

- FORM:** 111 – EXTENSION (NON –HT) CONSENT STATUS
- Version:** 1.1 – October 1, 2005
- Description:** Completed by Field Center (FC) staff; 1-page form; key-entered at CC.
- When used:** At Transition (close-out) for non-HT participants and anytime after closeout is completed to indicate the participant consents to join the Extension Study.
- Purpose:** To document whether or not the Non-HT participant signed the Extension Consent, a participant who was not presented with the consent because she could not be contacted, or a participant not presented with the consent.

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### GENERAL INSTRUCTIONS

1. Use to indicate the Extension Study consent form was signed, refused, participant not contacted, or not presented with the consent.

Do not use to indicate a participant wants to stop follow-up in the Extension Study; instead, use *Form 9 – Participation Status* to change the participant’s participation status.

2. Review the form for completeness and forward to Data Entry.
3. Data Entry: Key-enter the form into WHILMA. See *Section 10 – Data Management* for specific instructions on how to key-enter this form. Initial form after key-entry.
4. File the key-entered form in the participant’s file.

**Item Instructions**

1. Date of contact Date the participant signs, refuses to sign, or staff member completes the form if the participant is not contacted or not presented with the consent.
2. Completed by Standard 5-digit WHI employee ID. (See common data items.)
3. Contact type Mark appropriate box. (See common data items.)
4. Status Signed/Presented and Refused/No response/Not approached.  
  
Mark “1 – Signed” if the participant signed the consent form.  
  
Mark “2 – Consent refused” if the participant decides not to sign the consent form presented to her.  
  
Mark “3 – No response to contact attempts” if the participant was not presented with the consent because she could not be contacted.  
  
Mark “4 – Not approached” if the participant was not presented with the consent. Specify reason the participant was not presented with the consent (i.e., participant is absolutely no contact). The reason is not data-entered.