

SECTION 7 FATAL EVENTS

INTRODUCTION

The complete ascertainment and accurate adjudication of fatal events is of major importance in WHI. Mortality, as a WHI clinical outcome, includes all-cause or total mortality and cause-specific mortality in each of the studies (CT, OS). Cause specific mortality is classified as death due to cardiovascular, cancer, injuries or other causes.

This manual section intends to provide guidelines for ascertainment of fatal events, communication with participant's survivors and finally, adjudication of the fatal event.

7.1 Overview of Fatal Events in WHI

Fatal events in WHI are classified as:

- **Total mortality:** The total number of deaths occurring in each of the respective studies and the components of each study (HT, DM, CaD, OS).
- **Cause-specific mortality:** Subclassified into one of the following:
 1. Cardiovascular Disease (See *Section 5 – Cardiovascular Outcomes*): This category includes:
 - a) Definite Coronary Heart Disease (CHD)
 - b) Cerebrovascular Disease
 - c) Pulmonary Embolism
 - d) Possible Coronary Heart Disease (CHD)
 - e) Other Cardiovascular
 - f) Unknown Cardiovascular
 2. Cancer by site (see *Section 4 – Cancer Outcomes*)
 - a) Breast*
 - b) Colon*
 - c) Rectum*
 - d) Recto-sigmoid junction
 - e) Endometrium*
 - f) Uterus
 - g) Ovary*
 - h) Other
 - i) Unknown
 3. Injury
 - a) Homicide
 - b) Accidental
 - c) Suicide
 - d) Other (Specify)
 4. Other Cause of Death: Those conditions not listed above, e.g., non-cardiovascular, non-cancer, and non-traumatic death; include “unknown” cause of death, when the underlying cause of death cannot be determined from the information currently available.
 - a) Other cause of death, known
 - b) Unknown cause of death

* WHI Primary Cancer Outcomes

7.2 Ascertainment of Fatal Events

The ascertainment (i.e., identification, investigation, and documentation) of fatal events can occur routinely (missed 6 month follow-up, returned mail, etc) or non-routinely (i.e., communication by relatives, friends, etc). It requires sensitive and resourceful communication and investigative strategies. Although many WHI staff may identify a participant's death, the Outcomes Coordinator (OC) is usually responsible for the investigation and documentation of this important WHI outcome. See *Fig 7.1 – WHILMA Database Procedures for Fatal Events* for WHILMA procedures.

7.2.1 Identification

WHI staff may become aware of a participant's death in a variety of ways, including but not limited to the following:

- Family members, friends, or the Post Office in response to routine (e.g., semi-annual or annual follow-up, newsletter) contacts or mailings (e.g., forwarded mail or returned mail marked "addressee deceased," participant's family members contact CC, etc).
- Health care providers (e.g., medical records departments, clinics) from whom outcomes documentation has been requested to investigate earlier WHI outcomes.
- CCC National Death Index (NDI) Search. (Special procedures apply. See *Section 7.6 – National Death Index*)
- A proxy (e.g., health care professional, family member, or friend) who is aware of participant's participation in WHI and the need to provide such information to the CC.
- Obituaries or articles in local newspapers or other publications.
- Follow-up of participants lost to contact.

News of a participant death can occur at any time and by any staff member. Having a packet of materials readily available can reduce staff anxiety and assist with efficient yet respectful collection of information surrounding the participant's death. The packet may include the following:

- A script for staff to use when talking with a family member or friend.
- A sympathy card to route to CC staff.
- *Form 120 – Initial Notification of Death.*
- *Proxy Form 33/33D – Medical History Update (Detail)*
- Release of Information (ROI) or proxy ROI.
- A check list to ensure that all relevant documents are collected and promptly routed to both the OC and for data entry.

Upon receipt of a report of death, CC staff:

- Should send a sympathy card(s) to the next of kin and/or proxy as soon as possible. The card(s) can serve as a prelude to a longer contact, at an appropriate time, during which the *Form 33/33D* is completed or the appropriate person is mailed the forms to complete on their own.
- Complete *Form 120 – Initial Notification of Death*. Information obtained from the proxy or other source is used to complete *Form 120*. Not all information may be available when completing the *Form 120*, however, staff should collect, record, and data enter as much information as possible. This form flags the participant as deceased in WHILMA and stops all mailings thus preventing the participant from appearing on follow-up reports.
- Collect a Release of Information (ROI) or proxy release form signed by the participant's next-of-kin (see *Vol. 8, Appendix B.1 – Model General Medical Release Form*). Although some providers may accept an earlier medical release signed by the participant, most will require permission from the executor of the

participant's estate. If there was no executor appointed before the participant's death, the hospital might require proof that the person signing is next-of-kin.

- *Form 33/33D*: Final *Forms 33/33D* are completed by a proxy to identify any other outcomes not yet reported or investigated (i.e., those outcomes ascertained only by "self-report" and those that require further investigation). Note that a sensitive CC staff person with good communication skills should speak with the proxy and may decide, based on this initial contact, to defer completion of these two forms until an appropriate amount of time (e.g., 2 to 3 months) has passed since the death. Refer to *WHIP1225 – Unresolved Death Report* to identify deceased participants missing a *Proxy 33/33D*.

7.2.2 Investigation

The investigation of fatal events, particularly out-of-hospital fatal events, is challenging and requires:

- Knowledge of the WHI documentation priorities for processing death outcomes.
- Ability to communicate appropriately with health care professionals, family members, and friends.
- Familiarity with local legal systems and requirements (for obtaining death certificates, autopsy reports, and coroner's reports).

WHILMA analysis of the *Form 120* will identify a documentation set for inpatient and outpatient visits. If the location of death is unknown and the visit is flagged as "other" in WHILMA, a documentation set is not generated. Once the location of death is confirmed, update the visit status (other) to generate the appropriate documentation set (see *Fig 7.1 – WHILMA Database Procedures for Fatal Events, Section F.5.3 – Requesting and Receiving Medical Record Documentation for a Fatal Event*).

- **Hospitalized death documentation set:**
 - a) Face sheet.
 - b) Discharge summary/Death Summary (including additional documentation that may be needed to obtain information on ICD-9-CM codes).
 - c) Outpatient, emergency room, or emergency medical services reports preceding the hospitalization.
 - d) Death certificate (a certified copy is **not** required).
 - e) Autopsy report (if applicable) (this will usually be noted on the death certificate).
 - f) Coroner's report (if applicable).

In cases of inpatient coronary death, electrocardiograms (ECGs) and cardiac enzymes should also be requested.

- **Non-hospitalized death documentation set:**
 - a) Last WHI adjudication (i.e., adjudication case packet from the most recent hospitalization while a WHI participant). For reference only.
 - b) Outpatient, emergency room, or emergency medical services reports.
 - c) Death certificate (a certified copy is **not** required).
 - d) Autopsy report (if applicable—this will usually be noted on the death certificate).
 - e) Coroner's report (if applicable).

7.2.2.1 Communication

Communications with individuals who have knowledge of or documents about a WHI participant's death require:

- The staff member to be sensitive to and comfortable with possible emotional responses and coping mechanisms and the need to address WHI priorities as well as respond to these issues (e.g., by sending sympathy or condolence cards, listening to individual concerns, providing empathy, and/or making referrals, as appropriate). Although you are required to try and obtain information needed to secure

appropriate medical records and medical history update information, you are not required to conduct in-depth interviews with next-of-kin for descriptive information about events, signs, and symptoms leading up to the death. Refer to *Figure 7.2 – Guidelines for Contacts with Participant Survivors* for further information on appropriate communication considerations.

- Basic understanding of medical conditions and terminology (both professional and common lay terms).
- Ability to prioritize WHI requirements for information (e.g., in rare circumstances, a participant's vital status—alive or dead—is all the information that can be confirmed).
- Understanding about legal requirements, costs, and organizational channels (e.g., at a Vital Statistics office or institutional medical records department, a specific application may need to be completed and costs reimbursed). Some CCs will be able to circumvent some of these requirements [by submitting special applications (e.g., to Institutional Review Boards [IRBs]) for ongoing requests.] Your PI or other CC authority may be the most appropriate person to sign such an application and/or serve as author of other written communications.

If you are not successful in obtaining required documents via your initial and/or usual communication strategies, try other modes of communication (e.g., fax, phone call) as well as other individuals at the institution. With appropriate application and approval, some institutions may allow specific CC staff to abstract medical records information themselves on-site.

7.2.3 Documentation

A complete list of required documentation for a fatal event is listed in *Section 7.2.2 – Investigation* (see also *Table 2.1 – Documentation Requirements for WHI Outcomes*). Documentation (including a hard copy of the death certificate) and forms for the death should be in the same adjudication case packet as the hospitalization and any other WHI outcomes associated with the death case. This is to ensure that the local adjudicator has all relevant medical records when adjudicating cause of death.

7.2.3.1 Special Considerations

- **Essential Documents for Fatal Events**

Every attempt should be made to obtain all documentation needed for adjudication (see *Section 2.3.3.1 – Special Considerations, Essential Documents by Outcomes Type*). Except for central NDI searches, the essential documents for a fatal event include:

• Hospitalized death:	Discharge Summary/Death Summary, and Death Certificate.
• Non-hospitalized death:	Death Certificate, <i>Form 120 – Initial Report of Death</i> (WHI form), and last WHI-Adjudicated hospitalization (for reference only).

- **Death Cases > One Year Old**

If all attempts (using multiple strategies) have been unsuccessful in obtaining documents, **and one year has passed since the death outcome was reported**, assign the case packet and forward it to the Physician Adjudicator with all available documentation. Clearly document steps taken to obtain relevant medical records. Note that in unusual circumstances in which additional time will clearly **not** yield the required documentation (e.g., some deaths occurring outside the United States), **and with approval of your Principal Investigator (PI)**, an adjudication case can be assigned to your Physician Adjudicator after six months of the report of death. See *Figure 7.1 – WHILMA Database Procedures for Fatal Events* for procedures to prepare the fatal event case for adjudication.

- **Participants on Absolutely No Follow-Up (Required)**

No mail or phone contacts or attempts to collect data should be made with participants who have requested absolutely no follow-up.

7.3 Overview of Fatal Events Forms

Form 124A/B – Report of Death must be completed by the Clinical Center (CC) physician adjudicator in the event of death of a participant. The Outcomes Coordinator (or appropriate designee) will place the participant's barcode label in the space provided at the top of the form and route the appropriate outcome form and a copy of the supporting documents to the CC physician adjudicator for completion and signature.

7.3.1 *Form 124A – Preliminary Report of Death*

In April of 1999, at the request of the DSMB, WHI instituted an interim report of death procedure with the goal to report cause of death information in a more timely fashion. *Form 124A – Preliminary Report of Death* is completed upon receipt of any fatal event records within 60 days of notification of participant's death and is entered into the database. Do not complete *Form 124A* if at the sixty day mark, all relevant medical records are available (see *Figure 7.3 – Fatal Event – Flow Diagram for Forms Completion*). Skip to *Form 124B – Final Report of Death* in this instance.

Physician Adjudicator:

Complete questions 1-3 on *Form 124A*. (Question 1, 2, and 3 on *Form 124A – Preliminary Report of Death* are completed in the same way as questions 4, 5, and 6 on the *Form 124B* as detailed under *Section 7.5 – Physician Adjudication – Determining Cause of Death [COD]*).

If no medical records information to confirm cause of death is available within 60 days of notification of participant's death, *Form 124A* is completed as follows:

- Select Cause of Death (COD) 99 – “unknown” under question 2, subclassification of cause of death. An unknown cause of death can be updated on *Form 124B* with COD information when relevant information is received.
- CC Physician Adjudicator should initial the first page of the form prior to key entry.

Outcomes Coordinator:

Upon completion of *Form 124A*, the OC routes the form for data entry and commits *Form 124A* with COD information into the database. Do **not** enter a close date for the adjudication case packet (the close date is entered when the *Form 124B* is complete. See *Volume 5 – Data* for detailed key entry procedures).

7.3.2 *Form 124B – Final Report of Death*

Form 124B – Final Report of Death, is completed upon receipt of all required medical records documentation. *Form 124B* may be completed without first completing *Form 124A* if all associated death information is available within the 60 day time limit allowed for *Form 124A* completion.

Physician Adjudicator:

Complete questions 4-9 on *Form 124B* as detailed under *Section 7.5 – Physician Adjudication – Determining Cause of Death (COD)*.

Outcomes Coordinator:

Route the form for data entry and commit the form. Upon receipt of the completed *Form 124B*, review the form for completeness and discuss any questions with the physician adjudicator.

Enter a *Form 124B* close date for the adjudication case packet. Question 6, subclassification of the underlying cause of death, must be completed before a close date can be entered into WHILMA.

File the form and a copy of all supporting documentation in the participant's outcomes file. Hold the adjudication case packet (completed forms and documentation) at the CC. A WHILMA report will identify those adjudication case packets that need to be copied for central adjudication (placed on local servers monthly).

7.4 **Reports: WHIP 1225 – Unresolved Death Report**

WHIP1225 – Unresolved Death Report is the only report designed to track all tasks surrounding the participant death and should be run monthly. The report tracks the following:

- Duplicate entry of *Form 120* and/or *Form 124*
- Death conditions, created by the WHILMA analyzer, not linked to a provider visit
- Open death adjudications missing a proxy *Form 33/33D*
- Pending and completed *Form 124A – Preliminary Report of Death*
- Closed death adjudications missing a proxy *Form 33/33D*
- Excludes NDI discovered deaths and no contact/absolutely no contact participants.

7.5 **Physician Adjudication – Determining Cause of Death (COD)**

It is the Physician Adjudicator's responsibility to assign the final cause of death. This final decision may, at times, disagree with the causes of death identified on the death certificate. However, the decision should be based on a full review of the documents in the adjudication case packet. Occasionally the Physician Adjudicator may need to return the adjudication case packet back to the OC to investigate further specific required documents that are missing.

7.5.1 ***Form 124B – Final Report of Death (Ver. 4)***

7.5.1.1 **Question 4 – Date of death:**

Date of death is a required field and must be entered. Obtain the date of death from the Death Certificate (DC). If DC is not available, then use the medical records death summary, hospital records, *Form 120 – Initial Notification of Death*, or other sources, in that order.

7.5.1.2 **Question 5: Cause of Death:**

Underlying, contributory, and immediate cause of death.

- **Underlying cause of death** is the disease or injury that initiated the events resulting in death. The underlying cause of death is that one disease or condition that you believe is mainly responsible for causing the woman's death. WHI will use the underlying cause of death as the main classification for WHI death outcomes.

An underlying cause of death must be recorded on the *Form 124B – Final Report of Death*. If the cause of death is unknown as per available documents, the underlying cause may be coded as "unknown cause of death" under question 5.1 and check Box 99 – "unknown" in question 6 on *Form 124B*.
- **Contributory cause(s) of death** is (are) the medical condition that might have contributed to a death. For example, Diabetes (Contributory cause of death) in a patient with Acute Myocardial Infarction (Underlying cause).
- **Immediate cause of death** is the final disease or condition resulting in death. This is the terminal event. While cardiopulmonary arrest is present in all deaths, this is only an acceptable "immediate cause" in rare cases. If an organ system failure, such as congestive heart failure, renal failure, hepatic failure, or respiratory failure is listed, that should be coded for under immediate cause of death. Always report an etiology for the end stage condition as the underlying cause. For example, Congestive heart failure (immediate cause of death) due to ischemic heart disease (underlying cause of death).

If death certificate diagnosis does not agree with medical record information available, then use medical records information which should generally be more detailed and accurate.

Occasionally, the Death Certificate is the only available document. In this case, code the underlying cause as mentioned on the Death Certificate. If the cause of death is incorrectly ordered on the death certificate, adjudicator may code *Form 124*, according to what he/she thinks should be the sequence of events leading to death.

At times the Physician Adjudicator may need to return the adjudication case packet back to the Outcomes Specialist to investigate further specific required documents that are missing.

7.5.1.3 **Question 6: Subclassification of the underlying cause of death:**

One and only one category must be selected to sub-classify underlying cause of death. Subclassification of the underlying cause of death in question 6 (*Form 124B Ver. 4*) should reflect the “underlying cause of death” noted in 5.1.

ICD-9-CM codes (if present on the death certificate or recorded on the hospital face sheet) for these causes of death will be recorded for future analyses. In addition to the above, the subclassification of underlying cause of death (specific causes related to cancer, cardiovascular disease, accident/injury, other, or unknown) will be recorded. The appropriate ICD-9-E-Code for accidents/injuries will also be recorded for future analyses.

Tips for Cancer Deaths:

- If the cause of death is a metastatic cancer, and the primary site is known, then the primary site should be coded as the cause of death, and subclassification of the underlying cause under question 6 should also be based on the primary site of cancer.
- When death certificate states colo-rectal cancer, review all available records to determine if primary site was colon or rectum.
- If the death certificate is the only available document, and states colo-rectal primary, AND there is a history of either colon or rectal cancer, assume the colo-rectal cancer previously documented was the primary site at death. In this case, code 6 (subclassification of the underlying cause of death) to the site of previous colo-rectal primary.
- Case with Death Certificate only (no other information): If death certificate stating “colo-rectal” cancer is the only available document and there is no history of either colon or rectal cancer, then code question 6 - “Subclassification of underlying cause of death” as “4 – Colon”. In this situation, although it is unknown whether the primary is Colon, recto-sigmoid junction or rectum, this will be a trigger, so that the DSMB will know it is a colo-rectal primary cancer site. Also complete a *Form 122 – Report of Cancer Outcome*. The central cancer coders will follow-up with these cases to determine the primary site.
- Cancer of Sigmoid Colon: Sigmoid Colon is included in Colon and not in recto-sigmoid junction.
- Cancer of Appendix: Though the appendix is a part of the colon, WHI DOES NOT INCLUDE APPENDIX in the primary colon cancer endpoint. It is coded to “86 – Appendix” on *Form 122* and to “8 – Other Cancer” on *Form 124* instead of “18 – Colon” for the study.
- Cancer of Uterine Cervix is not included in Cancer Uterus. Cancer of Cervix should be coded as box “8 – Other cancer” under subclassification of underlying cause of death.
- Chronic Leukemia/ Lymphoma: These are considered a malignancy. If one is specified as the underlying cause of death (question 5.1), then Question 6 should be coded to “8 – Other cancer” on *Form 124*.

- Myelo-proliferative disorders (Polycythemia vera, essential thrombocythemia): These are not considered malignancy. Hence are coded for as “Other known cause”

Tips for Cardiovascular Disease

Definite CHD: Definite CHD may be coded for, when death certificate is consistent with death due to Coronary disease and there is a history of chest pain prior to death, or evidence of pre-existing coronary disease such as:

- a history of CHD in the absence of valvular heart disease or non-CHD
- use of Nitroglycerin
- Echocardiogram showing focal wall motion abnormalities

History of CHD may be documented with a noted history in hospital records or with confirmed prior outcomes listed on the IDS sheet.

Possible CHD: Possible CHD may be coded for, when the death certificate is consistent with death due to coronary disease, and there is no prior evidence of pre-existing coronary disease. Generally, an out-of-hospital sudden death is coded as possible CHD death if there is no other information available and in the absence of other possible causes.

Cerebrovascular: Only ischemic and hemorrhagic strokes are included under cerebrovascular deaths. Subdural hematoma, and venous infarcts are not included under cerebrovascular events.

Pulmonary embolism: Pulmonary Embolism may be coded as the underlying cause of death if this diagnosis is supported by available hospital records, or in the absence of hospital records, if listed on the Death Certificate as the Cause of Death.

Other CV may be coded for to encompass non-ischemic cardiomyopathy, alcoholic heart disease, myocarditis, valvular heart disease, congenital heart diseases, CHF (unrelated to coronary disease), aortic dissection, ruptured aortic aneurysm and other Cardiovascular causes.

7.5.1.4 Question 7: Was an autopsy performed?

Record from death certificate. If Death Certificate not available, record from *Form 120 – Initial Notification of Death*.

7.5.1.5 Question 8: Documents used for adjudication:

Mark all the documents used for completing *Form 124*. If a prior adjudication is used, it may be mentioned in Box 8.

7.5.1.6 Question 9: Coronary Death (In and out-of-hospital deaths)

To be filled in for all deaths coded as definite CHD or possible CHD under question 6.

7.5.2 Completion of Additional Outcomes Forms

In addition to the cause(s) of death (as described above), the Physician Adjudicator should review the case packet for any other possible WHI outcomes and either adjudicate those outcomes appropriately or request additional documentation from the OC.

Cancer deaths: If the cancer mentioned in the death certificate was not previously adjudicated, and was diagnosed after enrollment/randomization, *Form 122 – Report of Cancer Outcome* should be completed.

Cardiovascular deaths: In case of a hospitalized cardiovascular death/outcome, fill out *Form 121 – Report of Cardiovascular Outcomes*, if not already reported.

DVT/ PE: For participants in the HRT trial only, complete *Form 126* for all hospitalized PE/DVT. Complete *Form 126* if OP records confirm DVT or an autopsy report confirms PE.

7.5.3 Central Adjudication

The Cardiovascular Central Adjudication Working Group adjudicates all CT and a subsample of OS deaths. CCs will receive requests for adjudication case packets of participants with adjudicated deaths in the monthly central adjudication requests.

7.6 National Death Index

At regularly scheduled intervals, information from the National Death Index (NDI) – centralized database containing death certificate information from across the nation – will be reviewed by the CCC for information on WHI participants. This review will provide vital status information on WHI participants as well as codes for cause of death.

A data file of WHI Clinical Trial and Observational Study participants identified as lost-to-follow-up (known deceased or known to be alive) is submitted to the NDI.

Upon NDI search, if one or more of the women are newly identified as deceased, the CCC will send the CC the participant's fact of death information (date of death and subclassification of death) based on the NDI search results.

The Clinical Center will receive:

- The list of newly identified deceased participants for the CC.
- An original *Form 7 – Participation Status* and *Form 120 – Initial Notification of Death* for each participant not already identified as deceased, along with instructions for filing them in the participant's outcomes chart. The CCC completes and data enters the *Form 7* and *Form 120* into the local WHILMA database and the CC does not need to data enter these forms.
- A CCC completed *Form 124B – Final Report of Death* and instructions for filing the original *Form 124* in the participant's outcomes chart. The CCC will also data enter the *Form 124* information into WHILMA and the CC will not need to data enter it.

The NDI application states that the CCs are not allowed to do follow-back investigations with Next-of-Kin and/or health care providers. Hence, CC should not initiate any further contact with the participant's family or physician. The CCC has revised WHILMA database reports to exclude the deceased participants' information. Relevant outcome reports now exclude participants who have NDI indicated as the source of death status. Additionally, the CCC is updating the CC notes with a comment advising staff not to follow back for additional information.

**Figure 7.1 – Excerpt: Volume 5, Appendix F
WHILMA Database Procedures for Fatal Events**

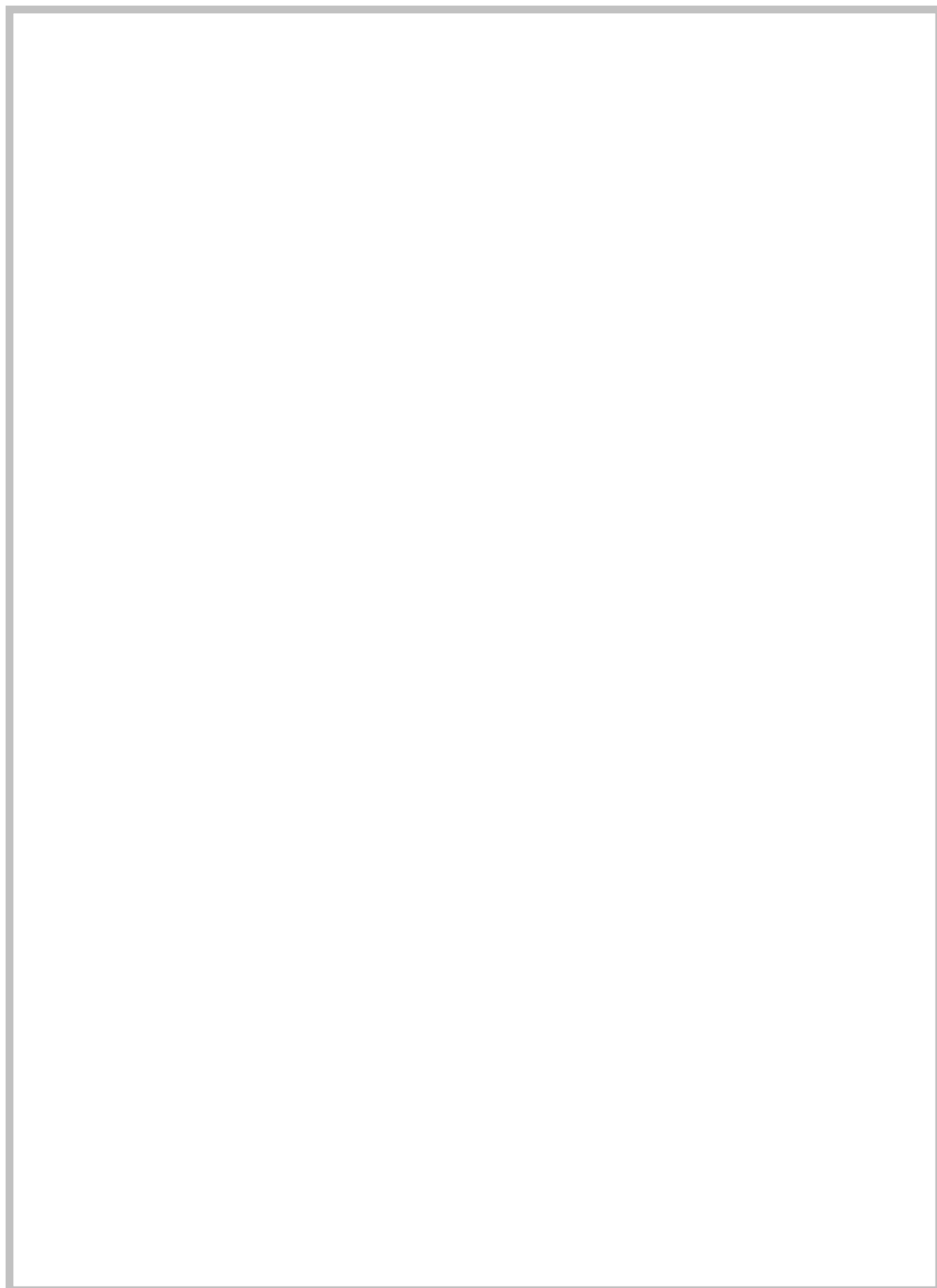


Figure 7.1 (cont.)



Figure 7.1 (cont.)



Figure 7.1 (cont.)



**Figure 7.2 – Excerpt from Volume 2, Section 6
Guidelines for Contacts with Participants' Survivors**



Figure 7.2 (cont.)



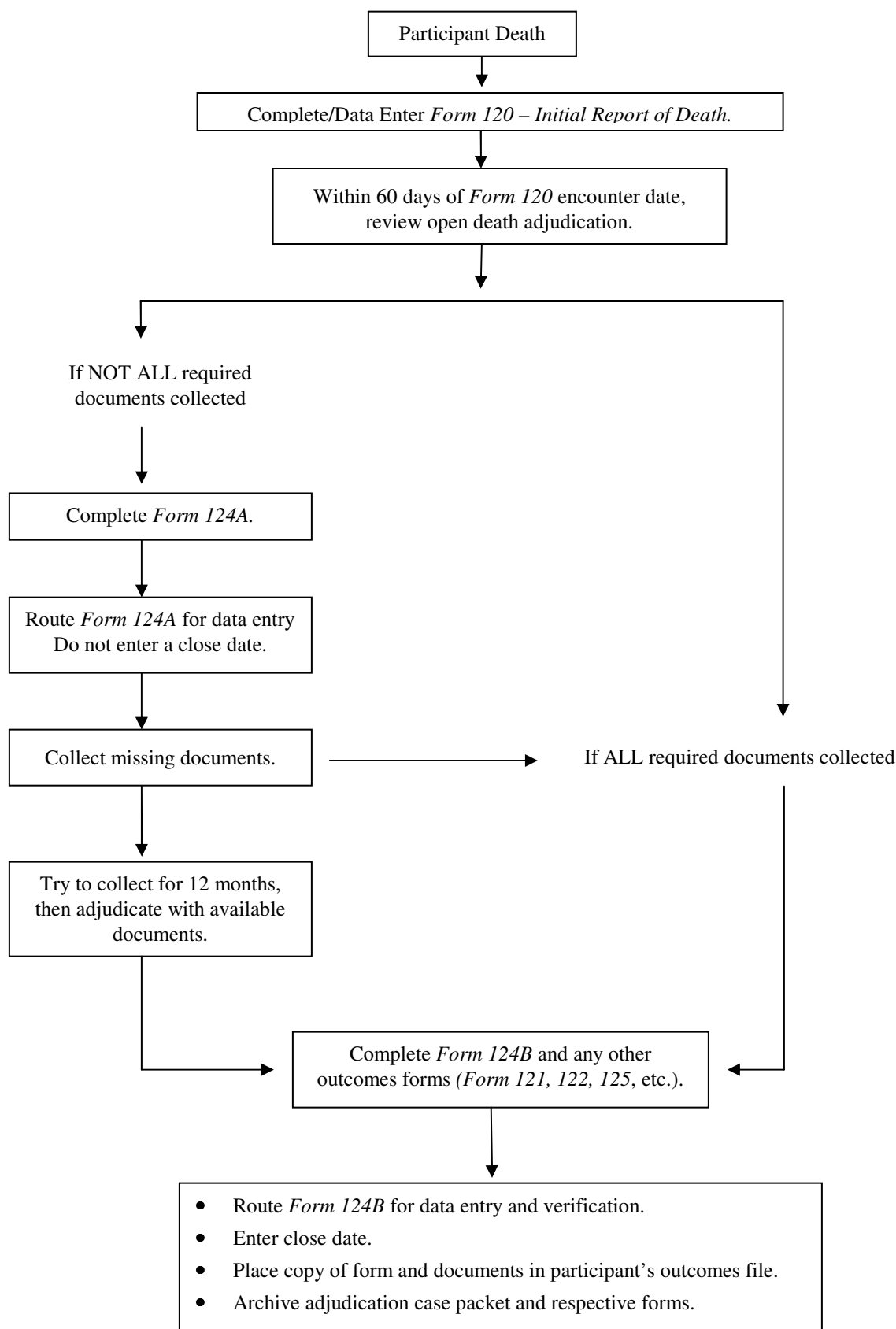
Figure 7.2 (cont.)



Figure 7.2 (cont.)



Figure 7.3
Fatal Event – Flow Diagram for Fatal Event Forms



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