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

WHI **Form 9 – WHI Extension Study Participation Status** **Ver. 8.1**

OMB # 0925-0414 Exp: 05/09

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:
   - ☐ 1 Participant
   - ☐ 2 Family Member or Friend
   - ☐ 3 Physician
   - ☐ 4 FC Staff
   - ☐ 8 Other
   - ☐ 5 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.)*

   ☐ 1 Full follow-up

   ☐ 2 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.

   4.1. Type of follow-up (for codes 2 and 4*).*
   - ☐ 2 No phone
   - ☐ 3 No CCC mail

   ☐ 4 Partial or Custom follow-up (*Complete 4.1* ***only*** *if applicable)*

   *(Contacts customized to meet specific participant needs.) Specify:*_____

   _____

   ☐ 5 No follow-up *(OK to have periodic contact with participant)*

   ☐ 8 **Absolutely** no contact *(No contact with participant)*

   ☐ 6 Deceased → Complete *Form 120 – Initial Notification of Death* (do not complete *Form 9*).

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

5. Change in Newsletter Status:
   - ☐ 0 Refuse Newsletter
   - ☐ 1 Receive Newsletter

Comments: _____

_____

_____

K _____

OMB # 0925-0414 Exp: 5/09

Comments:	**- Affix label here-** 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)**

   ☐ 1 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.)

   ☐ 4 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)**: .... _____

Comments	**- Affix label here-** Member ID: __ __ __ __ - __ __ __ - __ First Name ______________________M.I.______ Last Name ______________________________

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): Personal / Family	Travel / Scheduling	Other	Participation Level 0 = None 1 = Low 2 = Full	Continue Contacts? 0 = No 1 = Yes →	Recontact Date (m/d/y)	Data Entry Initial/ Date
			☐ 1	☐ 2	☐ 8				
Contact Note:									
			☐ 1	☐ 2	☐ 8				
Contact Note:									
			☐ 1	☐ 2	☐ 8				
Contact Note:									
			☐ 1	☐ 2	☐ 8				
Contact Note:									

* 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.*

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-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

☐8 Other _____

(CCC use only)

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: (____) _____

Provider ID ☐☐☐☐☐

Go to Page 2.

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

☐ 1 Breast

☐ 2 Ovarian

☐ 3 Endometrial

☐ 4 Colon

☐ 5 Rectosigmoid junction

☐ 6 Rectum

☐ 7 Uterus

☐ 10 Lung

☐ 8 Other cancer

_____

☐ 9 Unknown cancer site

Cardiovascular Disease

☐ 11 Coronary Heart Disease (CHD)

☐ 12 Cerebrovascular disease

☐ 13 Pulmonary Embolism

☐ 18 Other cardiovascular disease

_____

☐ 19 Unknown cardiovascular disease

Accident/Injury

☐ 21 Homicide

☐ 22 Accident

☐ 23 Suicide

☐ 28 Other Injury _____

"Other" Cause of Death

☐ 31 Alzheimer's Disease

☐ 32 COPD

☐ 33 Pneumonia

☐ 34 Pulmonary Fibrosis

☐ 35 Renal Failure

☐ 36 Sepsis

☐ 88 Another cause of death, known

_____

☐ 99 Unknown cause of death