



HCHS/SOL Visit 2- Informed Consent Tracking

ICT- QxQ

General Instructions

The Informed Consent Tracking (ICT) form is an internal administrative form to monitor the level of consent given by study participants to participate in the HCHS/SOL and records all restrictions specified by the participant (refer to Manual 2- Visit 2 Field Center Procedures for this data capture screen.) This form is completed by study personnel, and not administered to participants. This form is also used to capture updates by creating a new occurrence of the form.

ICT QXQ Instructions

- Q 0a.** Enter V2 participation date
- Q 0b.** Staff ID who consented participant
- Q1-9** Enter “Yes=1” (to allow) and “No=0” (to not-allow).

Informed Consent Updates (ICT new occurrence)

Consent to participate in a long term follow-up cohort study is a dynamic process. In the event that a study participant chooses to modify the scope of their consent in Visit 2, or in any of the AFU contact calls, the Update needs to be recorded in a new occurrence of the ICT form. This procedure will capture and track those changes.

ICT-Updates after V2 participation

When there is an update after V2 participation a new occurrence of the ICT form will capture changes.

- Q 0a.** Enter the date the change became effective
- Q 0b.** Staff ID who is reporting the change
- Q1-9** Update the consent by changing only the item(s) being changed from “yes” (allow) to “no” (dis-allow). Item(s) that have not changed will stay blank in the new occurrence of the ICT.

ICT-Updates Data Entry at AFU and have Not participated in V2

The described below data entry process is designed to capture a participant hard refusal at time of AFU Y5+ for future AFU’s and V2. That is, if the participant states they do not want to be contacted ever again for ANY PART OF THE STUDY, including AFU’s, V2 and future studies.

These cases require data entry in **ICT**, **GHE**, **AFT** and **ELE** forms as follows:

Form	Data entry
ICT	<ul style="list-style-type: none"> • Open the first occurrence of the form and complete data entry ONLY for ICT1 and ICT8 • ICT1=0, Agrees to yearly contact by HCHS/SOL staff to answer questions about health & address • ICT8=0, Agrees to allow HCHS/SOL staff to contact them about participating in future health-related studies
GHE	<ul style="list-style-type: none"> • For GHE any AFU year interview • GHE1=2, Participant contacted and refused interview
AFT	<ul style="list-style-type: none"> • AFT any AFU year tracking • AFT5=5, Contacted, Interview refused. Years 6+, provide codes for barriers to retention.
ELE	<ul style="list-style-type: none"> • ELE3=1, Refuses to participate
ETF	<ul style="list-style-type: none"> • ETF1d=5, Contacted, Refused to participate. Provide codes for barriers to retention.