

SECTION 2

OUTCOMES ASCERTAINMENT

INTRODUCTION

In the Women's Health Initiative (WHI), outcomes are defined as clinical events associated with one of the hypotheses being examined. For the Clinical Trial (CT), one of the most important aspect of outcomes procedures is the unbiased ascertainment of possible WHI outcomes. The procedures involved in ascertainment should in no way be influenced by a participant's treatment assignment. For the Observational Study (OS), the completeness of outcomes ascertainment is as important as its adjudication. In WHI, outcomes ascertainment procedures are by and large the same, regardless of study component. The most notable exception to this policy are the addition of safety outcomes for the Hormone Replacement Therapy (HRT) component and fracture outcomes, other than hip fractures, to be adjudicated for CT participants only at non-Bone Density sites.

Women's Health Initiative outcomes ascertainment procedures include the identification, investigation, and documentation of potential WHI outcomes. This section describes the procedures for outcomes ascertainment, including how to process the initial identification or report of an outcome, investigate and request the required documents for each outcome, assemble the documentation, and forward the adjudication case packet for local and central adjudication. Clinical Center Outcomes Coordinators and other local outcomes staff will usually have primary responsibility for implementing outcomes ascertainment procedures.

2.1 Overview

The purpose of outcomes ascertainment procedures is to collect the information necessary for the adjudication of an outcome. Outcomes data are to be ascertained in an unbiased, accurate, and expedient manner.

Women's Health Initiative outcomes are health events, conditions, or related procedures that have been chosen by WHI investigators as being of study interest. Outcomes ascertainment procedures include the identification, investigation, and documentation of potential WHI outcomes. The majority of outcomes will require documentation supporting the event or procedure. A small number of outcomes will be ascertained through self-report only (see *Section 2.1.1.1 - Outcomes Ascertained Only by Self-Report*).

The entire process of ascertainment of an outcome plus the adjudication of a final WHI diagnosis by the CC Physician Adjudicator, should be completed within 3 months of initial identification of a possible WHI outcome. This three month interval begins with the analysis of *Form 33D – Medical History Update (Detail)*. See *Section 1, Figure 1.1 - Local Ascertainment and Adjudication* for a flow diagram of this process.

Each CC will identify an Outcomes Coordinator (see *Vol. 2 - Procedures, Section 2.4 - Staffing*). This person is responsible for overseeing the activities of the outcomes team and the process of outcomes ascertainment, including:

- Identification of events and procedures.
- Investigation of sources of supporting documents.
- Ongoing tracking of documents and final assembly into adjudication case packets.

Each CC will also identify one or more Physician Adjudicators-local physicians who can adjudicate all types of events related to WHI outcomes (see *Section 3 - Physician Adjudication*).

It is recommended that the Outcomes Coordinator not have direct contact with participants during their follow-up clinic visits and procedures in order to ensure objectivity and uniformity in the outcomes process. It is **recommended** that the Clinic Practitioner (CP) and Group Nutritionist (or anyone exposed to information that is effectively or definitively unblinding) not be involved in outcomes ascertainment, and it is **required** that they not be directly involved with outcomes adjudication (see *Vol. 2 - Procedures, Section 4.6.5 - Blinding Considerations and Recommendations*).

2.1.1 WHI Outcomes to be Ascertained

Women's Health Initiative outcomes (listed in *Vol. 1, Section 1 - Protocol, Section 4.3 - Outcomes of Interest*) will be evaluated by ascertainment of the following clinical events. Most of the outcomes listed below will require full ascertainment and adjudication. Those outcomes identified by self-report alone (i.e., do **not** require investigation, documentation, or adjudication) are indicated as such in parentheses and in *Section 2.1.1.1 - Outcomes Ascertained Only by Self-Report*.

- **Coronary heart disease and other cardiovascular disease:**

Acute myocardial infarction (MI) (requiring hospitalization).

Coronary death (includes sudden death but does not include sudden cardiac arrest that does not result in a death).

Stroke (fatal and non-fatal) (requiring hospitalization).

Transient ischemic attack (TIA) (requiring hospitalization).

Congestive heart failure (CHF) (requiring hospitalization).

Angina pectoris (requiring hospitalization).

Peripheral arterial disease (requiring hospitalization).

Carotid artery disease (requiring hospitalization).

Coronary revascularization.

- **Death from any cause.**

- **Any cancer.**

- **Any fracture:**

Excluding fingers, toes, ribs, cervical spine, or neck, skull/face (including nose and jaw), chest/sternum

- **Venous thromboembolic disease:**

Pulmonary embolism (PE) (self-report, except for HRT) (requiring hospitalization).

Deep venous thrombosis (DVT) (self-report, except for HRT) (OP collection started January 2000).

- **Hysterectomy (self-report, except for HRT).**

- **Any overnight hospitalizations, excluding the elective procedures listed in Section 2.1.1.2 – Hospitalization Due Solely to the Following Conditions or Elective Procedures.**

- **Diabetes mellitus requiring therapy (self-report).**

- **Benign breast disease (self-report)** (full ascertainment and adjudication ceased March 1996).

- **Colorectal polyps (self-report)** (full ascertainment and adjudication ceased March 1996).

- **Other age-related outcomes (self-report):**

Inflammatory arthritis.

Glaucoma.

Urinary incontinence.

2.1.1.1 Outcomes Ascertained Only by Self-Report on Medical History Updates (*Form 33/33D*)

The outcomes listed below will only be ascertained by self-report alone on *Form 33 - Medical History Update* or *33D - Medical History Update (Detail)*. They do not require investigation, documentation, or local or central adjudication unless the outcome is associated with an overnight hospitalization that needs further ascertainment and adjudication. Although these events could be part of a hospitalization, no specific documentation or adjudication of these self-reports is required.

- Diabetes mellitus requiring therapy.

- Benign breast disease (through analysis, a breast biopsy without eventual diagnosis of cancer, is classified as benign breast disease).

- Colorectal polyps.

- Other age-related outcomes:

Inflammatory arthritis.

Glaucoma.

Urinary incontinence.

- Non-melanoma skin cancer.

- All other (non-hip) fractures for OS participants, who are at non-Bone Density CCs .

- Fractures **not** requiring documentation or adjudication for **any** participant:

Ribs.

Chest/sternum.

Skull/face, including nose and jaw.

Fingers.

Toes.

Cervical vertebrae or neck.

2.1.1.2 Hospitalizations Due Solely to the Following Conditions or Elective Procedures

Below are specific overnight hospitalization procedures that do not require investigation, documentation, adjudication, nor completion of *Form 125 – Summary of Hospitalization Diagnosis* if the participant reports it is the only reason/event during the hospitalization. In the WHILMA outcomes subsystem, adjudication screen, enter Closure Code 3 – *Bunionectomy indicated, not adjudicated* to close-out the following procedures (see *Vol. 5 – Data System* for detailed database instructions).

Appendectomy

Bunionectomy

Carpal tunnel repair/release

Club foot release

Corneal transplant

Extracapsular cataract extraction (ECCE)

Hemorrhoidectomy

Inguinal herniorrhaphy

Knee arthroscopy

Laminectomy

Ligation and stripping, vascular (varicose vein stripping)

Rhinoplasty/septoplasty/ septorhinoplasty

Scleral buckle

Shoulder replacement

Stapedectomy

Synovectomy of wrist

Tonsillectomy & adenoidectomy (T&A)

Turbineectomy

Tympanostomy tube

Upper gastrointestinal endoscopy

Vitreectomy

Cosmetic/plastic surgery, other than breast

Lacerations repair

Rotator cuff repair

Overnight hospitalization for:

- Any research study (that does not involve a WHI outcome)
- Sleep studies (not related to a research study)

Rehabilitation facility not directly attached to an acute care hospital

Any psychiatric admissions

Out of country overnight hospitalization for gastrointestinal (G1) symptoms related to travel. (Requires PI signature.)

2.2 Identification of Outcomes

Clinical Centers may become aware of potential outcomes through different mechanisms, depending upon study component:

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

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

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

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 to screen for those participants who have had major clinical events that may require adjudication. Those participants who report hospitalizations, new diagnoses of cancer or fractures, hysterectomy, outpatient treatment for deep vein thrombosis (HRT only – January 2000), or outpatient revascularization procedure (August 1997) on *Form 33* will be asked to complete *Form 33D*. This latter form will collect more specific information regarding the potential WHI outcomes, as well as names and addresses of the providers who might have the participant's medical records related to the clinical event. Clinical Centers are advised to obtain new, signed medical release forms when *Form 33* or *Form 33D* is collected.

2.2.1.1 *Form 33 - Medical History Update*

Clinical Trial participants are to complete *Form 33 - Medical History Update* every 6 months at the semiannual contacts and annual visits. Participants will usually complete *Form 33* as a self-administered form (sent through the mail or handed out at a clinic visit), although CCs may choose to administer it as an interview if the participant is unable or unwilling to come for visits, or if the participant has difficulty understanding or completing forms.

Each year through the mail, OS participants will receive a *Form 33* to be completed and returned to the CC. The CCC will be responsible for mailing the *Form 33*s to all OS participants (see Vol. 2 - *Procedures, Section 16 - Follow-Up Contacts*). Thus, *Form 33* will usually be completed as a self-administered form. Additional information may need to be gathered by the CC through an interview in order to resolve questions or missing data.

For incapacitated or deceased participants, a participant's proxy (e.g., family, friend, or health care provider) may complete a *Form 33* (See Vol. 2 - *Procedures, Section 16 - Follow-Up Contacts*).

2.2.1.2 *Form 33D - Medical History Update (Detail)*

Following the data entry of a completed *Form 33 - Medical History Update*, a WHILMA report (*Potential Outcomes Report WHIP0622*) can be generated to identify those participants for whom more detailed information is required. *Form 33D - Medical History Update (Detail)* is required from those participants who indicate on *Form 33* that they have been hospitalized overnight for any reason, have been newly diagnosed with cancer or a fracture or have had a hysterectomy, or outpatient treatment for DVT (HRT only) or outpatient coronary revascularization. In 1996, it is estimated that approximately 10% of CT participants will meet these criteria every 6 months, and approximately 17% of OS participants will meet these criteria each year. As the study population ages, the number of participants asked to provide more detailed information will likely increase.

On *Form 33D*, participants are asked to provide names and addresses of hospitals and clinics where possible WHI outcomes were diagnosed and treated. Participants are also asked to provide more detailed information regarding specific cardiovascular diagnoses, specific cancer diagnoses, sites and causes of fractures, hysterectomy procedures or outpatient treatment for DVT (HRT only) or revascularization procedures. *Form 33D* can either be self-administered or completed by interview (either in-person or by phone). Refer to the current *Form 33* form instructions for the algorithm that will trigger the need for a participant to complete a *Form 33D*. Clinical Centers will probably find that administration of *Form 33D* by interview results in more complete data for proceeding with a timely outcomes investigation process. Therefore, clinics are strongly encouraged to post the current algorithm at the clinic and collect *Form 33D* by interview.

In 2000, *Form 33D* was revised to allow the participant to report six overnight hospitalizations. If the participant indicates more than six, the participant is instructed to write the details for the additional hospitalizations on a separate sheet of paper and attach it to the *Form 33D*. The OC must investigate the hospitalizations, then manually create and link the additional visits indicated on the form. Forms indicating greater than six hospitalizations will appear on *WHIP0983 – Forms to Pull* report. (See *Vol. 5, Appendix F, Section 1.1 – Provider Visits Screen* for instructions on manually creating and linking conditions).

2.2.1.3 Abnormal Results of WHI Procedures or Tests

For CT participants, results of some routine WHI procedures or tests may identify a potential WHI outcome. In general, these results will be collected as part of the clinic visit, hence there is no need for further reporting of this outcome on the *Form 33/33D* collected at the time of the visit. The participant should report any such potential outcomes on her next routine *Form 33*.

Certain findings from HRT safety procedures (e.g., CBE, mammogram, pelvic exam, Pap smear, or endometrial aspiration) may require investigation to determine if the participant has developed a condition that would necessitate HRT pill discontinuation (see *Vol. 2 - Procedures, Section 5 - Hormone Replacement Therapy*).

2.2.2 Amendments to Routine *Form 33* or *Form 33D*

If a participant or proxy notifies the CC of a correction to a participant's most recently completed *Form 33/33D*, edit the most recently completed *Form 33* or *33D* following the usual guidelines for editing forms (see *Vol. 2, Section 18.2.4 – Editing Forms*). If the *Form 33* or *33D* has already been key-entered, also update the data in WHILMA. *Form 33D* may need to be re-analyzed following the form correction/edits. Do not record the updated information on a new i.e., "amendment" *Form 33* or *Form 33D*.

2.2.3 Interim Reports of Possible WHI Outcomes (Other than Deaths)

It may happen that a participant contacts a CC to report a potential WHI outcome before administration of the next routine *Form 33*. Such contact is termed an 'interim report' of an outcome and WHI does not collect interim reports. Participants should be asked to report the information at its next routine administration. Reporting interim events at the next routine semi-annual or annual contact will maintain a standard method of ascertaining potential outcomes and allow measurement of potential reporting bias in Dietary Modification (DM) participants (because participants randomized to the intervention arm are more likely to report interim outcomes due to their more frequent contact with CC staff). If the participant does not report the outcome at her next routine contact, do not provide any reminder prompts nor investigate the outcome.

Previously, a report of death was considered an interim report of an outcome. As of March 13, 1998, an "interim" report of death is considered a "non-routine" visit type, rather than an "interim" visit type (see *Section 7 – Fatal Events*).

2.2.3.1 Interim Reports of Serious Adverse Experiences (SAEs)

Effective March 13, 1998, CCs are not required to report serious adverse experiences (SAEs) to the CCC or Project Office. The Food and Drug Administration (FDA) has approved the Project Office's proposal to

monitor SAEs via the WHI outcomes data. CCs are still required to follow their own institution's requirements for reporting SAEs. CCs should ensure that there is a system in place to promote good communication between the clinic practitioner and the outcomes coordinator so that both are aware of events that may require the stoppage of study pills or require investigation as a possible outcome. See safety report *WHIP1613 – Participants Dispensed HRT/CaD Pills After a Definitive Clinical Safety Event was Reported*. The report lists participants who have a study pill dispensation after a “definitive” safety event was reported and which requires permanently stopping HRT or CaD study pills.

HRT participant outcomes requiring CP notification:

- breast cancer
- endometrial cancer
- Ovarian cancer
- malignant melanoma
- meningioma
- hysterectomy
- endometrial hyperplasia
- deep vein thrombosis (DVT)
- pulmonary embolism (PE)

CaD participant outcomes requiring CP notification are collected on *Form 17 - CaD Management and Safety* and include:

- kidney or urinary tract stones
- hypercalcemia

See *Vol. 2, Section 5- HRT and Section 7 - CaD* for further information on safety events.

2.2.4 Reports of Death

Participant deaths will be reported to CC staff by proxy (e.g., family, friend, health care provider) or other sources (e.g., newspaper obituary, returned mail, National Death Index report). Information from such reports should be used to complete *Form 120 - Initial Report of Death*. Note that **all** information may not be available when *Form 120* is completed. Regardless of the amount of information gathered on the *Form 120*, data enter the available information. Data entry of *Form 120* creates the death condition in the WHILMA database, stops participant mailings and modifies other WHILMA reports on the participant (see *Section 7 – Fatal Events*). A final *Form 33 - Medical History Update* and *33D - Medical History Update (Detail)* (if appropriate) should be completed by proxy (to identify any **other** outcomes since the last *Form 33*).

2.2.5 Release of Information Forms

To obtain documents from a participant's medical record, you must have a current Release of Information form (*Appendix B.1 - Model General Medical Release Form*) signed by the participant. Hospital, state, and local institutional Review boards (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) Release of Information form, with an original participant signature accompany any request for medical records. Some institutions will accept a blanket consent, good for an indefinite or a fixed period of time. Multiple (e.g., three to six) Release of Information forms should be obtained at each participant contact because documentation may be required from several providers. Some institutions will charge for duplicating and sending medical records and/or death certificates. If your CC is part of a non-profit organization or other special approvals (e.g., Institutional Review Board [IRB]) are obtained, the hospital may waive charges for your requests for medical records.

2.2.5.1 Refusal to Sign a Release of Information Form

If a participant refuses to sign a current Release of Information form, you cannot request medical records for potential WHI outcomes. Note in the participant's chart that she has declined to sign a current Release of Information form. Participants declining to sign this form will continue to have regular CC contacts according to her WHI component(s), if they are willing (see *Vol. 2 - Procedures, Section 17 - Retention*). Contact participants refusing to sign a Release of Information 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). Some participants may be willing to sign a Release of Information form that specifically documents the information needed to investigate 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 WHI primary outcomes (i.e., coronary heart disease, the five major cancers, and hip fractures), but may choose not to risk annoying a participant by pursuing other outcomes.

2.2.6 Routine Processing of Forms

Scan *Form 33* and key-enter the *Form 33D* or *Form 120* as directed in the appropriate forms instructions. There are two outcomes reports to help determine which participants need to complete a *Form 33D* based on their *Form 33* (version 3 and above) responses.

- The *Outcomes Screening Action Report (WHIP0621)* shows *Form 33s* that are incomplete and need follow-up. There is not enough information on the *Form 33* for the WHILMA database to determine if a *Form 33D* is required.
- The *Potential Outcomes Report (WHIP0622)* shows *Form 33s* that require a *Form 33D*. This report also shows a *Form 33* that indicates an outcome present but is incomplete in some way. In this case, a *Form 33D* is required and additional *Form 33* information collected to accurately complete the *Form 33*. *WHIP0622* also includes participant phone number and contact information to facilitate data collection.

2.2.7 Outcomes Reports

There are multiple outcomes reports available to track and monitor outcomes ascertainment and adjudication. Many reports can be selected and printed from the WHILMA Outcomes Subsystem menu; others are distributed from the CCC or created by the clinic via the Custom Data Extract (CDE) system. Given the complexity of outcomes processing, use of reports is essential. Refer to *Appendix I – Outcomes Reports, Section I.1 – Outcomes Reports Schedule (Recommended)* for a list of relevant reports. The table includes brief report descriptions, a suggested timeframe for running reports, and is formatted to correspond to steps in the outcomes and adjudication process.

2.3 Investigation of Outcomes

The investigation of a potential WHI outcome is a time-intensive activity that involves locating relevant health care providers (e.g., hospitals, clinics, physicians) and requesting medical records that may support its diagnosis. The documents requested of a particular provider will depend on the outcome type and WHI study component. Request documents for completing the appropriate outcome form based on *Table 2.1 - Documentation Requirements for WHI Outcomes*. 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 CC Outcomes Coordinator. Institutional, local, and state regulations will also impact the ease and expense of completing an investigation.

2.3.1 First vs. Recurrent Events

Certain WHI outcomes require full ascertainment and adjudication of only the first confirmed event of that type. The WHILMA database can provide information about which outcomes have already had a first adjudication on the *Members Outcomes Status Report (WHIP1215)* and will identify required document sets appropriately on the *Investigation Documentation Summary (IDS - WHIP0988)*.

For cardiovascular outcomes, usually only the **first** occurrence of the specific outcome will require investigation, documentation, or adjudication. See *Section 3 - Adjudication, Table 3.3 - Subsequent Conditions* for a complete list of subsequent conditions and whether they do or do not require further investigation, documentation, and adjudication. Hospitalized subsequent outcomes that do not require further processing as a specific WHI outcome will still be treated as hospitalizations and adjudicated as such locally. Therefore, the documentation set for a hospitalization (excluding the Emergency room report) needs to be requested. Note that certain coronary heart disease (CHD)-related events (e.g., hospitalized angina, CHF, coronary revascularization) will require continued ascertainment and adjudication until the first MI is adjudicated. Likewise, hospitalized TIAs will require continued ascertainment and adjudication until the first stroke is adjudicated. Once locally confirmed, a **second** MI occurring during WHI follow-up will only require investigation, documentation, and adjudication as a hospitalization.

A cancer metastasis from a primary cancer site that has already been adjudicated would not require adjudication. However, a second **primary** breast cancer would require local and central adjudication, as this would be considered a new cancer and not a metastasis.

Only the first hip fracture will be adjudicated. For all other fractures, only the first fracture at each anatomical site (the first humerus fracture) will be adjudicated in CT participants at non-Bone Density sites or CT and OS participants at Bone Density sites (see *Section 6 – Fractures Outcomes*).

2.3.1.1 Subsequent Events for CaD Participants

Because randomization into CaD occurs one year (or in specific cases two years) after randomization into the HRT or DM components, M&M approved a proposal to “reset” outcomes following randomization into the CaD trial. That is, outcomes identified while the participant was in DM and/or HRT but not yet randomized to CaD will not be used to determine subsequent conditions. This procedure will impact only those participants randomized to CaD that:

- Have an outcome adjudicated and confirmed after randomization to HRT and/or DM but before randomization to CaD; and
- The outcome currently under investigation met the definition of a subsequent condition. That is, a second report of an outcome that would otherwise not require full documentation review prior to the CaD randomization date now requires full ascertainment and adjudication. (See *Vol. 8, Section 3, Table 3.3 – Subsequent Conditions* for a list of outcomes.)

2.3.1.2 Prevalent Disease

Prevalent cardiovascular diseases at baseline do **not** count as WHI outcomes. Thus, for example, an MI occurring in a woman who had an MI before entering WHI would be classified for WHI as a **first** MI (not as recurrent) and would trigger a full outcomes investigation. The first fracture occurrence of a particular site after WHI randomization/enrollment is adjudicated. For cancers however, only adjudicate newly diagnosed primary cancers. Do not adjudicate a relapse, recurrence or metastatic site of a cancer diagnosed prior to study onset except to confirm that it is not a primary cancer.

2.3.1.3 Adjudication Rules Report

Outcomes that need to be adjudicated for a participant varies based on the study or studies to which she is randomized or enrolled and whether an outcome is determined to meet subsequent condition rules (see *Section 3 – Adjudication, Table 3.3 – Subsequent Conditions*). To assist the OC and PA track a participant's outcomes, the *Adjudication Rules Report (WHIP1001)* is available when manually updated at the CC (see *Volume 5, Appendix F, Section 2.3 – Adjudication Rules*).

The report indicates the study or studies to which a participant is randomized or enrolled, the date of CT randomization or OS enrollment, and the date of her CaD randomization, if any. The report lists confirmed outcomes with the date of the latest confirmed diagnosis date 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: non-hip fractures in OS participants at non-Bone Density sites, and hysterectomy and DVT for non-HRT participants. These are automatically set to “no”.

2.3.2 Standard Hospital Medical Records

A hospitalization, for WHI purposes, is defined as any overnight stay in an **acute** care hospital for any reason. There is no minimum length of stay required. Short stays, observation stays, and day surgeries may be referred to in medical records as outpatient visits, but for WHI, these stays are considered hospitalizations if they result in an overnight stay (due to a complication or need for close observation). Note that an overnight stay in a rehabilitation facility (**not** attached to an acute care hospital) is **not** considered an overnight hospital stay. Any overnight hospitalization for a psychiatric admission will not be investigated or adjudicated in WHI.

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 Outcomes Coordinator and Physician Adjudicator should understand the course of events from admission to discharge to generally reconstruct the hospitalization and outcome event(s).

The WHILMA outcomes management system automates the process of determining which documents (specific to a possible WHI outcome type) need to be requested. The OC will then print out *Request for Medical Information Form (WHIP0980)* document request forms suitable for mailing to identified providers (see *Vol. 5 - Data System*). If you are writing to a hospital for records (which will be the most common method for requesting documents in the WHI) it is the responsibility of the medical records department at that hospital to find the relevant documents in the record.

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 reports can be printed. Both methods provide access to medical information not otherwise available to all OCs and introduces the potential for a CC to over-report outcomes (ascertainment bias). To prevent over-reporting of events and ensure standardization of procedures among clinics, clinics must develop rigorous procurement procedures. Moreover, all OCs should be cognizant of ascertainment procedures as outlined in *Vol. 8 – Outcomes* (see *Sections 2.2 – Identification of Outcomes* and *Section 2.3 – Investigation of Outcomes*).

The following medical record components and their contents may be needed to complete WHI adjudication case packets. If you collect (abstract) documents directly from the medical records department, you can look in the indicated sections for the required documents. Be aware, however, that some medical records may not be well organized, and documents may be scattered throughout the record. The list below is in the order that documents might be found in a medical record, not in any specific order for WHI. Do not routinely add additional documentation to your document requests or adjudication case packets. Select the appropriate medical documents from *Table 2.1 - Documentation Requirements for WHI Outcomes*.

- **Face Sheet** - Demographic data; admission and discharge information (including dates and physicians, discharge diagnoses, procedures, and associated ICD-9-CM codes). If the ICD-9-CM codes are not documented on the Face Sheet, request a Physician Attestation Statement with the ICD-9-CM codes or any other accessible documents that indicate ICD-9-CM codes, such as a universal billing (UB) form, or a coding abstract.
- **Ambulance Report or Emergency Room 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. It will **not** be required for most WHI outcomes.
- **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 outcomes.

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. This document is required in WHI only for the five major cancers, but may be necessary for other outcomes if the discharge summary is not available or is very brief.

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 and other specimen analysis results, cardiac enzyme or Troponin results for MI, pathology, and/or cytology results for cancer are usually found in this section. Laboratory results may be interspersed with other documents, however. It is not uncommon for cardiac enzymes to be recorded on a separate lab sheet.
- **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 cardiovascular outcomes, not the individual rhythm strips that might be found attached to daily progress notes. The specific 12-lead ECGs are required for WHI CHD outcomes (e.g., MI, angina, CHF, coronary revascularization, and hospitalized death, if available). You should 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, MRIs, echocardiograms, coronary angiographies (heart catheterizations), doppler flow studies, autopsy reports, tumor biopsies, colonoscopies, breast cancer estrogen and progesterone receptor 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 coronary artery bypass graft (CABG), percutaneous transluminal coronary angioplasty (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** - Oncology consultation reports are needed in WHI for the five major cancers only. 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.
- **Tumor Registry Abstract Form** - Many larger hospitals have tumor registries that document and track cancer patients. This form, if present, may help the CC Physician Adjudicator to determine such issues as date of diagnosis (for a cancer diagnosed before a hospitalization) or breast cancer estrogen receptor status. The location of this form in the chart will vary by hospital.

2.3.3 Procedures for Requesting Outcomes Documents

The CC Outcomes Coordinator or outcomes staff should:

1. Identify all appropriate providers (document sources) in WHILMA such as the hospital, physician's office, or other facility recorded on *Form 33D – Medical History Update*.
2. Generate a *Request for Medical Information Form (WHIP0980)* from the WHILMA outcomes management system for each provider. A list of required documents for each reported outcome will be generated for each provider. This report will also include the participant's name and ID number, date of birth, social security number, approximate last visit date, requesting clinic, and provider organization. For example, if a stroke is identified, the list of required documents will include: Face Sheet and/or physician attestation statement with ICD-9-CM codes, discharge summary, operative or procedural reports, and reports of echocardiography, CT scan, lumbar puncture, magnetic resonance imaging (MRI), and carotid studies.
3. Mail out a request for all of the documents required for each identified outcome. See *Table 2.1 - Documentation Requirements for WHI Outcomes* for a summary. This request to providers should include a cover letter from your CC, the *WHILMA Request for Medical Information Form (WHIP0980)*, and a Release of Information form signed and dated by the participant. A *Model Request for Medical Information* cover letter can be found in *Vol. 8 - Appendix B*.
4. Create (or pull) an outcomes file for each participant with an identified outcome. Keep it separate from other WHI participant charts. 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.
5. Every attempt should be made to obtain the minimum documentation needed for adjudication. If some of the requested documents cannot be obtained after diligent effort (the Morbidity and Mortality Committee established a guideline of 4 attempts), their absence should not delay the submission of the other information for local adjudication. However, in the WHILMA system, document their absence in the *Visit Documents Screen* indicating the reason why records were not obtained. This text information is printed out on reports and is available to the local and central adjudicators.
6. Receive requested documents:
 - Upon receipt, match the documents with the WHI-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 on each page of the outcome materials. Keep a copy of all documents pertaining to one participant in her outcomes file.
 - Clip or staple together documents that will be required for adjudication of the outcome in the participant's outcomes file (not her WHI participant file). These clipped or stapled documents will eventually form the adjudication case packet.

7. Extraneous/Miscellaneous Documents:

- On occasion, a hospital or provider may furnish the CC with documents not needed for WHI adjudication. These extraneous documents should not be placed in the participant's WHI chart, but can become part of the participant's outcomes file to be available if additional documents are requested by the Physician Adjudicator. These extraneous documents must be destroyed (e.g., shredded), however, once the outcome is closed.* To avoid excessive accumulation of extraneous documents, CCs should avoid routinely requesting entire medical records. If the Outcomes Coordinator has a question about the appropriateness of a document, the CC Physician Adjudicator should be consulted before discarding the document.

8. Monitoring Reports

Use the WHILMA outcomes management system to track which outcome documents you have requested from a provider, when the documents are received, and when follow-up requests need to be initiated (see *Vol. 5 - Data System* 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 listings of all participants for whom a possible WHI outcome was identified in the database but no final documentation has been received. The report *Outcome Visit Requiring Requests Summary (WHIP1213)* will show:

- Participant ID number
- Provider information and visit dates
- Reported conditions
- Documentation requested (e.g., laboratory results, autopsy report)

Verify the status of each identified outcome with WHILMA. Follow up promptly with any document request that is overdue.

2.3.3.1 Special Considerations

- Hospitalization:** For all hospitalizations, the Hospital Face Sheet and/or the Physician Attestation Statement (computer-generated Face Sheet) with ICD-9-CM diagnosis and procedure codes and the discharge summary should be requested as the initial step in determining an outcome.

* 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.

A hospital admission is defined as an overnight stay in an acute care facility and may include 23-hour observations. A hospital Emergency Room (ER) visit is not considered an admission *even if the date changes*. However, if any ER visit results in an overnight hospital admission, you adjudicate the overnight hospitalization/outcome which includes procurement of appropriate ER medical records. Additionally, you would adjudicate an ER visit when the participant reports a revascularization procedure, is diagnosed with a 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 isn't actually admitted to the "acute care facility," (i.e., the hospital itself) it wouldn't be considered an overnight hospitalization. If you have a question about a particular institution's definition of an overnight hospital stay, please do not hesitate to contact your CCC outcomes liaison.

- **Death certificate:** Copies of the death certificates are required to confirm a death. Other documents may be required, such as autopsy report or medical records from a personal physician, cancer (tumor) registry, 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 7 - Fatal Events* for more information.
- **Hysterectomy:** In addition to the hospital discharge summary and Face Sheet, the operative report is required.
- **Merging adjudication case packets:** In February 1997, the Morbidity and Mortality Committee established adjudication case packet merging rules. Each hospitalization or other provider visit should be a separate adjudication case unless one of the following scenarios is present.

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 Diagnoses* for each hospitalization (and the adjudicator completed outcomes form, as appropriate).

Within-hospital transfers (e.g., transferred from the ICU to a rehabilitation floor attached to the acute care hospital). Complete only one *Form 125* (and the adjudicator completed outcomes form, as appropriate).

Note: Transfers from an acute care hospital to a free-standing rehabilitation facility are exempt from merging. Only the hospitalization is adjudicated. See *Table 2.2 – Selected hospitalized procedures requiring no follow-up (no required outcomes forms)*.

Merging rules by specific outcomes types:

- 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.
- Fracture. An outpatient (OP) x-ray confirms a fracture and the participant is subsequently hospitalized for treatment of the fracture. Merge the OP record with the subsequent definitive care into one adjudication.
- Cardiovascular. Other than participant transfer procedures defined above, each cardiovascular hospitalization stands alone as one adjudication.
- **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 Morbidity and Mortality Committee established a goal of four attempts), their absence should not delay the submission of the other information for local adjudication. (Note the absence of these documents in the WHILMA outcomes subsystem with the reason why the records were not obtained.) For each WHI 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 local adjudication or continue to request records. For all inpatient outcomes, the discharge summary is an essential document.

WHI Outcome	Essential Document(s)
MI/Angina	Cardiac Enzymes, ECGs, diagnostic procedures (CABG, PTCA)
Coronary Revascularization	Operative or procedure report
CHF	Chest X-ray (CXR)
Stroke	Carotid studies, CT or MRI report
Cancer	All pathology reports (ERA, PRA for breast cancer only)
PE/DVT (HRT only)	Procedure report
Hysterectomy (HRT only)	Operative report
Fracture	Radiology report, X-ray, or MRI
Death – Hospitalized	Discharge summary (death summary)
Death – Out of hospital	Death certificate, <i>Form 120 – Initial Report of Death</i> , and last WHI-adjudicated hospitalization in which the admit date is closest to the day of death (if available).

2.4 Documentation of Outcomes

Each WHI outcome has specific documents that must be collected and reviewed (if available) to adjudicate an outcome. See *Table 2.1 - Documentation Requirements for WHI Outcomes* for detailed documentation requirements for specific WHI outcomes types.

2.4.1 Preparing the Adjudication Case Packet

1. When all required documents are received, assemble them for adjudication in the order they are listed on the *Investigation Documentation Summary (WHIP0988)*.
2. It is recommended the OC make a copy of the entire adjudication case packet for the Physician Adjudicator and keep the original. This step can be omitted if the case packet will remain at the CC for review.
3. For each outcome, include the WHI outcomes forms that the adjudicator needs to complete (see *Table 2.2 - WHI Outcomes and Required Outcomes Forms*). It is recommended that you attach a participant barcode label (with ID number only) to the upper right corner of all outcomes forms that you include with the documentation. Write in the CC staff ID of the Physician Adjudicator on the outcomes forms.

If two potential outcomes are included in one packet (i.e., from the same hospitalization), you do not need to make two copies of the documents. However, be sure to check that all necessary documents and outcomes forms for **all** possible WHI outcomes are in the packet, including *Form 125 - Summary of Hospitalization Diagnosis* for all outcomes that occur during a hospitalization. The Physician Adjudicator can adjudicate all outcomes in a packet at one time. Note that because the Physician Adjudicator may identify other outcomes during the adjudication process, you should make sure that he or she has a ready supply of all current WHI outcomes forms on hand.

4. Attach to the top of each adjudication case packet the two required WHILMA reports:

- *Investigation Documentation Summary [IDS] (WHIP0988)* that you generate from the WHILMA adjudication screen, and the
- *Members Outcomes Status Report (WHIP1215)*.

The *Adjudication Rules Report (WHIP1001)*, when manually updated, summarizes each participant's confirmed outcomes by the event date, outcomes that still require adjudication, and outcomes that meet subsequent condition rules thus not requiring adjudication. Use of this report is optional.

5. Send the adjudication case packet to the Physician Adjudicator with instructions on how to return the completed outcome form and packet to you and the time by which it should be returned (i.e., 2 weeks after it was sent). Ensure that the case packets are routed in a secure envelope via a system that preserves participant confidentiality. Your local IRB may have other specific guidelines.

2.4.2 Routing Completed Local Adjudication Case Packets

When the local Physician Adjudicator returns the outcomes packet with completed outcomes forms, the Outcomes Coordinator should:

- Review the outcomes forms 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.
- Key-enter the completed outcome forms in WHILMA (see *Vol. 5 - Data System* for more details).
- Enter the date that the outcome case is closed (the date of final local adjudication) and select the appropriate closure code (see *Section 2.4.2.1 – Closure Codes*) for a description of closure codes.

- Retain a copy of all documents in the adjudication case packet for the participant's outcomes file.
- Once the outcome case is closed, you should destroy (e.g., shred) extraneous documents in the participant's outcomes file that were not included in the adjudication case packet.

Table 2.1
Documentation Requirements for WHI Outcomes

Documentation Requirements for WHI Outcomes	WHI/MA Ref. #	CHD, MI	CHF	Angina Pectoris	PAD	CAD	Stroke/TIA	Fractures	5 Main Cancers	Other Cancers	Coronary Death ⁹	All Deaths ⁹	Hospitalizations	PE ⁸	DVT ⁸	Hysterectomy ⁸	Outpatient Coronary Revasc
Face Sheet physician attestation statement with ICD-9-CM Codes, or other Coding Abstract ^{1, 5}	1, 44	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	
Discharge summary (dictated or handwritten) ^{1, 5}	3	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	
Operative or procedural report for treatment of disease	15	☒	☒	☒	☒	☒	☒		☒	☒					☒	☒	☒
Outpatient, Day Surgery, short stay ^{1, 7}	13							☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
ER reports ^{1, 7}	48	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	
Emergency Medical Service (EMS) or ambulance report	39								☒		☒	☒					
History and physical (dictated or handwritten)	2								☒								
Physician Notes ¹⁰	49														☒		
12-lead ECG Report: All	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	☒		☒													☒
RVG or MUGA ³ report	47	☒	☒	☒													
Chest X-ray report	4		☒					☒	☒					☒			
Radiology and/or bone scan reports/isotope or nuclear medicine bone scan	30							☒	☒					☒			
Echocardiography	22	☒	☒	☒			☒										
CT scan report	27						☒										
Lumbar puncture (LP) report	29						☒										
MRI report (magnetic resonance imaging)	28						☒	☒									
Ultrasound report (other than echocardiography)	23				☒												
Ankle-arm blood pressure procedure	24				☒												
Doppler flow study report	20				☒									☒	☒		
Carotid studies (doppler, angiography or isotope scan)	16					☒	☒										
All pathology reports	31								☒	☒							
ERA/PRA hormone receptor report (breast cancer only)	35								☒								
Oncology consult ⁴	33								☒								
Cytology report	32								☒								
Pulmonary angiography	26													☒	☒		
Isotope scan	21													☒	☒		
Lung scan report	25													☒	☒		
Impedance plethysmography	19													☒	☒		
Venogram report	18													☒	☒		
Autopsy or Medical Examiner/ Medical Examiner / Coroner's report	38										☒	☒					
Death certificate	37										☒	☒					

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.

3 RVG - Radionuclide ventriculogram or MUGA - Multigate Acquisition

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

5 For non-hospitalized deaths, cancers, fractures, and OP DVT do not request Face Sheet with ICD-9-CM codes and Discharge Summary.

6 For hip fractures only.

7 Obtain documentation if OP, day surgery, short stay, or ER visit result in an overnight hospitalization. Not required for subsequent conditions.

8 HRT only.

9 For out of hospital deaths only, include last WHI hospitalization that preceded the death.

10 For Outpatient DVT only.

Table 2.1
WHI Outcomes and Required Outcomes Forms
(identified on Form 33, Form 33D, or Form 120)

Outcomes Requiring Adjudication	Outcomes <u>Not</u> Requiring Adjudication																
• Coronary heart disease & other cardiovascular disease <i>Form 121 (Form 125 for hospitalization)</i> Acute myocardial infarction (MI) Coronary death (need not be hospitalized) Stroke TIA Congestive heart failure Angina pectoris Peripheral arterial disease, symptomatic and/or requiring a procedure Carotid artery disease requiring a procedure or surgery Coronary revascularization (PTCA, coronary stent) (need not be hospitalized) Coronary death (need not be hospitalized) • Five major cancers - <i>Form 122 (Form 125 for hospitalization):</i> <table border="0"> <tr> <td>Breast</td><td>Colon</td></tr> <tr> <td>Endometrium</td><td>Rectal</td></tr> <tr> <td>Ovary</td><td></td></tr> </table> • Other Cancers (excluding non-melanoma skin cancer) <i>Form 122 (Form 125 for hospitalization)</i> • Fractures - <i>Form 123 (Form 125 for hospitalization)</i> Hip [CT & OS] For CT & Bone Density sites only: <table border="0"> <tr> <td>Upper Leg (not hip)</td><td>Tailbone</td></tr> <tr> <td>Pelvis</td><td>Spine or back</td></tr> <tr> <td>Knee</td><td>Lower arm or wrist</td></tr> <tr> <td>Lower Leg or ankle</td><td>Hand (not finger)</td></tr> <tr> <td>Foot (not toe)</td><td>Elbow</td></tr> </table> Collarbone: all clavicular and scapular fractures Excludes: ribs, chest/sternum, skull/face, including nose and jaw, fingers, toes and cervical vertebrae or neck (complete <i>Form 125</i> for overnight hospitalization) • Venous thromboembolic disease - <i>Form 126 (for HRT participants only) (Form 125 for hospitalization):</i> Pulmonary embolism (PE) - hospitalized Deep venous thrombosis (DVT) (need not be hospitalized) • All hospitalizations except those solely for certain procedures (see <i>Section 2.1.1.1</i>) - <i>Form 125</i> • All deaths - <i>Form 120, 124 (Form 125 for hospitalization)</i>. Note for out of hospital death: Adjudicate death with last WHI hospitalization (if available). • Hysterectomy - <i>Form 131 (for HRT participants only) (Form 125 for hospitalization)</i>	Breast	Colon	Endometrium	Rectal	Ovary		Upper Leg (not hip)	Tailbone	Pelvis	Spine or back	Knee	Lower arm or wrist	Lower Leg or ankle	Hand (not finger)	Foot (not toe)	Elbow	• Self-report events on Form 33 or Form 33D (no required outcomes forms [unless the self-report results in an overnight hospitalization - <i>Form 125</i> only]): Diabetes mellitus requiring therapy Other age-related outcomes: inflammatory arthritis glaucoma urinary incontinence Non-melanoma skin cancer Benign breast disease Colorectal polyps Venous thromboembolic disease (non HRT) Other fractures in OS participants at non-Bone Density sites. • Selected hospitalized procedures requiring no follow-up (no required outcomes forms): Appendectomy Bunionectomy Carpal tunnel repair/release Club foot release Corneal transplant Extracapsular cataract extraction (EEC) Hemorrhoidectomy Inguinal herniorrhaphy Knee arthroscopy Laminectomy Ligation and stripping, vascular (varicose vein strip) Rhinoplasty / septoplasty / septorhinoplasty Scleral buckle Shoulder replacement Stapedectomy Synovectomy of wrist Tonsillectomy & adenoidectomy (T & A) Turbinectomy Tympanostomy tube Upper gastrointestinal endoscopy Vitrectomy Cosmetic/plastic surgery, other than breast Laceration repair Rotator cuff repair Overnight hospitalization for: • Any research study (that does not involve a WHI outcome) • Sleep studies (not related to a research study) A rehabilitation facility not attached to an acute care facility Any psychiatric admission Out of country overnight hospitalization for gastrointestinal (GI) symptoms related to travel. (Requires PI signature.) • Recurrence of selected events (associated hospitalizations must still be adjudicated; See <i>Section 3 - Adjudication, Table 3.3 - Subsequent conditions</i>)
Breast	Colon																
Endometrium	Rectal																
Ovary																	
Upper Leg (not hip)	Tailbone																
Pelvis	Spine or back																
Knee	Lower arm or wrist																
Lower Leg or ankle	Hand (not finger)																
Foot (not toe)	Elbow																

2.4.2.1 Closure Codes

The WHILMA database closure codes:

Closure Codes:		Meaning:
1	<i>WHI outcomes found</i>	At least one WHI outcome with a corresponding outcomes form. (Exclude Form 125).
2	<i>Adjudicated, no evidence of WHI outcome found</i>	Case has been forwarded to the adjudicator for review. Indicates no outcomes identified. (Include Form 125)
3	<i>Bunionectomy indicated, not adjudicated</i>	All conditions linked to visits in this case have “bunionectomy” flag (i.e., inpatient “other” hospitalization).
4	<i>Duplicate visit, not adjudicated</i>	All visits in this case are flagged as duplicates.
5	<i>Cannot get documentation for visit, not adjudicated</i>	Unable to obtain documents from provider.
6	<i>Cannot get Release of Information, not adjudicated</i>	Unable to obtain Release of Information from participant, next of kin (NOK) or family.
7	<i>Administrative problems (details in comments), not adjudicated</i>	Problem case – does not fit any of the above categories. Note: WHILMA requires that you include a comment “7” is indicated as the closure code.
8	<i>Case submitted to Scientific Advisory Committee at CCC</i>	Case sent to CCC for SAC review.

Consider the following guidelines when determining the correct closure code reason:

Closure Codes 1 & 2

For adjudications forwarded to the local adjudicator for review, either Closure Code 1 – *WHI outcomes found* OR Code 2 – *Adjudicated, no evidence of WHI outcome found* is most often selected. Occasionally another code may be appropriate.

Note: For death adjudications without medical records, utilize *Form 120 – Initial Notification of Death* as the record source if no other medical records or death certificate are available. The WHILMA database requires medical records are present in adjudications with Code 1 or Code 2 status and, in WHI, all deaths require adjudication.

Closure Code 3

An adjudication (or provider visit) listed in *Section 2.1.1.1 – Outcomes Ascertained Only by Self-Report on Medical History Updates (Form 33/Form 33D)* or *Section 2.1.1.2 – Hospitalizations Due Solely to the Following Conditions or Elective Procedures*, select Closure Code 3 – *Not adjudicated, documents not required* to close-out the case.

Closure Code 4

An adjudication (or provider visit) determined to be a duplicate of a previously adjudicated visit (e.g., participant self reports identical information on a subsequent *Form 33D*), select Code 4 – *Duplicate visit, not adjudicated*. Procurement of medical records to confirm the duplicate visit is not required (see *Volume 5 – Data System, Appendix F – Outcomes, Section F.1.1 – Provider Visits Screen for duplicate visit instructions*).

Closure Codes 5, 6, & 7

Typically, Codes 5 – *Cannot get documentation for visit, not adjudicated*; Code 6 – *Cannot get Release of Information, not adjudicated*; and Code 7 – *Administrative problems (text entry required), not adjudicated* are reserved for non-death outcomes that are greater than one year old (See Section 2.5.1 – *Closing Problem Case Packets (Excludes Death)*).

Closure Code 8

Requesting central adjudication of outcomes, also known as Scientific Advisory Committee (SAC) review is available to the local physician adjudicator who requests feedback on a particular case of interest. Select Code 8 – *Case submitted to Scientific Advisory Committee [SAC] at CCC*. When you enter this reason code, WHILMA automatically sets the "Req CCC" flag to "Y". You must then select "Send to CCC" from the Run menu in the Member Adjudication block of the Adjudications screen to enter the current date in the "Sent to CCC" field (see *Volume 5 – Data System* for detailed database instructions).

Note: Following SAC review, the CCC will re-open the case in WHILMA. If the case requires central adjudication, the adjudication will be subsequently requested on the CCC *Pull List Report* (CCC0054).

2.5 Outcomes Coordinator Responsibilities Post-Adjudication

In addition to the documentation of the adjudication case packet, the Outcomes Coordinator ensures that the completed adjudication packet is tracked, data-entered, filed, prepared, and sent for central adjudication (if required).

If you do not receive the completed outcomes form (with the adjudication case packet) within two weeks remind the Physician Adjudicator and allow one more week for completion of adjudication (to track outstanding adjudications, see *WHIP1228 Adjudications by Adjudicator Report*). Ascertainment and local adjudication procedures should be completed within 3 months of the date of *Form 33D* analysis.

2.5.1 Closing Problem Adjudication Case Packets (Excludes Death)

In 1997, the Morbidity and Mortality Committee (M & M) approved guidelines for closing out problem adjudication case packets. 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 WHILMA database); and
- The OCS 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, it may be closed using the appropriate closure code (see *Section 2.4.2.1 – Closure Codes*).

2.5.2 Adjudication Case Packets for Scientific Advisory Committee

The local Physician Adjudicator may request the Scientific Advisory Committee (SAC) review and provide written feedback on a case before she/he completes local adjudication. The local PA documents the questions about a case on *WHIP0988 Investigation Documentation Summary*. Although not required, the PA should make an attempt to complete appropriate outcomes forms. This step aids the CCC scientist reviewing the case. Following SAC feedback, the local PA completes adjudication which includes modifying the outcome form(s), if appropriate. (For instructions on how to process a case for SAC review, see Closure Code 8 under *Section 2.4.2.1 – Closure Codes*).

2.6 Centrally-Adjudicated Outcomes

In addition to local adjudication of the WHI outcomes listed in *Section 2.1.1 – WHI Outcomes to be Ascertained*, certain cases may also require central adjudication. Clinical Centers will be notified about which locally-adjudicated cases will require central adjudication via the WHILMA database Pull list report.

2.6.1 Sending Outcomes Packets for Central Adjudication

“Pull list instructions.”

Each month the CCC generates a list of cases to be forwarded to the CCC for central adjudication. The *Pull List Report (CCC0054)* is sent to the OC and lists all cases to be sent from a respective clinic. Using the report, locate all adjudication case packets identified for central adjudication and complete the mailing instructions outlined below:

1. Photocopy all medical record documents, required WHI reports, and completed outcomes forms present in the adjudication case packet.
2. Send the original records to the CCC and archive the photocopied records at the clinic.
3. Black-out all personal identifiers on the original records to be forwarded to the CCC. These include but are limited to the participant’s name, address, phone number, social security number, and all next-of-kin/emergency contact information. **Note:** Do not black out the date of birth or death on the death certificate of other medical records. Do not black out pathology or specimen numbers listed on a lab report. Do not black out dates of service or dates when procedures occurred. These are not considered personal identifiers.
4. Place the original adjudication case packet in the following order:
 - *Investigation Documentation Summary (IDS) (WHIP0988)*.
 - *Member Outcomes Status Report (WHIP1215)* (released March 1996).
 - Outcome Forms (*Forms 120-131*, as appropriate).
 - Medical record documents placed in the order listed on the *IDS*
5. Securely staple or bind each individual case packet. **Note:** When attaching the last WHI hospitalization as reference for a death case, clearly indicate “last WHI hospitalization, for death reference only”.
6. Include a copy of the *Pull List Report (CCC0054)* as a packing list to ensure all cases requested are sent and subsequently received at the CCC.
7. Send the copied, blacked-out adjudication case packet via fed-ex to the:

Women’s Health Initiative
CCC Outcomes Program Assistant
FHCRC, 1100 Fairview Avenue N., MP-1002
P.O. Box 19024, Seattle, WA 98109-1024
8. In the WHILMA outcomes subsystem, use the “Send to CCC” hot key to indicate a case has been forwarded to the CCC for central review.

2.6.2 Query for Missing Medical Records Information

The Outcomes Staff at the CCC will review the outcomes packets submitted for central adjudication for completeness and legibility. The CC will be notified via query of any additional materials required to complete the case packet before central adjudication of the case. The case packet will be held at the CCC until the additional information is obtained.

Each month’s request for new cases to send for central adjudication will include those cases and deficiencies previously requested or reported that have not been received at the CCC.

2.7 Central Monitoring of CC Ascertainment Adjudication

The CCC, Morbidity and Mortality Advisory Committee (M&M) and Outcomes Performance Monitoring Committee (OPMC) will develop initial and ongoing criteria for local ascertainment and adjudication performance (e.g., timeliness and accuracy of local outcomes activities). These groups will work with the CC to monitor local performance via centralized WHILMA database reports of outcomes-related data and make recommendations for performance enhancement.

SECTION 2

OUTCOMES ASCERTAINMENT

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