose, description of research, risks, contact info, etc)

• Consent information must be in **language understandable** to the participant.

• Consent information must be conveyed in a manner that **minimizes coercion or undue influence** regarding their decision to participate.

• Prospective participants must be **provided with the information** that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to **discuss** that information with investigators.

• Appropriate **written documentation** of consent must be obtained (where applicable).
Remote Informed Consent

The informed consent process has two components. Both must be considered when planning remote consent:

1. The Consent Process
2. Documentation of Consent
Remote Informed Consent – The Consent Process

A refresher:

• The informed consent process is the critical communication link between the participant and a researcher.

• It begins with the initial approach by a researcher to a prospective participant (e.g. recruitment flyer, email, Facebook post) and continues throughout the lifecycle of the study until the participation has been completed.

This is why we call it a PROCESS, because it’s ongoing!

It’s not just this:
Remote Informed Consent – The Consent Process

The entire informed consent process can take place remotely. The investigator must ensure several things:

1. Consent is still conducted as a process/conversation (when appropriate), and the participant experiences a consent process as close to what it would be like in-person as possible.

2. If no direct interaction with a participant will occur (e.g. online survey), consent can be obtained via an embedded consent form which states that completion of the survey indicates the participant’s consent.

3. The participant should have ample time and opportunity to review the consent form in advance, and then discuss it and ask any questions together with the investigator.

4. The IRB-approved consent form is used and the IRB-approved Research Protocol includes an accurate description of the entire consent process.

5. The physical location of the investigator and participant can be any place convenient to them (e.g. at home) but must provide adequate space for privacy and confidentiality.

6. The remote environment can be virtual/online or on the phone. Video conferencing (e.g. Zoom) is allowable. The participant must be informed in advance if the consent process will be audio and/or video recorded (i.e. at the time of recruitment or screening).
Remote Informed Consent – Documentation of Consent

The IRB expects informed consent is documented with the use of a consent form approved by the IRB and signed by the participant.

...UNLESS written documentation of consent (signature) is waived or not required by the regulations. More in a moment!
Remote Informed Consent – Documentation of Consent

• If written documentation of consent is required, the participant can sign the consent during the remote consent process, as witnessed by the investigator, and it can be returned via one of the methods noted below.

• The regulations consider written documentation of consent to include electronic format.

• To obtain a signature remotely, investigators have several options:
  – Using a digital consent form:
    • Collect a signature on an e-consent document with fillable text fields (e.g. PDF) that is sent to and from the participant via secure email/file transfer.
    • The entire consent document can be provided on a secure online platform with an e-signature collected at the end (e.g. an online survey using the Signature option in Qualtrics).

  – Using a paper consent form sent to a participant in advance of the consent discussion:
    • Collect a signature using a picture of the signature sent via secure email/file transfer.
    • Collect a scanned signed copy of the signed form via secure email/file transfer.
    • Collect a signed hard copy via snail mail. Postage should be provided by investigator. In this case there should not be a place for the researcher to sign and date on the form itself. It is recommended to use a consent or enrollment log to capture this information instead.
    • Collect a signed hard copy via fax.
Remote Informed Consent – Documentation of Consent

• If written documentation of consent is not required per the federal regulations, researchers can request a waiver of documentation of consent and obtain only verbal consent remotely via phone or video.

• A waiver of documentation is appropriate when:
  – a signature would be the only record linking back to the participant’s identity, and/or
  – the research is minimal risk and the procedures would not require written consent outside of the research context (e.g. online-only interactions)

• Exempt human subjects research does not require:
  – written documentation of consent
  – a request for a waiver of written documentation
HLC IRB Remote Consent Requirements

• All consent procedures (remote or otherwise) must be described in the Research Protocol.

• Any remote technology used in the consent process (e.g. email, video applications, survey software) must comply with the Harvard Research Data Security Policy.
  – A Modification to add remote technology may require IT security review.

• Consider including a method to verify that the person providing consent is the participant (e.g. verification of state identification, other identifying documents, use of personal questions, and/or visual methods).

• Researchers must maintain regulatory documentation on remote consent procedures. Consider using QIP’s Study Management Tools (regulatory binder tabs, consent log) for this purpose.
Reference & Resources

• HLC IRB Website: https://www.hsph.harvard.edu/orarc
• HLC IRB Investigator Manual: https://www.hsph.harvard.edu/regulatory-affairs-and-research-compliance/investigator-manual/
• HLC IRB Tip Sheets: https://www.hsph.harvard.edu/regulatory-affairs-and-research-compliance/irb-tip-sheets/
• HLC IRB Decision Tool: http://bit.ly/2LBTcYx
• ESTR Support Site: http://estrsupport.fss.harvard.edu

QUESTIONS?