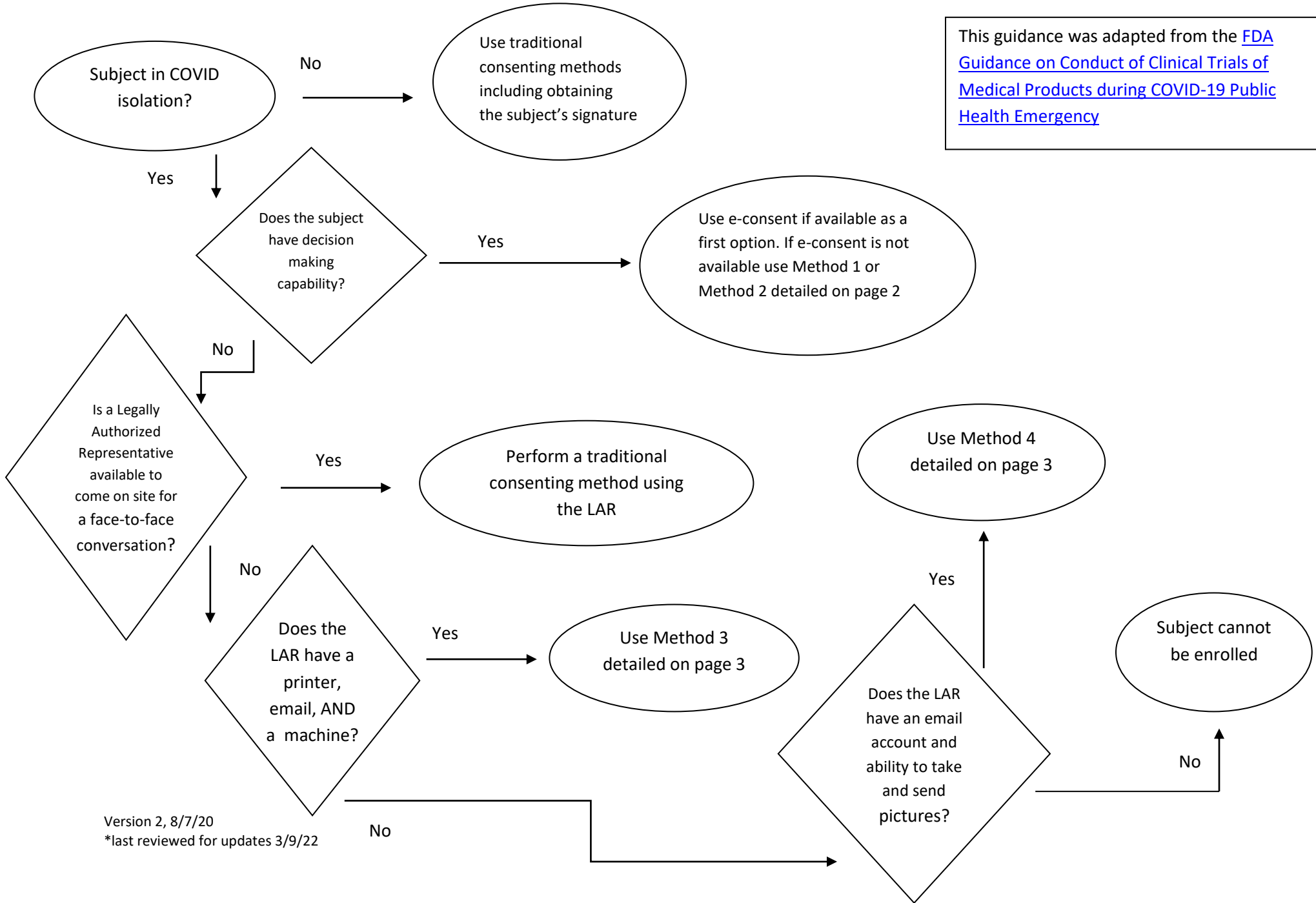




# Guidance for Consenting During a COVID-19 Public Health Emergency

This guidance was adapted from the [FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency](#)





# Guidance for Consenting During a COVID-19 Public Health Emergency

## **Method 1: A photograph of the signed informed consent document can be transmitted to the trial staff**

1. An unsigned consent form is provided to the patient by a person who has entered the room.
2. The investigator/designee arranges a telephone call or video conference call with the patient (and, if desired and feasible, additional individuals requested by the patient (e.g., next of kin)).
3. 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 document with the patient by the investigator/designee and response to any questions the patient may have.
  - Verbal confirmation by the patient that their questions have been answered, 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. The patient (or an individual in the room) takes a photograph of the signed informed consent document and sends it to the investigator/designee.
5. A trial team member enters the photograph into the trial records along with an attestation that states how that photograph was obtained and that it is a photograph of the informed consent document signed by the patient.

## **Method 2: A witness can attest to the signature, but a photograph of the signed informed consent document cannot be transmitted**

1. An unsigned consent form is provided to the patient by a person who has entered the room.
2. The investigator/designee arranges a three-way telephone call or video conference call with the patient, a witness who is not otherwise connected with the clinical investigation, and, if desired and feasible, additional individuals requested by the patient (e.g., next of kin). Alternatively, in lieu of using a witness, a recording of the conversation can be made.



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3. 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 document with the patient by the investigator/designee and response to any questions the patient may have.
  - Verbal confirmation by the patient that their questions have been answered, 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. When using a witness, documentation in the trial records includes: (1) a signed and dated attestation by the witness who participated on the call that the patient confirmed their agreement to participate in the trial and signed the informed consent document, and (2) a signed and dated attestation by the investigator/designee stating why the informed consent document signed by the patient was not retained (e.g., due to potential contamination of the document by infectious material).

When using a recording in lieu of a witness, documentation in the trial records includes: (1) the recording of the conference call, and (2) a signed and dated attestation by the investigator/designee who participated on the call stating why the informed consent document signed by the patient was not retained (e.g., due to potential contamination of the document by infectious material).

## **Method 3: Using an LAR that has a printer, email, AND a scanner/fax machine**

1. Send the consent form to the legally authorized representative by facsimile or email
2. The Investigator/designee can perform the consent interview by telephone when the legally authorized representative can read the consent form during the discussion
3. After the consent discussion, the legally authorized representative can sign and date the consent form.
4. The signed consent form can be returned to the investigator/designee by facsimile or email



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## **Method 4: Using an LAR that only has an email account and ability to take and send photos**

1. Send the consent form to the legally authorized representative by email
2. The investigator/designee arranges a telephone call or video conference call with the legally authorized representative, the investigator/designee, a witness who is not otherwise connected with the clinical investigation and, if desired and feasible, additional participants requested by the prospective participant (e.g., next of kin). Alternatively, in lieu of using a witness, a recording of the conversation can be made.
3. To ensure that the prospective participant (or legally authorized representative) is approached in a consistent fashion, a standard process should be used that will accomplish the following:
  - a. Identification of who is on the call.
  - b. Review of the informed consent document with the prospective participant (or legally authorized representative) by the investigator/designee and response to any questions the prospective participant (or legally authorized representative) may have.
  - c. Verbal confirmation by the prospective participant (or legally authorized representative) that their questions have been answered and that they would like to participate in the trial.
4. Verbal confirmation by the legally authorized representative that they signed and dated a blank piece of paper with a written statement that they voluntarily agree to participate in the protocol, noting both the Protocol 'NUMBER' and brief protocol title.
5. After signing and dating the newly created document, the legally authorized representative sends a photograph of the signed and dated statement by facsimile, text message, or email to the investigator/designee; OR returns the document to the investigator by mail at a later date, or at a future study visit that might occur in person.
6. When using a witness, documentation in the trial records includes a signed and dated attestation by the witness who participated on the call that the patient confirmed their agreement to participate in the trial and signed the document referenced above. When using a recording in lieu of using a witness, documentation in the trial records includes the recording of the conference call.
7. After the signed and dated document is received by trial staff, it should be appended to a copy of the consent document that was reviewed with the legally authorized representative and retained in the trial records as would normally be done for a signed informed consent



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document. Additionally, a note in the trial records should be made explaining the circumstances of why informed consent was obtained through an alternative method. The case history for each trial participant must document that informed consent was obtained prior to participation in the trial.