

Consenting Hospitalized Patients by Phone or Video Conference for Clinical Trials While on Isolation for Confirmed/Suspected COVID-19

The following procedures would satisfy documentation of the FDA's requirement on informed consent and accommodation of trial participants if the patient signing the paper informed consent form is on COVID-19 isolation:

- The research team should obtain permission from the patient's primary treating physician to initiate an informed consent discussion with the patient for the study. The research team should also notify the patient's nurse.
- There will be two copies of the Informed Consent Form. The research coordinator will prep the forms – i.e. insert research team contact person, participant's printed name, and date. One copy will go into the isolation room for the patient to read and sign. That form will stay with the patient and not come out of the room. A research coordinator who is an engaged study team member will hold the second identical copy of the consent and stay outside of the room.
- If desired, a study physician (principal investigator or a physician co-investigator) may enter the patient's room once to discuss the study. It is anticipated that this interaction will serve the purpose of educating the patient about the study, and enabling questions to be answered directly by the investigator. However, formal documentation of informed consent can only occur (1) after the patient has had reasonable time to review the informed consent document; and (2) after an impartial witness¹ has attested to having witnessed a complete informed consent discussion, per the process below.
- Research coordinators or other research staff may not enter the patient's room.
- Either the investigator or a health care worker (e.g., nurse who is taking care of the patient) who has entered the room during the course of clinical care can provide one of the two copies of the unsigned consent form to the patient.
- To document a consent discussion, the investigator (or their designee²) 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 requested by the patient, e.g. next of kin.
- Review of the informed consent with the patient by the investigator (or their designee) takes place during which any questions the patient may have are addressed.
- Patient signs their copy of the ICF and keeps that copy in the room.
- The investigator (or their designee) and impartial witness sign their copy of the informed consent document to attest that the patient is willing to participate in the trial and signed the informed consent document while the witness was listening on the phone. This copy of the ICF will be scanned into the Epic system.

1. An impartial witness is a person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process either by phone or in person.
2. A designee is any designated site personnel who are delegated significant trial-related duties by the PI.

Once the informed consent is obtained, a note to file will be generated by the investigator or their designee, to include and document the following:

- Identification of who was on the call, and when (date/time) the call took place.
- That a review of the informed consent with the patient by the investigator (or their designee) took place and any questions the patient had were answered.
- That the witness confirmed that the patient's questions were answered.
- That the patient was willing to participate in the trial and signed the informed consent document while the witness was listening on the phone.
- That there was a verbal confirmation by the patient that they would like to participate in the trial and that they have signed and dated the informed consent document that is in their possession.

Hospital infection prevention processes do not allow for paper forms or other documents to be removed from patient rooms/locations of patients with suspected or confirmed COVID-19. If the signed informed consent document will not be able to be collected from the patient's location and included in the study records, FDA considers the following option acceptable to provide documentation that the patient signed the informed consent document:

- Attestations by the impartial witness who participated in the call and by the investigator (or their designee) that the patient confirmed that they agreed to participate in the study and signed the informed consent.

If the patient is unable to provide informed consent and there is a legally authorized representative, investigators (or their designee) should obtain consent from the participant's legally authorized representative in accordance with 21 CFR 50.27(a).

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