

UK Office of Research Integrity Best Practices for Remote Informed Consent

When circumstances require consent to be obtained remotely, best practices must be followed to ensure the process is effective and documentation is valid.

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 signer of the consent form is the person who plans to enroll as a subject or is the legally authorized representative of the subject.

Modifying an existing protocol in response to a pandemic:

Per federal regulations, an investigator can make changes to a protocol to eliminate apparent hazards to research participants without first obtaining IRB approval. In response to the COVID-19, research protocols may be temporarily modified without submitting a Modification Request to the IRB. The change may apply to a single participant or all participants enrolled in the research study.

New research with communicable conditions:

Include remote process proposal with initial IRB submission. Process must be prospectively reviewed and approved by an Institutional Review Board (IRB).

Note: The steps described below should not be confused with the IRB finding that a protocol meets the criteria for a waiver of consent or consent documentation. It is an alternative for obtaining valid consent and consent documentation when a face-to-face process is not possible. All [required elements and general regulations](#) apply, in addition to alterations to accommodate [vulnerable or special populations](#) (e.g., impaired consent capacity, non-English speaking, minors, etc.).

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1. If using an electronic consent document and process, follow guidance summarized in the [ORI Outline of FDA Guidance for Industry: Use of Electronic Informed Consent in Clinical Investigations](#) with attention to system security, e-signatures, and provision of subject copies.
 2. If using hard copy paper consent, provide two copies of consent document* to potential subject and/or legally authorized representative (LAR) in advance. Document may be delivered by personnel in contact with potential subject or sent via secure method (mail, UK email, fax), or posted to a secure internet address.

*See below for process alterations in cases where potential subject may have communicable condition.

3. Investigator or study personnel authorized to obtain consent contact the potential subject/LAR by phone or video conference. UK Healthcare has a HIPAA compliant contract with Zoom for secure videoconferencing. Link to ukth.zoom.us to set up account with Link Blue ID and password. In addition, [UK](#)

[Telehealth](#) may provide resources to UK Healthcare. 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. Refer to the [UK IT Cybersecurity Best Practices When Working Remotely](#).

4. Ask permission to discuss study opportunity with potential subject. Before beginning, ask open-ended questions to assess health literacy, familiarity with research concepts, motives, or initial concerns. Provide any background information needed to clarify concepts (e.g., difference between voluntary research consent and clinical consent).
5. Once potential subject has a copy of the consent in front of them, invite questions during and after discussion. Introduce the study beginning with key information which focuses on study purpose, key reason(s) a reasonable person would choose to participate or decline participation, and alternatives that would influence that decision.
6. Use clear speech to review informed consent and summarize key concepts. Do not just read the document to the potential participant.
7. Stop frequently to highlight key points and ask teach-back questions to assess understanding and clarify misunderstandings.
8. After the detailed consent has been reviewed and all questions answered, the investigator or study personnel are confident that subject or LAR understands and appreciates voluntary nature of research, instruct subject or LAR to sign and date both copies of the consent document (use flags or highlight the correct signature line).
9. Provide a secure means for the subject to return one of the signed consent forms to the investigator (scanned PDF or faxed copy).
10. Instruct subject to retain remaining signed copy for their records.
11. Once received, the investigator or study personnel who provided the consent discussion should print his/her name on the on the line labeled "name of [authorized] person obtaining informed consent". Enter the current date (do not back date if date is later than when subject signed).
12. Document in a separate note details of process, obtained on __ date by [phone/videoconference, individuals present, questions, clarifications, methods for ensuring understanding] and date signed document received by investigator. See **Detailing the Informed Consent Process in the Subject's Source Document** on the [ORI Quality Improvement Program Resource page](#).
13. Do not initiate study procedures until subject's signed consent document is received. Retain a copy of the signed consent with the subject's case history.

If potential subject is quarantined, has a possible contagious condition, or research involves communicable condition:

1. If using electronic consent, send (mail/secure email) subject a copy of the signed consent for his/her records.
2. If using paper consent, attempt to obtain a photograph, screenshot, or video record the subject or LAR's signature and date, rather than removing the paper from the containment unit. Where no such technology is available, include documentation of the informed consent process (who, how, when, where). Include in the subject's case history a description of the specific means by which the prospective subject or LAR communicated agreement, signed the form to take part in the clinical investigation and how questions were answered.

If potential subject is competent but physically impaired:

1. A person who is physically challenged (for example, physically unable to talk or write or has hearing or visual loss) can enroll in a study, if study staff provide accommodations for impairment and subject is competent and able to affirmatively signal consent. A witness to the process is needed if subject is unable to read the document.
2. The records relating to the study must include documentation of the informed consent process (who, how, when, where). Include in the subject's case history a description of the specific means by which the prospective subject communicated agreement to take part in the clinical investigation and how questions were answered

See [FDA 2020 Guidance](#) **Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency** for additional detail.

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