Section 8

Outcomes

Introduction

The Women's Health Initiative (WHI) Extension Study (ES) outcomes are diverse and complex. The aim of the WHI Extension Study is to continue to assess the relationship of particular interventions on a broad range of health and illness conditions in women. Primary, subsidiary, and intermediate outcomes have been identified as important for the study. To ensure that the identified outcomes represent true disease states, detailed outcomes ascertainment procedures and diagnostic criteria for adjudication have been developed by study investigators. The standardized outcome procedures detailed below help ensure that the outcomes are ascertained in an unbiased manner.

The WHI Extension Study outcomes ascertainment and adjudication procedures are by and large the same as those used for the main WHI program. Outcomes ascertainment procedures performed by Field Center (FC) staff include the identification, investigation, and documentation of potential outcomes, and adjudication procedures include the review of assembled case packets by Physician Adjudicators.

All WHI Clinical Trial (CT) participants were unblinded to their treatment assignment before the close of the main WHI study (October 1, 2004 – March 31, 2005). While this information is located in the FC chart documentation and is readily accessible, the treatment assignment information should **not** be made available to the Physician Adjudicator who is adjudicating the possible WHI Extension Study outcomes. This is to maintain continued objectivity and uniformity in the adjudication process and ensure unbiased adjudication of events.

In August 2009, the Extension Study Executive Committee (ESEC) and Principal Investigators (PIs) voted and approved to reinstate investigation and adjudication of Heart Failure (HF), formerly called Congestive Heart Failure (HF), and to expand ascertainment and adjudication of Venous Thromboembolism (VTE) to include African American and Hispanic participants (previously HT only). See *Table 8* for a detailed summary of HF and VTE ascertainment and adjudication over time. These participants are eligible to be in the Documented Cohort (DC*). The "*" will be used for the remainder of the Extension Study to differentiate those who are eligible to be in the Documented Cohort (DC*) vs. those who ultimately consent and become part of the official 2010-2015 Documented Cohort (DC). On September 14, 2009 the new procedures were implemented and will include retrospective pulls to collect WHI archived cases at FCs and prospective ascertainment of HF and VTE Extension Study self-reports. Adjudication of these cases will be conducted during the 2010-2015 Extension period.

8.1 Overview of Outcomes Process

The types of events collected in the WHI main program have been streamlined in the WHI Extension Study and outcomes ascertained through self-report alone has been expanded. Major outcomes of interest require full ascertainment and documentation supporting the event or procedure. See the list of outcomes requiring adjudication in *Table 8.1 – WHI Extension Study Outcomes*. Those outcomes identified by self-report alone (i.e., do **not** require investigation, documentation, or adjudication) are also included in the table under "Self-reported outcomes requiring adjudication for a hospitalization of 2 nights or more."

The entire process of ascertainment of an outcome plus the adjudication of a final diagnosis by the Physician Adjudicator should be completed within 3 months of initial identification of a possible outcome. The three-month interval begins with the completion of *Form 33 – Medical History Update* and ends with the adjudication of the event by completion of the appropriate outcomes form. See *Figure 8.1 – Outcomes Ascertainment and Adjudication Process* for a flow diagram of the entire process. Given the delays often inherent in obtaining records, it may at times not be possible to meet this 3-month deadline. However, all efforts should be made to obtain and process all documents as quickly as possible.

Table 8
Summary of Heart Failure (HT) and Venous Thromboembolism (VTE) over Time

<table>
<tr><th></th><th colspan="2">WHI</th><th colspan="2">Extension</th><th colspan="2"></th></tr>
<tr><th></th><th colspan="2">1994-2005</th><th colspan="2">2005-2008</th><th colspan="2">2009-Present</th></tr>
<tr><th>Outcome</th><th>Local Adj.</th><th>Central Adj.</th><th>FC</th><th>Central</th><th>FC</th><th>Central</th></tr>
<tr><td rowspan="3">Heart Failure (HF, CHF)</td><td rowspan="3">Full ascertainment & adjudication of all HF self-reports</td><td>HT: Adjudicate all locally confirmed HF</td><td colspan="2" rowspan="3">Drop HF investigation & adjudication as a streamlining measure</td><td colspan="2">Reinstitute HF investigation & adjudication for the Documented Cohort* (DC*)</td></tr>
<tr><td rowspan="2">OS: Adjudicate majority of locally confirmed HF (AS126)</td><td>DC*: Retrieve WHI locally confirmed and denied HF from FC archive (forward to CCC)</td><td rowspan="2">DC*: Hold for adjudication in 2010-2015 Extension Study</td></tr>
<tr><td>DC*: Investigate Extension Study self-reports HF</td></tr>
<tr><td rowspan="3">Venous Thromboembolism (VTE)</td><td rowspan="3">HT: Investigate & adjudicate all self-reports</td><td rowspan="3">HT: Adjudicate all locally confirmed and denied cases</td><td rowspan="3">HT: Investigate self-reports</td><td rowspan="3">HT: Adjudicate all self-reports</td><td colspan="2">Expand VTE investigation & adjudication from HT only to the DC</td></tr>
<tr><td>DC*: Retrieve WHI cases with self-reports of VTE</td><td rowspan="2">DC*: Hold for adjudication in 2010-2015 Extension Study</td></tr>
<tr><td>DC*: Investigate Extension Study self-reports of VTE</td></tr>
<tr><td colspan="7">Documented Cohort (DC*): All HT, African American, and Hispanic participants</td></tr>
</table>

These sections of the WHI Extension Study Manual contain instructions and resources for FC physicians and staff to follow for each step of the outcomes and adjudication process.

- *Section 8.2– Identification of Outcomes, Section 8.3 – Investigation of Outcomes,* and *Section 8.4 – Documentation of Outcomes* describe how to process the initial identification of an outcome, investigate and obtain the required documents for each outcome, assemble the documentation into an adjudication case packet, and forward the case packet with appropriate outcomes forms to the CCC for central adjudication. Note that other outcomes ascertained only by self-report are identified in *Table 8.1 – WHI Extension Study Outcomes.*
- *Section 8.5 – Fatal Events – Special Considerations* describes additional procedures and guidelines for follow-up of participant deaths, including contacts with participant families.
- *Section 8.6 – Physician Adjudication* describes the procedures Physician Adjudicators must follow in reviewing documents related to a possible WHI Extension Study outcome and assigning a WHI Extension Study-defined diagnosis.

- *Sections 8.6 to 8.11 – Fatal Events, Cardiovascular, Other, Fracture, and Cancer Adjudication* describe in detail how to complete the specific outcomes forms which assign specific diagnoses.
- *Appendix A – Field Center and Participant Forms:* Includes *Forms 33, 33D, 120, 125, and 134* as well as other forms completed by participants and FC staff.
- *Appendix B – Coding Reference, ICD 9-CM and ICD-10*
- *Appendix C – Explanation of Medical Terms*: medical terms used in outcomes documents.
- *Appendix D – Medications Used for Treatment of Cardiovascular Disease*
- *Appendix E – Model HIPAA Medical Release of Information*

8.1.1 Definitions Used for WHI Extension Study Outcomes

Definitions specific to WHI Extension Study outcomes and outcomes investigations are included below.

Adjudication: The assignment of the final decision/diagnosis by a Physician Adjudicator or Clinical Coordinating Center (CCC) Cancer Coder after reviewing the outcome documents contained in an adjudication case packet and recording the decision/diagnosis and details supporting the diagnosis on the outcomes forms.

Adjudication case packet: Materials relevant to a specific outcome case. Each case packet includes an *Investigation Documentation Summary* (*WHIX0988*), *Members Outcomes Status Report* (*WHIX1215*), relevant outcomes forms, and required medical record documents pertaining to the type of outcome(s) being adjudicated.

Ascertainment: The initial identification of a possible WHI Extension Study outcome, investigation of sources of supporting medical records, and documentation for an adjudication case.

Closed outcome case: A WHIX database function in which further ascertainment and/or adjudication procedures are stopped or concluded, either because a final diagnosis has been assigned or it has been determined that no WHI Extension Study outcome occurred. A closed outcome is recorded in the database via assignment of a "close date" in the WHIX Outcomes Management Subsystem.

Discovery: Review of medical records indicates a possible WHI Extension Study outcome or provider visit not self-reported by the participant on her *Form 33 – Medical History Update* or *Form 33D – Medical History Update (Detail)*. Investigation of the unreported outcome or provider visit is appropriate as they were located in medical records the Outcomes Coordinator (OC) is authorized to review. Also includes identification of a death through the Social Security Death Index or National Death Index (SSDI or NDI) and obituaries.

Documentation: The assembly of required supporting medical records (obtained through investigation of a possible outcome) into an adjudication case packet. Documentation also includes tracking these documents and packets through the WHIX database and/or manual tracking systems until the adjudication case is closed.

Emergency Room (ER) or Emergency Department (ED) visit: Visit or admission to a hospital ER/ED. This may or may not lead to a hospital admission. Several events (i.e., newly diagnosed hip fractures, cancers, PTCAs, strokes, deep vein thrombosis [DVT, DC*] or hysterectomy [HT only]) occurring or diagnosed solely at an ER visit (without subsequent hospitalization) will be investigated, documented, and adjudicated as possible outcomes. Also includes ER/ED documentation in all adjudication case packets when the ER visit results in a WHI ES defined outcome.

Five major cancers: The five primary WHI cancer outcomes sites: breast, colon, rectum, endometrium, and ovary.

Hospitalization: An overnight stay in an acute care hospital, for any reason. In the WHI Extension Study, there is no minimum length of stay required for specified outcomes of interest. Other selected outcomes are investigated only if the hospitalization is for 2 nights or more. (See *Table 8.1 – WHI Extension Study Outcomes* for the complete list of outcomes to investigate based on the hospitalization length of stay.) Short stays, observation stays, and day surgeries may be referred to in medical records as outpatient visits, but for the WHI ES these stays are considered hospitalizations if they result in overnight stays at an acute-care facility due to a complication or need for close observation. (Note that an overnight stay in a rehabilitation facility is **not** considered an overnight hospitalization.) Psychiatric admissions are also not investigated or

adjudicated in the WHI ES. Transfers from one hospital to another, on the same day, are considered one "case" for WHI ES purposes, and medical records are obtained from both facilities.

Identification: The routine procedures through which the FC learns of a possible outcome, which is typically through participant completion of an annual *Form 33 – Medical History Update* and subsequent *Form 33D – Medical History Update (Detail)* or in the event of a participant's death, through some other interim report to FC staff by the participant's proxy (family, friend or health care provider). The initial notification of a participant's death may also come from other sources (e.g., CCC returned mail, newspaper obituaries, National Death Index reports).

Investigation: The process of locating provider (e.g., hospitals, clinics, physicians) information about a possible outcome, requesting medical records that may support its diagnosis, and filing such documents in a participant's outcomes file.

Medical History Update Forms: *Form 33 – Medical History Update* is a self-administered form (routinely mailed by the CCC to the participant) annually. *Form 33* collects information on those outcomes that do not require further ascertainment procedures, as well as screens for those participants who have had a major clinical event. *Form 33D – Medical History Update (Detail)* is required from those participants who indicate on *Form 33* that they have had a major clinical event that may require adjudication. *Form 33D*, collected by FC staff by phone or mail, is used to obtain more detailed information to assist the OC with outcomes ascertainment.

Outcomes file: A participant's file of outcomes-related documents. This file may include medical records documents that are not currently required for a pending adjudication case packet, as well as copies of pending and closed adjudication case packets. There is no required organization for the WHI ES chart. Instead the CCC recommends the following be included in the charts: *Form 33 – Medical History Update*, *Form 33D – Medical History Update (Detail)*, *Form 85 – Mammogram* with accompanying documentation attached, Personal Information Updates (PIU), Consents, and Release of Information (ROI). The Personal Information Updates (PIUs) from the WHI chart may be included in the outcomes chart. It may also be helpful to keep the *Form 85*s and chart/progress notes from WHI with the chart. The original WHI outcomes charts need to be accessible during the WHI Extension Study, but it is not necessary for immediate or frequent retrieval.

Outcomes forms: *Forms 120-132*, are completed by the FC Outcome Coordinator (OC), Physician Adjudicator, or CCC resource. Forms completed by FC staff and participants are located in *Appendix A* and outcomes forms are located in *Sections 8.6 – 8.11*.

Outpatient visits: Any short stay, observation stay, clinic visit, or day surgery that does not involve an overnight stay. Only certain events (e.g., newly diagnosed stroke, hip fractures, cancers, cardiac revascularization procedures, hysterectomy [HT only], and DVT for the DC*) occurring at an outpatient visit alone without hospitalization will be investigated, documented, and adjudicated as possible outcomes. If the selected outpatient visit results in an overnight hospital stay, collect and include the outpatient documentation in the adjudication case packet. See *Table 8.1 – WHI Extension Study Outcomes* for a complete list of outpatient visits requiring investigation.

WHIX: The WHI Extension Study database that assists with the collection and tracking of outcome cases through the ascertainment and adjudication process. The review of the participant's outcomes chart should not be replaced by the sole use of the WHIX tracking system.

Table 8.1
WHI Extension Study Outcomes

As identified on *Form 33*, *Form 33D*, and *Form 120*

Outcomes Requiring Adjudication

- **Coronary heart disease & other cardiovascular disease*** *Form 121*
  Hospitalized one or more nights:
  Acute myocardial infarction (MI)
  Coronary artery bypass graft (CABG)
  Heart failure (HF)**
  Peripheral arterial disease, symptomatic and/or requiring a procedure
  Carotid artery disease requiring a procedure or surgery
  Hospitalization not required:
  Coronary death
  Coronary revascularization (PTCA, coronary stent, laser)
- **Stroke*** (hospitalization not required) *Form 132*
- **Venous thromboembolic disease**** – *Form 126*
  Hospitalized one or more nights:
  Pulmonary embolism (PE)
  Hospitalization not required:
  Deep venous thrombosis (DVT)
- **Five major cancers*** – *Form 130*
  Hospitalization not required:
  Breast, Colon, Endometrium, Rectal, Ovary

  Other Cancers* (excludes non-melanoma skin cancer)
- **Hip and Upper Leg Fractures*** – *Form 123*
  Hospitalization not required
- **All deaths*** – *Form 120, 124*
  Out of hospital death: Adjudicate death with last relevant hospitalization (if available).
- **Hysterectomy*** – *Form 131* (HT only)
  Hospitalization not required:
- **Any hospital stay of 2 nights or more except those solely for certain procedures** – *Form 125*

Self-reported outcomes requiring adjudication for a hospitalization of 2 nights or more. *Form 125*

- **Self-report events on *Form 33***
  Diabetes mellitus requiring therapy
  Other age-related outcomes:
  inflammatory arthritis
  macular degeneration
  moderate or severe memory problems (dementia, Alzheimer's)
  Benign breast disease
  Colorectal polyps
  Venous thromboembolic disease (non HT)
  Angina pectoris (chest pain)
  TIA
  Parkinson's disease
  Systemic lupus erythematosus (lupus)

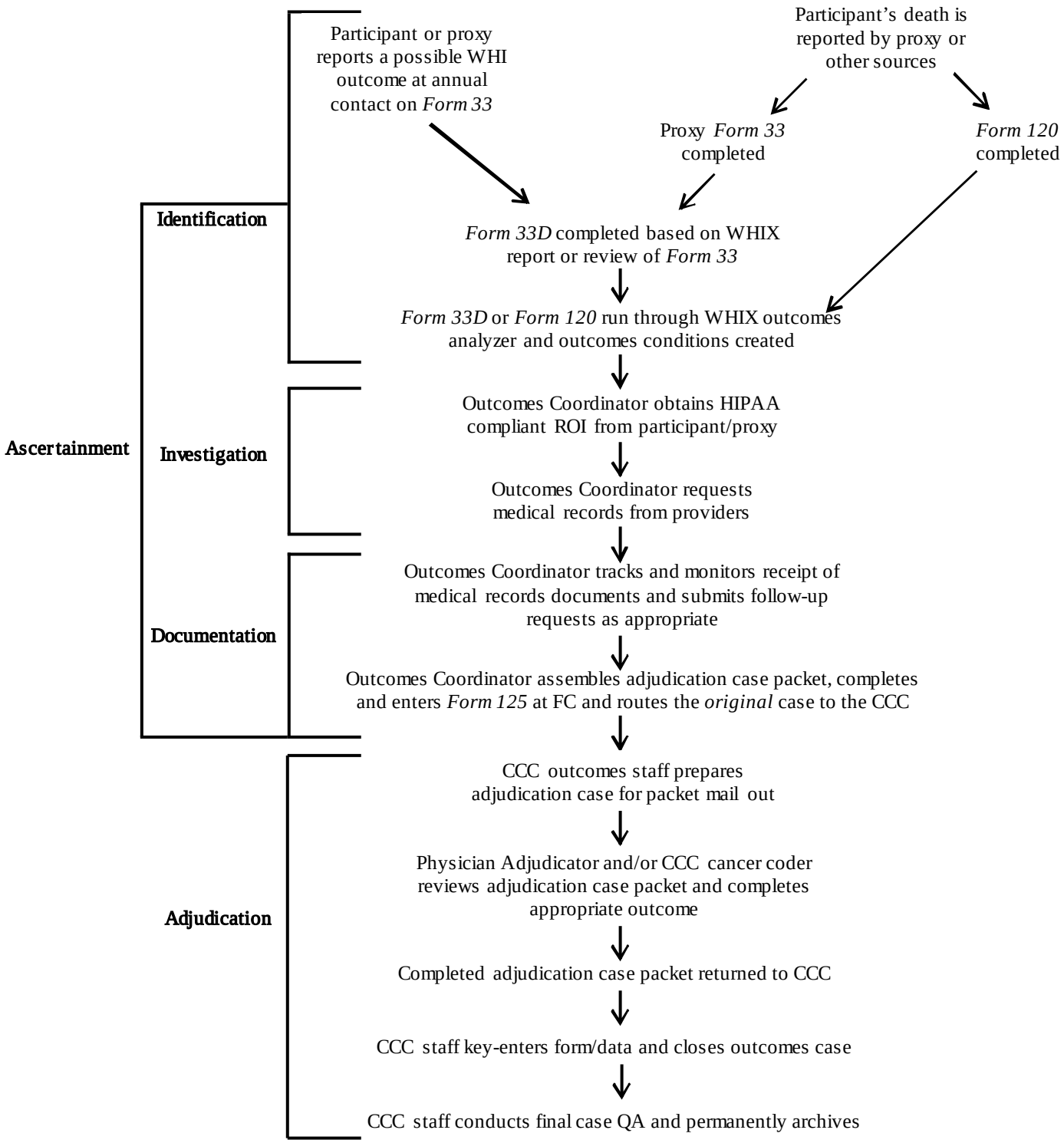
Investigation and Adjudication NOT Required

- **Selected hospitalized procedures requiring no follow-up** (no required outcomes forms):
  Appendectomy
  Bunionectomy
  Carpal tunnel repair/release
  Cholecystectomy
  Club foot release
  COPD exacerbation
  Corneal transplant
  Cosmetic/plastic surgery, **other than breast**
  Extracapsular cataract extraction (EEC)
  Fractures, other than hip and upper leg
  Glaucoma
  Hemorrhoidectomy
  Inguinal herniorrhaphy
  Knee arthroscopy
  Laceration repair
  Laminectomy (see spinal disorders below)
  Ligation and stripping, vascular (varicose vein strip)
  Out of country overnight hospitalization for gastrointestinal (GI) symptoms related to travel. (Requires PI signature.)
  Overnight hospitalization < 2 **nights (excludes extension outcomes of interest)**
  Overnight hospitalization for:
  - Any research study (that does not involve a WHI outcome)
  - Sleep studies (not related to a research study)

  Pelvic floor surgeries (for stress urinary incontinence, vaginal, uterine or rectal prolapse)
  Psychiatric admission
  Rhinoplasty / septoplasty / septorhinoplasty
  Rehabilitation facility admissions
  Rotator cuff repair
  Scleral buckle
  Skin disorders and procedures (includes non-melanoma **and excludes melanoma**)
  Spinal disorders/procedures: For example, spinal stenosis, spondylolisthesis, degenerative disc disease, spinal fusion, facectomy
  Stapedectomy
  Synovectomy of wrist
  Tonsillectomy & adenoidectomy (T & A)
  Total joint replacement (knee, hip or shoulder)
  Turbinectomy
  Tympanostomy tube
  Upper gastrointestinal (GI) endoscopy
  Vitrectomy
- **Recurrence of selected outcomes** (associated hospitalizations **must** still be adjudicated; see *Table 8.3 – Subsequent Conditions*)

* Complete *Form 125* if hospitalized one or more nights.
**Documented Cohort: All eligible HT, African American and Hispanic participants

Figure 8.1
Outcomes Ascertainment and Adjudication Process



8.1.2 Field Center Outcomes Staff

Each FC will identify an Outcomes Coordinator. This person is responsible for overseeing the activities of the outcomes team and the process of outcomes ascertainment, including:

- Identifying medical events and having working knowledge of outcomes procedures.
- Collecting *Form 33D* from participant.
- Requesting medical records documentation from providers.
- Ongoing tracking of documents.
- Final assembling into adjudication case packets.
- Forwarding the case packets to the CCC.

The Outcomes Coordinator (OC) is the key FC person involved in outcomes ascertainment, but other WHI Extension Study staff may assist in this effort. The OC contacts participants by phone or mail to obtain detailed self-report information about potential WHI Extension Study outcomes and thereby initiates the ascertainment process with the identification of potential outcomes. Investigation commences when the OC requests medical records documentation from the healthcare provider and prepares the documentation for the Physician Adjudicator. The OC is responsible for performing data entry, generating reports, conducting interviews to elaborate self-report data, requesting documents, and preparing and tracking case packets for adjudication.

To ensure unbiased ascertainment of outcomes, it is **recommended** that FC staff involved in outcomes ascertainment **not** be exposed to information through participant contacts or reports that is effectively or definitively unblinding (i.e., information that, respectively, allows "educated guesses" or provides "proof" of treatment arm.). However, each FC will determine, based on local resources and operations, the extent to which these recommendations can be followed.

8.1.3 Physician Adjudicator

The Physician Adjudicator is responsible for review of assembled adjudication case packets and assigning the appropriate outcome diagnosis based on WHI Extension Study defined criteria. It is **strongly recommended** that WHI Extension Study Physician Adjudicators **not** be exposed to information through participant contacts or reports that is effectively or definitively unblinding (i.e., information that, respectively, allows educated guesses or provides "proof" of treatment arm). Thus, Physician Adjudicators should not have contact with participants or participant files (except appropriate adjudication case packets) to ensure unbiased adjudication. See *Section 8.6 – Physician Adjudication* for more information on the Physician Adjudicator's roles and responsibilities.

An outcome case is assigned to committees based on outcome type following a single-adjudicator review model. The four adjudication Committees include:

- Cardiovascular Disease (CVD)/Death: The CVD Committee is responsible for adjudicating myocardial infarction, CABG, HF (DC*), coronary revascularization, peripheral arterial disease, carotid artery disease, and venous thromboembolic disease (Documented Cohort). The Committee will also adjudicate all deaths, selected hospitalization stays of two nights or more, and hysterectomies (HT only). They complete *Form 121 – Report of Cardiovascular Outcome*, *Form 124 –Final Report of Death*, and *Form 126 – Report of Venous Thromboembolic Disease (*Documented Cohort*)* as needed, and review *Form 125 – Summary of Hospitalization Diagnosis* as requested by CCC outcomes staff. See *Sections 8.7 – 8.9* for details of completing the forms.
- Stroke: A group of neurologists who adjudicate all strokes, completing *Form 132 – Report of Stroke Outcome* (see *Section 8.8 – Cardiovascular Outcomes*).
- Fracture: Staff at University of California, San Francisco (UCSF), adjudicate all hip fractures, completing *Form 123 – Report of Fracture Outcome* (see *Section 8.10 – Fracture Outcomes*).
- Cancer: The CCC cancer coders adjudicate the five primary sites (breast, ovary, endometrium, colon, and rectum), completing *Form 130 – Report of Cancer Outcome* (see *Section 8.11 – Cancer Outcomes*)

using SEER (Surveillance, Epidemiology, and End Results) guidelines. Cancer cases for which the CCC staff cannot assign a final diagnosis will be forwarded to the CCC consulting pathologist for coding and adjudication. The CCC cancer coders also adjudicate all "other cancers", with the goal to have the "other cancers" SEER coded by the end of the Extension Study.

Adjudication case packets are typically distributed to one of four central adjudication committees based on the participant's self-report. In the event that a case has more than one outcome included (or discovered) in the documentation, the case may be routed to more than one committee.

Physician Adjudicators will primarily adjudicate by mail, with cases being routed from and returned to the CCC. The exception is cancer coding, which is conducted at the CCC.

8.1.4 Outcomes Adjudication Committee (OAC)

The Outcomes Adjudication Committee (OAC), formerly called the Morbidity and Mortality Committee (M&M) in WHI, is an Advisory Committee whose role is to review protocol, policy, and procedures as they relate to outcomes and adjudication, and make recommendation to the Extension Study Executive Committee (ESEC). The OAC is comprised of Physician Adjudicators from FCs, other WHI Extension Study investigators, an OC FC representative, and appropriate CCC staff. Adjudicators and staff are assigned to central adjudication subcommittees based on their professional expertise.

8.2 Identification of Outcomes

Field Centers (FCs) may become aware of potential outcomes through different mechanisms:

- Routine annual *Form 33 – Medical History Update* and/or *Form 33D – Medical History Update (Detail)*.
- Death reported by proxy (e.g., family, friend, health care provider) or other source (e.g., newspaper obituary, returned mail to the CCC, National Death Index report).

Note that even if a participant reports a primary outcome, she will continue to be followed for the duration of the study for other WHI Extension Study outcomes.

8.2.1 Outcomes to be Identified

8.2.1.1 Outcomes Requiring Full Adjudication

Outcomes to be identified and forwarded for adjudication are listed in *Table 8.1 – WHI Extension Study Outcomes*, under "Outcomes Requiring Adjudication". In general, only the first occurrence of a particular outcome is adjudicated. There are however some outcomes that require ongoing investigation and adjudication. See *Section 8.3.2 – First vs. Recurrent Events* for more detailed information.

8.2.1.2 Outcomes Identified Only by Self-Report on *Form 33/33D - Medical History Update* (Detail)

Specific outcomes are identified by the participant's self-report alone on *Form 33 – Medical History Update* or *Form 33D – Medical History Update (Detail)*. See the list of outcomes under the heading "Self-Reported outcomes requiring adjudication for a hospitalization of 2 nights or more" in *Table 8.1 – WHI Extension Study Outcomes*. These self-reported outcomes do not require investigation, documentation, or adjudication unless the outcome is associated with a hospital stay of 2 nights or more.

8.2.1.3 Hospitalizations Due Solely to Selected Conditions or Elective Procedures

Selected outcome diagnoses and elective procedures do not require investigation, documentation, or adjudication. See the list in *Table 8.1 – WHI Extension Study Outcomes* in the column labeled "Investigation and Adjudication NOT Required." Do not complete *Form 125 – Summary of Hospitalization Diagnosis* if the participant reports these events or procedures as the only reason/event during the hospitalization, even if the hospital stay is 2 nights or more. In the WHIX outcomes subsystem adjudication screen, enter Closure Code 10 – *Extension case, not adjudicated, not forwarded to the Clinical Coordinating Center (CCC)*. (See *Section 8.4.3 – WHIX Outcomes Closure Codes* for more details.

8.2.2 Routine Administration of *Form 33 – Medical History Update*

Potential outcomes will primarily be identified through the routine administration of *Form 33 – Medical History Update* and, if needed, *Form 33D – Medical History Update (Detail)*. *Form 33* collects information on those outcomes that do not require further ascertainment procedures (outcomes by self-report alone), as well as screens for those participants who have had a medical problem, event, or procedure that may require adjudication.

CCC mailing of Form 33: Participants typically complete *Form 33* as a self-administered form, although FCs may choose to administer it as an interview if the participant is unable or unwilling to complete and mail in the form, or if the participant has difficulty understanding or completing forms. At each annual contact date, the CCC will mail a *Form 33* to the participant to be completed and returned to the CCC for scanning. The CCC is responsible for mailing the *Form 33*s to all WHI Extension Study participants as part of their annual contact (see *Section 7 – Follow-Up Contacts*).

CCC repeat mailings: Following the CCC mailing, if the *Form 33* is not returned within three months of the first mailing, the CCC will send it again. If the form is not returned within two months of the second mailing, the CCC will send it a third time. If the form is still not returned, the FC becomes responsible for collecting the missing *Form 33*.

FC Follow-up: The FC is also responsible for collecting any additional information from the participant to resolve questions or missing data identified when the CCC scans the returned *Form 33* (see *Section 8.2.8 - Forms Processing Reports* for more details). For incapacitated or deceased participants, a participant's proxy (e.g., family, friend, or health care provider) may complete a *Form 33* (see *Section 8.5 – Fatal Events – Special Considerations*).

8.2.3 Routine Administration of *Form 33D - Medical History Update (Detail)*

When a participant reports an outcome of interest or a hospital stay of 2 nights or more on *Form 33*, FCs follow-up by asking her to complete *Form 33D*, which collects more specific information about the potential outcomes. *Form 33D* asks participants to provide names and addresses of hospitals, outpatient clinics, and physician offices where possible outcomes were diagnosed or treated. *Form 33D* also asks participants to provide more detailed information regarding cardiovascular and stroke diagnoses, incident cancer, causes of hip fractures, venous thromboembolic disease (DC*) and hysterectomy operations (HT only), and revascularization procedures.

Identify participants needing a *Form 33D*: Following the scanning of *Form 33 – Medical History Update*, the FC can run *WHIX0622 – Members with Potential Outcomes Report* to identify those participants who need to complete *Form 33D – Medical History Update (Detail)*. Based on WHI experience, an estimated 10% of the completed *Form 33s* will need a *Form 33D*. As the study population ages, the number of participants needing a *Form 33D* will likely increase. Refer to the *Form 33* form instructions (in *Appendix A*) for the algorithm that indicates, based on the participant's form responses, who needs to complete a *Form 33D*.

Administer *Form 33D*: FCs will probably find that administration of *Form 33D* by interview gathers more complete data for proceeding with a timely outcomes investigation. However, depending on the FC staffing levels it may be more time efficient to mail *Form 33Ds* to participants and follow up with information errors as they arise. FCs are advised to obtain new, signed medical release forms when *Form 33D* is collected.

Additional hospitalizations: If the participant indicates more hospitalizations/provider visits than are allotted on the *Form 33D*, the participant is instructed to write the details for the additional hospitalizations on the last page of the form. The OC then manually creates and links the additional visits indicated on the form and investigates the possible outcomes as appropriate (see *Section 10 – Data Management* documentation for instructions on manually creating and linking conditions).

8.2.4 Administration of *Form 134 – Addendum to Medical History Update*

Form 134 is a one-time form included in the first year WHI Extension Study mailings. The form collects information on whether Parkinson's disease, diabetes (non-gestational) or high blood sugar was **ever** diagnosed. As with the routine *Form 33*, FCs are responsible for collecting any missing *Form 134s* that the participant does not return in response to the three routine mailings, or resolving any missing data or discrepancies on the form.

8.2.5 Editing or Updating a Routine *Form 33*, *Form 33D*, and *Form 134*

If a participant or proxy notifies the FC of a correction to a participant's most recently completed *Form 33/33D* or to a *Form 134*, edit the most recently completed form following the usual guidelines or *Form 134* for editing forms (see *Section 10 – Data Management*). If the *Form 33* has been scanned at the CCC or *Form 33D* key-entered at the FC, update the data in WHIX. *Form 33D* may need to be re-analyzed following the form correction/edits. Do not record the updated information on a new *Form 33*, *Form 134*, or *Form 33D*.

8.2.6 Interim Reports of Possible Outcomes (Other than Deaths)

A participant may contact a FC to report a potential outcome between the administration of her routine annual *Form 33s*. Such contact is termed an 'interim report' of an outcome and the WHI ES <u>does not</u> collect interim reports, excluding a report of death (see *Section 8.5 – Fatal Events – Special Considerations*). When the participant makes such a report, FCs should ask the participant to report the information at her next routine contact. Reporting interim events at the next annual routine contact will help maintain a standard method of

ascertaining potential outcomes. If the participant does not report the outcome at her next routine contact, do not provide any reminder prompts or investigate the outcome.

8.2.6.1 Interim Reports of Serious Adverse Experiences (SAEs)

There are no safety events to monitor or report in the WHI Extension Study as there is no clinical intervention component.

8.2.7 Reports of Death

Participant deaths can be reported to FC staff by proxy (e.g., family, friend, health care provider) or other sources (e.g., CCC returned mail, newspaper obituary, FC returned mail, National Death Index report). FCs use information from such reports to complete *Form 120 – Initial Report of Death*. Note that **all** information may not be available when *Form 120* is initially completed. *Form 120* is designed to take an "unknown" response if information is not currently available. Regardless of the amount of information gathered on the *Form 120*, key-enter the available information as soon as possible. Key-entry of *Form 120* creates the death condition in WHIX, stops further participant mailings, and modifies other WHIX reports accordingly. FCs should complete a final *Form 33 - Medical History Update*, and *Form 33D – Medical History Update (Detail)* if indicated, by contacting the participant's proxy (to identify any **other** outcomes that may have occurred since the last completed *Form 33)*. See *Section 8.5 – Fatal Events – Special Considerations*.

8.2.8 Forms Processing Reports

After the CCC scans *Form 33* (and *Form 134* in the first year), FC staff can run various reports in WHIX. These reports include:

- *FCA001 - Forms with Comments to Review* lists forms for which the CCC staff have marked the comment bubble page 1 of *Form 33* indicating that a participant has hand-written a comment on the form that the FC staff should review. FCs can view an image of the form in WHIX.

- *WHIX0621 - Outcomes Screening Action Report* lists *Form 33*s that are incomplete or have missing or discrepant data and there is not enough information on the *Form 33* for WHIX to determine if a *Form 33D* is required.

- *WHIX0622 - Potential Outcomes Report* lists *Form 33*s that require a *Form 33D*. This report also lists *Form 33s* that indicate an outcome is present but the form data is incomplete in some way. In this case, a *Form 33D* is required as well as additional *Form 33* information to complete the *Form 33*. *WHIX0622* also includes participant phone numbers and contact information to facilitate data collection.

There are many other outcomes reports available to track and monitor outcomes ascertainment and adjudication. Many reports can be selected and printed from the WHIX Outcomes Subsystem menu; others may be distributed from the CCC or created by the FC via ACCESS or other tracking systems. Given the complexity of outcomes processing, use of reports is essential. Refer to *Section 10 - Data Management* for the list of relevant reports, along with a brief description of the report and suggested timeframe for running reports.

8.3 Investigation of Outcomes

The investigation of a potential outcome is a time-intensive activity that involves locating relevant health care providers (e.g., hospitals, clinics, and physicians) and requesting medical records that may support a diagnosis. The documents FC staff request from a particular provider will depend on the outcome type and WHI component. See *Table 8.2 – Required Documents for Outcomes* for a list of the documents to request for completing the investigation of the outcome. The success of an outcome investigation (i.e., obtaining copies of required supporting documents) will depend on the expertise, resourcefulness, and communication skills of the FC Outcomes Coordinator. Institutional, local, and state regulations will also impact the ease and expense of completing an investigation.

8.3.1 Release of Information (ROI) Forms

To obtain documents from a participant's medical record, the FC must have a current Health Insurance Portability and Accountability Act (HIPPA) compliant Release of Information (ROI) form signed and dated by the participant. Hospital, state, and local Institutional Review Board (IRB) requirements differ with regard to obtaining medical records. Many hospitals will require that a current (e.g., signed within the last three to six months) ROI form, with an original participant signature, accompany any request for medical records. Some institutions will accept a blanket consent, acceptable for an indefinite or a fixed period of time. Others may require an institution-specific signed release.

It is recommended the FC keep a supply of institution-specific ROIs to mail participants when indicated. Obtain multiple (e.g., three to six) ROI forms because documentation may be required from several medical providers. Some institutions will charge for duplicating and sending medical records and/or death certificates. If your FC is part of a non-profit organization or other special approvals (e.g., IRB) are obtained, the hospital may waive charges for your requests for medical records.

8.3.1.1 Refusal to Sign a Release of Information Form

If a participant refuses to sign a current ROI form, you cannot request medical records for potential outcomes. Contact participants refusing to sign a ROI and explain why the medical information is needed and the importance of outcome ascertainment to the study. Sometimes it may help to have a supervisor or Principal Investigator [PI] make this contact (see *Section 9 – Retention*). Some participants may be willing to sign a ROI form that specifies the provider and/or medical documents being requested for a particular outcome.

The amount of time and effort you spend trying to convince a reluctant participant to sign the Release of Information will depend on the type of event. You should make considerable effort to obtain a release to investigate primary outcomes (i.e., CHD, the five major cancers, and hip fractures), but may choose not to risk annoying a participant by pursuing other outcomes. If the participant continues to refuse to sign the release, note her refusal in her outcomes chart.

Table 8.2
Required Documents for Outcomes

☒ Essential document, if done; ✖ Recommended documents

Documentation Requirements for WHI Outcomes	WHIX #	MI CABG	HF[8]	PAD	CAD	Heart Revasc	Stroke	Hip Fracture	5 Main Cancers	Other Cancers	Coronary Death[7]	All Deaths[7]	Hospital stay ≥2 nights	PE[8]	DVT[8]	HT only: Hysterectomy
Face Sheet physician attestation statement with ICD-9-CM Codes, or other Coding Abstract[1]	1,44	✖	✖	✖	✖	✖[5]	✖[5]	✖[5]	✖[5]	✖[5]	✖[5]	✖[5]	✖	✖	✖[5]	✖[5]
Discharge summary (dictated or handwritten)[1]	3	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
Operative or procedural report for treatment of disease	15	✖	✖	☒	☒	☒	☒		✖	✖					✖	☒
Outpatient, Day Surgery, short stay[1, 6]	13					✖	✖	✖	✖	✖	✖	✖			✖	✖
ER reports[1, 6]	48	✖	☒	✖	✖	✖	✖	✖	✖	✖	✖	✖	✖	✖	✖	✖
Emergency Medical Service (EMS) or ambulance report	39										✖	✖				
History and physical (dictated or handwritten)	2	✖	☒	✖	✖	✖	✖	✖	✖	✖	✖	✖	✖	✖		
Physician Notes (Outpatient only)	49					✖[5]	✖	✖[5]	✖[5]		✖[5]				✖[5]	
All 12-lead ECG Reports	45	☒	☒			☒					✖					
Cardiac enzyme report (Lab)	8	☒	☒			☒					✖					
PTCA report (angioplasty), cardiac stent, atherectomy	11	☒		✖		☒										
Cardiac catheterization / angiogram / arteriogram report, contrast ventriculogram	17/46	✖	☒	☒		✖										
Stress test by ECG, echo, or perfusion scintigraphy report[2] (with thallium, technetium or other isotope)	12/14	✖	☒	✖		✖										
CABG report	9	☒				✖										
Nuclear scans: e.g., RVG/MUGA[3], myoview, stestemi	47	✖	☒			☒										
Labs (HF only): BNP, BUN/Creatinine [Essential]; CBC, electrolytes [Recommended]	60, 61, 62, 63		☒													
Chest x-ray report	4		☒													
Radiology and/or bone scan reports/isotope or nuclear medicine bone scan (includes mammograms)	30							☒	✖					☒		
Cardiac MRI, Cardiac CT	64, 65		✖													
Echocardiography	22	✖	☒			✖	✖									
CT scan report of head or neck; CT scan report of hip	27						☒	☒								
Lumbar puncture (LP) report	29						✖									
MRI/MRA report of head or neck; MRI of hip	52/28				☒		☒	☒								
Doppler flow study report; Ultrasound report (other than echocardiography)	20/23			☒										☒	☒	
Ankle-arm blood pressure procedure	24			☒												
Carotid studies (Doppler, angiography or isotope scan)	16				✖		☒									
All pathology reports	31								☒	☒						
ERA/PRA hormone receptor report; Her2/Neu (breast cancer only)	35								☒							
Oncology consult[4] /Neurology consultation	33/53						✖		✖[4]							
Cytology report	32								✖	✖						
Pulmonary angiography	26													☒	☒	
Isotope scan; Venogram report	21/18													☒	☒	
Lung scan report	25													☒	☒	
Impedance plethysmography	19													☒	☒	
Autopsy or Medical Examiner/ Medical Examiner / Coroner's report	38										✖	✖				
Death certificate, Form 120-Initial Report of Death	37/51										☒	☒				

[1] A final progress note, discharge note, or the Hospital Face Sheet may be substituted for the Discharge Summary for short stays or hospitalization less than 48 hours.

[2] Possible stresses include exercise, dobutamine, dipyridamole, pacing.

[5] For non-hospitalized outcomes.

[6] Obtain documentation if OP, day surgery, short stay, or ER visit result in a hospital stay ≥ 2 nights. Not required for subsequent conditions.

[7] For all deaths, include last relevant WHI hospitalization.

[3] RVG - Radionuclide ventriculogram or MUGA - Multigate Acquisition

[4] Obtaining Oncology/Radiology consult corresponding to first course of cancer treatment.

[8] Documented Cohort (DC*)

8.3.2 First vs. Recurrent Events

In general, only the **first** confirmed occurrence (after randomization/enrollment into the WHI) of a **particular** outcome is adjudicated as an outcome of interest. This definition is the same one used for WHI. Once certain outcomes are confirmed by adjudication, subsequent self-reports do not require investigation unless the subsequent report is part of a hospital stay of 2 nights or more, in which case the hospitalization stay is adjudicated. There are, however, some outcomes that require ongoing investigation and adjudication until the primary outcome of interest is confirmed. Other outcomes require ongoing investigation and adjudication, regardless of the number of times the participant self-reports the event. See *Table 8.3 – Subsequent Conditions* for a complete list of subsequent conditions and whether they do or do not require further investigation, documentation, and adjudication.

Note that the definition of **prevalent disease** does not change with enrollment into the WHI Extension Study. The definition of prevalent disease for the Extension Study remains based on the participant's "original" WHI randomization or enrollment date. Thus, prevalent cardiovascular diseases at WHI baseline do **not** count as WHI Extension Study outcomes. For example, an MI occurring in a woman who had a previous MI before entering WHI would be classified as a **first** incident MI (not as recurrent) and would require a full outcomes investigation. The same is true for stroke.

Cardiovascular Disease

- Adjudicate only the **first** incident occurrence **after WHI randomization or enrollment** of a myocardial infarction (MI), stroke, or peripheral arterial disease.
- A second MI occurring in a woman with a previously-adjudicated and confirmed MI during the main WHI or WHI Extension Study will **not** require adjudication.
- First and recurrent revascularization procedures and hospitalizations will be adjudicated until a first incident MI is confirmed.
- A first and recurrent carotid artery disease will be adjudicated until a first stroke is confirmed.
- First and recurrent VTE are adjudicated. (DC*)
- First and recurrent HF are adjudicated. (DC*)

Fractures

- Only the first hip fracture (after WHI randomization or enrollment) will be adjudicated in the WHI Extension Study. A subsequent self-report is only adjudicated for a 2 or more night hospital stay.

Cancer

- Adjudicate **newly diagnosed** primary cancers.
- A second primary breast cancer occurring in a woman who previously had a diagnosis of breast cancer will also require documentation and adjudication.
- A cancer of a different primary site developing in a woman who has previously had a cancer outcome will always require investigation and adjudication (except for non-melanoma skin cancer).
- Do not adjudicate a cancer relapse, recurrence, or metastasis except to confirm that it is not a primary cancer.
- First insitu and first invasive melanoma will be SEER coded (CCC, Spring 2009).

Hospitalization

- Hospitalized subsequent outcomes do not require investigation or adjudication unless the hospital stay was for 2 nights or more. In such a case, the documentation set for a 2 night hospital stay needs to be requested and the hospitalization is adjudicated. For example, once confirmed, a **second** MI occurring during the WHI Extension Study will only require investigation, documentation, and adjudication as a hospitalization, if the hospital stay was two nights or more.

WHIX1215 - Members Outcomes Status Report (*WHIX1215*) lists all previously adjudicated cases and those currently in-process for that participant. Outcomes confirmed in both WHI and WHI Extension Study are included on the report.

Table 8.3
Subsequent Conditions

Tied to First Incident Outcomes

Event	Adjudicate *all* events before incident MI?	Adjudicate *first* event after incident MI?
Coronary revascularization (PTCA, stent, laser)	Yes	Yes
CABG	Yes	No
MI	Yes	No
Event	**Adjudicate *all* events before incident stroke?**	**Adjudicate *first* event after incident stroke**
Carotid Artery Disease	Yes	No
Stroke	Yes	No

Not Tied to First Incident Outcomes

Event	Adjudicate First event?	Adjudicate subsequent event?
Venous Thrombolic Disease (DC*)		
DVT	Yes	Yes
PE	Yes	Yes
Cardiovascular		
Heart Failure (HF) (DC*)	Yes	Yes
Peripheral Arterial Disease	Yes	No
Cancer		
Incident Breast Cancer	Yes	Yes*
Incident Cancer, site specific (excludes breast)	Yes	No
Fracture		
First Hip fracture CT/OS	Yes	No
Hysterectomy (HT only)	Yes	N/A
Death	Yes	N/A

*Adjudication is required if initial breast cancer is in-situ or if a second primary breast cancer is diagnosed.

8.3.3 Adjudication Rules Report

Outcomes that need to be adjudicated vary based on the study or studies to which WHI component the participant was randomized or enrolled and whether an outcome is determined to meet subsequent condition rules (see *Table 8.3 – Subsequent Conditions* above). The *Adjudication Rules Report (WHIX1001)* is available to assist the OC and Physician Adjudicator track a participant's outcomes.

The *Adjudication Rules Report* indicates the WHI study or studies to which a participant was randomized or enrolled, the date(s) of CT randomization(s) or OS enrollment. The report lists confirmed outcomes with the date of the latest confirmed diagnosis and those outcomes that still require adjudication. By default, the "adjudication required" flag for each outcome type is typically set to "yes" (i.e., requires adjudication). Exceptions to the default parameter include: hysterectomy (HT only) and VTE for non-Documented Cohort participants. These are automatically set to "no".

The FC OC manually updates this report. There are future plans to automate the report once the WHI Extension Study is underway.

8.3.4 Standard Hospital Medical Records

WHI Extension Study definition of hospitalization: A hospitalization, for WHI Extension Study purposes, is defined as any overnight stay in an **acute** care hospital only for selected outcomes of interest and a two night stay for any other reason. Short stays, observation stays, and day surgeries may be referred to in

medical records as outpatient visits, but for the WHI Extension Study, these stays are considered hospitalizations if they result in a hospital stay of two or more nights. Note that a stay of two nights or more in a rehabilitation facility (even if the participant is a direct transfer from an acute care hospital) is **not** considered a hospital stay and is not investigated in the WHI Extension Study. Any overnight hospitalization for a psychiatric admission will not be investigated or adjudicated.

Medical record: The medical record from a hospitalization consists of documents dating from the first health care contact for the event to the individual's discharge or death. The OC and Physician Adjudicator should understand the course of events from admission to discharge to generally reconstruct the hospitalization and outcome event(s).

Medical record requests: The WHIX outcomes management system automates the process of determining which documents (specific to a possible outcome type) need to be requested. The OC will then print document request forms suitable for mailing to identified providers (*Request for Medical Information Form - WHIX0980)*. If you are writing to a hospital for records, which will be the most common method for requesting documents), the medical records department at that hospital will need to locate the relevant documents in the medical chart.

Alternatives to mailing a request for medical records include sending a FAX or collecting and copying relevant portions of the medical chart, known as *abstracting*. Abstracting medical records can be done in person or via a hospital computer link from which documents/reports can be printed. Both methods provide access to medical information not otherwise available to all OCs and introduce the potential for a FC to over-report outcomes (ascertainment bias). To prevent over-reporting of events and ensure standardization of procedures among FCs, OCs must develop rigorous procurement procedures. Moreover, all OCs should be cognizant of procedures as outlined in *Section 8.2 – Identification of Outcomes* and *Section 8.3 – Investigation of Outcomes*).

Records needed for case packet: The following medical records documentation and their contents may be needed to complete adjudication case packets. If you pull documents directly from the medical records department, you can look in the indicated sections for the required documents. Only include those records you are requesting, or a designated substitute, in the adjudication case. Be aware, however, that some medical records may not be well organized, and documents may be scattered throughout the medical chart.

The list below is in the order that documents might be found in a medical record, not in any specific order for the outcomes case packets. Do not routinely add additional documentation to your document requests or adjudication case packets. Select the appropriate medical documents from *Table 8.2 – Required Documents for Outcomes*. Or, rely on *WHIX0980 – Request for Medical Records* for the outcome being investigated -- this report provides a comprehensive list of documents to request.

- **Face Sheet** - Demographic data; admission and discharge information (including dates and physicians, discharge diagnoses, procedures, and associated ICD-9-CM or ICD-10-CM codes). If the ICD-9-CM or ICD-10-CM is not documented on the Face Sheet, request a Physician Attestation Statement with codes or any other accessible documents that indicate ICD-9-CM or ICD-10-CM, such as a universal billing (UB) form obtained through the billing office, or a coding abstract.
- **Ambulance Report or Emergency Room/Department Report** - Description of symptoms, initial treatment en route to hospital, vital signs, dates and times of symptoms, treatment, responses to treatment, and disposition. This report is most useful for patients who were dead on arrival (DOA) at the hospital or for those dying in the ER before admission.
- **Discharge Summary** - Narrative summary of entire hospitalization, including the reason for hospitalization, significant findings, procedures performed, treatment(s) rendered, patient's condition on discharge, and any specific instructions given to the patient and/or family. The discharge summary will be one of the most important documents for adjudicating WHI Extension Study outcomes. A written discharge summary is often not available for hospital stays less than 48 hours.

A final progress note, discharge note, or the hospital face sheet may be substituted for the discharge summary for short-stays (i.e., events or procedures that require less than a 48-hour period of hospitalization).

- **Admission History and Physical (H&P)** - Detailed description of symptoms leading to admission, condition of the patient on admission, medical history, review of systems (including vital signs), medications before and at admission, provisional diagnoses, and treatment plan.

  If a complete physical examination has been performed within 30 days before admission, such as in a physician's office, a copy of that report may be the only H&P in the patient's hospital medical record, (provided there have been no changes or the changes have been recorded at the time of admission).

- **Laboratory Results** - Standard blood work (complete blood count [CBC]; electrolytes; BUN/creatine) and other specimen analysis results, cardiac enzyme or Troponin results for MI, pathology (biopsies), and/or cytology results for cancer are usually found in this section. Brain natriuretic peptide (BNP) also known as B-type natriuretic peptide is a marker of cardiac insufficiency or Heart Failure (HF). Laboratory results may be interspersed with other documents, however. It is not uncommon for cardiac enzymes to be recorded on a separate lab sheet. As a reference, the laboratory report should include the institution's normal value/range for the given test as results and normal ranges vary between medical institutions.

- **ECGs (electrocardiograms)** - Twelve-lead ECGs performed during the hospitalization are often contained in a separate section of the chart, but may also be interspersed with other records, such as progress notes. Only 12-lead ECGs are required for WHI Extension Study cardiovascular outcomes, not the individual rhythm strips that might be found attached to daily progress notes. The specific 12-lead ECGs are required for CHD outcomes (e.g., MI, coronary revascularization, and hospitalized death, if available). Request **all** ECG reports from each hospitalization, as the medical records department may not select the correct ECGs.

- **Diagnostic or Radiology (including Nuclear Medicine) Procedures** - Chest X-rays, stress tests, CT scans, magnetic resonance images (MRI), magnetic resonance angiographies (MRA), ECGs, coronary angiographies (heart catheterizations), doppler flow studies, tumor biopsies, colonoscopies, breast cancer estrogen and progesterone receptor reports, Her2/Neu reports, bone scans, mammograms, and all other diagnostic procedures are often found in this section. These reports may also be interspersed in the medical record.

- **Operative Reports** - Surgical reports for CABG, PTCA, cancer resections or exploratory surgeries, tumor biopsies, colonoscopies, carotid endarterectomy, and other procedures are often found in this section. These reports may also be interspersed in the medical record.

- **Consultations** - Neurology consultation reports are used to adjudicate strokes and Oncology consultation reports are needed for the five primary cancers. These will be found in a separate section of chart with typed or handwritten notes from the consulted medical or surgical specialists, in notes interspersed in the medical record, or in the progress notes.

8.3.5 Procedures for Requesting Medical Records Documentation

The Outcomes Coordinator or outcomes staff implement the following steps:

1. Identify all appropriate provider visits (document sources) in WHIX such as the hospital, physician's office, or other facility recorded on *Form 33D – Medical History Update (Detail)*.

2. Obtain a HIPPA compliant ROI signed and dated by the participant. A valid ROI is required before a request for medical records can be sent. For some FCs, this does not apply to a request for a death certificate from the local or state Vital Statistics Office.

3. Generate a *Request for Medical Information Form* (*WHIX0980*) from the WHIX outcomes management system for each provider visit. A list of required documents for each reported outcome will be generated for each provider. This report will also include the participant's name, participant ID number, date of birth, last four digits of social security number, approximate last visit date, requesting FC, and provider organization. For example, if a stroke is self-reported, the list of required documents (listed on WHIX0980) will include: Face Sheet and/or physician attestation statement with ICD-9 or ICD-10-CM codes, discharge summary,

operative or procedural reports, history and physical, and reports of echocardiography, CT scan, lumbar puncture, MRI, MRA, and carotid studies.

4. Mail, fax, or deliver a request for all of the documents required for each identified outcome. See *Table 8.2 – Required Documents for Outcomes* for a summary. For each request, include a cover letter from your FC, the WHIX *Request for Medical Information Form (WHIX0980)*, and a Release of Information form signed and dated by the participant.

5. Create (or pull) an outcomes file for each participant with an identified outcome. Information and documents from this file will be used to assemble the adjudication case packet. The adjudication case packet will contain the required subset of the participant outcomes file documents that are appropriate for the outcome being investigated.

6. Make every attempt to obtain the complete documentation needed for adjudication. If some of the requested documents cannot be obtained after diligent effort (the Outcomes Adjudication Committee [OAC]) established a guideline of 4 attempts), forward the case for adjudication. See *Table 8.4 – Essential Medical Record Documents* to determine if the case contains documents needed to meet minimum adjudication requirements. Record in WHIX the documents' absence in the *Visit Documents Screen* indicating the reason why records were not obtained. This text information is printed on reports and is available to the adjudicator reviewing the adjudication case. Documentation details prevent unnecessary queries and adjudication delays.

7. Receive requested documents:

   Upon receipt, match the documents with the WHI Extension Study-defined document set that was requested of a provider for a participant. Compare demographic data from medical records to study data to ensure accurate identification of participant.

   It is suggested that you attach a participant barcode label or write the participant's ID number on each page of the outcome materials. Keep a copy of all documents pertaining to one adjudication in her outcomes file.

   Clip or staple together documents that will be required for adjudication of the outcome in the participant's outcomes file. These clipped or stapled documents will eventually form the adjudication case packet.

8. Extraneous/Miscellaneous Documents:

   On occasion, a hospital or provider may furnish the FC with documents not needed for a WHI Extension Study adjudication. Hold these records in the participant's outcomes file and make them available to the Physician Adjudicator, if requested. If the adjudicator requests these records, add them to the list of medical records received in the WHIX provider visit screen. If the records are not added to the case, these extraneous documents must be destroyed (e.g., shredded), once the outcome is closed.* To avoid excessive accumulation of extraneous documents, FCs should request only those records included in the approved documentation set. At no time should an OC request the entire medical record. If the Outcomes Coordinator has a question about the appropriateness of a document, contact your CCC Outcomes Coordinator Liaison before discarding the document.

9. Upon assembly of the required medical records documentation and WHIX generated reports, forward the case to the CCC for adjudication.

10. Monitoring Reports

    Use the WHIX outcomes management system to track which medical documents you have requested from a provider, when the documents are received, and when follow-up requests need to be initiated (see *Section 10- Data Management* for details). If you do not receive the requested documents within two to four weeks of the initial request, repeat the request.

    As part of data monitoring, generate general reports of all participants for whom WHIX identified a possible WHI Extension Study outcome but no final documentation has been received. See *Section 10 - Data Management* for a complete list of outcome tracking and monitoring reports. The reports will allow you to verify the status of each identified outcome and assist with any document request that is pending.

8.3.6 Special Considerations

8.3.6.1 Hospitalization

For all hospital stays of 2 nights or more, the Hospital Face Sheet and/or the Physician Attestation Statement (computer-generated Face Sheet) with ICD-9 or ICD-10-CM diagnosis and procedure codes should be requested as the initial step in determining an outcome.

For selected outcomes of interest, a hospital admission is defined as an overnight stay in an acute care facility and may include 23-hour observations. For all other outcomes, a hospital stay must be for 2 nights or more. A hospital Emergency Room (ER) visit is not considered an admission *even if the date changes.*

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* the NIH Program Office has Communicated the following:

As cited in the DHHS Implementing Regulations for the Privacy Act (Federal Register, Vol. 40, No. 196, page 47410, 10/08/75), "No record will be maintained by the Department unless it is relevant and necessary to accomplish a Department function required to be accomplished by statute or Executive Order." In other words, our Privacy Act records should only contain information relevant to the purpose for which the record was created.

Information documents added to a record may require reduction/modification/summarization, such that the document only contains information essential to the collection. Also, if review of a record indicates that non-relevant information/material is present; such information/material may be removed, as appropriate. This latter situation is not to be confused with purposeful action to alter a record, (e.g., to remove relevant documents or misrepresent research findings, etc.), which is illegal and subversive to the Privacy Act. The action of removing information not relevant to the record may be performed as part of any audit or periodic review activity. Those responsible for maintaining WHI records should, in accordance with the Privacy Act, make reasonable efforts to ensure that such records are accurate, complete, timely and relevant for agency purposes.

- However, if any ER visit results in an overnight hospital admission, and meets the outcome definition of a one-night vs. two-night stay, adjudicate the outcome by requesting the appropriate ER medical records.
- Additionally, adjudicate an ER visit when the participant reports a revascularization procedure, a DVT or hysterectomy (HT only), is diagnosed with a hip fracture or cancer, or when the participant dies in the ER, regardless of length of stay.

An overnight hospital admission and an overnight stay in an Emergency Room are not used interchangeably. If the participant is not actually admitted to the "acute care facility," (i.e., the hospital itself) it would not be considered a hospitalization. Forward questions about a particular institution's definition of an overnight hospital stay to the CCC Outcomes Coordinator Liaison.

8.3.6.2 Death Certificate

Copies of death certificates are required to confirm a cause and date of death. Other documents may be required, such as autopsy report or medical records from a personal physician, or State Board of Health death certificate registry. If conflicting information is obtained regarding the exact date of death, use the information from the most reliable source (with hospital records or death certificates considered more reliable than word of mouth from family or physician). See *Section 8.5 - Fatal Events – Special Considerations* for more information. A certified copy of the death certificate is not required.

8.3.6.3 Hysterectomy

In addition to the hospital discharge summary and Face Sheet, the operative report is required.

8.3.7 Merging Adjudication Case Packets

In general, each hospital stay or other provider visit should be a separate adjudication case unless one of the following scenarios is present.

8.3.7.1 Transfers Between Facilities

Any participant transfer that occurs during an episode of care (i.e., the participant is not discharged to home but is transported to another hospital) for definitive treatment is merged into a single adjudication. Participant transfers include:

- Between-hospital transfers (e.g., discharged from one hospital and admitted to another hospital on the same date). Complete a *Form 125 – Summary of Hospital Diagnosis* for each hospitalization (and the adjudicator completed outcomes form, as appropriate).
- Within-hospital transfers (e.g., transferred from the ICU to a step-down unit. Complete only one *Form 125* and have the Physician Adjudicator complete the outcomes forms, as appropriate).

Note: Transfers from an acute care hospital to a rehabilitation floor or free standing facility are exempt from merging. Only the acute care hospital stay is adjudicated (see *Table 8.1 – WHI Extension Study Outcomes)*.

8.3.7.2 Merging Rules by Specific Outcomes Types

- **Cardiovascular**. Other than participant transfer procedures defined above, each cardiovascular hospitalization stands alone as one adjudication.
- **Fracture**. An outpatient (OP) X-ray confirms a hip fracture and the participant is subsequently hospitalized for treatment of the fracture. Merge the OP record with the subsequent definitive care into one adjudication.
- **Cancer**. Identify the first biopsy of a primary cancer site to determine the date of diagnosis. Merge the biopsy records with the subsequent definitive care into one adjudication case packet.
- **Hospitalized deaths:** Merge the death case (death certificate and WHI *Form 120 – Initial Notification of Death*) with the hospitalization.

8.4 Documentation of Outcomes

Each WHI Extension Study outcome has specific documents that must be collected and reviewed (if available) to adjudicate that outcome. See *Table 8.2 – Required Documents for Outcomes* for detailed documentation requirements for specific WHI Extension Study outcome types.

8.4.1 Essential Documents by Outcomes Type

Every attempt should be made to obtain the documentation needed for adjudication. If some of the requested documents cannot be obtained after diligent effort (the OAC established a goal of four attempts), their absence should not delay the submission of the other information for adjudication. (Note the absence of these documents in the WHIX outcomes subsystem with the reason why the records were not obtained.) For each WHI Extension Study outcome, there are some "essential" documents. These medical records are more important than others. Again, these medical records may not be available because the test or procedure was not completed, but knowing what these documents are can assist with your decision on whether to forward the case for adjudication or continue to request records. For all inpatient outcomes, the discharge summary is an essential document, though often not available for hospital stays of less than 48 hours. See *Table 8.4 – Essential Medical Record Documents* for a list of the essential documents for a specific outcome type.

Table 8.4
Essential Medical Record Documents

WHI Extension Study Outcome	Essential Document(s)
MI	Cardiac enzymes, ECGs, diagnostic procedures (CABG, PTCA)
Coronary Revascularization	Operative or procedure report; cardiac enzymes, ECGs
HF (DC*)	H&P, Nuclear Scans, CXR, Echocardiogram, cardiac cath, BNP, cardiac enzymes, ECGs, BUN/creatinine, ED report
Stroke	Carotid studies, CT or MRI report of head and neck
Cancer	**All** pathology reports (ERA, PRA, and Her2/Neu for breast cancer only)
PE/DVT (DC*)	Procedure report
Hysterectomy (HT only)	Operative report
Hip Fracture	Radiology report, X-ray, or MRI
Death – Hospitalized	Discharge Summary (death summary) and Death Certification
Death – Hospitalized, Coronary	Discharge Summary (death summary), Death Certificate, ECGs, and cardiac enzymes
Death – Out of hospital	Death Certificate, *Form 120 – Initial Report of Death*, and last relevant adjudicated hospitalization (if available).
Hospitalization	Discharge Summary (though often not available for stays of less than 48 hours

8.4.2 Preparing and Routing the Adjudication Case Packet to the CCC

1. When all required documents are received, assemble them for adjudication in the order they are listed on the *Investigation Documentation Summary (WHIX0988)*.
2. Complete a *Form 125 – Summary of Hospitalization Diagnosis* for hospital stay and include the *Form 125* with the adjudication case.
3. In the adjudication screen, enter the appropriate closure code. Upon review of the medical records documentation, assign and key-enter a closure code in WHIX. See *Table 8.5 – WHIX Outcomes Closure Codes*.

The WHIX closure code indicates the status of the case, indicating that a case requires adjudication (code 9) or if the case will not be adjudicates and the reason (codes 10-14). For example, if a case is determined to be a duplicate visit, enter the closure code "11 – Duplicate visit, not forwarded to the CCC", close the case, and archive the case at the FC.

4. Copy the entire adjudication case packet for adjudication. Keep the copy at the FC and forward the original packet to the CCC. For confidentiality purposes, black out all participant identifiers on the original adjudication case using the guidelines below:

   Black-out: all personal identifiers on the original records to be forwarded to the CCC. These include but are not limited to:

   - participant's name
   - address
   - phone number
   - all next-of-kin/emergency contact information
   - social security number
   - medical record number
   - billing account number
   - If the participant died at home black out the address and write in "residence"

   Do not black out the following (they are not considered personal identifiers)**:**

   - date of birth
   - death on the death certificate or other medical records
   - name of hospital or institution if the participant died outside their home
   - pathology or specimen numbers listed on a lab report
   - dates of service or dates when procedures occurred
   - accession number on pathology reports

   If two potential outcomes are included in one adjudication case (i.e., from the same hospitalization), you do not need to make two copies of the documents. The CCC will route the case to the appropriately if the Physician Adjudicator cannot adjudicate all outcomes in a packet.

5. Assemble each case packet in the following order:
   - *Investigation Documentation Summary (WHIX0988)*
   - *Members Outcomes Status Report (WHIX1215)*
   - *Form 125 – Summary of Hospital Diagnosis* (hospitalizations only)
   - The *Adjudication Rules Report (WHIX1001)*, when manually updated, summarizes 1) each participant's confirmed outcomes by the event date, 2) outcomes that still require adjudication, and 3) outcomes that meet subsequent condition rules thus not requiring adjudication. Using this report is optional.
   - Medical records documentation

6. Select "send to CCC" button located in the adjudication screen in WHIX, when the case is complete, even if cases are batched and mailed to the CCC a few days later.

7. Securely staple or bind each individual adjudication case packet. Note: when attaching the last hospital stay for reference for a death case, clearly indicate "last relevant hospitalization for reference only". This adjudication may be from the main WHI or the Extension Study.

8. Send the adjudication case packet to the CCC. Ensure that the cases are routed in a secure envelope using a system that preserves participant confidentiality and includes a packing sheet listing cases included in the sent packet. Your local IRB may have other specific guidelines. Send the cases to the following address to the attention of the designated CCC staff person:

   U.S. Mail and Federal Express Mailing:

   WHI Clinical Coordinating Center
   Fred Hutchinson Cancer Research Center
   1100 Fairview Ave N/M3-A410
   PO Box 19024
   Seattle, WA 98109

8.4.3 Closing Problem Adjudication Case Packets (Excludes Death)

In 2005 the OAC reviewed and re-approved guidelines for closing problem adjudication case packets. These criteria remain unchanged in the WHI Extension Study. A problem case is defined as:

- A non-death case that is greater than one year old (the annual date is based on the date of *Form 33D* analysis in the WHIX database); and
- The OC has exhausted all possible sources of medical records documentation/information (e.g., multiple medical records requests were made and records were not obtained; the outcome occurred out of the country and provider information is not available; unable to investigate the outcome because the participant refuses to sign the Release of Information).

If a problem adjudication case packet meets the above requirements, the FC staff and/or CCC may close the case using the appropriate outcomes closure code (see *Table 8.5 – WHIX Outcomes Closure Codes*).

Table 8.5
WHIX Outcomes Closure Codes

Closure Codes:		Meaning and Guidelines for Use
9	Extension case forwarded to CCC.	Case linked to at least one defined self-report outcome. For death adjudications without medical records, use *Form 120 – Initial Notification of Death* as the record source if no other medical records or death certificate are available. WHIX requires that one medical record be present for an adjudication with Code 9 status. All deaths require adjudication.
10	Not adjudicated, not forwarded to the CCC.	All conditions linked to visits in this case have "bunionectomy" flag; do not meet investigation criteria.
11	Duplicate visit, not forwarded to the CCC.	All visits in this case are flagged as duplicates. Use this code for an adjudication (or provider visit) determined to be a duplicate of a previously adjudicated visit from the main WHI or Extension Study (e.g., participant self-reports identical information on a subsequent *Form 33D*). Obtaining medical records to confirm the duplicate visit is not required (see *Section 10.6.2.7 – Closing a "Non-WHI Extension Outcome"* for instructions on how to process a duplicate visit.)
12	Cannot get documentation for visit, not forwarded to the CCC.	Case is > 12 months old (based on F33D contact date) and the FC is unable to local the provider or unable to obtain documents from provider. Typically reserved for non-death outcomes that are greater than one year old (see *Section 8.4.3 – Closing Problem Adjudication Case Packets (Excludes Death)*.
13	Cannot get Release of Information, not forwarded to the CCC.	Case is > 12 months old (based on F33D contact date) and the FC is unable to obtain a Release of Information from participant, next of kin (NOK) or family. Typically reserved for non-death outcomes that are greater than one year old (see *Section 8.4.3 – Closing Problem Adjudication Case Packets (Excludes Death)*.
14	Administrative problems (details in comments), not forwarded to the CCC.	Do not use this closure code before checking with your CCC Outcomes Liaison. Problem case – does not fit any of the above categories; case > 12 months old. Typically reserved for non-death outcomes that are greater than one year old (see *Section 8.4.3 – Closing Problem Adjudication Case Packets (Excludes Death)*. Note: WHIX requires that a comment be key-entered with this code.

8.4.4 CCC Routing of Adjudication Case Packets to Physician Adjudicator

Upon receipt at the CCC, the CCC outcomes staff review the outcomes packets for completeness and legibility, and notify the FC via query of any additional materials required to complete the case packet. The case packet will be held at the CCC until the additional information is obtained.

The case is then reviewed for hospital stays of 2 nights or more with no outcome of interest (self reported). The CCC Outcomes Liaison reviews the ICD-9-CM or ICD-10-CM codes and/or text descriptions and forwards to Physician Adjudicator if indicated. If no other outcomes are present, the CCC Outcomes Liaison will sign-off on the *Form 125* procedure and diagnoses codes. Adjudication case packets are then copied, and copies routed to the appropriate committee(s) for adjudication.

When the Physician Adjudicator returns the outcomes packet with completed outcomes forms to the CCC, the CCC outcomes staff is responsible for the following:

- Review completed outcome forms and reports to ensure that they are complete, the participant ID number is present on all forms, the outcome diagnosis is assigned or appropriate box marked, and the Physician Adjudicator has signed the last page of all forms.
- Route the case to additional committee(s) for adjudication, if required.
- Key-enter the completed outcome forms.
- Enter the date that the outcome case is closed (the date of the adjudication) and select the appropriate closure code (see *Table 8.5 – WHIX Outcomes Closure Codes* for a description of closure codes).
- File a copy of all documents in the original adjudication case packet and permanently archive the case at the CCC.

8.4.5 FC Responsibilities Post-Adjudication

The FC Outcomes staff ensures that the completed adjudication packet is tracked and filed at the FC for future reference and extraneous records are shredded.

FC staff also respond to any queries for additional information or records as needed.

8.4.6 Central Monitoring of FC Ascertainment and Centralized Adjudication

The CCC, OAC and Performance Monitoring Committee (PMC) have developed initial and ongoing criteria for ascertainment and adjudication performance (e.g., timeliness and accuracy of outcomes activities). These groups will work with the FC to monitor FC performance via centralized WHIX reports of outcomes-related data and make recommendations for performance enhancement as needed.

8.5 Fatal Events – Special Considerations

The identification, investigation, and documentation of fatal events can occur routinely through returned mail or non-routinely through communication by relatives, friends, etc. Follow-up on fatal events requires sensitive and resourceful communication and investigative strategies. Although any FC staff member may identify a participant's death, the Outcomes Coordinator is usually responsible for the investigation and documentation. This section provides guidelines for ascertainment of fatal events and communication with participant's survivors.

8.5.1 Identification

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

- Follow-up of participants lost-to-contact. For example, web based searches (SSDI) to locate lost participants.
- Family members, friends, or the Post Office in response to the routine annual mailings (e.g., forwarded mail or returned mail marked "addressee deceased").
- Health care providers (e.g., medical records departments, clinics) from whom outcomes documentation has been requested to investigate earlier WHI Extension Study outcomes.
- A proxy , such as health care professional, family member, or friend, who is aware of a woman's participation in the WHI Extension Study and the need to provide such information to the FC.
- Obituaries or articles in local newspapers or other publications.
- Clinical Coordinating Center (CCC) National Death Index search. Special procedures apply. See *Section 8.5.5 – National Death Index (NDI)*).

Initial Packet of Materials: News of a participant death can occur at any time and can be communicated to any FC 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 FC staff to use when talking with a family member or friend.
- A sympathy card to route to FC 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 data entry staff for data entry.

Procedures upon notice: Upon receipt of a report of death, FC staff:

- 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.* FC staff use information obtained from the proxy or other source 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 WHIX and stops all mailings thus preventing the participant from appearing on follow-up reports.

  If the initial notice is obtained at the CCC, CCC staff initiate the *Form 120*, including only the encounter information (contact date, completed by, contact type, and Q.2 - Source of notification), then key-enter this limited information into WHIX to capture the participant death. Following key-entry, the partially

completed *Form 120* is forwarded to the FC. The FC OC (or designee) is responsibile for completing the *Form 120*, Questions 3-7, key-entry of the information in WHIX, and beginning the death investigation.

- **Collect a Release of Information (ROI)** or proxy release form signed by the participant's next-of-kin. 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.

- **Complete *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). A FC staff person with good sensitivity and 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 *WHIX1225 – Unresolved Death Report* to identify deceased participants missing a *Proxy 33/33D*.

8.5.2 Investigation

The investigation of fatal events is challenging and requires:
- Knowledge of the 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.

WHIX analysis of the *Form 120* will identify a documentation set for inpatient and outpatient provider visits. If the location (inpatient or outpatient) of death is unknown and the provider visit is flagged as "other" in WHIX, a complete documentation set is not generated. Once the location of death is confirmed, update the visit status of "other" to generate the appropriate documentation set (see *Section 10 – WHIX Database Procedures for Fatal Events*).

Hospitalized death documentation set includes the following:
- Face sheet.
- Discharge summary/Death Summary (including additional documentation that may be needed to obtain information on ICD-9-CM or ICD-10-CM codes).
- Outpatient, emergency room, or emergency medical services reports preceding the hospitalization.
- Death certificate (a certified copy is **not** required).
- Autopsy report (if applicable—this will usually be noted on the death certificate).
- Coroner's report (if applicable).
- *Form 120 – Initial Report of Death* used for reference only.
- For inpatient coronary deaths, request ECGs and cardiac enzymes.

Non-hospitalized death documentation set includes the following:
- Last relevant adjudication, that is the adjudication case packet from the most recent, relevant hospitalization while a WHI participant. This may be from the main WHI study or the WHI Extension Study, and is made available for reference only.
- Outpatient, emergency room, or emergency medical services reports.
- Death certificate (a certified copy is **not** required).
- Autopsy report (if applicable—this will usually be noted on the death certificate).
- Coroner's report (if applicable).
- *Form 120 – Initial Report of Death*, used for reference only.

8.5.2.1 Communication

Communications with individuals who have knowledge of or documents about a WHI Extension Study 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 Extension Study 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 *Section 7 – Follow-up Contacts* for further information on appropriate communication considerations.
- Basic understanding of medical conditions and terminology (both professional and common lay terms).
- Ability to prioritize WHI Extension Study 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 FCs 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 FC 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 FC staff to abstract medical records information themselves on-site.

8.5.3 Documentation

A complete list of required documentation for a fatal event is listed in *Section 8.5.2.2 – Investigation* (see also *Table 8.2 – Required Documents for 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 outcomes associated with the death case. This is to ensure that the Physician Adjudicator has all relevant medical records when adjudicating cause of death.

8.5.3.1 Essential Documents for Fatal Events

Every attempt should be made to obtain all documentation needed for adjudication (see *Table 8.4 – Essential Medical Record Documents*). Except for central NDI searches, the essential documents for a fatal event include:

Hospitalized death:	Discharge Summary/Death Summary, and Death Certificate
Hospitalized coronary death:	Discharge Summary/Death Summary, and Death Certificate; ECGs, and cardiac enzymes.
Non-hospitalized death:	Death Certificate, *Form 120 – Initial Report of Death* and last relevant adjudicated case (for reference only).

8.5.3.2 Death Cases More Than 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 CCC with all available documentation. Clearly document the 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 the CCC after six months of the report of death. See *Section 10 – WHIX Database Procedures for Fatal Events* for procedures to prepare the fatal event case for adjudication.

8.5.3.3 Participants on Absolutely No Contact (Required)

There should be no mail or phone contacts or attempts to collect data for participants who have requested absolutely no contact.

8.5.4 Report: *WHIX1225 – Unresolved Death Report*

WHIX1225 – Unresolved Death Report is the only report designed to track all tasks surrounding the participant death and should be run monthly. This report excludes NDI discovered deaths and no contact/absolutely no contact participants; the report tracks the following:

- Duplicate entry of *Form 120* and/or *Form 124*
- Death conditions, created by the WHIX analyzer, not linked to a provider visit
- Open death and closed adjudications missing a proxy *Form 33*

8.5.5 National Death Index (NDI)

At regularly scheduled intervals, information from the 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 Extension Study participants as well as codes for cause of death.

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

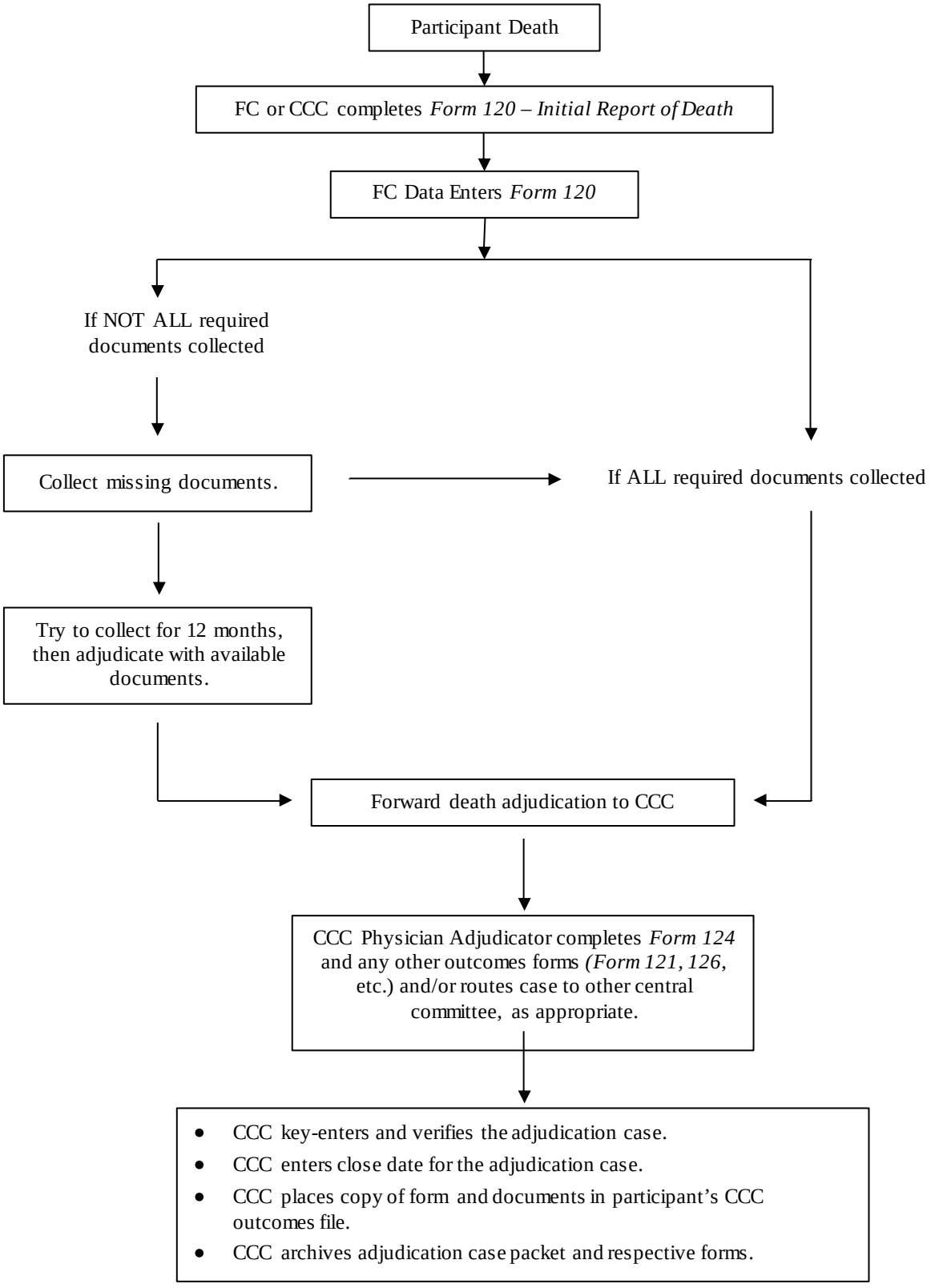
Upon NDI search, the CCC will send the FC the participant's fact of death information (date of death and subclassification of death) based on the NDI search results of each participant newly identified as deceased.

The FC will receive:

- The list of newly identified deceased participants.
- An original *Form 120 – Initial Notification of Death* for each participant, along with instructions for filing them in the participant's outcomes chart. The CCC completes and key-enters the *Form 120* into WHIX and the FC does not need to data enter these forms.
- A CCC completed *Form 124 – Report of Death (Final)* 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 WHIX and the CC will not need to data enter it.

The NDI application states that the FCs are not allowed to do follow-back investigations with Next-of-Kin and/or health care providers. Hence, the FC should not initiate any further contact with the participant's family or physician. The CCC has revised WHIX 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 has updated the FC reports with a comment advising staff not to follow back for additional information.

Figure 8.2
Fatal Event Flow Diagram



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