



HCHS/SOL - Informed Consent Tracking

ICT-QxQ

9/18/2024

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).

The ICT form is used to document informed consent status for main study visits and to document changes in informed consent for additional components such as future study contacts and use of data. If the participant requests to withdraw from the study entirely (no future contact), do not complete the ICT form. Instead, document the withdrawal in the Study Withdrawal (WTD) form.

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

ICT QXQ Instructions for consent changes after Visit 3 closure

Q0a. Date on which the individual requested a change to their consent status—not the data entry date.

Q0b. ID of the staff member that received that consent update from the participant or their proxy.

Q0c. Type of consent obtained. For consent changes that occur after Visit 3 closure, select Q0c=2 (IC Update). This will enable fields 1-9.

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.

Q0d. Consent for V3. When Q0c=2 (IC Update), this field will be disabled.

Q1-9. For each field, select “Yes” or “No” only if participant or their proxy changed consent status for that specific component. Leave the field blank if there is no update to that consent component.

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