

Supporting Statement A

Attachment 5

Next of Kin Questionnaire

Instructions

NEXT-OF-KIN FORMS

INSTRUCTIONS

Study Participation Status

Search to Locate Participant

Retention Worksheet

Initial Notification of Death

FORM: 9 – WHI EXTENSION STUDY PARTICIPATION STATUS

Version: 8 – October 1, 2005

Description: Completed by Field Center (FC) staff; 1-page form; key-entered at FC.

When used: At any contact during the WHI Extension Study in which the participant's follow-up status or newsletter status changes.

Purpose: To document a change in participant's status.

GENERAL INSTRUCTIONS

1. At the beginning of the WHI Extension Study, the participant's follow-up status from WHI will carry over to WHIX. Newsletter status will be set to "1 - Receive newsletter" for extension participants who do not have a status of dead or absolutely no contact.
2. Use this form as needed to change the follow-up or newsletter status of WHI Extension Study participants. See *Section 9.5 – Changes in Participation Status* for more details of follow-up options and changing participation status.
3. Deceased and lost-to-follow-up participants: Do not complete *Form 9 – Participation Status* for a participant identified as deceased or lost-to-follow-up. Complete *Form 120 – Initial Notification of Death* (for deceased participants) or *Form 23 – Search to Locate Participant* (for lost-to-follow-up participants), as appropriate. With data entry of *Form 120* and/or *23*, WHIX will automatically update a participant's follow-up and/or intervention status on the member status screen and will stop newsletter mailings. [See also *Section 9.4.1 – Initiating a Search to Locate Participant (Form 23)*].
4. Complete Items 1 - 3 identifying the date, staff person completing the form, and source of information.
5. Complete Items 4 and 5 as indicated by type of change in status.
Note: Completion of "Item 4 – Change in Follow-up Status" is required when a participant who was previously marked as lost-to-follow-up on *WHI1591 – Participants Who Are Lost to Follow-up* is located.
6. Review the form for completeness and forward to Data Entry.
7. Data Entry: Key-enter the form into the Member Status screen. See *Section 10.5.2 – Updating Participant Status* for specific instructions on how to key-enter this form. Initial the first page after key-entry.
8. File the key-entered form in the participant's file.

Item Instructions

1. **Effective Date** Record the date on which:
 - A participant tells the FC she wants to change her status to resume follow-up activities that had previously stopped, or
 - A FC staff member changes the participant's status when she becomes unwilling to participate in follow-up activities and retention activities have failed.

2. **Completed by** Standard 5-digit WHI employee ID of staff person completing the form.

3. **Source of Information** The source of the information about the change in the participant's status. Mark one only to identify who provided the responses for the form.
 - 1 - Participant: The woman on whom the form is being completed.
 - 2 - Family member or friend: Include household members, even if not related.
 - 3 - Physician: This is a physician outside of WHI.
 - 4 - FC staff member: Use this only if you are inactivating a participant and you are not in voice contact with any of the above.
 - 8 - Other: Mark if the above categories do not apply.
 - 5 - CCC database update: for CCC use only. Do not mark. FCs cannot key-enter this code.

4. **Change in Follow-Up Status** The new follow-up status to which the participant is changing (this may be an increase or decrease in follow-up activities). See *Section 9.5 – Changes in Participation Status* for guidelines on when to change status.
 - 1 - Full follow-up: Mark if the participant indicates that she is willing to follow the regular contact schedule including completing all routine phone calls, mail contacts, or other activities.
 - 2 - Proxy follow-up: Mark if the participant is unable to respond to forms (both interview- and self-administered) because she can no longer communicate orally or in writing (e.g., due to a stroke or dementia). Fill in the proxy name, relationship to participant (e.g., if proxy and participant are brother and sister, record brother), address, and phone number, as well as the reason why the participant is no longer able to complete the forms personally. Complete item 4.1 (type of follow-up) only if applicable.

Data Entry: Key-enter the proxy information in the Personal Information screen in WHIX.
 - 4 - Partial or Custom follow-up: Mark if the participant is unable or unwilling to continue phone contact, CCC mail contact, or if she asks to have a contact that is different from routine contacts. Indicate which contact types are to be discontinued by completing item 4.1 (type of follow-up) when applicable. Specify any changes from the routine contact schedule when applicable
 - 5 - No follow-up: Mark if the participant wants no follow-up (no phone and no mail contact), and retention activities have failed. Women in this category should be contacted periodically to ask them to reconsider participation. However, if a woman is hostile towards WHI and unlikely to change and indicates that she wishes no further contact ever, select the "8 – Absolutely no contact" option instead.

8 - Absolutely no contact: Judiciously select only if the participant has become hostile to WHI and is unlikely to change and should never be contacted to ask her to reconsider participation in the WHI Extension Study. Ideally, the participant has put her request in writing. Proxy and personal contacts should not be contacted.

6 - Deceased. Do not mark this item. (FCs cannot key-enter this code.) This category will remain on the form for continuity with earlier versions of the form and to provide a link between the form and the various reports that use this data item. WHIX automatically updates this category based on data entry of *Form 120 – Initial Notification of Death*.

7 - Lost-to-follow-up. Do not mark this item. (FCs cannot key-enter this code.) Lost-to-follow-up status is based on data entry of specific forms (e.g., *Form 33 – Medical History Update* and *Form 23 – Search to Locate Participant*) and can no longer be selected at the FC's discretion. WHIX automatically updates this category when appropriate. This category remains on this version of the form for continuity with earlier versions of the form and links to relevant reports.

4.1. Type of follow-up
(For codes 2 and 4)

For participants indicating “2 – Proxy follow-up” or “4 – Partial follow-up” in item 4.

2 - No phone: Mark if the participant requests no telephone contact from FC staff.

3 - No CCC mail: Mark if the participant requests no mail contact from the CCC.

Note: Type of follow-up may also be applicable for participants indicating “2 - Proxy follow-up.” Only complete type of follow-up for the participants if they specifically request no phone or no mail follow-up. “2 - No phone” or “3 – No CCC Mail” may be indicated if requested by proxy.

5. Change in Newsletter
Status

Change in newsletter status. All participants receive an annual newsletter, unless they request otherwise.

0 - Refuse newsletter: Mark if the participant requests that she not receive the WHI Extension Study newsletter.

1 - Receive newsletter: Mark if the participant requests that she receive the WHI Extension Study newsletter after having previously requested that it be stopped.

- FORM:** 23 – SEARCH TO LOCATE PARTICIPANT
- Version:** 8 – October 1, 2005
- Description:** Completed by Field Center (FC) staff conducting a Lost-to-Follow-Up search; 2-page form; key-entered at FC.
- When Used:**
1. Required annually for participants listed on *WHIX 1591 – Participants who are lost to follow-up*.
 2. Optional during attempts to search for participants who cannot be contacted by phone or mail.
- Purpose:** To guide and document attempts to contact a participant the FC has lost contact with and who cannot be located.

GENERAL INSTRUCTIONS

1. A search should be initiated in any of the following circumstances:

Required

- Document search for each participant listed on the *WHIX 1591 – Participants who are lost to follow-up*. Complete a *Form 23* for each participant on the report (refer to *Section 9.4 - Locating "Hard to Find" Participants* for detailed instructions).

Optional

- Participant fails to return a mailed questionnaire to the CCC and FC staff cannot make contact with the participant by phone or mail.
 - The CCC has been unable to make contact with the participant by mail, mail sent to the participant has been returned to the CCC with no updated address information, and the FC cannot locate the participant.
2. To initiate a search, affix a participant barcode label to the top of form and complete and key-enter items 2-3.
 3. Conduct a search to locate the participant. Make repeated attempts to locate the participant over a 6 month period. Refer to *Section 9.4 – Locating "Hard to Find" Participants* for details on conducting a search to locate participants. Document the search attempts in item 7.
 4. When the search is concluded, complete items 4-6. Update existing key-entered form (e.g., do not start a new *Form 23*).
 5. Review the form for completeness and forward to data entry.
 6. Data entry – complete data entry of the previous, partially key-entered form (previously entered items 2-3). Do not key-enter a new form.
 7. File the key-entered form in the participant's chart.

Item Instructions

1. Background of Search
- 1.1 Date of last contact Indicate date of last contact with participant (if known or approximate if unknown).
- 1.2 Reasons for search Indicate reasons for initiating search (mark all that apply).
- Participant identified on *WHIX 1591 – Participants who are lost to follow-up*
 - Incorrect, incomplete, or invalid address (optional)
 - Telephone number incorrect (optional)
 - Other (specify)
- Date entry: Items 1.1-1.2 are not data entered.
2. Initiation Date Date search to locate participant started.
3. Initiated By Standard 5-digit employee ID of person initiating search.
4. Date Search Ended Indicate date the search to locate the participant ended. End a search when:
- The participant has been contacted, or
 - Repeated attempts over a 6-month period to contact the participant and her personal contacts using all strategies are exhausted and you fail to locate the participant.
5. Search Ended By Standard 5-digit employee ID of person ending search.
6. Search Result Mark the appropriate box to indicate the result of the search. Update WHIX with new address/phone number information, if obtained.
- 1 - Participant located:
This category includes deceased participants. Complete *Form 120 – Initial Notification of Death* for any participant found to be deceased.
- If you located a “lost” participant listed on *WHIX 1591 – Participants who are lost to follow-up*, complete *Form 9 – Participation Status* with current follow-up status information.
- 4 - Participant not located: Mark if participant cannot be located after repeated search attempts over a 6-month period. Do not complete a *Form 9* for a lost to follow-up participant.
7. Record of Attempts to Locate a Participant Mark activities completed to locate the participant. Use any, all, or other strategies available.
- Check local telephone directory for current telephone number and address.
 - Check with directory assistance for current phone number (if participant has an unlisted number, you may request that a supervisor (directory assistance) call her and ask that she contact the FC).
 - Make phone calls to participant’s home to verify address.
 - Mail a letter to the last known address for the participant, requesting that she contact the FC.
 - Make phone calls to personal contacts listed on *Form 20 – Personal Information Update*.

- Contact any other sources listed on *Form 20 – Personal Information Update*.
- Make phone calls to participant's employer, if applicable.
- Consult reverse directory and contact current resident and/or neighbors at last know address.
- Make phone calls to physician/medical contacts.
- Consult Post Office for current address.
- Mail a certified letter (marked restrictive delivery) to the last known address of the participant, requesting that she contact the FC.
- Check with the Department of Motor Vehicles for current address.
- Check with the Social Security Administration for vital status.
- Conduct Internet searches for lost participants (see below).
- Other (specify)

Optional Internet Sites

You may use Internet web sites to assist in the lost to follow-up searches.

An Internet search is optional, but recommended. You can find a link to suggested web sites on the WHI web site (Search Sites for Lost Participants). This list is not exhaustive, but includes a variety of sources to select from.

Search Sites

AnyWho	www.anywho.com
InfoSpace	www.infospace.com
Yahoo People Search	people.yahoo.com
Worldwide Search	www.numberway.com
InfoUSA	www.abii.com
Reverse Phone Search	www.reversephonedirectory.com
KnowX	www.knowx.com
Search Bug	www.searchbug.com
ZABAsearch	www.zabasearch.com
Military Locator Service	www.militarycity.com

State Vital Records

State Vital Records	www.vitalrec.com
Obituary Registry	www.obituaryregistry.com

Social Security

Social Security Death Index (SSDI)	www.ancestry.com
SSN Lookup	www.informus.com/hdocs/intrpt.html

Obituaries

Newspaper obituaries	www.legacy.com
Obituary registry	www.obituaryregistry.com

Date entry: Item 7 is not data entered.

FORM: 24 - RETENTION WORKSHEET

Version: 8 – October 1, 2005

Description: Completed by Field Center (FC) staff; 1-page form; key-entered at FC.

When used: Recommended for use when the FC has made a contact to conduct special retention activities with a participant who has a retention problem.

Purpose: To indicate that a FC contact has been made to encourage participants with retention problems to remain active in all follow-up aspects of WHI. To indicate the reason(s) for the problem, the result of the contact, and to identify which participants need further retention assistance. This form is a tool to help track and monitor FC efforts to address retention problems and is not required.

GENERAL INSTRUCTIONS

1. Use this form as needed when a contact has been made to negotiate continued participation of WHI Extension Study participants. See *Section 9.3.3 – Documenting and Tracking Special Activities for Follow-up Retention Challenge* for details of procedures. When the participant wants to reduce her participation in the WHI Extension Study, FC staff complete the “Follow-Up Contacts” section of this form to indicate that a retention contact has been made. You may record up to four contacts.
2. When the participant wants to reduce her participation in the WHI Extension Study, FC staff complete the “Follow-Up Contacts” section of this form to indicate that a retention contact has been made. You may record up to four contacts.
3. General retention activities (e.g., newsletters) are not included on this form. This form is for special retention activities that occur between a participant with a retention problem and the FC primary contact for that activity.
4. Complete the contact date, staff ID (ID of staff making the contact), contact type, reasons for retention problem, participation level, and re-contact information.
5. Record contact notes beneath key-entered boxes, as appropriate. It is recommended these notes be key-entered.
6. Review the form for completeness and forward to data entry.
7. Data Entry: Key-enter items in WHIX. Data entry staff may choose to initial or date the form after key-entry.
8. File the key-entered form in the participant's file.
9. Date for future contacts will appear on *WHIX1238 – The Member Adherence and Retention Activity Tracking Report* to help FCs keep track of the need for and timing of additional participant contacts.

Item Instructions

Contact Date	Date on which FC contacts the participant to discuss a problem with her level of retention.
Staff ID	Standard 5-digit WHI employee ID of staff person making the participant contacts(s).
Contact Type	Indicate if the contact is made by phone, mail, or by some other method.
Reason for Problem	<p>This item will assist the FC staff to identify and communicate the problem(s) addressed during the contact. Mark all that apply.</p> <p>Indicate the reasons (if known) that the participant has for reducing her participation. Mark all that apply. Write or key enter information that will help staff choose appropriate retention strategies, as appropriate, under Contact.</p> <p>Personal/Family Problems:</p> <p style="padding-left: 20px;">Includes (not limited to) the following:</p> <ul style="list-style-type: none"> • Demands of work • Family or personal illness, emergency, or other family demands • Vision or hearing problems • Conflicting priorities other than work or family • Financial problems, including unemployment • Lack of cooperation/support from family/friends • Living in nursing homes/sheltered care setting <p>Travel/Scheduling Problems:</p> <p style="padding-left: 20px;">Includes (not limited to) the following:</p> <ul style="list-style-type: none"> • Unable to schedule follow-up (e.g., phone interviews, mammograms) when convenient for participant • Transportation problems, traffic or parking concerns at mammogram facilities
Participation Level	<p>Record the result of the contact as initiated by the participant's stated participation level.</p> <p>Mark "2-Full" if the participant agrees to participate in the appropriate full follow-up activities.</p> <p>Mark "1-Low" if the participant agrees to continue with some, but not all, of the appropriate follow-up activities.</p> <p>Mark "0-None" if the participant wants to stop all follow-up activities.</p>
Continue Contacts?	<p>Mark "0 – No" if FC staff do not plan any further retention contact with the participant.</p> <p>Mark "1 – Yes" if additional retention contacts are needed.</p>
Recontact Date	Date participant is to be recontacted.
Contact Note	<p>Record contact notes beneath key entered boxes as appropriate. These notes may be key entered (recommended).</p> <p>Use this area to describe the nature of the problem, the type of strategies used, the result of the contact, or plans for future contacts.</p> <p>For suggested retention strategies, refer to <i>Section 9.4 – Locating "Hard to Find" Participants</i>.</p>

FORM:	120 – INITIAL NOTIFICATION OF DEATH
Version:	8.1 – May 1, 2005
Description:	2-page form filled out by Field Center (FC) or Clinical Coordinating Center (CCC) staff.
When used:	Completed when a participant death is reported. The FC or CCC may receive notification of the death when a participant's next of kin (NOK), friend/associate, or personal physician calls or writes the FC or CCC and reports the death. Notification of the death may also come from some other source (newspaper obituary, returned mail, or National Death Index report).
Purpose:	To record initial information about the participant death and to capture the report of death in the WHIX database, ensuring mailings stop and study reports are modified accordingly.

GENERAL INSTRUCTIONS

A. Field Center notification of death:

1. FC staff complete *Form 120* immediately upon notification of a participant death. Enter as much information about the death as possible from the notification source. Because full or complete details surrounding the death may not yet be available, all key-entered questions except Q.1 - *Date of death* and Q.2 - *Source of Notification* are formatted to accept an "unknown" response. You have the option of updating the information at a later time.
2. Place the participant's barcode label on the front page of the form.
3. Data Entry: Key-enter the form and initial the front page of the form after key-entry. Following data entry, the WHIX outcomes analyzer creates a death condition. (See *Form 120 (Ver.8) algorithm* [page 4 of these instructions] for information on how the WHIX database analyzer interprets the form responses and determines the death condition/provider link).
4. File the completed *Form 120* in the participant's outcomes file and include it as a reference document (not a source document) for the death adjudication.

B. Clinical Coordinating Center (CCC) notification of death:

1. CCC staff initiate a *Form 120* immediately upon notification of a participant death. CCC staff complete only encounter information: contact date, completed by, contact type, and Q2. -*Source of notification*. This is the minimum information required for CCC key-entry of the form.
2. Data Entry: CCC staff key-enter the *Form 120* with minimal information to ensure the death is captured in the WHIX database and participant mailings stop.

Form audit procedure: when FC staff update a previously data entered *Form 120*, document the reason for the form response update (e.g., a blank question updated with a form response after the FC interviews the next-of-kin (NOK)/proxy). In the form key-entry screen, update the form response and document the reason for the change following the WHIX screen instructions provided.

3. Report *WHIX 1225 – Unresolved Death Report* will show CCC and FC identified deaths. The FC processes CCC identified deaths (along with those identified at the FC), including contacting the next-of-kin and completing/updating the necessary *Form 120* information, analyzing the *Form 120*, and initiating the death investigation.

Item Instructions

- | | |
|--|---|
| Contact date | Month, day, year. Date that the form is completed. |
| Completed by | 5-digit WHI Extension study employee ID. |
| Contact type | Mark appropriate box. |
| 1. Date of death (required) | The date (month, day and year) that the participant died as reported by the notification source. If the exact date is unknown, estimate the date of death. For example, if the month and year are known but not the exact day, use the 15 th of the month as the default date. If the date of death is not available, use the contact date. Indicate on the <i>Form 120</i> that the date recorded is an estimate. |
| 2. Source of notification | Mark the appropriate box. Note: Box 4-NDI is for CCC use and marked only for NDI identified deaths. |
| 2.1. Contact information | The name, address, and phone number where this person can be contacted. |
| 3. Death occurring in a hospital/medical institution | No/Yes/Unknown. Mark 'Yes' for deaths that occur in a hospital, extended care facility, hospice, or nursing home. |
| 3.1. Contact information | The hospital/medical institution name, city, and state where death occurred. Also obtain the address and phone number where this provider can be contacted if available. Enter the provider identification number assigned by the WHIX database in the provider ID box.

Data Entry: Key-enter only the provider identification number. Do not key-enter the facility name and address. |
| 3.2. Location of death | If death did not occur in a hospital/medical institution (home, nursing home, extended care facility, etc.) indicate location and address.

Data Entry: Do not key-enter this information. |
| 4. Autopsy | No/Yes/Unknown. Mark "yes" if the notification source reports that an autopsy was done, even if you do not have appropriate provider information. |
| 4.1. Contact information | The name, address, and phone number where the autopsy was done. Enter the provider identification number assigned by the WHIX database in the provider ID box.

Data Entry: Key-enter only the provider identification number. Do not key-enter the facility name and address. |
| 5. Location of death certificate | Mark the appropriate box. Box 3-Vital Statistics office can serve as a default provider since a death certificate is most often obtained from the state or local vital statistics office (optional). |

- 5.1. Contact information The name, address, and phone number from where the death certificate is obtained. Enter the provider identification number assigned by the WHIX database in the provider ID box.
- Data Entry: Key-enter only the provider identification number. Do not key-enter the facility name and address.
6. Cause of Death Write out what the source (person or documentation) indicates was the cause of death. It can be a single cause or a description of the event.
- Data Entry: Do not key-enter this information.
7. Cause of death, categorized Based on currently available data, select a cause of death. Mark one category only. Mark "99 - Unknown" if you have no information about the cause of death. If selecting "88 – Other cause of death, known," write out the cause of death on the line provided.
- Data Entry: Key-enter the code corresponding to the box checked. Do not key-enter the text corresponding to the "other" box for cancer, cardiovascular, injury, or other cause of death, known.

Analyzing Form 120 – Initial Notification of Death

Form 120 – Initial Notification of Death, is analyzed in the WHIX analyzer. WHIX creates only one death condition and links it to a maximum of one provider, regardless of how many provider IDs are documented on Form 120. The WHIX analyzer uses the algorithm shown in the following table to determine the appropriate condition/provider link on Form 120, Ver. 8.

Form 120, Ver. 8 Analyzer Algorithm

Questions marked on Form 120, Ver.8	Analyzer Result	Action Necessary (see Extension Data management instructions on Linking a Death Condition to a Provider)
<ul style="list-style-type: none"> • Question 3 is marked <u>yes and</u> • Question 3.1 has a provider ID. 	<ul style="list-style-type: none"> • “Death” condition is created and linked to the inpatient provider in Question 3.1. • “Inpatient death” document set is created. • Adjudication case is created. 	None
<ul style="list-style-type: none"> • Question 3 is marked <u>no or unknown, and</u> • Question 4 is yes, <u>and</u> • Question 4.1 has a provider ID. 	<ul style="list-style-type: none"> • “Death” condition is created and linked to provider in 4.1. • Visit is flagged as an “other” type. • Adjudication case is created. 	<ul style="list-style-type: none"> • Determine whether the death occurred as an inpatient or an outpatient visit and change the visit type flag in WHIX to create the document set or • <u>Manually create the document set</u>
<ul style="list-style-type: none"> • Questions 3 and 4 are marked <u>no or unknown, and</u> • Question 5 is any response <u>except unknown, and</u> • Question 5.1 has a provider ID. 	<ul style="list-style-type: none"> • “Death” condition is created and linked to provider in 5.1. • Visit is flagged as an “other” type. • Adjudication case is created. 	<ul style="list-style-type: none"> • Determine whether the death occurred as an inpatient or an outpatient visit and change the visit type flag to create the document set in WHIX or • <u>Manually create the document set.</u>
<ul style="list-style-type: none"> • Questions 3, 4, and 5 are all marked <u>no or unknown, and</u> • Question 2 is answered with <u>any</u> of the possible responses. 	<ul style="list-style-type: none"> • “Death” condition is created. • <u>No</u> provider visit is created and linked to the condition. • No adjudication case is created. • <i>(The comments section of the analyzer screen will display the message “Death condition created but no visit information exists.”)</i> 	<ul style="list-style-type: none"> • <u>Manually create the provider visit and assign the appropriate visit type (inpatient, outpatient, other)</u> • <u>Link the provider visit to the death condition.</u> • <u>Create the document set (if the visit type is “other.”)</u> • <u>Create the adjudication case for the visit.</u>