ORARC Tip Sheet:
REMOTE INFORMED CONSENT

Purpose:

There are scenarios in which researchers may find that a remote informed consent process is more appropriate and/or efficient than an in-person one. For example: when conducting an online survey, when the researchers and participants are in different physical locations, or where it is safer or more convenient to the participant, etc. Remote consent is permissible by the federal regulations that govern human subjects research. The purpose of this tip sheet is to provide guidance on how to conduct a remote informed consent process.

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. Consent information must be in language understandable to the participant and conveyed in a manner that minimizes the possibility of 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, see #6-7 below).

Remote Informed Consent Processes:

The entire informed consent process can take place remotely, where the investigator and participant are not physically in the same location, however the investigator must ensure several things:

1. Consent is still conducted remotely 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.
    a. For an online survey where no direct interaction with the participant will occur, it is permissible to construct the survey with an embedded consent form at the beginning whereby completion of the survey indicates the participant's consent. In this example, an in-person consent conversation may not be required.
2. 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.
3. The IRB-approved consent form is used and the IRB-approved Research Protocol includes an accurate description of the entire consent process.
4. 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.
5. The remote environment can be virtual/online or on the phone. Video conferencing (e.g. Zoom) is allowable. Regardless of the environment, 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). Note: MA State Law requires disclosure of audio recording. See Resources below for more information.
6. If written documentation of consent (i.e. signature) is required, the participant can sign the consent during the remote consent process and it can be returned via one of the methods noted below. The signed and returned consent form should include *all* pages, not just the signature page. If written documentation is obtained remotely, the investigator must provide the person signing the consent form with a copy of the consent document unless this requirement is waived

by the IRB. Copies can be sent via secure email, snail mail, hyperlink for download on a secure website, etc. Enough copies should be provided that, if the participant is expected to return a hard copy, a second copy remains in their possession for their reference. If participants do not have access to a printer and cannot sign digitally, the investigator should provide a hard copy via snail mail.

a. The regulations consider written documentation of consent to include electronic format. To obtain an electronic signature remotely, investigators have several options:
    i. Using a digital consent form/platform:
        1. 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). Should this method be used, it is preferable to use a platform that is easy to navigate, allows the participant to stop, save, and/or move forward and backward within the form. Electronic strategies such as hyperlinks or checkboxes can be used to provide participants with supplemental information or to confirm they have made explicit selections required within the document (e.g. specific consent to audio record an interview if this is not a required part of the study's eligibility criteria).
        2. 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.
    ii. Using a paper consent form sent to a participant in advance of the consent discussion:
        1. Collect a picture of the entire consent form (all pages + signed signature page) sent via secure email/file transfer.
        2. Collect a scanned signed copy of the entire consent form. Scans can be created with a digital document scanner or mobile app (e.g. Genius Scan), then sent via secure email/file transfer.
        3. Collect a signed hard copy of the entire consent form 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.

7. 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, nor a request for a waiver of written documentation. It is recommended that a log entry be used to capture the date that informed consent was obtained, the name or initials of the researcher obtaining consent, and verification that a written copy of the consent was provided to the participant.

FDA Regulatory Requirements:

In addition to the HHS regulatory requirements described in the section above, there are additional remote consent requirements when the research study is *also* FDA-regulated. The FDA regulates research on human subjects that involves drugs (human drugs and therapeutic biologicals), biological products (products derived from living sources), medical devices (instruments/products used for treating or diagnosing disease), and food additives.

There are three scenarios that researchers conducting FDA-regulated research must adhere to. They are not mutually exclusive; one, a combination, or all may apply.

1. FDA-regulated research that employs an **electronic informed consent (eIC) process**. Per the FDA, eIC "refers to the use of electronic systems and processes that may employ multiple electronic media, including text, graphics, audio, video, podcasts, passive and interactive Web sites, biological recognition devices, and card readers, to convey information related to the study and to obtain and document informed consent." For these projects, the FDA requires verification of participant's identity during the consent process. Note that using an online video or audio conferencing program (e.g., Zoom) to conduct the consent process is not considered eIC if it is being conducted in real time.
2. FDA-regulated research that **maintains records in electronic format** in place of, or in addition to, paper format. This primarily applies to consent forms and consent documentation, but could apply to any research records (e.g. records in a database). For these projects, the FDA requires Part 11 compliance for electronic records. Part 11 system compliance and validation should be checked with the researcher's School-based Information Security Officer.
3. FDA-regulated research that **utilizes electronic signatures** to document consent/assent. For these projects, the FDA requires Part 11 compliance for electronic records and verification of participant's identity for electronic signatures. Part 11 system compliance and validation should be checked with the researcher's School-based Information Security Officer.

HLC IRB Requirements:

- All consent procedures (remote or otherwise) must be described in the Research Protocol. Consider whether the research plan can benefit from outlining both remote and in-person consent procedures to maximize flexibility.
- Any remote technology used in the consent process (e.g. email, video applications, survey software) must comply with the Data Security Level assigned by the IRB. If deemed Sensitive, the Level must be reviewed/certified by IT via the Data Safety System. All research data collection must adhere to the Harvard Research Data Security Policy. Researchers should consult their School-based Information Security Officer with questions.
- Consider including a method to verify that the person providing consent is indeed the participant (e.g., ask to see state identification/driver's license or other identifying documents, use personal questions, and/or biometric methods).
- Researchers must maintain documentation on remote consent procedures. Consider using QIP's Study Management Tools (e.g., enrollment log or consent log) for this purpose. The IRB also strongly recommends retaining complete communication threads between investigator and participant (e.g. email) that relate to the remote consent process within the studies' participant files.

Regulatory Resources:

- HHS Regulations 45 CFR §46 – Protection of Human Subjects
  - §46.116 - General requirements for informed consent
  - §46.117 - Documentation of informed consent
- FDA Regulations 21 CFR §50 – Protection of Human Subjects
  - §50 Subpart B - Informed consent of Human Subjects
  - §11 Subchapter A - Electronic Records; Electronic Signatures
  - Guidance for Industry - Part 11, Electronic Records; Electronic Signatures
- 2016 HHS & FDA procedural guidance regarding the use of electronic informed consent
- Massachusetts General Law Ch. 272, § 99 - Interception of wire and oral communications

Additional ORARC Toolkit Materials:

- HRP-103-HLC Investigator Manual
- HRP-410-CHECKLIST-Waiver or Alteration of Consent Process
- HRP-411-CHECKLIST-Waiver of Written Documentation of Consent
- HRP-502-HLC Adult Consent Form Template
- HRP-502-HLC Adult Surrogate Consent Form Template
- HRP-502-HLC Child Assent Form Template
- HRP-502-HLC Consent Template for HIPAA-covered entities
- HRP-502-HLC Parental or Guardian Permission Template
- HRP-502-HLC Short Form Consent Template
- HRP-502-HLC Exempt Human Research Consent Script Template
- HRP-502-HLC Debriefing Statement
- HRP-317-WORKSHEET-Short Form of Consent Documentation
- HRP-012-SOP-HLC-Observation of the Consent Process
- HRP-090-SOP-HLC-Informed Consent Process for Research
- HRP-091-SOP-HLC-Written Documentation of Consent
- HRP-602-QAQI TOOL-Regulatory Binder Tabs ORARC - ALL