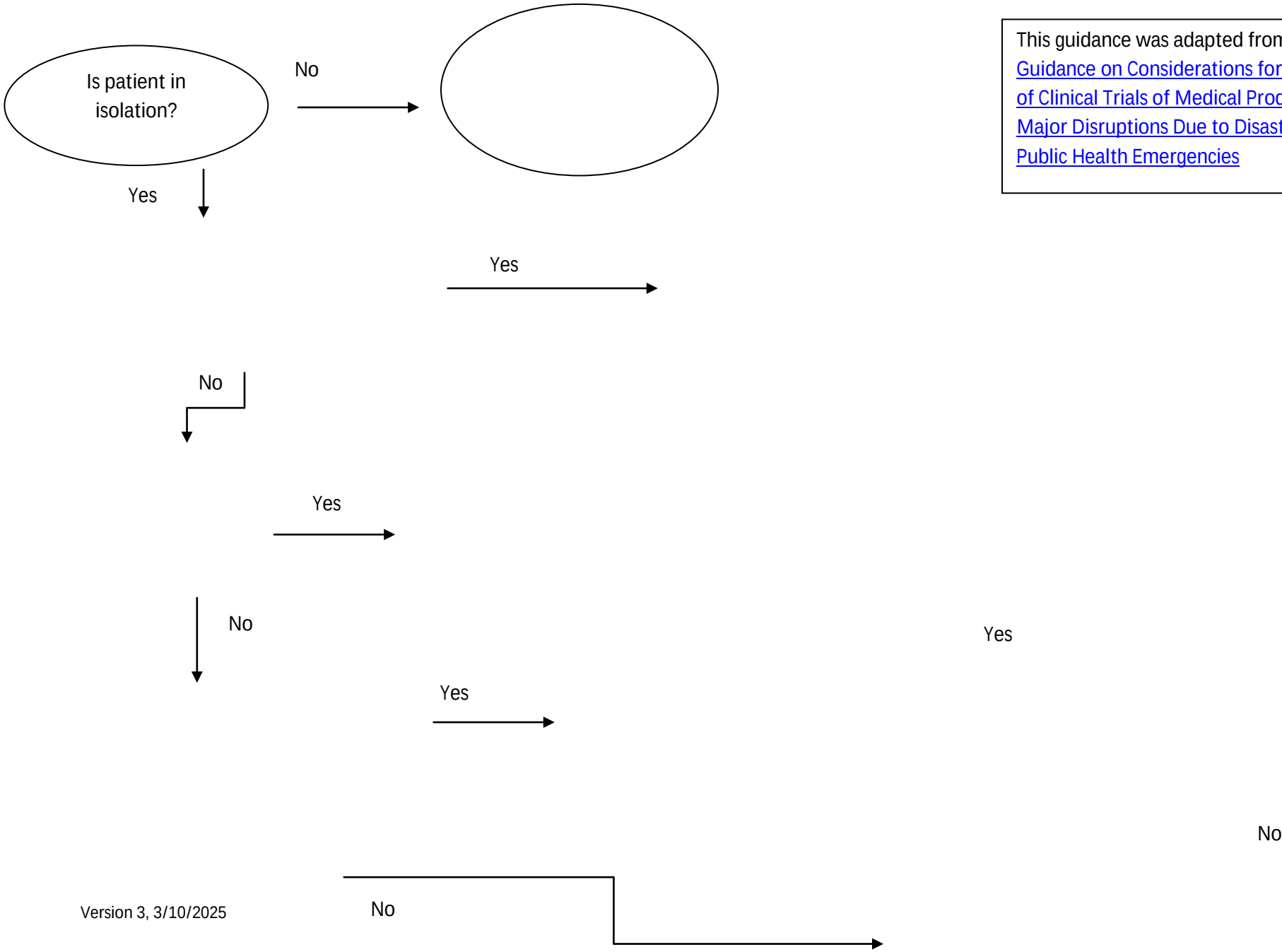
Guidance for Obtaining Remote Consent for Patients in Isolation During a Disaster or Public Health Emergency



This guidance was adapted from the FDA Guidance on Considerations for the Conduct of Clinical Trials of Medical Products During Major Disruptions Due to Disasters and Public Health Emergencies

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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.
    -

through an alternative method. The case history for each trial participant must document that informed consent was obtained prior to participation in the trial.