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, marking on the ICF where the patient signs, dates and initials if required. Both copies will go into the isolation room for the patient to read and sign. One form will stay in the room with the patient as their signed copy and the other form will be removed from the room by the engaged study team member who consented the patient or the health care worker (e.g., nurse who is taking care of the patient) to become a permanent part of their research record.
- If desired, a study physician (principal investigator or a physician co-investigator) or other authorized designee[1] (e.g., research coordinator) may enter the patient's room 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 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 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 call or video conference with the patient, 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 both copies of the ICF, keeping one copy in the room for their records and the second copy will be removed from the room by the engaged study team member who consented the patient or by the health care worker.
- The investigator (or their designee) that obtained consent from the patient 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. 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 patient was willing to participate in the trial and signed the informed consent document.
- 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 does allow for paper forms or other documents to be removed from patient rooms/locations of patients with suspected or confirmed COVID-19, but **good hand hygiene MUST be performed before and after handling the informed consent document**.

All WU staff entering BJH patient rooms that require use of a N95 respirator, must have an annual fit test for the N95 respirators used at BJH-3M1804, 3M1860 or Halyard fluidshield respirators (if applicable).

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). The IRB must have approved the inclusion of decisionally impaired individuals and assent obtained as required by the IRB.

1. A designee is any designated site personnel who are delegated significant trial-related duties by the PI.