

Supporting Statement A

Attachment 4

Next of Kin Questionnaires

## NEXT-OF-KIN FORMS

Study Participation Status

Search to Locate Participant

Retention Worksheet

Initial Notification of Death

COMMENTS:

- Affix label here-

Member ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

First Name \_\_\_\_\_ M.I. \_\_\_\_\_

Last Name \_\_\_\_\_

1. Effective Date: \_\_\_\_\_ (M/D/Y)

2. Completed By: \_\_\_\_\_

3. Source of Information:

<sub>1</sub> Participant <sub>4</sub> FC Staff

<sub>2</sub> Family Member or Friend <sub>8</sub> Other

<sub>3</sub> Physician <sub>5</sub> CCC Database Update

4. Change in Follow-Up Status. If participant is changing her follow-up status at this contact, mark the new follow-up status. (Mark only one.)

<sub>1</sub> Full follow-up

<sub>2</sub> Proxy follow-up (Complete 4.1 **only** if applicable.)

Proxy Name: \_\_\_\_\_

Relationship: \_\_\_\_\_

Address: \_\_\_\_\_

Phone Number(s): \_\_\_\_\_

Reason: \_\_\_\_\_

(Enter the Proxy information in the Personal Information Update screen. Notify proxy and request permission.)

<sub>4</sub> Partial or Custom follow-up (Complete 4.1 **only** if applicable) (Contacts customized to meet specific participant needs.) Specify: \_\_\_\_\_

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

<sub>2</sub> No phone

<sub>3</sub> No CCC mail

<sub>5</sub> No follow-up (OK to have periodic contact with participant)

<sub>8</sub> **Absolutely** no contact (No contact with participant)

<sub>6</sub> Deceased → Complete Form 120 – Initial Notification of Death (do not complete Form 9).

<sub>7</sub> Lost-to-follow-up → Complete Form 23 – Search to Locate Participant (Vital Status Investigation) (do not complete Form 9).

5. Change in Newsletter Status:

<sub>0</sub> Refuse Newsletter

<sub>1</sub> Receive Newsletter

Comments: \_\_\_\_\_

K \_\_\_\_\_

<b>Comments:</b>	<b>- Affix label here-</b>
	Member ID: ____ - ____ - ____ - ____
	First Name _____ M.I. _____
	Last Name _____

**Complete questions 1, 2, and 3 to initiate a search. Complete questions 4, 5 and 6 at conclusion of search. Complete Question 7 to document all attempts to locate participant.**

1. Background of search

1.1 Date of last contact with the WHI FC: \_\_\_\_ - \_\_\_\_ - \_\_\_\_ (M/D/Y)

1.2 Reasons for starting the search (more than one may apply):

- WHI Extension Study participant has been identified as "lost to follow-up (e.g., appears on *WHIX 1591 – Participants Who Are Lost to Follow-up*)
- Incorrect, incomplete, or invalid mailing address
- Telephone number is incorrect, disconnected, or no longer in service (optional search)
- Other (*Specify*): \_\_\_\_\_

2. Initiation Date: \_\_\_\_-\_\_\_\_-\_\_\_\_ (M/D/Y)

3. Initiated By: \_\_\_\_-\_\_\_\_-\_\_\_\_

**Data enter questions 4, 5, and 6 at conclusion of search. (Update existing key-entered form; do not start a new form. Complete Form 9 – Participation Status for a change in participant follow-up status.)**

4. Date Search Ended: \_\_\_\_-\_\_\_\_-\_\_\_\_ (M/D/Y)

5. Search Ended By: \_\_\_\_-\_\_\_\_-\_\_\_\_

6. Search Result: **(Required at conclusion of Lost-To-Follow-Up search)**

<sub>1</sub> The participant has been located.  
 (If participant was lost-to-follow-up and has been found, complete and key enter *Form 9 – Participation Status* with updated follow-up status information.)  
 (Includes deceased participants. Complete *Form 120 – Initial Notification of Death* for a participant identified as deceased.)

<sub>4</sub> The participant could not be located.

Comments: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

7. Record of attempts to locate a participant. Complete and document all relevant tasks associated with the Vital Status/Lost-to-Follow-Up search. (Use any, all, or other sources as available.) Note: all tasks may not apply.

Check activities completed

- a) Check **local telephone directory** for current telephone number and current address ..... \_\_\_\_\_
- b) Check with **directory assistance** for current phone number..... \_\_\_\_\_
- c) **Make phone calls to participant’s home** to verify address ..... \_\_\_\_\_
- d) **Mail a letter** to the last known address for the participant, requesting that she contact the FC ..... \_\_\_\_\_  
Date\_\_\_\_\_ Date\_\_\_\_\_ Date\_\_\_\_\_
- e) **Make phone calls to personal contacts** listed on *Personal Information Update*..... \_\_\_\_\_  
Date\_\_\_\_\_ Date\_\_\_\_\_ Date\_\_\_\_\_
- f) Contact any **other sources listed on Personal Information Update** ..... \_\_\_\_\_
- g) **Consult reverse directory** (Polk or Coles) and contact current resident and/or neighbors at last known address. .... \_\_\_\_\_
- h) Make phone calls to **physician/medical contacts**..... \_\_\_\_\_  
Date\_\_\_\_\_ Date\_\_\_\_\_ Date\_\_\_\_\_
- i) **Consult Post Office** for current address..... \_\_\_\_\_
- j) **Mail a certified letter** (marked “restrictive delivery”) to the last known address for the participant, requesting that she contact the FC ..... \_\_\_\_\_  
Date\_\_\_\_\_ Date\_\_\_\_\_
- k) Check with the **Department of Motor Vehicles** for current address..... \_\_\_\_\_
- l) Check with **Social Security Administration** for vital status..... \_\_\_\_\_
- m) Conduct **Internet** search for lost-to-follow-up participant. See *Form 23* Instructions for a variety of web sites. \_\_\_\_\_
- n) **Other (specify):** ..... \_\_\_\_\_

<p><b>Comments</b></p>	<p style="text-align: center;">- Affix label here-</p> <p>Member ID: _____ - _____ - _____</p> <p>First Name _____ M.I. _____</p> <p>Last Name _____</p>
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**FOLLOW-UP CONTACTS**

Contact Date (m/d/y)	Staff ID	Contact Type  1 = Phone 2 = Mail 8 = Other	Reason for Problem* (Check All That Apply)			Participation Level  0 = None 1 = Low 2 = Full	Continue Contacts?  0 = No 1 = Yes	Recontact Date (m/d/y)	Data Entry Initial/Date
			Personal/ Family	Travel/ Scheduling	Other				

_ _ _ _ _ _ _	_ _ _ _ _ _ _	_	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_	_	_ _ _ _ _ _ _
Contact Note:			1	2	8			

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_ _ _ _ _ _ _	_ _ _ _ _ _ _	_	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_	_	_ _ _ _ _ _ _
Contact Note:			1	2	8			

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_ _ _ _ _ _ _	_ _ _ _ _ _ _	_	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_	_	_ _ _ _ _ _ _
Contact Note:			1	2	8			

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_ _ _ _ _ _ _	_ _ _ _ _ _ _	_	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_	_	_ _ _ _ _ _ _
Contact Note:			1	2	8			

\* Reason for Problem: 1 = Personal/Family issues, 2 = Travel/Scheduling problems, 8 = Other

Note: If participation status has changed when retention activities have ended, complete *Form 9 – Participation Status*.

Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Office, 6705 Rockledge Drive, MSC 7730, Bethesda, MD 20892-7730, ATTN: PRA (0925-0414). Do not return the completed form to this address.

-Affix label here-

Member ID: \_\_\_\_\_  
 First Name \_\_\_\_\_ M.I. \_\_\_\_\_  
 Last Name \_\_\_\_\_

Contact date: \_\_\_\_\_ (M/D/Y)

Completed by: \_\_\_\_\_

Contact type: \_1 Phone \_2 Mail \_8 Other

1. What is the date of death? \_\_\_\_\_ (M/D/Y)

2. Source of notification: (Mark one.)

- \_1 Family member
- \_2 Friend/associate of deceased
- \_3 Personal physician
- \_4 NDI (CCC use only)
- \_8 Other \_\_\_\_\_

2.1. Name, address and phone number of the source.

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Phone Number: (\_\_\_\_) \_\_\_\_\_

Provider ID
_____

3. Did the death occur in a hospital/medical institution (i.e., hospital, long term care facility, hospice)?

- \_0 No      \_1 Yes      \_9 Unknown → Go to Page 2.

3.1. Name, address and phone number of the hospital/medical institution (i.e., hospital, long term care facility, hospice).

Hospital Name: \_\_\_\_\_

City/State: \_\_\_\_\_

Phone Number: (\_\_\_\_) \_\_\_\_\_

**Go to Page 2.**

Provider ID
_____

3.2. Location and address of death, if death did not occur in a hospital/medical institution.

Location: \_\_\_\_\_

Address: \_\_\_\_\_

RV \_\_\_\_\_ K \_\_\_\_\_ V \_\_\_\_\_

4. Was an autopsy done?

0 No

1 Yes

9 Unknown

4.1. Name, address and phone number where autopsy was performed.

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Phone Number: (\_\_\_\_) \_\_\_\_\_

Provider ID  
 \_\_\_\_\_

5. Where will the death certificate be obtained?

1 Coroner/Medical Examiner

2 Personal physician

3 Vital Statistics Office

8 Other (Specify): \_\_\_\_\_

9 Unknown

5.1. Name, address and phone number of individual providing the death certificate.

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Phone Number: (\_\_\_\_) \_\_\_\_\_

Provider ID  
 \_\_\_\_\_

6. (Ask of source): To the best of your knowledge, what was the underlying cause of death?

\_\_\_\_\_

7. On the basis of currently available data, what was the underlying cause of death? (Mark one.)

- | Cancer   | Cardiovascular Disease  | "Other" Cause of Death   |
|--|---|--|
| <input type="checkbox"/> 1 Breast                | <input type="checkbox"/> 11 Coronary Heart Disease (CHD)          | <input type="checkbox"/> 31 Alzheimer's Disease                    |
| <input type="checkbox"/> 2 Ovarian               | <input type="checkbox"/> 12 Cerebrovascular disease               | <input type="checkbox"/> 32 COPD                                   |
| <input type="checkbox"/> 3 Endometrial           | <input type="checkbox"/> 13 Pulmonary Embolism                    | <input type="checkbox"/> 33 Pneumonia                              |
| <input type="checkbox"/> 4 Colon                 | <input type="checkbox"/> 18 Other cardiovascular disease<br>_____ | <input type="checkbox"/> 34 Pulmonary Fibrosis                     |
| <input type="checkbox"/> 5 Rectosigmoid junction | <input type="checkbox"/> 19 Unknown cardiovascular disease        | <input type="checkbox"/> 35 Renal Failure                          |
| <input type="checkbox"/> 6 Rectum                |   | <input type="checkbox"/> 36 Sepsis                                 |
| <input type="checkbox"/> 7 Uterus                | <b>Accident/Injury</b>  | <input type="checkbox"/> 88 Another cause of death, known<br>_____ |
| <input type="checkbox"/> 10 Lung                 | <input type="checkbox"/> 21 Homicide                              | <input type="checkbox"/> 99 Unknown cause of death                 |
| <input type="checkbox"/> 8 Other cancer<br>_____ | <input type="checkbox"/> 22 Accident                              |  |
| <input type="checkbox"/> 9 Unknown cancer site   | <input type="checkbox"/> 23 Suicide                               |  |
|  | <input type="checkbox"/> 28 Other Injury _____                    |  |