

Supporting Statement A
Attachment 7
Physician Questionnaire
Instructions

PHYSICIAN FORM
INSTRUCTIONS

Initial Notification of Death

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

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| 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>