**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 (ICF). 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) or other authorized designee1 (e.g., research coordinator) 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, research coordinator, or other designee. 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 witness2 has attested to having witnessed a complete informed consent discussion, per the process below.
* Either the investigator, research coordinator, 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 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 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 impartial witness will attest that the patient’s questions have been answered, that the patient agreed to participate in the study and that they have signed the informed consent. Attestation by the witness can be documented via the following ways:
	+ The most preferred mechanism is for electronic consent (eConsent) to be enabled for the study in Epic, for the witness to sign the electronic ICF in Epic at the time of consent, and for the study team to complete a note-to-file to summarize the attestation process.
	+ If eConsent is not available in Epic **and the witness is in-person for the consent discussion**, they may sign the copy of the ICF that is being signed by the PI/Research Coordinator/delegate. The study team will need to complete a note-to-file to summarize the attestation process, to be filed in the patient record with the ICF.
	+ If eConsent is not available in Epic **and the witness is not in-person for the consent discussion**, the witness may complete another form of attestation remotely (i.e., email or OVCR-provided documentation of informed consent [<https://research.wustl.edu/covid-19-tool-kit-hsr/>]). The completed attestation should be signed and dated by the witness at the time of the consent and an electronic copy provided to the study team (e.g., scanned and emailed). The original copy with signature needs to end up in the patient record along with the ICF as soon as possible, or the study team may follow applicable procedures to certify a copy (<https://research.wustl.edu/electronic-storage-research-study-documents/>) of the signed attestation that was provided electronically.
	+ If the witness is providing a remote attestation **and does not have access to a printer or scanner at the time of the consent**, they may send an attestation to the study team via email. The witness should, when able at a later date, provide a signature and date on the email attestation, to be scanned and emailed to the study team. The original copy with signature needs to end up in the patient record along with the ICF as soon as possible, or the study team may follow applicable procedures to certify a copy (<https://research.wustl.edu/electronic-storage-research-study-documents/>) of the signed attestation that was provided electronically. If a signature and date are being provided after the date of the consent, the study team should document the reason for this in a note-to-file and retain in the patient record with the ICF and signed attestation.
* The investigator (or their designee) will sign their copy of the informed consent document to confirm that the patient is willing to participate in the trial and that they 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.

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).