

HCHS/SOL Visit 3 - Informed Consent Tracking ICT-QxQ

4/26/2022

General Instructions

The Informed Consent Tracking (ICT) form is an internal administrative form completed by study personnel. The form is not administered to the participant. The form is designed to record, update, and monitor the level of consent given by participants. Details about consent are provided in Manual 2 (Field Center Procedures).

Updates to the ICT form should be made by creating a new occurrence. Never update a form from a prior date.

ICT QXQ Instructions

- Q 0a. Date on which the individual provided consent—not the data entry date.
- **Q 0b.** ID of the staff member that consented the participant—not staff member who entered the data.
- **Q 0c.** Type of consent obtained.
 - 1= Visit Consent. Used when consent is obtained in the clinic or during a home visit. If selected, go to Q0d. If participant agrees (Q0d=1 or Q0d=2), Q1-9 must be completed.
 - **2=** IC Update. Used when the participant changes their consent. Changes can be made during any participant contact, including clinic visits, home visits, and phone calls. **If selected, update Q1-9.** Update **ONLY** the items that are changing. Leave the other items blank.
 - **3=** V3 Phone Interview. Used when consent is obtained during a phone interview for Visit 3. **If selected, complete Q0d**, then save and close form.

NOTE: V3 Phone Interviews should not be administered to participants who require a proxy.

- Q 0d. Consent for V3. Recorded only when Q0c is Visit Consent (1) or V3 Phone Interview (3).
 - **0=** Refused. Used when participant does not consent to V3. Save and close the form.
 - **1=** Agreed. Used when participant consents to V3 or V3 phone interview.
 - **2=** Agreed via Proxy. Used when a proxy is needed to provide participant consent for V3. Details about this process are provided in Section 4.5 of Manual 2 (Field Center Procedures).
- **Q 1-9** Select "Yes=1" if participant or their proxy agrees to a specific level of consent. Select "No=0" if participant or their proxy refuses.

Refer to AFU QXQs for additional information related to AFU participation updates.