Written Consent Exceptions

Affirmative consent is required to be in a written/electronically signed or audio/visual recorded format. Exceptions are only allowed for the following circumstances:

1. When a patient is physically present but unable to sign (e.g., due to physical limitation) and a legal representative is not available to sign on their behalf.

2. When consent is being collected during a telehealth visit.
   - *2.1. Telehealth: the use of electronic information and two-way, real-time communication technologies to deliver health care to patients at a distance. Such communication technologies include both audio-video and audio-only (e.g., telephonic) connections.*
   - ***2.2. If you conduct a telehealth visit, you must comply with the requirements outlined in Section 1.2.13 Telehealth of the Privacy and Security Policies and Procedures for both HealtheConnections and the Statewide Health Information Network of New York (SHIN-NY):***
     - HealtheConnections Privacy and Security Policy and Procedures
     - SHIN-NY Policies and Procedures

HealtheConnections advises Participating Organizations to follow their internal policies to obtain and document verbal consent as allowed noted under the section above, noting that such policies shall comply with all requirements of HealtheConnections Privacy and Security Policy.

If a Participating Organization does not already have a policy, HealtheConnections recommends the Participant consider the following when developing a policy and process for documenting consent when a patient cannot sign a consent form due to one of the circumstances noted above.

- Utilize a two (2) witness approach. This means two (2) individuals need to witness the patient's response, either verbally, head movement, or some distinguishable way. It should be noted on the paper consent form or stored electronically in the electronic health record that the patient was unable to sign the form and how the consent was communicated. If considering this method, select methods that align with their organization's workflow. Witnesses may include, for example:
  - The scheduler may act as a witness and note/confirm the patient's choice.
  - The staff member that calls to confirm the patient's appointment may act as a witness and note/confirm the patient's choice.
  - The doctor or other healthcare professional conducting the telehealth visit may act as a witness and note/confirm the patient's choice.
- If available, audio/video recordings may be a potential option to document consent.
- Maintain a record of the consent, including documentation of the collection process being used, for audit purposes.

If an organization is unable to comply with HealtheConnections and SHIN-NY telehealth requirements, the alternative options, listed below, may be used to obtain affirmative consent. **When the alternative option is utilized, consent is considered valid upon receipt of the completed affirmative consent by the Participating Organization, and unlike verbal consent, it does not need to be expired.**

- Send an electronic document to the patient to obtain their signature
- Mail a copy of the consent form to the patient to be completed and returned

443 North Franklin St., Suite 001
Syracuse, NY 13204
healtheconnections.org