UK Office of Research Integrity Best Practices for Remote Informed Consent

Circumstances such as national disasters or public health emergencies require consent to be obtained remotely. Applicable regulations and best practices must be followed to ensure the process is effective and documentation is valid. The proposed remote process must be prospectively reviewed and approved by an Institutional Review Board (IRB).

Methods other than an “in person” consent discussion may be acceptable if those methods allow for an adequate exchange of information and documentation, and a method to ensure that the signee of the consent form is the person who plans to enroll as a subject or is the legally authorized representative (LAR) of the subject.

The following guidance outlines requirements and best practices for remote consent of subjects unable to travel to the research site and those isolated for infection control reasons. Additional guidance regarding requirements specific to FDA-regulated research are included (i.e., FDA electronic records 21 CFR part 11).

Note: The steps described below should not be confused with the IRB determination that a minimal-risk protocol meets the criteria for a waiver of informed consent or waiver of consent documentation. The process is an alternative for obtaining valid consent (and documentation of that consent) when a face-to-face process would normally be conducted but, due to extenuating circumstances, is not possible. All required elements and general regulations apply, including alterations to accommodate vulnerable or special populations (e.g., impaired consent capacity, non-English speaking, minors, etc.).

Remote informed consent for prospective subjects unable to travel to the site due to illness or travel restrictions:

Remote Consent Format

- Electronic Consent - If using an electronic consent document and process, follow the guidance summarized in the ORI Outline of FDA Guidance for Industry: Use of Electronic Informed Consent in Clinical Investigations with attention given to system security, e-signatures*, and the provision of subject copies.

- Hard Copy (Paper) Consent - If using a hard copy paper consent, provide two copies of consent document to the potential subject and/or legally authorized representative (LAR) in advance. The documents may be delivered by personnel in contact with potential subject or sent via secure method (e.g., postal mail, UK email, fax). See below for process alterations in cases where the potential subject is in isolation or may have a communicable condition.
Remote Consent Process

The Investigator or study personnel authorized to obtain consent contact the potential subject/LAR by phone or video conference. Refer to the UK IT Cybersecurity Best Practices When Working Remotely.

- UK Healthcare has a HIPAA compliant contract with Zoom for secure videoconferencing. Go to [ukth.zoom.us](http://ukth.zoom.us) to set up an account with your linkblue ID and password.
- **UK Telehealth** may provide resources for UK Healthcare.
- Select patient rooms in the UK Hospital are equipped with smart televisions.
- When using sources outside of UK Healthcare, be aware that the platform’s terms of use would apply and may need to be referenced in the consent document.

Ask permission to discuss the study opportunity with the potential subject. Before beginning the discussion, ask open-ended questions to assess health literacy, familiarity with research concepts, motives, and initial concerns. Provide any background information needed to clarify concepts (e.g., difference between voluntary research consent and clinical consent).

Once the potential subject has a copy of the consent in front of him/her, invite questions during and after the discussion. Introduce the study beginning with the key information which focuses on the study purpose, key reason(s) a reasonable person would choose to participate or decline participation, and alternatives that would influence that decision.

Use clear speech/language to review the informed consent and summarize key concepts. Do not just read the document to the potential subject.

Stop frequently to highlight key points and ask teach-back questions to assess understanding and clarify misunderstandings.

Signatures & Documentation

After the detailed consent has been reviewed and all questions answered, the investigator or study personnel are confident that the subject or LAR understands and appreciates the voluntary nature of the research, instruct the subject or LAR to sign and date both copies of the consent document (use flags or highlight the correct signature line(s)).

Provide a secure means for the subject or LAR to return one of the signed consent forms to the investigator (e.g., postal mail, fax, scanned PDF or photographic image of the signed consent form sent by fax or email).
Instruct the subject or LAR to retain the remaining signed copy for their records.

Do not initiate study procedures until the subject's signed consent document is received.

Once received, the investigator or study personnel who provided the consent discussion should print his/her name on the line labeled “name of [authorized] person obtaining informed consent.” Enter the current date (i.e., the date the investigator/study personnel sign it, do not backdate if the signature date is later than when the subject or LAR signed).

Retain a copy of the signed consent with the subject's case history.

Document in a separate note that informed consent was obtained prior to participation in the study. Include details in the note regarding the process, such as:

- Date (prior to participation);
- Individuals present (study personnel, witness, subject, others);
- methods (phone/videoconference);
- discussion points (questions, clarifications, methods for ensuring understanding); and
- method by which and the date the signed document was received.

See *Detailing the Informed Consent Process in the Subject’s Source Document* on the ORI Quality Improvement Program Resource page.

Remote consent for potential subjects who have a contagious condition, are in medical isolation, or where research involves communicable condition:

Infection control measures, such as isolation in a negative pressure room, present specific challenges including possible staff exposure, the need for personal protective equipment (PPE), and the potential destruction of paper forms or electronic devices considered to be contaminated once introduced into the environment.

See Remote Consent Process section above for best practices in conducting a consent conference.

Remote Consent Format, Signatures, & Documentation

Electronic:

If the technology is available (e.g., potential subject’s personal phone, smart TV), electronic methods of obtaining informed consent should be considered. Follow the guidance summarized in the ORI Outline of FDA Guidance for Industry: Use of Electronic Informed Consent in Clinical Investigations with attention given to system security, e-signatures*, and the provision of subject copies.
Hard Copy (Paper) Consent:

When it is not possible to obtain informed consent electronically, the Food and Drug Administration (FDA) recommends the following steps:

1. An unsigned consent form is provided to the patient (or if applicable, the LAR) by a healthcare worker who has entered the room.

2. If direct communication with the patient in isolation is not feasible or safe, the investigator (or designee) obtains the patient’s phone number and arranges a three-way call or video conference with the patient, an impartial witness and, if desired and feasible, additional participants as requested by the patient.

3. To ensure that patients are approached in a consistent manner, a standard process should be used that will accomplish the following:
   - Identification of who is on the call
   - Review of the informed consent with the patient by the investigator (or designee) and responses to any questions the patient may have
   - Confirmation by the witness that the patient’s questions have been answered
   - Confirmation by the investigator that the patient is willing to participate in the research/trial and that the patient signs the consent document while the witness is listening on the phone
   - Verbal confirmation from the patient that he/she would like to participate in the research/trial and that he/she has signed and dated the informed consent document that is in his/her possession

4. If the signed informed consent document cannot be safely collected from the patient’s location and included in the study records, the FDA considers the following two options acceptable for providing documentation that the patient signed the informed consent document:
   - A dated written attestation from the witness who participated in the call and the investigator that the patient confirmed that he/she agreed to participate in the study and signed the informed consent.
     OR
   - A photograph of the informed consent document with written attestation from the person entering the photograph into the study record that states how the photograph was obtained and that it is a photograph of the informed consent signed by the patient.

5. A copy of the informed consent document signed by the investigator and witness should be placed in the subject’s research/trial source documents with a notation by the investigator of how the consent was obtained (e.g., telephone call). The research/trial record at the investigational site should document how it was confirmed that the patient signed the consent form (i.e., either using a dated written attestation by the witness and investigator or a photograph of the signed consent). The note should include a statement of why the informed consent document signed by the patient was not retained (e.g., due to potential contamination of the document by infectious material).
*Requirements for electronic signatures:

All research must ensure the method of e-signature (digital, signature pad, fingerprint & date), is the legally binding equivalent to the traditional handwritten signature. The University of Kentucky Center for Clinical and Translational Science (CCTS) has shared a video demo of their process for obtaining remote consent of UK COVID-19 Biobank participants using REDCap.

In addition, FDA-regulated research must comply with requirements outlined in FDA regulations at 21 CFR part 11 (“Part 11”). FDA studies must document that commercial off-the-shelf software is Part 11 compliant. The FDA MyStudies app is available to investigators as a free platform to obtain informed consent securely from patients for eligible clinical trials when face-to-face contact is not possible or practical due to COVID-19 control measures. Click for detailed instructions.

If the potential subject is mentally competent but physically impaired:

A person who is physically challenged (e.g., physically unable to talk or write, has hearing or visual loss) can enroll in a study if study personnel provide accommodations for the impairment and the subject is mentally competent and able to affirmatively signal his/her informed consent. A witness to the process is needed if the subject is unable to read the informed consent document.

The records relating to the study must include documentation of the informed consent process (i.e., who, how, when, where). A description of the specific means by which the subject communicated his/her agreement to take part in the research and how questions were answered must be included in the subject’s case history.

Source: FDA 2020 Guidance Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency