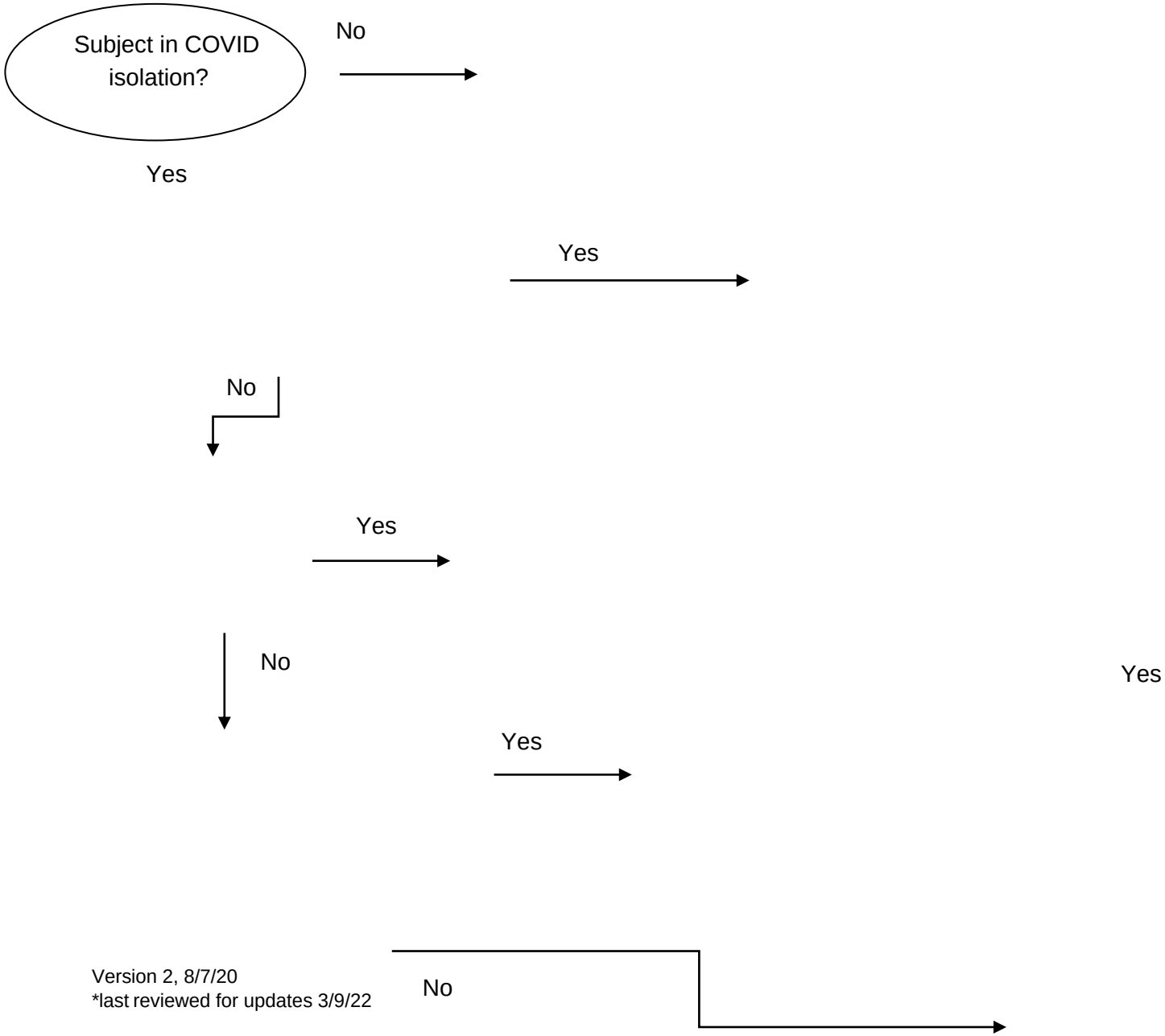
Guidance for Consenting During a COVID-19 Public Health Emergency



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