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:

- 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.
- 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 provides one of the two copies of the unsigned consent form to the patient.
- If face to face communication with the patient in isolation is not feasible, the investigator (or their designee₁) obtains the patient’s phone number and arranges a three-way call or video conference with the patient, an impartial witness₂, 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 the ICF and keeps that copy in the room.
- The impartial witness will confirm that the patient’s questions have all been answered.
- The investigator (or their designee) will confirm that the patient is willing to participate in the trial and signed the informed consent document while the witness is listening on the phone.

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.

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. It is the responsibility of the investigator to identify the individual that will serve as the impartial witness.
2. A designee is any designated site personnel who are delegated significant trial-related duties by the PI.
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).