

- FORM:** 114 – WHI GENETIC STUDIES CONSENT STATUS
- Version:** 1.1 – October 1, 2005
- Description:** Completed by Clinical Center (CC) staff; 1-page form; Key-entered at CC.
- When used:** Use only for participants who request one of the following changes in their WHI genetic studies consent status:
1. The participant requests her blood not be used for WHI genetic studies; or
 2. The participant who has previously asked that her blood not be used for WHI genetic studies now agrees to allow her blood to be used in WHI genetic studies.
- Purpose:** This is not a routine task. It is only used to document a participant's refusal of her blood for WHI genetic studies, or to re-instate a previous refusal of blood to be used for WHI genetic studies.

GENERAL INSTRUCTIONS

1. Use to indicate the refusal of blood to be used for WHI genetic studies, or to indicate a participant who originally refused to allow her blood to be used for genetic studies has now agreed to allow her blood to be used. Do not prompt or ask the participant this question.

Note: If a participant refuses all blood studies, and not just genetic studies, there is not a form to document this refusal. If the participant makes such a report, call the CCC about the participant's request to not be included in any blood study, and the CCC will delete the participant's samples from the database.

2. Review the form for completeness and forward to Data Entry.
3. Data Entry: Key-enter the form into WHILMA. See *Vol. 5 – Data System, Section 7.1 – Key-Entry* 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 changes her blood consent status, by either:
 1. Currently refusing to allow her blood to be used for WHI genetic studies;
or
 2. Changing her previous refusal for WHI genetic studies and now wants her blood to be included.
2. Completed by Standard 5-digit WHI employee ID. (See common data items.)
3. Contact type Mark appropriate box. (See common data items.)
4. Change in consent No/Yes

Mark “0 – No” if the participant requests her blood not be used for any WHI genetic studies.

Mark “1 – Yes” if the participant previously refused permission for her blood to be used for WHI genetic studies, but now wants to allow WHI genetic studies to be performed using her blood.