



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

10/30/2020

General Instructions

The Informed Consent Tracking (ICT) form is an internal administrative form completed by study personnel, not to the participant. It is designed to record, update, and monitor the level of consent given by study volunteers to participate in the HCHS/SOL (refer to Manual 2 - Visit 3 Field Center Procedures).

REMEMBER: Always create a New Occurrence of the form, Never Update a form that is present in the system.

ICT QXQ Instructions

Q 0a. Completion Date: Date of consent participation, not the data entry date.

Q 0b. Staff ID: Staff ID that consented the participant, not data entry staff.

Q 0c. This is a: Type of study participation consent, i.e. tracks the type consent form occurrence.
Description of options below.

- 1=** Visit Consent, is the in person V3 participation, used when the consent is done in Clinic or Home visit. Then, **Go to Q0d**. If participant Agrees to participate all **Questions 1-9** need to be completed. If they Refuse, save and close the form.
- 2=** IC Update, when the participant is changing a previous consent.
IC Updates can be done during any participant contact. V3 clinic/home visit consent, and V3-phone-interview and/or AFU contact calls.

Proceed to update Q 1-9

Select No=0, for the items the participant is changing to refuse.

Select Yes=1, for the items the participant is changing to agrees.

Update **ONLY** the items that are changing, leave the others blank.

Refer to AFU QXQs for information on how to code AFU or Visit refusals.

- 3=** V3_Phone Interview, completed at contact call for the V3 phone interviews.
Go to Q0d to record if participant Agrees or Refuses V3-Phone-interview participation.
Questions 1-9 will NOT be completed, this interview is an abbreviated consent and Q1-9 are not part of this abbreviated consent.

NOTE: V3 Phone Interviews should not be conducted for participants needing proxy/informant completion. Set these IDs aside for now and contact/re-assess at a later time.

Q 0d. Participant consented to V3, consent is recorded only when **Q0c.=** Visit consent (1) or V3_Phone_Interview (3). Update to consent (**Q0c.=2**), Does Not require a value for Q0d.

Q 1-9 Enter "Yes=1" (if participant agrees) and "No=0" (if participant refuses)
When participant agrees to participate in a study visit and full informed consent is administered [**Q0c=1 & Q0d=1**] OR when a previous IC is updated [**Q0c=2**].

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