

## Remote Consenting Procedures for COVID-19 Research Studies

Due to isolation procedures of patients with suspected and/or confirmed COVID-19 infection, a modified consent process is necessary for patient and provider safety and to minimize the unnecessary use of personal protective equipment. The following outlines the process for consent under these precautions. These methods may also be applicable in outpatient settings that include COVID-19 patients. Note: These methods are not to be utilized outside of COVID-19 circumstances as they represent FDA guidance for obtaining consent during the pandemic.

- A. Consent of participants in isolation with suspected and/or confirmed COVID-19 infection
- B. Consent of participants who require Legally Authorized Representative (LAR) (who have not been quarantined)
- C. Consent of participants who require LAR (who are quarantined)
- D. Consent of participants in isolation with suspected and/or confirmed COVID-19 infection, who have a high risk for decompensation or who are already decompensating and when time is not sufficient to obtain a full written consent from the patient before decompensation.
- E. Consent of a Legally Authorized Representative (LAR) of a participant in isolation with suspected and/or confirmed COVID-19 infection, who have a high risk for decompensation or who are already decompensating and when time is not sufficient to obtain a full written consent from the LAR before decompensation.
- F. Consent of non-English speaking patients or their LARs

### **A. Consent of participants in isolation with suspected and/or confirmed COVID-19 infection**

1. Research staff or the patient's Clinical Care provider will provide the patient with a brief introduction to the research studies available for participation.
2. The patient's Clinical Care Team Member (nurse or physician) will take the consent form into the room for the patient to read and review, if the patient is able.
3. Research staff will speak to patient via telephone or video conference to review the consent form. Preferably, the participants should include: the patient, an impartial witness, the investigator/research staff member, and if desired and feasible, additional participants requested by the patient (e.g., next of kin). To ensure that patients are approached in a consistent fashion, a standard process should be used that will accomplish the following:
  - Identification of who is on the call
  - Review of the informed consent with the patient by the investigator (or their designee) and response to any questions the patient may have
  - Confirmation by the witness that the patient's questions have been answered
  - Confirmation by the investigator that the patient is willing to participate in the trial and sign the informed consent document while the witness is listening on the phone
  - 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
4. If the patient chooses to participate, the patient will provide consent by completing the following:
  - i. Participant will initial on the appropriate HIPAA sections (as needed) and print their name, sign, and date the consent form.

- ii. Participant will take a picture of the initialed HIPAA page and full study consent signature page with their cell phone or tablet and send via email or text to the Investigator/Coordinator.
  - iii. Due to isolation precautions, the consent will remain with the patient and not be removed from the room. Upon patient discharge the consent form will be destroyed.
5. If it is not possible to safely capture the image of the signed consent/HIPAA pages, a signed and dated attestation by the witness who participated in the call and by the investigator may also serve as documentation of informed consent. This attestation should include:
  - An unsigned consent form was provided and received by the prospective participant
  - No imaging technology was available to capture the signed consent form
  - How consent was obtained (e.g., a telephone call or video conference with the prospective participant, investigator, and witness [at minimum])
  - There is a record of all parties who participated in the consent process
  - There is a record that the informed consent was reviewed and questions answered
  - The witness confirmed questions were answered
  - Investigator confirmed the patient/LAR is willing to participate
  - Investigator confirmed that the patient/LAR stated they signed the consent form
  - Witness confirmed that the witness heard the patient/LAR confirm that they signed/dated the consent form
6. COVID-19 patients who have capacity to consent but are not able to sign the consent form (e.g., physical impairment prevents them from signing; monitoring and medical equipment prevent signing) may provide verbal consent with a Clinical Care Team Member as witness. The Clinical Care Team Member will:
  - i. Observe the patient's verbal confirmation of understanding and verbal confirmation that they wish to participate in the study.
  - ii. From outside the patient room, notate patient provided verbal consent for HIPAA page and consent to participate in this study and sign and date the witness line of the consent signature page. The means by which the prospective subject communicated agreement to take part in the study and how questions were answered should be documented.
  - iii. Scan or take a picture of the signed consent signature page and send to the investigator/coordinator.
7. The research investigator/coordinator will:
  - i. Sign a separate consent form after the patient has consented. If receiving a scanned consent form signed by the patient/LAR, the investigator/coordinator may sign the scanned copy and document why the original signatures ("wet signatures") are not being used. If the investigator/coordinator signs on a different date than the patient/LAR, document the reason for the different dates.
  - ii. Print images of patient's HIPAA and consent signature page or Clinical Care Team Member's witness attestation and place in patient's study source document.
  - iii. A copy of the informed consent document signed by the investigator and witness should be placed in the patient's trial source documents, with a notation by the investigator of how the consent was obtained (e.g., telephone call). The trial record at the investigational site should document how it was confirmed that the patient signed the consent form (i.e., either using attestation by the witness and investigator or the photograph of the signed consent). The note should include a statement of why the original informed consent document signed by the patient was not retained (e.g., due to potential contamination of the document by infectious material).

- iv. Ensure that the patient's electronic medical record (EMR) is updated with either a note describing the consent procedure, the witness attestation, or an image of the signed consent/HIPAA form.
- v. Send a copy of the signed consent form to the patient in the mail following their discharge from the hospital.

**B. Consent of participants in isolation with suspected and/or confirmed COVID-19 infection who requires an LAR who is not quarantined and able to consent face to face.**

1. Research staff or the patient's Clinical Care provider will provide the patient with a brief introduction to the research studies available for participation.
2. Research staff will provide the consent form to the patient's LAR to read. The Investigator/Coordinator will speak to the LAR to review consent, answer questions and confirm understanding of research study.
3. If the LAR chooses to include the patient in the study, the LAR will provide consent by completing the following:
  - i. Initialing on HIPAA page and printing their name and relation to the patient, sign, and date the consent form.
4. The Research Investigator/Coordinator will:
  - i. Sign and date the consent form after the LAR has consented.
  - ii. Provide LAR with a signed copy of the consent form.
  - iii. Provide documentation of the informed consent process by completing consenting progress note and place in patient's study source document.
  - iv. Ensure that the patient's electronic medical record (EMR) is updated with either a note describing the consent procedure or an image of the signed consent/HIPAA form.

**C. Consent of participants in isolation with suspected and/or confirmed COVID-19 infection who requires an LAR that is in quarantine or are unable to consent face to face.**

1. Research staff or the patient's Clinical Care provider will provide the patient with a brief introduction to the research studies available for participation.
2. Research staff will provide the consent form to the patient's LAR electronically (i.e., via email, facsimile) to read.
3. Research staff will speak to LAR via telephone or video conference to review the consent form. Preferably, the participants should include: the LAR, an impartial witness, the investigator/research staff member, and if desired and feasible, additional participants requested by the LAR. To ensure that LARs are approached in a consistent fashion, a standard process should be used that will accomplish the following:
  - Identification of who is on the call
  - Review of the informed consent with the LAR by the investigator (or their designee) and response to any questions the patient may have
  - Confirmation by the witness that the LAR's questions have been answered

- Confirmation by the investigator that the LAR is willing to have the patient participate in the trial and sign the informed consent document while the witness is listening on the phone
  - Verbal confirmation by the LAR that they would like the patient to participate in the trial and that they have signed and dated the informed consent document that is in their possession
4. If the LAR chooses to have the patient participate, the LAR will provide consent by completing the following:
    - i. LAR will initial on the appropriate HIPAA sections (as needed) and print their name, sign, and date the consent form.
    - ii. LAR will take a picture of the initialed HIPAA page and full study consent signature page with their cell phone or tablet and send via email or text to the Investigator/Coordinator. The consent will remain with the LAR and not be returned.
  5. If it is not possible to safely capture the image of the signed consent/HIPAA pages, a signed and dated attestation by the witness who participated in the call and by the investigator may also serve as documentation of informed consent. This attestation should include:
    - An unsigned consent form was provided and received by the LAR
    - No imaging technology was available to capture the signed consent form
    - How consent was obtained (e.g., a telephone call or video conference with the LAR, investigator, and witness [at minimum])
    - There is a record of all parties who participated in the consent process
    - There is a record that the informed consent was reviewed and questions answered
    - The witness confirmed questions were answered
    - Investigator confirmed the LAR is willing to have the patient participate
    - Investigator confirmed that the LAR stated they signed the consent form
    - Witness confirmed that the witness heard the LAR confirm that they signed/dated the consent form
  6. There may be circumstances when an LAR intends to provide consent on behalf of a patient who is unable to give informed consent, but the LAR is physically incapable of signing an informed consent document (e.g., they may be hospitalized and facing the same circumstances as outlined in the patient scenario above). The study team should follow the procedures outlined in A6 above for the patient to secure the consent of the LAR.
  7. The Research Investigator/Coordinator will:
    - i. Sign a separate consent form after the LAR has consented. If receiving a scanned consent form signed by the patient/LAR, the investigator/coordinator may sign the scanned copy and document why the original signatures (“wet signatures”) are not being used. If the investigator/coordinator signs on a different date than the patient/LAR, document the reason for the different dates.
    - ii. Print images of LAR’s HIPAA and consent signature page or Clinical Care Team Member’s witness attestation and place in patient’s study source document.
    - iii. A copy of the informed consent document signed by the investigator and witness should be placed in the patient’s trial source documents, with a notation by the investigator of how the consent was obtained (e.g., telephone call). The trial record at the investigational site should document how it was confirmed that the LAR signed the consent form (i.e., either using attestation by the witness and investigator or the photograph of the signed consent). The note should include a statement of why the original informed consent

document signed by the LAR was not retained (e.g., due to potential contamination of the document by infectious material).

- iv. Ensure that the patient's electronic medical record (EMR) is updated with either a note describing the consent procedure, the witness attestation, or an image of the signed consent/HIPAA form.
- v. Send a copy of the signed consent form to the patient/LAR in the mail.

**D. Consent of participants in isolation with suspected and/or confirmed COVID-19 infection, who have a high risk for decompensation or who are already decompensating and when time is not sufficient to obtain a full written consent from the patient before decompensation.**

1. Research staff or the patient's Clinical Care provider will provide the patient with a brief introduction to the research studies available for participation. They will ask the patient to verbally confirm that they are interested in participating in the study.
2. The Research Investigator/Coordinator will:
  - i. Speak to the Clinical Care Team Member (nurse or physician) via telephone to inform them that we are providing the 'Key Information Verbal Consent' verbally to start the patient on the trial.
  - ii. Provide the Clinical Care Team Member with the consent forms for the study and provide instruction to bring the 'Key Information Verbal Consent' and the Informed Consent Form into the patient room the next time the Clinical Care Team Member needs to enter the patient room.
  - iii. Read the 'Key Information Verbal Consent' to the patient via telephone, answer questions, and confirm understanding of research protocol.
  - iv. Obtain a verbal consent to participate in the study.
  - v. Document the patient's verbal consent which was first observed by the Clinical Provider and then by the Investigator/Coordinator. The means by which the prospective subject communicated agreement to take part in the study and how questions were answered should be documented.
  - vi. Begin screening and randomization after the patient provides verbal consent.
    - a. If after screening and randomization the patient is able to consent with the full Informed Consent Form, the Investigator/Coordinator will reconnect with the patient and proceed with obtaining documentation of consent outlined in D3 below.
    - b. If the patient further decompensates after screening and randomization and is no longer able to consent, the Investigator/Coordinator will contact the LAR and proceed with obtaining documentation of consent outlined in E4 below.
3. Following Screening and Randomization
  - i. The participant will confirm their willingness to continue participation in the study and:
    - a. Participant will initial on the appropriate HIPAA sections (as needed) and print their name, sign, and date the consent form.
    - b. Participant will take a picture of the initialed HIPAA page and full study consent signature page with their cell phone or tablet and send via email or text to the Investigator/Coordinator.

- c. Due to isolation precautions, the consent will remain with the patient and not be removed from the room. Upon patient discharge the consent form will be destroyed.
  - ii. If it is not possible to safely capture the image of the signed consent/HIPAA pages, a signed and dated attestation by the witness who participated in the call and by the investigator may also serve as documentation of informed consent. This attestation should include:
    - An unsigned consent form was provided and received by the prospective participant
    - No imaging technology was available to capture the signed consent form
    - How consent was obtained (e.g., a telephone call or video conference with the prospective participant, investigator, and witness [at minimum])
    - There is a record of all parties who participated in the consent process
    - There is a record that the informed consent was reviewed and questions answered
    - The witness confirmed questions were answered
    - Investigator confirmed the patient/LAR is willing to participate
    - Investigator confirmed that the patient/LAR stated they signed the consent form
    - Witness confirmed that the witness heard the patient/LAR confirm that they signed/dated the consent form
  - iii. COVID-19 patients who have capacity to consent but are not able to sign the consent form (e.g., physical impairment prevents them from signing; monitoring and medical equipment prevent signing) may provide verbal consent with a Clinical Care Team Member as witness. The Clinical Care Team Member will:
    - a. Observe the patient's verbal confirmation of understanding and verbal confirmation that they wish to participate in the study.
    - b. From outside the patient room, notate patient provided verbal consent for HIPAA page and consent to participate in this study and sign and date the witness line of the consent signature page. The means by which the prospective subject communicated agreement to take part in the study and how questions were answered should be documented.
    - c. Scan or take a picture of the signed consent signature page and send to the investigator/coordinator.
  - iv. The research investigator/coordinator will:
    - a. Sign a separate consent form after the patient has consented. If receiving a scanned consent form signed by the patient/LAR, the investigator/coordinator may sign the scanned copy and document why the original signatures ("wet signatures") are not being used. If the investigator/coordinator signs on a different date than the patient/LAR, document the reason for the different dates.
    - b. Print images of patient's HIPAA and consent signature page or Clinical Care Team Member's witness attestation and place in patient's study source document.
    - c. A copy of the informed consent document signed by the investigator and witness should be placed in the patient's trial source documents, with a notation by the investigator of how the consent was obtained (e.g., telephone call). The trial record at the investigational site should document how it was confirmed that the patient signed the consent form (i.e., either using attestation by the witness and

investigator or the photograph of the signed consent). The note should include a statement of why the original informed consent document signed by the patient was not retained (e.g., due to potential contamination of the document by infectious material).

- d. Ensure that the patient's electronic medical record (EMR) is updated with either a note describing the consent procedure, the witness attestation, or an image of the signed consent/HIPAA form.
- e. Send a copy of the signed consent form to the patient in the mail following their discharge from the hospital.

**E. Consent of a Legally Authorized Representative (LAR) of a participant in isolation with suspected and/or confirmed COVID-19 infection, who have a high risk for decompensation or who are already decompensating and when time is not sufficient to obtain a full written consent from the LAR before decompensation.**

1. Research staff or the patient's Clinical Care provider will provide the patient with a brief introduction to the research studies available for participation. They will ask the LAR to verbally confirm that they are interested in having the patient participate in the study.
2. The Research Investigator/Coordinator will provide the LAR via email with the 'Key Information Verbal Consent' and the Informed Consent Form.
3. The Research Investigator/Coordinator will:
  - i. Read the 'Key Information Verbal Consent' to the LAR via telephone, answer questions, and confirm understanding of research protocol.
  - ii. Obtain a verbal consent for the patient to participate in the study.
  - iii. Document the LAR's verbal consent which was first observed by the Clinical Provider and then by the Research Investigator/Coordinator.
  - iv. Begin screening and randomization after the LAR provides verbal consent.
4. Following Screening and Randomization
  - i. If the LAR chooses to have the patient participate, the LAR will provide consent by completing the following:
    - a. LAR will initial on the appropriate HIPAA sections (as needed) and print their name, sign, and date the consent form.
    - b. LAR will take a picture of the initialed HIPAA page and full study consent signature page with their cell phone or tablet and send via email or text to the Investigator/Coordinator. The consent will remain with the LAR and not be returned.
  - ii. If it is not possible to safely capture the image of the signed consent/HIPAA pages, a signed and dated attestation by the witness who participated in the call and by the investigator may also serve as documentation of informed consent. This attestation should include:
    - An unsigned consent form was provided and received by the LAR
    - No imaging technology was available to capture the signed consent form
    - How consent was obtained (e.g., a telephone call or video conference with the LAR, investigator, and witness [at minimum])
    - There is a record of all parties who participated in the consent process

- There is a record that the informed consent was reviewed and questions answered
  - The witness confirmed questions were answered
  - Investigator confirmed the LAR is willing to have the patient participate
  - Investigator confirmed that the LAR stated they signed the consent form
  - Witness confirmed that the witness heard the LAR confirm that they signed/dated the consent form
- iii. There may be circumstances when an LAR intends to provide consent on behalf of a patient who is unable to give informed consent, but the LAR is physically incapable of signing an informed consent document (e.g., they may be hospitalized and facing the same circumstances as outlined in the patient scenario above). The study team should follow the procedures outlined in D3iii for the patient to secure the consent of the LAR.
- iv. The Research Investigator/Coordinator will:
- a. Sign a separate consent form after the LAR has consented. If receiving a scanned consent form signed by the patient/LAR, the investigator/coordinator may sign the scanned copy and document why the original signatures (“wet signatures”) are not being used. If the investigator/coordinator signs on a different date than the patient/LAR, document the reason for the different dates.
  - b. Print images of LAR’s HIPAA and consent signature page or Clinical Care Team Member’s witness attestation and place in patient’s study source document.
  - c. A copy of the informed consent document signed by the investigator and witness should be placed in the patient’s trial source documents, with a notation by the investigator of how the consent was obtained (e.g., telephone call). The trial record at the investigational site should document how it was confirmed that the LAR signed the consent form (i.e., either using attestation by the witness and investigator or the photograph of the signed consent). The note should include a statement of why the original informed consent document signed by the LAR was not retained (e.g., due to potential contamination of the document by infectious material).
  - d. Ensure that the patient’s electronic medical record (EMR) is updated with either a note describing the consent procedure, the witness attestation, or an image of the signed consent/HIPAA form.
  - e. Send a copy of the signed consent form to the patient/LAR in the mail.

**F. Consent of non-English speaking patients or their LARs:**

1. All activities with the patient/LAR will be performed with the aid of a translator. As per institution policies, family members or LARs may not act as the translator for the patient. Translators may also serve as the witness as long as they are not also the person obtaining consent. If the person obtaining consent is translating, a separate witness fluent in the patient’s native language must be used.
2. Patients or LARs will be consented in their preferred language and following appropriate procedures in scenarios A-E above.
  - a. If a translated consent is available, the patient/LAR and the bilingual person obtaining consent will sign the translated consent.
  - b. If a consent form is not available in their preferred language, a short form consent from will be provided to the patient/LAR. The short form document is signed by the



patient/LAR. The short form is signed by a witness (can be the interpreter, unless the interpreter is also the person obtaining consent). The study summary or English consent is signed by the person obtaining consent. The study summary or English consent is signed by a witness (can be the interpreter, unless the interpreter is also the person obtaining consent). The patient/LAR will receive copies of both the study summary/English consent and the short form document.