Obtaining Verbal Consent for FDA-regulated Research for Participants in Isolation (Either the Participant or Through a LAR) during a Public Health Emergency (PHE)

This is an internal guide (with workflows) provided to Trinity Health ministries to help understand the nuances of verbal consenting for a research study and the needed supporting documentation when the prospective study participant (patient) is hospitalized in an isolation room during a public health emergency (PHE). This guide is in response to the FDA Guidance Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency Guidance for Industry, Investigators, and Institutional Review Boards³ posted March 2020, updated September 21, 2020, and it is specific to FDA-regulated medical products. If a ministry wants to use this guide more broadly, consult with the ministry’s IRB.

FDA regulations generally require that the informed consent of a patient be documented by the use of a written consent document that typically includes the elements of informed consent, as described in 21 CFR 50.25, has been approved by the IRB, and is signed and dated by the patient or her/his legally authorized representative (LAR) at the time of consent (21 CFR 50.27(a)). When feasible, it is recommended that a traditional method of obtaining and documenting informed consent using a signed paper copy of the consent form or use of electronic informed consent is utilized.²

When a patient is in an isolation room during a PHE, utilizing a paper consent document is a challenge because once the document is taken into the isolation room, it is considered to be contaminated and cannot be taken out of the room and then filed in the research study record.

This guidance provides four options for obtaining consent for FDA-regulated research from patients who are being treated in an isolation room during a PHE:

- Verbal Consent Process – Patient Able to Sign the Consent
- Verbal Consent Process – Patient Able to Consent but Unable to Sign
- Verbal Consent Process – LAR (Patient Unable to Consent) Able to Sign the Consent
- Verbal Consent Process – LAR (Patient Unable to Consent) Able to Consent but Unable to Sign

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² Ibid
The method for obtaining consent for research implemented at your ministry should be detailed and prospectively approved by the IRB that has regulatory oversight for the research. Consult with the IRB, as well as your state and local laws and regulations, for additional information and guidance. Depending upon the operating environment at your ministry, there may be additional or different steps from what is provided in this guidance that will need to be implemented.

**General Guidance**

- For purposes of this guidance, it is assumed that the HIPAA Authorization form is included in the informed consent document (ICF) or is part of the ICF.
- Always follow HIPAA procedures to verify the identity of the person (e.g., the prospective participant/patient, the LAR) with whom the presenter is interacting, no matter the communication format (e.g., telephone, videoconference call, patient call light).
- Some studies will be prescriptive on how consent is obtained, and details may be stipulated in the clinical trial protocol. Some will only accept a signature by the traditional handwritten method of either the patient/LAR, while other studies will accept a photographic image of the signed ICF or a recording of the patient/LAR. Review all guidance by the study prior to implementing the verbal informed consent process. If the prescribed process presents an infection control concern, this concern should be addressed prior to implementing the process.
  - The IRB-approved ICF should be approved with a witness signature and date line. Additional information should NOT be handwritten on the ICF. If additional information/explanation is required, then this information should be placed in the research notes regarding the consent discussion.
  - It is recommended that the ICF presenter not enter the isolation room of the patient to administer the informed consent.
  - Use the most appropriate and available three-way technology to administer the informed consent verbally (e.g., telephone, audio-visual device, patient call light) to the patient/LAR.
  - The verbal consent discussion is a conversation to ensure that the patient/LAR comprehends the purpose of the research; the content of the ICF, including the risks and benefits; and what s/he is agreeing to (e.g., time, effort, responsibilities).
  - Be conscious of your surroundings when speaking to the patient/LAR during the consent process to ensure to the extent practicable that you are not being heard by others.
  - The person who is identified as the witness should be present throughout the entire verbal consent process.
  - It is strongly recommended that an electronic ICF with an electronic signature process be used (e.g., consent in Adobe Acrobat pdf file format loaded onto a ministry-provided tablet with electronic signature in Adobe) that meets applicable regulatory requirements, and is validated and approved for use by the ministry.
    - If the ICF can only be provided to the patient as a paper document, and the signature is written in ink on the paper document, the document is considered contaminated and cannot leave the patient’s room. After a photographic image of the signed signature page is taken, follow ministry procedures for the destruction of the paper document.
  - The signed ICF contains PHI and therefore must be treated as PHI. PHI can only be stored in ministry-provided devices and -secured software applications.

**Legally Authorized Representative (LAR) Guidance**

- Legally Authorized Representative (LAR) means the person who is either the LAR, medical Designated Power of Attorney (DPOA), legal guardian, personal representative, consensus surrogate, or next of kin.
- If the patient is unable to discuss and sign the ICF for study (e.g., due to severe illness, is intubated, is in an induced coma), follow your ministry policy for obtaining informed consent. If no policy exists, you should determine whether the patient has an Advance Directive on file that may be applicable or if any other documentation exists, like guardianship paperwork to support LAR status. If none exists, contact your ministry’s Legal Department for assistance. LAR status should be documented in the research study record and the medical record.
- If an LAR was used because the patient was not able to consent, and if the patient is able to communicate at a later time, inform the patient of her/his participation in the research study by providing her/him a copy of the signed ICF and answering any questions that s/he may have. Obtain re-consent from the participant, at the earliest appropriate time in accordance to Ministry policies.

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3 45 CFR 164.514(h)
Preparation for Verbal Consent
1. The healthcare provider introduces the research study to the patient and verifies interest.
   a. If the healthcare provider is not able to determine interest (e.g., patient is intubated), the provider will contact the LAR to determine interest in participating in the study.
2. The healthcare provider confirms the email address and other contact information (e.g., cell phone number) that the research team will use to contact the patient/LAR.
3. ICF presenter contacts patient/LAR. The ICF presenter:
   a. Follows HIPAA procedures to confirm the identity of the patient/LAR.
   b. Explains the verbal consent process.
   c. Confirms the email/snail mail address and sends the ICF and any other communications containing PHI via a secure method per ministry policy.
   d. Asks if the patient/LAR would like additional attendees to join the verbal consent discussion.
   e. Confirms a date/time to have a discussion to obtain consent.
4. ICF presenter identifies an individual who may act as a witness.

Verbal Consent Process – Patient Able to Sign the Consent
1. ICF presenter contacts the patient via three-way communication.
2. ICF presenter:
   a. Identifies self.
   b. Introduces witness and other individuals participating.
   c. Follows HIPAA procedures to confirm the identity of the patient.
3. ICF presenter states the purpose of the call.
4. ICF presenter asks the patient to confirm that the patient has:
   a. Received and read the ICF.
   b. A copy (paper or electronic) of the ICF available to follow along during this discussion.
5. ICF presenter:
   a. Reviews the ICF with the patient, stopping frequently to ask for questions about information presented.
   b. Answers questions and confirms that all questions have been answered.
6. ICF presenter confirms with the patient that s/he would like to participate in the research study.
7. The witness confirms with the patient that:
   a. All questions have been answered.
   b. The patient would like to participate in the research study.
8. Patient verbally agrees to be a participant in the research study.
9. ICF presenter instructs the patient to sign and date the consent in his/her possession by either:
   a. The traditional handwritten method, or
   b. The electronic signature method utilized at the ministry.
10. Patient signs and dates the ICF using either:
    a. The traditional handwritten method, or
    b. The electronic signature method utilized at the ministry.
11. If the traditional handwritten method is used, the patient takes a photographic image of the signature page(s) of the ICF and sends it to the ICF presenter.
12. ICF presenter and witness sign and date their copy of the ICF during or immediately after completing the communication, attesting to the consent being obtained, using either:
    a. The traditional handwritten method, or
    b. The electronic signature method utilized at the ministry.
13. ICF presenter closes the three-way communication.

Verbal Consent Process – Patient Able to Consent but Unable to Sign
1. ICF presenter contacts the patient via three-way communication.
2. ICF presenter:
   a. Identifies self.
   b. Introduces witness and other individuals participating.
   c. Follows HIPAA procedures to confirm the identity of the patient.
3. ICF presenter states the purpose of the call.
4. ICF presenter asks the patient to confirm that the patient has:
   a. Received and read the ICF.
b. A copy (paper or electronic) of the ICF available to follow along during this discussion.

5. ICF presenter:
   a. Reviews the ICF with the patient, stopping frequently to ask for questions about information presented.
   b. Answers questions and confirms that all questions have been answered.

6. ICF presenter confirms with the patient that s/he would like to participate in the research study.

7. The witness confirms with the patient that:
   a. All questions have been answered.
   b. The patient would like to participate in the research study.

8. Patient verbally agrees to be a participant in the research study.

9. ICF presenter and witness sign and date their copy of the ICF during or immediately after completing the communication, attesting to the consent being obtained, using either:
   a. The traditional handwritten method, or
   b. The electronic signature method utilized at the ministry.

10. ICF presenter closes the three-way communication.

Verbal Consent Process – LAR (Patient Unable to Consent) Able to Sign the Consent

1. ICF presenter contacts the LAR via three-way communication.

2. ICF presenter:
   a. Identifies self.
   b. Introduces witness and other individuals participating.
   c. Follows HIPAA procedures to confirm the identity of the LAR.

3. ICF presenter states the purpose of the call.

4. ICF presenter asks the LAR to confirm that the LAR has:
   a. Received and read the ICF.
   b. A copy (paper or electronic) of the ICF available to follow along during this discussion.

5. ICF presenter:
   a. Reviews the ICF with LAR, stopping frequently to ask for questions about information presented.
   b. Answers questions and confirms that all questions have been answered.

6. ICF presenter confirms with the LAR that s/he would like the patient to participate in study.

7. The witness confirms with the LAR that:
   a. All questions have been answered.
   b. S/he would like the patient to participate in the research study.

8. LAR verbally agrees for the patient to be a participant in the research study.

9. ICF presenter instructs the LAR to sign and date the ICF in her/his possession by either:
   a. The traditional handwritten method, or
   b. The electronic signature method utilized at the ministry.

10. LAR signs and dates the consent using either:
    a. The traditional handwritten method, or
    b. The electronic signature process utilized at the ministry.

11. If the traditional handwritten method is used, the LAR takes a photographic image of the signature page(s) of the ICF and sends it to the ICF presenter.

12. ICF presenter and witness sign and date their copy of the ICF during or immediately after completing the discussion, attesting to the consent being obtained, using either:
    a. The traditional handwritten method.
    b. The electronic signature method utilized at the ministry.

13. ICF presenter closes the discussion.

Verbal Consent Process – LAR (Patient Unable to Consent) Able to Consent but Unable to Sign

1. ICF presenter contacts the LAR via three-way communication.

2. ICF presenter:
   a. Identifies self.
   b. Introduces witness and other individuals participating.
   c. Follows HIPAA procedures to confirm the identity of the LAR.

3. ICF presenter states the purpose of the call.

4. ICF presenter asks the LAR to confirm that the LAR has:
   a. Received and read the ICF.
b. A copy (paper or electronic) of the ICF available to follow along during this discussion.

5. ICF presenter:
   a. Reviews the ICF with LAR, stopping frequently to ask for questions about information presented.
   b. Answers questions and confirms that all questions have been answered.

6. ICF presenter confirms with the LAR that s/he would like the patient to participate in study.

7. The witness confirms with the LAR that:
   a. All questions have been answered.
   b. S/he would like the patient to participate in the research study.

8. LAR verbally agrees for the patient to be a participant in the research study.

9. ICF presenter and witness sign and date their copy of the ICF during or **immediately after completing the discussion**, attesting to the consent being obtained, using either:
   a. The traditional handwritten method.
   b. The electronic signature method utilized at the ministry.

10. ICF presenter closes the discussion.

**Documentation of Verbal Consent Process**

1. ICF presenter receives the photographic image of the signature pages of the ICF from the participant/LAR (if patient/LAR able to sign).
   a. Uploads the photo into the research study record.
   b. Combines into one document the consent form, the photo, and the pages signed by the ICF presenter and witness.
      i. Saves the combined document to the research study record.
   c. Sends a copy of the combined document:
      i. To the patient/LAR.
      ii. To the medical record.

2. ICF presenter documents the informed consent process in the medical record and the research study record. Documentation includes:
   a. How the consent was obtained: *Consent obtained via telephone or videoconference (verbal).*
   b. The reason why verbal consent was obtained (e.g., due to potential contamination of the document by infectious material): *Due to COVID 19 pandemic and/or patient is under droplet, contact, and/or airborne precautions.*
   c. How the verbal consent was confirmed (e.g., attestation of witness and ICF presenter).
FREQUENTLY ASKED QUESTIONS

Q1. What requirements must be met in order to utilize the verbal consent process?
A1. Follow your ministry’s informed consent, diminished capacity, and related procedures to determine when to utilize the verbal consent process.

Q2. When is a LAR to be used?
A2. Use a LAR when:
   - The patient is nonverbal (e.g., intubated, in an induced coma; refer to ministry policy).
   - The patient who is vented and awake but unable to speak
   - As otherwise required by ministry policy.
   Always follow the ministry’s LAR procedure when a LAR is used.

Q3. Does the witness need to have human subjects protection training prior to being a witness?
A3. Some ministry IRBs require that witnesses are to have completed have human subjects protection training and a completion document/certificate on file with the IRB in order to participate as a witness in the verbal consent process. Confirm with the IRB before implementing the verbal consent process at your ministry.

Q4. What is the acceptable process if the patient/LAR is unable to sign the consent form either electronically or traditional handwritten method?
A4. It is NOT ACCEPTABLE to do the following:
   - Verbal confirmation by the patient/LAR that s/he writes on a blank piece of paper a written statement that s/he voluntarily agrees to participate in the protocol, noting both the Protocol ‘NUMBER’ and brief protocol title with her/his signature and date.

   It is ACCEPTABLE to do the following:
   - When a signed paper ICF cannot be collected from the patient's location, an attestation by the ICF presenter and witness is considered acceptable by the FDA (e.g., due to potential contamination of the document by infectious material and the patient cannot electronically sign). This attestation is also documented in the medical record.

Q5. What is the guidance for taking a photographic image of the signature page(s) of the ICF when the traditional handwritten method of signing the ICF is used?
A5.
   - Use of a personal cell phone by a LAR is acceptable if the LAR consents to do so.
   - Use of a personal cell phone by a Trinity Health colleague is allowed to take a photographic image of the signed ICF ONLY when the cell phone has a HIPAA compliant and Trinity Health approved app installed and the owner/user of the phone has been trained on how to correctly use the app.
   - Use of a ministry-provided image capture/photographic device for taking a photographic image of the signed signature page of the consent document and sending the image to the electronic medical record (EMR) and the research study record.

Q6. When is it allowable to record the verbal consent?
A6. A recording (e.g., telephone, video) memorializing the verbal consent conversation is allowable in lieu of using a witness (e.g., a witness is unavailable). The ICF presenter should ensure that the recording is done in a manner consistent with applicable state and local laws and that all parties agree to being recorded. Include in the IRB approved ICF that consent will be obtained via a recording and include that the recording will be retained after the study closes and that it will be used to document the potential participant’s consent to participate in the research study. Store the recording in the research study record along with an attestation signed and dated by the ICF presenter who participated on the call stating why the ICF signed by the patient was not retained (e.g., due to potential contamination of the document by infectious material). The recording technology should be approved for use by the ministry.
Q7. When a witness can attest to the signature, but a photograph of the signed ICF cannot be transmitted, what are the options for documenting the signature of the ICF?

A7. Utilize one of these options:

- **Using a witness:**
  - Document in the research study record:
    - A signed and dated attestation by the witness who participated on the call stating that the patient confirmed her/his agreement to participate in the research study and signed the ICF, and
    - A signed and dated attestation by the ICF presenter stating why the ICF signed by the patient was not retained (e.g., due to potential contamination of the document by infectious material).
    - Also place the attestation into the medical record.
  - Using a telephone or video conference call that is recorded:
    - When using a recording in lieu of a witness, documentation in the research study record includes:
      - The recording of the conference call, and
      - A signed and dated attestation by the ICF presenter stating why the ICF signed by the patient was not retained (e.g., due to potential contamination of the document by infectious material).
      - Also place the attestation into the medical record.

Q8. What are the HIPAA procedures to confirm the identity of the patient/LAR?

A8. Under 45 CFR 164.514(h) a covered healthcare entity must make a reasonable effort, prior to disclosure of PHI, to:

- Verify the identity of a person requesting PHI and the authority of any such person to have access to PHI, if the identity or any such authority of such person is not known to the covered entity; and
- Obtain any documentation, statements, or representations, whether oral or written, from the person requesting the PHI when such documentation, statement, or representation is a condition of the disclosure.

**Definitions**

- **Healthcare provider** means the treating physician.
- **ICF** means Informed Consent Form.
- **ICF presenter** means the person who obtains consent. The ICF presenter may be the principal investigator, research nurse coordinator, or research coordinator.
- **Legally Authorized Representative (LAR)** means the person who is either the LAR, medical Designated Power of Attorney (DPOA), legal guardian, personal representative, consensus surrogate, or next of kin.
- **Principal Investigator (PI)** means the person, usually a physician, who has overall responsibility for the conduct of the research study.
- **Prospective participant** means the patient who is interested in participating as a human subject in a research study.
- **Research study record** means the physical binders and electronic files of the research study kept by the investigator and the research study team.
- **Traditional handwritten method** means signing a paper document with an ink signature.
- **Witness** means an individual to see an event, typically either a physician, research coordinator, or research nurse. The witness is invoked to confirm that informed consent has occurred. Check with your ministry’s IRB for further guidance.

**Attachments**

- Verbal Consent Workflow for Patient
- Verbal Consent Workflow for LAR