

## 8.6 Physician Outcomes Adjudication

A WHI Extension Study 2010-2020 outcome is adjudicated by assigning the appropriate outcome diagnosis based on study-defined criteria for each condition and recording clinical and supporting diagnostic information on an outcomes form.

The Physician Adjudicator (PA) is responsible for all final assignments of diagnoses in the adjudication process and submitting each outcome form indicating that he or she has completed or has overseen the diagnostic decision-making and agrees with the final diagnosis. Physicians doing adjudication must be familiar with general internal medicine principles, and in particular, with the diagnostic work-up of cardiovascular disease (CVD), strokes, cancers, and fractures.

### 8.6.1 Physician Adjudication Orientation and Training

Each potential PA is vetted by the Outcomes Adjudication Committee (OAC) to ensure compatibility with adjudication requirements and completion of required documents including a Consulting Agreement. Orientation to WHI and adjudication training is required before a physician can adjudicate for WHI. Physician Training can take several months to complete and includes the following:

#### Central Training:

- Adjudicator training conference call #1 – Overview of WHI Outcomes Adjudication Procedures and assignment of training cases.
- Adjudicator training conference call #2 – Review of assigned training cases.
- Participate in the mentoring program whereby a new adjudicator is paired with a veteran adjudicator who was centrally trained and is familiar with WHI adjudication and Extension Study procedures. Both the trainee and trainer are assigned the same batch of cases and will work through the cases together and submit one set of adjudications forms, completed by consensus, to the CCC. Training cases will continue to be assigned until the trainer agrees the trainee is qualified to adjudicate independently.
- PAs will receive continual training through central adjudication feedback, case quality assurance review, individual emails and/or phone calls, and during the Outcomes Adjudication Committee calls.

#### ECG Reading Resources:

- For adjudicators not currently familiar with reading electrocardiograms (ECGs), the following reading may be helpful: (references available upon request)
  - Dubin, D. (1996). Rapid Interpretation of EKG's, 6th Ed. Tampa, Florida, Cover Publishing Co.
  - Dubin, D. (2000). Rapid Interpretation of EKGs, Tampa, Florida, Cover Publishing Co.
  - Wagner, G and Strauss, D. (2015), Marriott's Practical Electrocardiography, 12th Edition. Lippincott, Williams & Wilkins, Philadelphia, PA
  - Goldberger, A; Goldberger, Z; Shvilkin, A. (2013). Goldberger's Clinical Electrocardiography, a Simplified Approach. 8<sup>th</sup> Edition Elsevier, Philadelphia, PA.

### 8.6.2 Outcomes Adjudication Procedures

The WHI Extension Study 2010-2020 central adjudication model is a centralized, single review adjudication process. Field Center (FC) outcomes staff electronically transmit all outcomes cases to the CCC, who then redacts all Personal Health Information in the x.pdf file using Adobe Acrobat Pro and distributes these electronic case files through a secure website for adjudicator review. The PA completes outcomes cases in either hard copy or electronically and submits the completed forms and reports to the CCC using the online system.

The PA is responsible for reading the entire adjudication case packet including all medical documents and WHIX database reports. More than one outcome may be present in a packet, even if the Investigation Documentation Summary (IDS) report may not reflect this. Thus, all documents in a case packet (including those hospitalizations that are not thought to include outcomes) should be reviewed for possible outcomes, and the case routed to other committees, as appropriate. The MOSR contains information to assist the PA with these determinations (see *Section 8.6.4* for more detail).

Each outcome is adjudicated via an electronic form. See *Table 8.6 – Required Adjudication forms* for a list of the forms to complete for each outcome type. Refer to *Sections 8.8-8.11* for specific instructions for completing each form. In general, only one outcome form is completed for each outcome being investigated with some exceptions for cancer outcomes and CVD outcomes.

The adjudicator reviews each adjudication case and completes the following steps:

- Review the electronic medical records to ensure all required documents are included in the case; review the participant’s self-report(s) documented on WHIX 1215 – Member’s Outcomes Status Report (MOSR) to view previously confirmed outcomes and those currently self-reported by the participant for the admission under review.
- Determine if *any* WHI outcome of interest exists. This includes those not self-reported by the participant. (See *Table 8.2* for a complete list of outcomes).
- Complete the Outcomes Reports with any additional actions as needed. See *Section 8.6.6* for details on completing the Outcomes Reports.
- Submit the completed forms to the CCC within 60 days of case assignment.

### 8.6.3 Completing Electronic Outcomes Adjudication

The adjudication system is a secure, web-based platform that requires an assigned user name and password to access. The system is accessed via the following link: [www.whiops.org](http://www.whiops.org). All redacted medical records are posted to this site for adjudicator review. Adjudicators use online forms because it is faster and has built-in quality control to reduce reconciling form responses (missing responses, duplicates, etc.).

#### On-line Adjudication

Online Adjudication is selected from the whiops.org screen.

The Adjudicator Case List is divided into two tabs: the *Active* list contains cases that have been assigned and are due for adjudication, and the *Pending* list contains cases closed by the adjudicator that are now being processed at the CCC. The *Pending* tab includes fully or partially completed adjudications including requests for more documents (queries), issues with adjudication and cases flagged for full committee review.

#### Instructions:

To open a case, select the 6-digit *CCC number* link on the *Active* tab and it will open the Adjudication Results Page (ARP). The ARP for online adjudication is the portal for forms completion and for marking additional case actions (see *Section 8.6.6* for more detail). To review the records select *Medical Records* (see *Section 8.6.3* for case content details). If an outcome of interest is found, complete the proper electronic outcome type form (see *Section 8.7-8.11* for form completion details). If no outcome is found, select *Close, no outcomes found* at the bottom of the ARP. Each online form mirrors the paper copy. Sub-questions will expand or collapse depending on form responses. If any required questions are missing they will remain orange until the question is complete. Once all questions are complete, click *Next* to move to the next page. Every time the *Next* button is selected, the form responses will be saved. Proceed through the form to the *Case Summary Page*. Review the responses prior to submitting the form. If any questions were missing they are listed in red text. The form cannot be submitted until all required questions have been completed. Once the form(s) are submitted, complete the ARP (see *Section 8.6.6* for details). Select *Close, Outcomes Found* when the page is complete to submit it to the CCC. The case has been submitted when it moves to the *Pending* tab.

### 8.6.4 Contents of the Case Packet

There are five central adjudication committees: CVD, Fatal Events, Fracture, Cancer and Stroke. Each case is assigned to one or more of these committees based on the participant’s self-report or by outcomes conditions added by FC staff. See *Table 8.6 – Required Adjudication Forms*. When reviewing the adjudication case packet, the PA will decide, for each outcome, whether the relevant medical records documents are present (see *Table 8.2 – Required Documents for Outcomes Adjudication*).

For all outcomes involving a hospitalization, this documentation will include, at a minimum, a hospital Face Sheet, and/or Physician Attestation Sheet (including admit and discharge dates and discharge diagnoses). Most hospitalized outcomes also require a history and physical (H&P) while all require the hospital

Discharge Summary, which will include admitting signs and symptoms, initial impressions, hospital course, procedures, and final discharge diagnoses.

**Note:** On 6/23/16 the Steering Committee (SC), at the recommendation of the OAC dropped collection of ICD-9 & 10 diagnostic and procedures codes as a formal streamlining measure. As of this date, FC staff are not required to collect these codes or, if codes are obtained, staff are no longer required to key enter them into the database.

The adjudication case packet consists of the following documents:

- *Investigation Documentation Summary (IDS), WHIX0988:* This page lists provider-specific information about the adjudication case packet documents. Based on the participant's self-report and/or conditions added by FC staff, the provider visits for which medical records have been requested are summarized. The name of the medical providers and dates of service are reported, along with the list of medical records requested and the status of each request (i.e., the document was received, not available, or a substitute document included). The Outcomes Coordinator (OC) often types useful comments about the status of the medical record documents on this report.
- *Members Outcomes Status Report (MOSR), WHIX1215:* This page provides individual participant information about all Confirmed Outcomes from the beginning of WHI, cases in progress at the Field Centers, and Extension Outcomes which were denied or closed locally. This information is helpful when determining randomization/ enrollment status and participants who are in the medical record cohort (MRC), self-report cohort (SRC) and/or ancillary studies, as well as assisting the adjudicators in determining the need to forward for a Discovered Event or to another Committee. (*Note:* Some ancillary studies may still necessitate forwarding a case, regardless of a prior outcome.) On 06/24/2015, the subsequent condition rule was lifted so now all outcomes of interest are investigated, regardless of prior history.
- *Form 125 – Summary of Hospitalization:* This truncated form lists the provider and the hospital admission/discharge dates for the case.
- *Medical Records:* The medical records documentation is initially generated by a participant's self-report. Each type of self-reported condition has a corresponding document set. The document set is quite extensive, requiring a number of documents to account for regional differences in health care among other things. The documents are further sub-divided into essential and recommended documents to help prioritize collection of the most critical records to accurately classify an outcome; see *Table 8.2 – Required Documents for Outcomes Adjudication.*

## 8.6.5 WHI Adjudication Forms

**Table 8.6  
Required Adjudication Forms**

<b>Outcomes</b>		<b>Required Forms</b>
<b>Deaths</b>	Due to CHD (Coronary death)	
	In hospital	121, 124, 125
	Out of hospital	124
	All other	
	In hospital	124, 125
	Out of hospital	124
<b>Cardiovascular</b> (Hospitalizations unless otherwise noted)		
	MI	121, 125
	Heart failure	121, 125
	Aortic aneurysm/dissection	121, 125
	Heart valve disease	121, 125
	Stroke (in and outpatient)	132, 125*
	Peripheral arterial disease	121, 125
	Carotid artery disease	121, 132, 125
	Coronary revascularization procedures (in and outpatient)	121, 125*
	Venous thromboembolic disease	
	In hospital	126, 125
	Out of hospital (DVT only)	126
<b>Cancers<sup>1</sup></b>	Breast, endometrium, ovary, colon, rectum, all other cancers	
	In hospital	130, 125
	Out of hospital	130
<b>Hip Fractures</b>	In hospital	123, 125
	Out of hospital	123
<b>Hospital stay of 2 nights or more</b> (post-death, MRC only and one night stays for select outcomes)		125

<sup>1</sup> All MRC and SRC cancers are adjudicated

\* Required only for inpatient visits.

**Form 121 – Report of Cardiovascular Outcome:** Diagnosis of cardiovascular outcomes, including myocardial infarction (MI), heart failure (HF), aortic aneurysm/dissection, heart valve disease, carotid artery disease, peripheral arterial disease, and coronary revascularization, (i.e., coronary artery bypass grafting [CABG] and percutaneous transluminal coronary angioplasty [PTCA]), but excludes stroke/transient ischemic attack (TIA) and venous thromboembolism (VTE). Only events requiring hospitalization or occurring during a hospitalization for another reason (except outpatient PTCA) are counted as cardiovascular outcomes. Completed by a CVD Adjudicator.

**Form 123 – Report of Fracture Outcome:** Any occurrence of a hip fracture. All other fractures are collected on *Form 33* by self-report, although self-report of an upper leg fracture is reviewed to identify a potential hip fracture which may have been misreported by a participant. Completed by a Fracture Adjudicator.

**Form 124 – Final Report of Death:** The final cause of death (COD) for MRC participants and some SRC deaths adjudicated for ancillary studies. For hospitalized deaths, the underlying cause can be taken from the Death summary/Discharge Summary, if available. An autopsy report, if done, will be sufficient to complete this form if no Death Summary/Discharge Summary is available. If no Death Summary/Discharge Summary or autopsy report is available, rely on the death certificate to complete *Form 124*. Completed by a Fatal Events Adjudicator.

**Form 125 – Summary of Hospitalization Diagnosis:** 06/23/2016 this form was truncated and only the provider name and admission and discharge dates are collected. Hospital discharge diagnosis is no longer required. Completed by an Outcomes Coordinator.

**Form 126 – Report of Thromboembolic Disease [MRC]:** Diagnosis of pulmonary embolism (PE) or deep vein thrombosis (DVT). Completed by a CVD Adjudicator.

**Form 130 – Report of Cancer Outcome [MRC & SRC]:** Diagnosis of cancer. Completed by a CCC Cancer Coder.

**Form 132 – Report of Stroke Outcome [MRC]:** Diagnosis of a stroke (or TIA) and carotid artery disease; completed by a Stroke Adjudicator.

### 8.6.6 Completing the Outcomes Reports

Once the outcomes forms have been completed, the adjudicator is required to complete the Outcomes Report. In the Online System this report is called the Adjudication Results Page (ARP) formally known as the Investigation Documentation Summary (IDS). Forward the case to another committee if there is any doubt about the presence of a WHI outcome or a second outcome, as the CCC will triage the case and route to the appropriate staff or adjudication committee. Additional actions to be completed on the APR/IDS include:

#### Forward to Committee:

Forward the case to the another committee(s) by checking the appropriate box(es) if an additional outcome of interest is found in the current records.

#### Discovered Event:

Select *Discovered Event* and add a comment when an outcome of interest is found within the current medical records, that occurred prior to the event currently being reviewed but after April 1, 2005. If a ‘discovered event’ is identified in the medical records and the PA is unsure if it has been investigated, mark the “discovered event” box on the ARP and provide event details in the comments section. The CCC will triage the case and request the FC investigate, if appropriate. Restrict queries for MRC *discovered* events to the following outcomes: MI, HF, aortic aneurysm/dissection, heart valve disease, stroke, hip fracture, death, cancer (primary and other cancers [excludes non-reportable skin cancers such as squamous cell and basal cell cancers]), and DVT/PE. For the SRC, all discovered cancers (excluding non-reportable skin cancers such as squamous cell and basal cell cancers) are also adjudicated events.

#### Request Full Committee Review:

The PA has the option to request Full Committee review or feedback when the diagnosis is challenging. To refer the case for Full Committee review, select *Full Committee Review* on the ARP and add a note in the comment field. The question will be triaged and routed to the appropriate Committee for discussion and consensus. The Committee Chair or the CCC will complete the final form based on the Committee’s decision.

#### Adjudication Issue:

If a case cannot be completed for a reason not stated above, select *Cannot Adjudicate* and provide a note in the comment field. The CCC will address the issue and follow-up.

#### Query for Records:

If the case packet is missing one or more essential documents (or on occasion a non-essential document), the PA may request additional documentation on the ARP screen. The CCC will forward the query for the additional documents to the FC and will reassign the case to the adjudicator for review when those documents are received. There may be instances when the FC cannot get complete documentation. When this happens, the PA will be notified and should proceed with assigning a diagnosis using the available documents.

Terms/conditions for which a discovered event/query would not be generated:

- A “remote” history of an outcome.
- No date of service provided or date of service is ***before April 1, 2005***.
- An outcome diagnosed “last year” or “last summer” without mention of date.
- Any future diagnostic test/work-up to diagnose a non-cancer outcome (e.g., hip fracture, stroke, or heart attack). (**Note:** Cancer queries are generated for future diagnostic workup when related to the initial cancer diagnosis for both MRC and SRC.)
- Aortic aneurysm, or heart valve disease with a diagnosis date on or before Oct. 1, 2010.
- TIA or carotid artery disease alone, i.e., not tied to a stroke outcome and a stroke is not suspected.

### 8.6.7 Adjudication Monitoring

#### Adjudicator Timeliness Report

PA’s are expected to submit their cases within 60 days of assignment in order to ensure adjudications are completed in a timely manner and that PA’s are continually proficient in procedures. The CCC utilizes a monthly Adjudicator Timeliness Report to monitors the PA’s work. Those who have outstanding cases (greater than 60 days) are contacted requesting their cases be completed.

Quality Assurance (QA)

Quality assurance of adjudication will be performed throughout the WHI Extension Study. Ten percent of all cases will be randomly assigned to two PA's to be reviewed for consistency. The outcomes of these QA cases will be evaluated annually to determine overall agreement rates and performance. For cases with disagreements, a third reviewer will be assigned. The final decision is based on the two who are in agreement. Once all discrepant QA cases have been reviewed, the agreement rates are finalized and feedback is provided to each PA. The goal is a 90% agreement rate.

**8.7 Fatal Events Adjudication****8.7.1 Overview of Fatal Events**

Mortality, as a clinical outcome, includes all-cause or total mortality and cause-specific mortality. Cause-specific mortality is classified as death due to cardiovascular diseases, cancer, injuries, or other known causes. Fatal events in the WHI 2010-2020 ES are classified as:

- **Total mortality:** The total number of deaths occurring in the WHI 2010-2020 ES.
- **Cause-specific mortality:** Subclassified into:
  - Cancer, the 5 primary WHI cancers (breast, endometrium, ovary, colon, rectum) and all other cancer diagnoses
  - Cardiovascular disease (CVD)
  - Injury
  - Other Cause of Death (COD), which includes those conditions not listed above, e.g., non-cardiovascular, non-cancer, and non-traumatic death. Several of the more common “other” causes of death are listed with check boxes on the form in *Qx. 3*; causes of death not listed should be coded “Other cause of death, known,” and the underlying cause entered in the blank of *Qx. 2.1*.
  - When the death certificate is not available and when the underlying COD cannot be determined from the information currently available, the case should be classified as “Unknown cause of death”. This will alert the CCC to pursue NDI coding for the COD.

It is the PA's responsibility to assign the final COD. This final decision may at times disagree with the causes of death identified on the death certificate. However, the decision should be based on a full review of the documents in the adjudication case packet. Occasionally the PA may ask the CCC to have the FC obtain required documents that are missing.

**8.7.2 Completing Additional Outcomes Forms**

In addition to the COD (as described below), the PA should review the case packet for any other possible outcomes and either adjudicate those outcomes or forward to another committee to review (e.g., the stroke committee).

**Cancer Deaths:** If the cancer documented in the death certificate was not previously adjudicated and was diagnosed after enrollment/randomization, indicate that an additional committee review is required and the case will be routed to the CCC Cancer Coders.

**Cardiovascular Deaths:** In the case of a hospitalized cardiovascular death/outcome, complete a *Form 121 – Report of Cardiovascular Outcomes*, as appropriate.

**Deep Vein Thrombosis (DVT)/PE:** For participants in the MRC, complete *Form 126 – Report of Venous Thromboembolic Disease* for all hospitalized DVT/PE. In addition, complete *Form 126* if outpatient records confirm DVT or an autopsy report confirms PE.

**8.7.3 Form 124 – Report of Death (Final)**

All MRC deaths will be adjudicated during the WHI 2010-2020 ES. Upon review of the death case, the PA will complete *Form 124 – Report of Death (Final)*.

**Qx. 1 – Date of death**

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

**Qx. 2 – Cause of death**

**Qx. 2.1 – Underlying cause (Required):** When reporting cause of death, use any information available, such as death certificate, medical history, medical records, laboratory tests, an autopsy report, or other sources of relevant information, including prior WHI adjudicated outcomes. Similar to many other diagnoses, a cause-of-death statement is an informed medical opinion that should be based on sound medical judgment drawn from clinical training and experience, as well as knowledge of current disease states and local trends (CDC guidance – see ref a ). The underlying cause of death is “(a) the disease or injury which initiated the train of morbid events leading directly to death or (b) the circumstances of the accident or violence which produced the fatal injury.” (b)

The study uses the underlying COD as the main classification for the death outcome thus a designation is required even if the COD is unknown.

Review the death certificate and all available medical records to determine the COD. If the death certificate diagnosis does not agree with available medical record information, then rely upon the medical records information which should generally be more detailed and accurate.

When the COD is somewhat ambiguous, e.g., due to the increasing numbers of co-morbidities, and there are medical records available, select the most likely underlying COD that will contribute to the dataset rather than leaving the COD unknown.

Often times the death certificate is the only available document. In this case, code the underlying COD as listed on the death certificate. If the COD is incorrectly ordered on the death certificate, the PA may code *Form 124 – Report of Death* according to what he/she thinks should be the sequence of events leading to death. If the causes are in hierarchical order yet unrelated, and either could be the COD, select the first cause listed. In instances where the death certificate is the only document available, it is considered to be the most accurate determination of the COD.

Occasionally, the PA may need to request additional medical records to accurately code the COD. In this instance, specify the missing documents on the ARP and return the form to the CCC. The outcome staff will follow up with the FC and request the additional documents on your behalf and then return them to you once they become available.

**Qx. 2.2 – ICD-10-CM - CCC use only:** The CCC will enter the ICD code that corresponds to the underlying COD as recorded by the PA.

**Qx. 2.4, 2.7, and 2.10 – Contributory cause(s) of death:** Indicate the events that contributed to the death but did not directly cause the death. Contributory cause(s) of death is/are the medical condition(s) that might have contributed to a death. For example, diabetes (contributory cause of death) in a participant with an acute myocardial infarction (underlying cause). You may list between zero and three contributory causes of death. Hierarchical order is not required.

**Qx. 2.13 – Immediate cause:** The immediate cause of death is the disease or condition that directly preceded death. The underlying cause of death is “(a) the disease or injury which initiated the train of morbid events leading directly to death or (b) the circumstances of the accident or violence which produced the fatal injury.” (ref b).

This is the terminal event. State the precise diagnosis in words. While cardiopulmonary arrest is present in all deaths, this is only an acceptable “immediate cause” in rare cases, e.g., when witnessed as sudden collapse with documented ventricular fibrillation or asystole. If an organ system failure or respiratory failure is listed, that should be coded under immediate COD. Always report an etiology for the end stage condition as the underlying COD. For example, cardiogenic shock (immediate COD) due to ischemic heart disease (underlying COD). The Immediate Cause field may contain the same diagnosis as 2.1 – Underlying cause, or may be left blank.

**Qx. 3 – Subclassification of underlying cause of death (Required):**

Select only one category to sub-classify the underlying COD. The item coded as the underlying COD in this question should reflect the text description of the “underlying cause of death” documented in *Qx. 2.1*

– *Underlying cause.* This classification must be completed; it should never be left blank. If the COD is unknown, check “Unknown cause of death” (code 99). The causes are grouped into the following four categories: cancer, cardiovascular, accident/injury, other/unknown.

**Cancer (codes 1-10, 37-41)** The list of cancers has been expanded for the WHI 2010-2020 ES to capture more cancer sites and now includes all of the following:

- Breast (code 1)
- Ovary (code 2)
- Endometrium (code 3)
- Colon (code 4)
- Rectosigmoid junction (code 5)
- Rectum (code 6)
- Uterus (code 7)
- Lung (code 10)
- Pancreas (code 37)
- Lymphoma (NHL only) (code 38)
- Leukemia (code 39)
- Brain (code 40)
- Multiple Myeloma (code 41)
- Other cancer (code 8)
- Unknown cancer site (code 9)

#### **Tips for cancer deaths**

- If the COD is a metastatic cancer, and the primary site is known, then code the primary site as the COD and sub-classification of the underlying cause under *Qx*. 3 should also be based on the primary site of cancer.
- When death certificate states colorectal cancer, review all available records to determine if primary site was colon or rectum.
- If the death certificate is the only available document, states colorectal primary, AND there is a history of either colon or rectal cancer, assume the colorectal cancer previously documented was the primary site at death. In this case, code the cancer site according to the previously adjudicated primary site of cancer, i.e., either colon or rectal.
- Case with Death Certificate only (no other information): If death certificate stating “colorectal” cancer is the only available document and there is no history of either colon or rectal cancer, then code this question as Colon (code 4). Also check the box on the ARP report to request review by the CA Committee and indicate what documentation in the present record suggests a cancer diagnosis. The CCC cancer coders will follow-up with this case to determine if there is a case for the cancer site.
- Cancer of Sigmoid Colon: Sigmoid Colon is part of the colon and coded as colon cancer.
- Cancer of Appendix: Though the appendix is a part of the colon, the WHI ES does not include appendix in the primary colon cancer endpoint. Instead, code appendix to Other cancer (code 8) under sub-classification of underlying COD.
- Cancer of Uterine Cervix is not included in Cancer of the Uterus. Code cancer of cervix as Other cancer (code 8) under subclassification of underlying COD.
- Chronic Leukemia/Lymphoma: These are considered a malignancy. If one is specified as the underlying COD (in *Qx*. 2.1), then code Leukemia (code 39) or Lymphoma (NHL only) (code 38), respectively. Hodgkin’s lymphoma is coded other cancer (code 8).
- Myelo-proliferative disorders (MPD) (Polycythemia vera, essential thrombocythemia): These are not considered malignancies and should be coded as Another cause of death, known (code 88). In the event that the participant had a MPD which transformed to acute leukemia, code leukemia as the underlying COD and MPD as contributory.
- If a death certificate or medical records indicates “Uterine cancer”, check prior adjudication documentation to determine if “endometrial cancer” was the correct pathologic diagnosis and code as endometrial, if appropriate. In the case without documented pathologic confirmation of endometrial or uterine (e.g., leiomyosarcoma of the uterus), code according to the terms used in the death certificate or in the available medical records.



**Cardiovascular disease** (codes 11-14, 18 and 19)**Tips for cardiovascular disease**

- Definite Coronary Heart Disease (CHD) (code 11)

No known non-CHD cause and at least one of the following: 1) documentation of chest pain within 72 hours of death and/or 2) history of chronic ischemic heart disease in the absence of heart valve disease or non-CHD, and death certificate consistent with CHD as the underlying cause.

Code **definite CHD** when the death certificate is consistent with death due to coronary disease and there is a history of chest pain before death or evidence of pre-existing coronary disease such as:

- A history of CHD in the absence of heart valve disease or non-CHD. History of CHD may be documented with a noted history of prior myocardial infarction, prior findings on catheterization or noninvasive testing, and prior coronary revascularization procedures in addition to confirmed prior WHI CHD as listed in hospital records or with confirmed prior outcomes listed on the accompanying MOSR.
- Use of nitroglycerin
- Echocardiogram showing focal wall motion abnormalities.

If Definite CHD is marked, also complete *Qx. 6 – Coronary Death*.

- Possible CHD (code 14)

No known non-CHD cause, and death certificate is consistent with CHD as the underlying cause.

Code possible CHD when the death certificate is consistent with death due to coronary disease, but there is no prior evidence of pre-existing coronary disease. Generally, an out-of-hospital sudden death is coded as possible CHD death if there is no other information available and in the absence of other possible causes especially if the participant had documented risk factors such as hypertension or diabetes.

If Possible CHD is marked, also complete *Qx. 6 – Coronary Death*.

- Cerebrovascular disease (code 12)

Includes ischemic and hemorrhagic strokes and **excludes** all subdural and epidural hematomas.

- Pulmonary embolism (code 13)

Pulmonary embolism may be coded as the underlying COD if this diagnosis is supported by available hospital records, or in the absence of hospital records, if listed on the death certificate as the COD.

- Other cardiovascular disease (code 18)

Use this code to encompass non-ischemic cardiomyopathy, alcoholic heart disease, myocarditis, heart valve disease, congenital heart diseases, HF (unrelated to coronary disease), aortic dissection, ruptured aortic aneurysm, and other cardiovascular causes.

Endocarditis is categorized as “other cardiovascular” disease and is therefore coded as “Other” cardiovascular disease (code 18), not “Another cause of death, known” (code 88).

- Unknown cardiovascular disease (code 19) – Use this code when inadequate information is available to allow determination of the kind of cardiovascular disease present, for example, if only a death certificate is available and it lists “cardiovascular disease” as the COD.

**Accident/Injury** (codes 21-23, 28)

- Homicide (code 21)
- Accident (code 22)
- Suicide (code 23)

- Other injury (code 28) – e.g., Undetermined if injury was accidentally or purposely inflicted.

Full Committee Call decisions:

- The legal term “vehicular homicide” should not be taken as intentional homicide. In general, motor vehicle accidents and car-pedestrian accidents are considered “accidental”. Code to Accident (code 22) not to homicide (code 21).
- Aspiration of food, in the absence of a known underlying etiology, e.g., stroke, is coded to Accident (code 22).
- When hip fracture is determined to be the underlying cause of death, code as “Other injury” (code 28).

**“Other” Cause of Death** (codes 31-36, 42-45, 88, and 99)

Other COD includes those conditions not listed above, e.g., non-cardiovascular, non-cancer, and non-traumatic death. A few of the more common “Other” causes of death are listed with check boxes on the form in *Qx. 3*. Code causes of death not listed on the form as “Another cause of death, known” and precisely write the underlying cause in *Qx. 2.1 – Underlying Cause*.

When the underlying COD cannot be determined from the information currently available, the case should be classified as “Unknown cause of death”.

- Alzheimer’s Disease (code 31) – Code if medical records or death certificate specifies the diagnosis as Alzheimer’s Dementia. Code Dementia, NOS (all subtypes except Alzheimer’s) Box 42 if medical records or death certificate states “Dementia” as the underlying COD. [OAC, Aug. 2018]
- COPD (code 32)
- Pneumonia (code 33)
- Pulmonary Fibrosis (code 34)
- Renal Failure (code 35)
- Sepsis (code 36)
- Dementia, NOS (code 42) - Code for all types of dementia other than Alzheimers
- Amyotrophic Lateral Sclerosis (ALS) (code 43)
- Parkinson’s (code 44)
- Hepatic Cirrhosis (code 45)
- COVID-19 (code 46)
- Another cause of death, known (code 88)
- Unknown cause of death (code 99)

If COVID–19 played a role in the death, this condition should be specified on the death certificate. In many cases, it is likely that it will be the underlying cause of death as it can lead to various life-threatening conditions, such as pneumonia and acute respiratory distress syndrome (ARDS). In these cases, COVID–19 should be reported as the underlying cause of death.

Generally, it is best to avoid abbreviations and acronyms, but COVID–19 is unambiguous, so it is acceptable to report on the death certificate.

In some cases, survival from COVID–19 can be complicated by pre-existing chronic conditions, especially those that result in diminished lung capacity, such as chronic obstructive pulmonary disease (COPD) or asthma. These medical conditions do not cause COVID–19, but can increase the risk of contracting a respiratory infection and death, so these conditions should be listed as contributing causes of death.

In cases where a definite diagnosis of COVID–19 cannot be made, but it is suspected or likely (e.g., the circumstances are compelling within a reasonable degree of certainty), it is acceptable to report COVID–19 on a death certificate as “probable” or “presumed.” In these instances, certifiers should use their best clinical judgement in determining if a COVID–19 infection was likely. However, please note that testing for COVID–19 should be conducted whenever possible. If listing the underlying cause of death as “probable” or “presumed” COVID-19, code the subclassification of death as COVID-19 (code 46).

- a. <https://www.cdc.gov/nchs/data/nvss/vsrg/vsrg03-508.pdf>
- b. World Health Organization. International statistical classification of diseases and related health problems, 10th revision (ICD–10), Volume 2. 5th ed. Geneva, Switzerland. 2016.

Full Committee Call decision:

Multiple Sclerosis (MS). Dying of complications related to a history of MS is a reasonable COD and can be coded to “Another cause of death, known” (code 88).

#### **Qx. 4 – Was an autopsy performed**

This information is often documented on the death certificate. If death certificate is not available, record from *Form 120 – Initial Notification of Death*, if documented.

#### **Qx. 5 – Documentation used for death adjudication**

- Medical records documentation (current case only)
- Report of autopsy findings
- Death certificate
- ER record
- EMS report
- Informant interview
- *Form 120 – Initial Notification of Death*
- NDI Search (CCC searches only. Excludes Social Security Death Index [SSDI] RC searches which are documented under “Other” below.)
- Coroner’s report
- Other, specify (e.g., a previously adjudicated case)

Mark all the documents used to complete *Form 124 – Report of Death (Final)*. If a prior adjudication is used or any other document is reviewed but not listed, mark “Other” (code 8) and record the adjudication number and/or document(s) in the space provided.

#### **Qx. 6 – Coronary Death (In and out-of-hospital deaths)**

Complete for all deaths coded as definite CHD or possible CHD under *Qx. 3 – Subclassification*. For all in-hospital deaths, also complete *Form 121 – Report of Cardiovascular Outcome*.

##### **Qx. 6.1 – Coronary death based on**

- Hospitalized myocardial infarction within 28 days of death (code 1)  
A diagnosis of fatal MI must meet both the first and second criteria, a) and b) below, or the third criterion alone, c):
  - a) No known non-atherosclerotic process or event
  - b) And MI within 28 days prior to death
  - c) Or autopsy evidence of acute MI
- Previous angina, MI, or revascularization procedure is documented in the medical records, on the death certificate or by prior WHI adjudication and no known potentially-lethal non-coronary disease process (code 2)
- Coronary heart disease (CHD) diagnosed as COD at post-mortem examination (code 3)
- Death resulting from a CHD-related procedure, such as coronary bypass grafting (CABG) or percutaneous coronary intervention (PCI) (code 4) [For any death resulting from a revascularization procedure or an in-hospital death.] Check the MOSR to see if the CVD condition is included for the visit dates. If so, request the case be forwarded to the CVD Committee, unless the Fatal Events and the CVD case are already assigned to the same adjudicator.
- Other (none of the above) (code 8)

##### **Qx. 6.2 – Coronary death subclassification**

Mark the one category that applies best.

- Definite fatal MI: No known non-atherosclerotic cause (and death within 28 days of definite MI) or autopsy evidence of acute MI (code 1).
- Definite fatal CHD: No known non-atherosclerotic cause and at least one of the following (code 2):
  - 1) chest pain within 72 hours of death, or
  - 2) history of chronic ischemic heart disease in the absence of heart valve disease or non-ischemic cardiomyopathy
- Possible fatal CHD: No known non-atherosclerotic cause, and death certificate consistent with CHD as the underlying cause (code 3).

#### **Qx. 6.3 – Timing of coronary death**

**Sudden death** (code 1) requires the presence of both characteristics listed below:

- Death witnessed as occurring within one hour after the onset of severe cardiac symptoms or within one hour after the participant was last seen without symptoms
- and**
- Death occurs in the absence of potentially lethal non-coronary disease process

#### **Rapid Death** (code 2)

- Death occurs within 1-24 hours of symptom onset

#### **Other coronary death** (code 3)

- Select this if criteria are not fulfilled for sudden or rapid coronary death, or information regarding timing of coronary death is not available

#### Responsible Adjudicator Submission

The PA should submit the form only when s/he is satisfied that the questions on the Fatal Events outcomes being reported have been filled in as completely and accurately as possible on the basis of all available information including documents from query requests.



Figure 8.3 (continued)

WHI

Form 124 - Report of Death (Final)

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3. Subclassification of underlying cause of death: **(Select only one underlying cause from the following 4 categories (Cancer, CVD, Accident, Other). One category must be completed.)**

**Cancer**

- |   |  |   |
|---|--|---|
| <input type="checkbox"/> <sub>1</sub> Breast                | <input type="checkbox"/> <sub>6</sub> Rectum               | <input type="checkbox"/> <sub>39</sub> Leukemia           |
| <input type="checkbox"/> <sub>2</sub> Ovary                 | <input type="checkbox"/> <sub>7</sub> Uterus               | <input type="checkbox"/> <sub>40</sub> Brain              |
| <input type="checkbox"/> <sub>3</sub> Endometrium           | <input type="checkbox"/> <sub>10</sub> Lung                | <input type="checkbox"/> <sub>41</sub> Multiple Myeloma   |
| <input type="checkbox"/> <sub>4</sub> Colon                 | <input type="checkbox"/> <sub>37</sub> Pancreas            | <input type="checkbox"/> <sub>8</sub> Other _____         |
| <input type="checkbox"/> <sub>5</sub> Rectosigmoid junction | <input type="checkbox"/> <sub>38</sub> Lymphoma (NHL only) | <input type="checkbox"/> <sub>9</sub> Unknown cancer site |

**Cardiovascular disease**

- |   |   |  |
|---|---|--|
| <input type="checkbox"/> <sub>11</sub> Definite Coronary Heart Disease (CHD)<br>(No known non-CHD cause and at least one of the following:<br>(1)-chest pain within 72 hours of death and/or (2)-history of chronic ischemic heart disease in the absence of valvular heart disease or non-CHD, and death certificate consistent with CHD as the underlying cause.) | → | If box 11 or 14 is marked, complete Question 6 on the next page. |
| <input type="checkbox"/> <sub>14</sub> Possible Coronary Heart Disease (CHD)<br>(No known non-CHD cause, and death certificate consistent with CHD as the underlying cause.)  |   |  |
| <input type="checkbox"/> <sub>12</sub> Cerebrovascular disease  |   |  |
| <input type="checkbox"/> <sub>13</sub> Pulmonary Embolism   |   |  |
| <input type="checkbox"/> <sub>18</sub> Other cardiovascular disease   |   |  |
| <input type="checkbox"/> <sub>19</sub> Unknown cardiovascular disease   |   |  |

**Accident/Injury**

- <sub>21</sub> Homicide
- <sub>22</sub> Accident
- <sub>23</sub> Suicide
- <sub>28</sub> Other injury

**“Other” Cause of Death**

- |  |  |  |
|--|--|--|
| <input type="checkbox"/> <sub>31</sub> Alzheimer’s Disease | <input type="checkbox"/> <sub>36</sub> Sepsis  | <input type="checkbox"/> <sub>45</sub> Hepatic Cirrhosis             |
| <input type="checkbox"/> <sub>32</sub> COPD                | <input type="checkbox"/> <sub>42</sub> Dementia, NOS (all subtypes except Alzheimer’s) | <input type="checkbox"/> <sub>46</sub> COVID-19                      |
| <input type="checkbox"/> <sub>33</sub> Pneumonia           | <input type="checkbox"/> <sub>43</sub> Amyotrophic Lateral Sclerosis (ALS)             | <input type="checkbox"/> <sub>88</sub> Another cause of death, known |
| <input type="checkbox"/> <sub>34</sub> Pulmonary Fibrosis  | <input type="checkbox"/> <sub>44</sub> Parkinson’s                                     | <input type="checkbox"/> <sub>99</sub> Unknown cause of death        |
| <input type="checkbox"/> <sub>35</sub> Renal Failure       |  |  |

Figure 8.3 (continued)

WHI

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4. Was an autopsy performed? **(Mark one.)**

- <sub>0</sub> No
- <sub>1</sub> Yes
- <sub>9</sub> Unknown

5. Documentation used for death adjudication: **(Mark all that apply.)**

- |  |  |
|--|--|
| <input type="checkbox"/> <sub>1</sub> Medical records documentation<br>(current case only) | <input type="checkbox"/> <sub>6</sub> Informant interview                                  |
| <input type="checkbox"/> <sub>2</sub> Report of autopsy findings                           | <input type="checkbox"/> <sub>7</sub> Form 120 – Initial Notification of Death             |
| <input type="checkbox"/> <sub>3</sub> Death certificate                                    | <input type="checkbox"/> <sub>9</sub> <b>NDI Search (CCC use only)</b>                     |
| <input type="checkbox"/> <sub>4</sub> ER record  | <input type="checkbox"/> <sub>10</sub> Coroner's report                                    |
| <input type="checkbox"/> <sub>5</sub> EMS report   | <input type="checkbox"/> <sub>8</sub> Other _____<br>(e.g., a previously adjudicated case) |

6. Coronary Death **(In and out of hospital deaths)**

6.1. **Coronary death based on: (Mark all that apply.)**

- <sub>1</sub> Hospitalized myocardial infarction within 28 days of death
- <sub>2</sub> Previous angina, myocardial infarction, or revascularization procedure and no known potentially-lethal non-coronary disease process
- <sub>3</sub> Coronary heart disease (CHD) diagnosed as cause of death at post-mortem examination
- <sub>4</sub> Death resulting from a CHD-related procedure, such as coronary bypass grafting (CABG) or percutaneous transluminal coronary angioplasty (PTCA) **[For any death resulting from a revascularization procedure or an in hospital death, complete Form 121 – Report of Cardiovascular Outcome]**
- <sub>8</sub> Other (none of the above)

6.2. **Coronary death subclassification: (Mark the one category that applies best.)**

- <sub>1</sub> Definite fatal MI: no known non-atherosclerotic cause (and death within 28 days of definite MI) or autopsy evidence of acute MI
- <sub>2</sub> Definite fatal CHD: no known non-atherosclerotic cause and at least one of the following:  
(1) chest pain within 72 hours of death, or (2) history of chronic ischemic heart disease in the absence of valvular heart disease or non-ischemic cardiomyopathy
- <sub>3</sub> Possible fatal CHD: no known non-atherosclerotic cause, and death certificate consistent with CHD as the underlying cause

6.3. **Timing of coronary death: (Mark one.)**

- <sub>1</sub> Sudden death: death occurring within one hour of symptom onset or after the participant was last seen without symptoms, and death occurs in the absence of potentially lethal non-coronary disease process
- <sub>2</sub> Rapid death: death occurs within 1-24 hours of symptom onset
- <sub>3</sub> Other coronary death (Does not fulfill criteria for sudden or rapid coronary death.)

\_\_\_\_\_  
Responsible Adjudicator Signature

7. Editor Code

## 8.8 Cardiovascular Outcomes

Specific CVDs are primary or secondary outcomes for the WHI 2010-2020 ES. The diagnosis of cardiovascular events is derived from a constellation of signs, symptoms, and objective evidence such as serum enzyme levels, diagnostic tests and procedure reports. These constellations for diagnosis may be different for different patients and the systematic assignment of cardiovascular outcomes diagnoses will be a challenge to the PAs.

This section describes the study-defined diagnostic criteria for the cardiovascular outcomes and outlines the necessary documentation to arrive at consistent diagnoses. Note that thromboembolic outcomes (i.e., deep vein thrombosis and pulmonary embolus) are described in detail in *Section 8.9 – Form 126 – Report of Thromboembolic Disease*.

For WHI purposes, CHD includes MI, coronary death, and coronary revascularization. The possible diagnoses of CHD will be based on:

- A reported hospitalization with appropriate documentation for CHD.
- A report of a death possibly due to heart disease with appropriate documentation.

The processing of CVD outcomes follows the established procedures for ascertainment and adjudication of outcomes as outlined in *Figure 8.1 – Outcomes Ascertainment and Adjudication Process*. Refer to *Sections 8.2 – 8.6* for more details on this multi-step, multi-component process.

### 8.8.1 Diagnostic Categories

The following cardiovascular diagnoses are monitored during the WHI 2010-2020 ES. (Thromboembolic diagnoses are discussed in *Section 8.9*.)

Obtained through self-report only:

- Angina pectoris (self-report on *Form 33*).
- TIA that results in a hospitalization of 2 nights or more is reviewed for a possible stroke.

Adjudicated outcome using *Form 121 – Report of Cardiovascular Outcome*:

- Myocardial infarction (MI) (definite, probable, or aborted). (See *Figure 8.4, Form 121*.)
- Coronary revascularization (CABG and PTCA).
- Carotid artery disease requiring hospitalization (also on *Form 132 – Report of Stroke Outcome*)
- Peripheral arterial disease requiring hospitalization.
- Heart failure requiring hospitalization.
- Aortic aneurysm/Dissection
- Heart valve disease

**Note:** As a streamlining measure, inpatient atrial fibrillation was dropped from investigation and adjudication [OAC, May 2017]

Adjudicated outcome using *Form 132 – Report of Stroke Outcome*:

- Stroke (fatal and nonfatal, hemorrhagic, ischemic, or unknown); includes inpatient and outpatient strokes.
- Transient ischemic attack (TIA)
  - Self-report on *Form 33*
- Any denied stroke determined to be a TIA is recorded using *Form 132 – Report of Stroke Outcome*
- Carotid artery disease requiring hospitalization (also on *Form 121 – Report of Cardiovascular Outcome*).

Adjudicated outcome using *Form 124 – Report of Death (Final)* (see *Section 8.7 – Fatal Events Adjudication*)

- Definite coronary heart disease (CHD) death
- Possible CHD death
- Other cardiovascular disease
- Unknown cardiovascular disease



### 8.8.2 Other Cardiovascular Events Associated with a Hospital Stay of 2 Nights or More

Any other cardiovascular event not fitting the above categories, yet requiring a hospital stay of 2 nights or more, are classified as “other cardiovascular events.” On June 6, 2018 the Steering Committee voted and approved to stop investigation and adjudication of all 2-night hospital stays, including 2-night stays for other cardiovascular self-reports. [Streamlining proposal, 2018] Do not complete *Form 121 – Report of Cardiovascular Outcome* for these outcomes. These other cardiovascular events include but are not limited to the following:

- Endocarditis
- Pericarditis
- Cardiac tamponade
- Cardiomyopathy
- Upper extremity peripheral vascular disease
- Valvular heart disease

### 8.8.3 First vs. Subsequent Cardiovascular Disease

On June 24, 2015, the Outcomes Adjudication Committee (OAC) lifted the subsequent condition rule for all MRC CVD events (and Hip fractures); these events will be fully investigated and adjudicated. Adjudication of all CVD events is to ensure the first incident CVD (e.g., MI, stroke and/or revascularization) is captured post randomization for two new ancillary study (AS)-intervention trials launched in 2015: AS355 - Randomized Trial of Cocoa Extract and Multivitamins for CVD and Cancer Prevention (COSMOS) and AS360 - Physical activity to improve cardiovascular health in women: A pragmatic trial (WHISH).

See *Table 8.3 – Subsequent Conditions* for a description of adjudicated cardiovascular outcomes. Prior to June, 2015, the WHI subsequent condition rule was as follows: Documentation of a first MI and, as appropriate, a second MI (one occurring during or as a result of a procedure during the same hospital stay) on *Form 121 – Report of Cardiovascular Outcome*. A subsequent myocardial infarction or stroke occurring during the WHI 2010-2020 ES did not require investigation unless the subsequent report is part of a hospital stay of 2 nights or more. Note that if the participant had a MI or stroke before WHI randomization/enrollment, her first MI or stroke after WHI enrollment would be counted as her first MI for study purposes.

### 8.8.4 Documentation Requirements

*Table 8.2 – Required Documents for Outcomes Adjudication* indicates the various medical record documents required and recommended for each type of cardiovascular outcome. The essential documents are indicated with an ✖ in a box (☒) and the recommended documents are indicated with an ✖. PAs are strongly encouraged to rely on the documentation requirements approved by the OAC, as listed in *Table 8.2*. Use of these approved document sets ensures consistency between FCs. PAs should review the IDS to determine if the outcome coordinator had already attempted to obtain a specific document and the reason the document is not included (e.g., it was not performed).

### 8.8.5 Form 121 – Report of Cardiovascular Outcomes

A PA completes *Form 121 – Report of Cardiovascular Outcomes* when a participant reports having had one or more of the WHI 2010-2020 ES cardiovascular outcomes listed below:

- Definite or probable myocardial infarction.
- Coronary revascularization (including outpatient coronary revascularization)
- Carotid artery disease requiring hospitalization
- Peripheral arterial disease requiring hospitalization
- Heart Failure requiring hospitalization
- Aortic aneurysm requiring hospitalization
- Aortic dissection requiring hospitalization
- Heart valve disease requiring hospitalization

**Qx. 1 – ECG pattern**

Complete for a confirmed MI, coronary revascularization and heart failure. Read all ECGs 12-lead ECG tracings in the case packet. Carefully note the date of each ECG to verify that it pertains to the dates of the event being adjudicated.

A written report summarizing the ECG findings can only be used to document a normal, not an abnormal ECG; rhythm stripes do not qualify as a valid document type.

Mark the one category that best describes the serial evolution of ECG pattern based on all available ECGs. If there is only one ECG, by definition an adjudicator will not be able to evaluate evolving ECG patterns. See *Section 8.6.1 – Physician Adjudication Training* for a list of recommended readings on ECG interpretation for a refresher on ECG interpretation.

- Evolving Q-wave and evolving ST-T abnormalities (code 1)
  - Requires serial ECGs. See exception below.
  - Will usually reflect clinical ST elevation MI (STEMI) with Q waves.

Coding ST-elevation MI in the absence of ECGs:

For acute ST elevation MIs (STEMI) only, if actual ECG tracings cannot be obtained, but an ECG interpretation is recorded on an available ECG report which clearly states the presence of acute ST segment elevations consistent with acute myocardial infarction AND other WHI criteria for acute myocardial infarction (chest discomfort, elevated enzymes) are met, then the CVD adjudicator may code as ECG code 1, “Evolving Q-wave and evolving ST-T abnormalities”. Note that in many such cases, the participant will also have undergone acute revascularization confirming the diagnosis of acute coronary occlusion and STEMI in the clinical setting. (OAC, February 27, 2013).

- Equivocal Q-wave evolution; or evolving ST-T abnormalities; or new left bundle branch block (code 2).
  - Requires serial ECGs demonstrating typical deep, symmetric T wave inversion and evolution over hours to days. Will not appear as downsloping ST-T changes associated with LVH. Changes must evolve over time.
  - Mark if there is documentation in the medical record indicating the left bundle branch block (LBBB) is new. Otherwise, mark Other ECG pattern, ECG uncodable, or normal ECG pattern (code 8).
- Q-waves or ST-T abnormalities suggestive of an MI and not classified as code 1 or 2 above (code 3).
  - Do not code if Q-wave is old, by documentation in medical record, the ECG interpretation or by serial ECG showing no typical evolution of acute MI.
- Other ECG pattern, ECG uncodable, or normal ECG pattern (code 8).
  - For left bundle branch block, mark if documentation in the medical record indicates that the pattern is old. Mark this code if LBBB is documented in the medical record, but ECG is not available
- ECG not available (code 9)

**Qx. 2 – Cardiac enzyme information available**

Complete for a confirmed MI, coronary revascularization and heart failure.

Record pertinent enzyme results as defined below. The timing of symptoms and enzyme measurements should be similar for the episode being adjudicated.

Do not record elevated cardiac enzymes if they are known to be due to another cause, e.g., a PE. Information on any non-ischemic causes for elevated enzymes is documented on the hospital discharge summary.

**Cardiac Enzymes**

If the actual laboratory report is not available in the case packet, the enzyme results, in some instances can still be recorded on *Form 121*.

- If enzymes are stated to be “normal” they can be recorded as such.
- If described as “abnormal” or a specific value is given, code only as >2 x ULN if this is unquestionably true.
- If enzymes stated to be abnormal without quantification, mark enzymes as “not available”.

A summary of the enzyme diagnostic criteria is given in *Table 8.8 – Cardiac Enzyme Diagnostic Criteria* and define the cardiac enzyme interpretations listed in *Table 8.7 – Diagnosis of Myocardial Infarction*.

#### Qx. 2.1 – Creatine kinase heart fraction (CK-MB)

CK-MB is expressed as a percent, index, or unit. WHI criteria for abnormal level require CK-MB value to be greater than or equal to twice the upper limit of normal for that hospital lab (if upper limit is given in the lab report) then it is classified as elevated. For options referring to “normal limits,” use the limits specified by the laboratory that conducted the test.

Note that the total CK may be elevated for reasons other than myocardial infarction or there may be known non-ischemic causes for the elevated CK-MB, such as cardiac surgery, cardiac defibrillation, severe muscle trauma, or rhabdomyolysis. In these instances, do not code enzyme information.

##### If CK-MB is available

- **expressed as a % or index:** (Record peak results only.)
  - CK-MB at least 2x upper limit of normal for % or index (code 1)
  - CK-MB greater than upper limit of normal but less than 2x upper limit of normal for % or index (code 2)
  - CK-MB within normal limits for % or index (code 3)
- **expressed in units** (usually ng/ml): (Record peak results only.)
  - CK-MB at least 2x upper limit of normal for units (code 4)
  - CK-MB greater than upper limit of normal but less than 2x upper limit of normal for units (code 5)
  - CK-MB within normal limits for units (code 6)

##### If CK-MB not available

- Total CK at least 2x upper limit of normal (code 9)
- Total CK greater than upper limit of normal but less than 2x upper limit of normal (code 10)
- Total CK within normal limits (code 11)

##### CK result not available (code 99)

- Check if CK was not measured or if no result is available

#### Qx. 2.2 – Troponin lab test

Mark the one category that applies best. If more than one Troponin test was conducted, indicate the type that was most elevated.

- Troponin C (code 1)
- Troponin I (code 2)
- Troponin T (code 3)
- Troponin not specified (code 4)
- Troponin not available (code 9)

If Troponin was not measured or if no result is available, mark “Troponin not available” and skip to Qx. 3 – Cardiac-Pain.

##### Qx. 2.2.1 – Results (Troponin)

Mark the one category that applies best. Code Troponin values using the upper limit of normal (ULN) and not upper limit of indeterminate/indecisive as the reference value; for example, if two cut points are given, choose the lower cut point for the upper limit of normal.

If more than one Troponin test was conducted, record the levels for the type that was most elevated. For the option referring to “normal limits,” use the limit specified by the laboratory that conducted the test.

- Troponin at least 2x upper limit of normal (code 1)
- Troponin greater than upper limit of normal but less than 2x upper limit of normal (code 2)
- Troponin within normal limits (code 3)
- Other (code 9)

### Qx. 3 – Cardiac pain

Complete for a confirmed MI, coronary revascularization and heart failure.

Cardiac pain refers to an acute episode of pain, discomfort, or tightness in the chest, arm, throat, or jaw, as defined below:

- Chest, jaw, throat, or arm pain, discomfort, or tightness of at least 15 minutes duration probably due to myocardial ischemia.
- Other equivalent ischemic symptoms, e.g., abrupt onset of shortness of breath, nausea, back pain, weakness, etc., if the medical records reasonably supports that these symptoms are produced by the myocardial infarction.
- And an absence of a definite non-cardiac cause of chest pain.

### Qx. 4 – Myocardial infarction: definite, probable, or aborted MI

Myocardial infarction is defined as the death of part of the myocardium due to an occlusion of a coronary artery from any cause, including spasm, embolus, thrombus, or the rupture of a plaque.

Use the responses to *Qx. 1 – 3* about ECG, cardiac enzymes, and cardiac pain to determine the occurrence of a myocardial infarction (MI). See *Table 8.7 – Diagnosis of Myocardial Infarction*. PAs may use clinical judgment to assess the diagnosis of an MI if the criteria in *Table 8.7* do not fit the particular case.

#### Aborted myocardial infarction

A diagnosis of aborted MI must meet all of the following criteria:

- Symptoms and ECG evidence for acute MI at presentation.
- Intervention (e.g., thrombolytic therapy procedure) is followed by resolution of ECG changes.
- All cardiac enzymes measured after the intervention is within normal limits.

#### Qx. 4.1 – Date of admission

The **admission date** on the hospital medical records or the date of diagnosis.

#### Qx. 4.2 – Diagnosis

Mark the one category that corresponds to whether or not the MI occurred as a result of or during a procedure.

- MI not occurring as a result of or during a procedure (code 1)
- MI occurred during a procedure or resulting from a procedure within 30 days (code 2)

#### Qx. 4.2.1 – Type of procedure

Mark the one category that applies best:

- A myocardial infarction that followed a cardiac procedure within 24 hours (for example, diagnostic coronary catheterization, percutaneous coronary intervention, CABG, pacemaker insertion, or cardioversion) (code 1)
- A myocardial infarction that followed a cardiac procedure within 2-30 days (for example, diagnostic coronary catheterization, percutaneous coronary intervention, CABG, pacemaker insertion, or cardioversion) (code 2)

- A myocardial infarction that followed a non-cardiac procedure within 30 days (for example, any elective or emergency non-cardiac vascular procedure regardless of type of anesthesia, or any elective or emergency surgical procedure requiring more than local anesthesia) (code 3)

If the myocardial infarction was related to a PCI of CABG, complete these additional questions using updated cardiac enzyme criteria.

**Note:** The enzyme levels documented in these new questions are collected in addition to our WHI defined criteria, which remain unchanged.

**Qx. 4.2.2 – Cardiac PCI procedure done**

No/yes

**Qx. 4.2.3 – If yes, were cardiac enzyme levels at least 3X ULN (99th) percentile)**

No/yes/unknown

**Qx. 4.2.4 – CABG procedure done**

No/yes

**Qx. 4.2.5 – If yes, were cardiac enzyme levels at least 5X ULN (99th percentile) and Q-Wave, new LBBB or evidence for graft closure found for CABG**

No/yes/unknown

**Qx. 4.3 – Was thrombolytic agent administered or emergent revascularization procedures performed**

An emergent revascularization is defined as occurring within 12 hours of symptom onset. Mark in this Qx. and in Qx. 5 – *Coronary revascularization*. Code non-emergent revascularization procedures only under Qx. 5. Examples of thrombolytic agents are streptokinase, reteplase (Retavase), tenecteplase (TNKase), alteplase tPA (Activase).

**Table 8.7**  
**Diagnosis of Myocardial Infarction**

ECG Pattern/Symptoms	Cardiac Enzyme Interpretation (see Table 8.8 below)			
	Abnormal	Equivocal	Incomplete	Normal
<b>Cardiac pain present:</b>				
Evolving Q wave and evolving ST-T abnormalities	Definite MI	Definite MI	Definite MI	Definite MI
Equivocal Q wave evolution; or evolving ST-T abnormalities, or new left bundle branch block	Definite MI	Definite MI	Probable MI	No MI
Q waves or ST-T abnormalities suggestive of an MI and not classified above	Definite MI	Probable MI	No MI	No MI
Other ECG, ECG absent or uncodable	Definite MI	No MI	No MI	No MI
<b>Cardiac Pain absent:</b>				
Evolving Q wave and evolving ST-T abnormalities	Definite MI	Definite MI	Definite MI	Probable MI
Equivocal Q wave evolution; or evolving ST-T abnormalities; or new left bundle branch block	Definite MI	Probable MI	No MI	No MI
Q waves or ST-T abnormalities suggestive of an MI and not classified above	Probable MI	No MI	No MI	No MI
Other ECG, ECG absent or uncodable	No MI	No MI	No MI	No MI

**Table 8.8**  
**Cardiac Enzyme Diagnostic Criteria\*\*\***

Cardiac Enzyme	Interpretation		
	Abnormal*	Equivocal	Normal
Creatine kinase MB fraction (CK-MB)	≥ 2x ULN (as %, index, or units); or “present” without quantification	1-2x ULN (as %, index, or units); or “weakly present”	WNL
Troponin (C, I, or T)**	Troponin ≥ 2x ULN	Troponin 1-2x ULN	Troponin is WNL
Total creatine kinase (CK) (no MB available)	N/A	Total CK ≥ 2x ULN	Total CK is 1-2x ULN or WNL

ULN = upper limit of normal  
WNL = within normal limits

\* If both CK-MB and Troponin are available, Troponin must be elevated to be considered abnormal, if only CK-MB is available, abnormal levels are enough to code enzymes as abnormal; i.e., WHI considers Troponin as the most accurate indicator of myocardial injury.

\*\* Code Troponin levels using the ULN and not Upper limit of undeterminate/indecisive as the reference value. Thus, if 2 cut points are given, choose the lower cut point for the ULN.

\*\*\* For procedure related MI: also code 5.3.1 or 5.3.2 using the following definitions: 3X ULN (99th percentile for PCI and 5X ULN (99th percentile) and Q-Wave, new LBBB, or evidence of graft closure for CABG.

**Qx. 5 – Coronary revascularization**

Coronary revascularization includes surgery or other procedures that are intended to provide improved coronary blood flow to the myocardium. This would include:

- CABG
- Percutaneous Coronary Intervention (PCI):
  - Coronary stent
  - Balloon
  - Artherectomy
  - Laser

Note that *Qx. 1 – ECG Pattern* and *Qx. 2 – Cardiac Enzyme Information* must be completed, if available.

**Qx. 5.1 – Date of admission**

Use the date of admission as the date of procedure, even if more than one procedure was done. If the percutaneous coronary intervention was performed on an outpatient basis, record the date of the intervention.

**Qx. 5.2 – Type of procedure**

Mark all that apply. If multiple procedures of the same type (e.g., two PTCA) were conducted during a single hospital admission, record only the first of that procedure. If both a CABG and PTCA were conducted during the same hospital admission, mark both.

- CABG (code 1)
- PTCA, coronary stent, or coronary atherectomy, PCI (code 2)

Definition of attempted/aborted revascularization procedure: In general, an attempted but aborted or unsuccessful revascularization procedure is still recorded on a *Form 121, Qx. 5 – Coronary revascularization*. For percutaneous coronary interventions (such as angioplasty, stent, or atherectomy), if the procedure was aborted before the guidewire was advanced across the lesion, and no other coronary lesions were opened (by balloon, stent or atherectomy), then this procedure should not be recorded in *Qx. 5.2.2*, because the revascularization procedure did not take place. If you have any doubt, the procedure can be referred by discussion by the full committee. [OAC, Feb. 21, 2008]

**Qx. 5.3 – Second MI**

Mark one. Mark only if a second MI not already reported in *Qx. 4 – Definite, probable, or aborted MI* occurred at this admission as a result of or during the coronary revascularization procedure.

Mark ‘No’ if enzymes were drawn after the revascularization and there is no evidence for an MI.

Mark ‘Yes’ if enzymes were drawn after the revascularization and there was evidence for an MI.

Mark ‘Unknown’ if no enzymes were drawn after the procedure or enzyme results are not available.

**Qx. 5.3.1** - Mark one. Mark ‘Yes’ if enzyme levels were at least 3X ULN (99th percentile) for PCI.

**Qx. 5.3.2** - Mark one. Mark ‘Yes’ if enzyme levels were at least 5X UNL and Q-Wave, new LBBB, or evidence for graft closure found for CABG.

**Qx. 6 – Carotid artery disease requiring and/or occurring during hospitalization**

Disease must be symptomatic and/or requiring intervention (i.e., vascular or surgical procedure). Mark the appropriate box and complete *Qx. 6.1* to *6.3* to confirm the carotid artery disease.

**Qx. 6.1 – Date of admission**

The admission date on the medical records or the date of diagnosis.

**Qx. 6.2 – Diagnosis**

Mark the one box that corresponds best to the PA's final diagnosis.

- Carotid artery occlusion and stenosis without documentation of cerebral infarction (code 1)
- Carotid artery occlusion and stenosis with documentation of cerebral infarction (code 2)

**Qx. 6.3 – Carotid artery disease based on**

Mark all that apply. Note that participant must be hospitalized plus have one or more of the following:

- Symptomatic disease with carotid artery disease listed on the hospital discharge summary (code 1)
- Symptomatic disease with abnormal findings ( $\geq 50\%$  stenosis) on carotid angiogram, MRA, or Doppler flow study (code 2)
- Vascular or surgical procedure to improve flow to the ipsilateral brain (code 3)

**Qx. 7 – Peripheral arterial disease requiring and or occurring during hospitalization**

Peripheral arterial disease (PAD) is defined as hospitalization for leg pain produced by ischemia from peripheral arterial disease; or hospitalization with a positive diagnostic test result or surgical intervention for lower extremity arterial occlusion.

This diagnosis refers to disease in the iliac arteries or below that are symptomatic and/or require intervention; symptomatic disease includes intermittent claudication, ischemic ulcers, gangrene, or surgery for amputation; and requires or occurs during a hospitalization.

**Qx. 7.1 – Date of admission**

The admission date on the hospital medical records or the date of diagnosis.

**Qx. 7.2 – Diagnosis**

Mark the one box that corresponds best to the PA's final diagnosis.

- Atherosclerosis of arteries of the lower extremities (code 2)
- Arterial embolism and/or thrombosis of the lower extremities (code 3)

**Qx. 7.3 – Peripheral artery disease based on**

Defined by hospitalization plus one or more of the following: Mark all that apply.

- Ultrasonographically, angiographically, or MRI-demonstrated obstruction, or ulcerated plaque ( $\geq 50\%$  of the diameter or  $\geq 75\%$  of the cross-sectional area) demonstrated on ultrasound or angiogram of the iliac arteries or below (code 1)
- Absence of pulse by Doppler in any major vessel of lower extremities (code 2)
- Exercise test that is positive for lower extremity claudication (code 3)
- Surgery, angioplasty, or thrombolysis for peripheral arterial disease (code 4)
- Amputation of one or more toes or part of the lower extremity because of ischemia or gangrene (code 5)
- Exertional leg pain relieved by rest and at least one of the following: (1) claudication diagnosed by physician, or (2) ankle-arm systolic blood pressure ratio  $\leq 0.8$  (code 6)

**Qx. 8. – Congestive heart failure (CHF, HF) requiring and/or occurring during a hospitalization**

Congestive Heart Failure is defined as a constellation of symptoms (such as shortness of breath, fatigue, orthopnea, and paroxysmal nocturnal dyspnea) and physical signs (such as edema, rales, tachycardia, a gallop rhythm, and a displaced point of maximum intensity [PMI]) that occur in a participant whose cardiac output cannot match metabolic needs despite adequate filling pressures. Only a hospitalization for new, acute or worsening CHF is adjudicated.

Data on additional evidence for the diagnosis of CHF, collected as part of the current episode of care, are also recorded. Thus, CHF on clinical grounds can be differentiated from CHF documented by imaging studies.



**Qx. 8.1 - Date of admission**

The admission date on the hospital medical records or the date of diagnosis.

**Qx. 8.2 - CHF based on one or more of the following:**

- CHF diagnosed by a physician and receiving medical treatment (diuretic, digitalis, vasodilator, or angiotension-converting enzyme inhibitor) for symptom relief (code 1)
- CHF diagnosed by physician and receiving medical treatment on this admission **plus** current medical record documents a history of an imaging procedure showing impaired systolic or diastolic LV function (code 2)
- Pulmonary edema/congestion by chest X-ray on this admission (code 3)
- On this admission, dilated ventricle or poor left (or right-side) ventricular function (e.g., wall motion abnormalities) by echocardiography; radionuclide ventriculogram (RVG)/multigated acquisition (MUGA), or other contrast ventriculography, or evidence of left ventricular diastolic dysfunction (code 4)

**Qx. 9 - Aortic aneurysm**

Disease must be symptomatic and/or requiring intervention (e.g., vascular or surgical procedure); the participant must be hospitalized for one or more nights.

**Qx. 9.1 - Date of admission**

The admission date on the hospital medical records or the date of diagnosis

**Qx. 9.2 - Diagnosis**

- Ultrasonographically- or angiographically-demonstrated (by any imaging modality) aortic aneurysm (code 1)
- Surgical or vascular procedure for aortic aneurysm (code 2)




**Qx. 9.3 – Location**

- Ascending aortic aneurysm (arising anywhere from the aortic valve to the left subclavian artery) (code 1)
- Descending aortic aneurysm (thoracic aorta from the left subclavian artery to the diaphragm) (code 2)
- Thoracoabdominal aortic aneurysm (descending aorta extending below the diaphragm) (code 3)
- Abdominal aortic aneurysm (AAA) (abdominal aorta below the renal arteries only) (code 4)
- Other (code 8)
- Unknown, not specified (code 9)

**Qx. 10 - Aortic dissection**

The participant must be hospitalized for one or more nights.

**Classification:**

			
Percentage	60%	10–15%	25–30%
Type	DeBakey I	DeBakey II	DeBakey III
	Stanford A (Proximal)		Stanford B (Distal)
Classification of aortic dissection from Wikipedia			

Rely primarily on the imaging or operative report rather than the discharge summary or H&P for dissection classification. Refer to the illustration to help determine dissection sub-type.

**Qx. 10.1 - Date of admission**

The admission date on the hospital medical records or the date of diagnosis

**Qx. 10.2 - Diagnosis**

The DeBakey Classification is considered the gold standard for classifying aortic dissection and should be used when available. Use the Stanford Classification only if DeBakey cannot be determined.

**DeBakey Classification**

- Type I (Dissection of the ascending and descending thoracic aorta) (code 1)
- Type II (Dissection of the ascending aorta) (code 2)
- Type III (Dissection of the descending aorta) (code 3)

If DeBakey classification cannot be determined, complete the following:

- Stanford Type A (Dissection involving the ascending aorta, regardless of the site of the primary tear) (code 4)
- Stanford Type B (Dissection of the descending aorta) (code 5)
- Not able to be classified with available documents (code 6)

**Qx. 11 - Heart valve disease**

Moderate to severe valvular disease involving one or more valves that requires medical treatment; surgical repair or replacement; or interventional procedure to treat stenosis or regurgitation. The participant must be hospitalized one or more nights.

**Qx. 11.1 - Date of admission**

The admission date on the hospital medical records or the date of diagnosis.

**Qx. 11.2 - No/yes.** Mark the valves involved (causing symptoms, hospitalization, treatment, or complications), and specify if due to stenosis and/or insufficiency, or unknown.

- Aortic
- Mitral
- Pulmonic
- Tricuspid
- Valve NOS

If “yes” mark the one corresponding diagnosis.

- Stenosis (code 1)
- Insufficiency (code 2)
- Both (code 3)
- Unknown (code 9)

**Qx. 11.3 - Mark the one category to indicate if a procedure or operation was performed.**

**Qx. 11.3.1 - Mark all that apply.** Indicate which Valve(s) the procedure or operation was performed.

- Aortic (code 1)
- Mitral (code 2)
- Pulmonic (code 3)
- Tricuspid (code 4)
- Unknown (code 9)

#### **Responsible Adjudicator Submission**

The PA should submit the form only when s/he is satisfied that the questions on the cardiovascular outcomes being reported have been filled in as completely and accurately as possible on the basis of all available information, including documents from query requests.

**Figure 8.4**  
**Form 121 – Report of Cardiovascular Outcome**

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<b>COMMENTS</b>	-Affix label here-
	Member ID: ____ - ____ - ____ - ____ - ____
<i>To be completed by Physician Adjudicator</i>	
Date Completed:    _ _ - _ _ - _ _  (M/D/Y)	Central Case No.:    _ _ _ _ _ _ _ _
Adjudicator Code:    _ _ - _ _ _ _	Case Copy No.:    _ _

**(For items 1-12, each question specifies “mark one” or “mark all” that apply.)**

Complete Q1 - ECG, Q2 - Cardiac enzyme, and Q3 - Cardiac pain information for the following WHI Extension Study outcomes: Myocardial infarction (MI), coronary revascularization, and heart failure.

1. **ECG pattern (Mark the one category that applies best.)**
  - <sub>1</sub> Evolving Q-wave and evolving ST-T abnormalities\*
  - <sub>2</sub> Equivocal Q-wave evolution; or evolving ST-T abnormalities; or new left bundle branch block
  - <sub>3</sub> Q-waves or ST-T abnormalities suggestive of an MI and not classified as code 1 or 2 above
  - <sub>8</sub> Other ECG pattern, ECG uncodable, or normal ECG pattern
  - <sub>9</sub> ECG not available

\*Mark if ECG formal interpretation report clearly indicates evidence for acute ST-segment elevation myocardial infarction (STEMI) when the actual ECG tracing cannot be obtained.

2. **Cardiac enzyme information available?**
  - <sub>0</sub> No → Skip to Question 3 on page 2.
  - <sub>1</sub> Yes

- 2.1 Serum creatine kinase (CK): (Mark all that apply.) (Always record % or index if available.)

**If CK-MB available:**

CK-MB expressed as a % or index: (Record peak results only.)

- <sub>1</sub> CK-MB at least 2x upper limit of normal for % or index
- <sub>2</sub> CK-MB greater than upper limit of normal but less than 2x upper limit of normal for % or index
- <sub>3</sub> CK-MB within normal limits for % or index

CK-MB expressed in units (usually ng/ml): (Record peak results only.)

- <sub>4</sub> CK-MB at least 2x upper limit of normal for units
- <sub>5</sub> CK-MB greater than upper limit of normal but less than 2x upper limit of normal for units
- <sub>6</sub> CK-MB within normal limits for units

<b>AS355 COSMOS only</b>	2.1.1 CK-MB peak result ____ . ____	2.1.2 CK-MB upper limit of normal ____ . ____
------------------------------	-------------------------------------	---

Figure 8.4 (continued)

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**If CK-MB not available:**

- <sub>9</sub> Total CK at least 2x upper limit of normal
- <sub>10</sub> Total CK greater than upper limit of normal but less than 2x upper limit of normal
- <sub>11</sub> Total CK within normal limits
- <sub>99</sub> CK result not available

<b>AS355 COSMOS only</b>	2.1.3 Total CK peak result _____	2.1.4 Total CK upper limit of normal _____
------------------------------	----------------------------------	--

2.2 Troponin lab test. *(Mark the one category that applies best.) (If more than one test was conducted, record the type with the most elevated lab result.)*

- <sub>1</sub> Troponin C
  - <sub>2</sub> Troponin I
  - <sub>3</sub> Troponin T
  - <sub>4</sub> Troponin, not specified
  - <sub>9</sub> Troponin not available
- } → Go to Question 2.2.1.
- } → Go to Question 3.

2.2.1	<p>Results <i>(Mark the <u>one</u> category that applies best.)</i> Troponin values should be coded using the upper limit of normal (ULN) and not upper limit of indeterminate/indecisive as the reference value. Thus, if 2 cutpoints are given, choose the lower cutpoint for the upper limit of normal.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/><sub>1</sub> Troponin at least 2x upper limit of normal</li> <li><input type="checkbox"/><sub>2</sub> Troponin greater than upper limit of normal but less than 2x upper limit of normal</li> <li><input type="checkbox"/><sub>3</sub> Troponin within normal limits</li> <li><input type="checkbox"/><sub>9</sub> Other</li> </ul>
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<b>AS355 COSMOS only</b>	
Most elevated Troponin:	
2.2.2	Troponin peak result _____ . _____
2.2.3	Troponin upper limit of normal _____ . _____

3. **Cardiac pain** defined as: an acute episode of pain, discomfort or tightness in the chest, arm, throat or jaw. *(Mark the one category that applies best.)*

- <sub>1</sub> Present
- <sub>2</sub> Absent
- <sub>9</sub> Unknown/Not recorded

Figure 8.4 (continued)

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Yes <sub>1</sub> No <sub>0</sub>

4. Definite, probable, or aborted myocardial infarction (See Table 1 – Definition of Criteria for Diagnosis of Myocardial Infarction and Table 2 – Algorithm for Enzyme Diagnostic Criteria on the last page of this form.)

4.1 Date of admission:  -  -  (M/D/Y)

4.2 Diagnosis: (Mark one.)

<sub>1</sub> Myocardial infarction not occurring as a result of or during a procedure. (Skip to Question 4.3.)

<sub>2</sub> Myocardial infarction during or resulting from a procedure, i.e., within 30 days of any procedure.



4.2.1 Type and timing of Procedure (Mark one.)

- <sub>1</sub> A myocardial infarction that followed a cardiac procedure within 24 hours (for example, diagnostic coronary catheterization, percutaneous coronary intervention (PCI), CABG, pacemaker insertion, or cardioversion).
- <sub>2</sub> A myocardial infarction that followed a cardiac procedure within 2-30 days (for example, diagnostic coronary catheterization, PCI, CABG, pacemaker insertion, or cardioversion).
- <sub>3</sub> A myocardial infarction that followed a non-cardiac procedure within 30 days (for example, any elective or emergency non-cardiac vascular procedure regardless of type of anesthesia, or any elective or emergency surgical procedure requiring more than local anesthesia). (Go to Question 4.3 below.)

Answer both questions:

4.2.2 Was the cardiac procedure a PCI?

<sub>0</sub> No

<sub>1</sub> Yes →

4.2.3 Were enzyme levels at least 3X ULN (99th percentile)?	No <input type="checkbox"/> <sub>0</sub>	Yes <input type="checkbox"/> <sub>1</sub>	Unknown <input type="checkbox"/> <sub>9</sub>
---	--	---	---

4.2.4 Was the cardiac procedure a CABG?

<sub>0</sub> No

<sub>1</sub> Yes →

4.2.5 Were enzyme levels at least 5X ULN (99th percentile) and Q-Wave, new LBBB or evidence for graft closure found for CABG?	No <input type="checkbox"/> <sub>0</sub>	Yes <input type="checkbox"/> <sub>1</sub>	Unknown <input type="checkbox"/> <sub>9</sub>
---	--	---	---

4.3 Was a thrombolytic agent administered or emergent\* revascularization procedure (e.g., angioplasty or stent) performed? (Mark one.)

\*An emergent revascularization is conducted within 12 hours of symptom onset; code both here and in Q5. Non-emergent revascularization procedures are coded only under Q5. Examples of thrombolytic agents are streptokinase, reteplase (Retavase), tenecteplase (TNKase), alteplase tPA (Activase).

<sub>0</sub> No

<sub>1</sub> Yes

<sub>9</sub> Unknown

Figure 8.4 (continued)

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4.4 Universal criteria of MI classification (*Mark one.*)

<sub>1</sub> Type 1: Spontaneous MI

<sub>2</sub> Type 2: Secondary MI

<sub>3</sub> Type 3: MI resulting in death (no biomarkers available)

<sub>4</sub> Type 4a: Post-PCI MI

<sub>5</sub> Type 4b: MI related to stent thrombosis

<sub>6</sub> Type 5: Post-CABG MI

Yes <sub>1</sub> No <sub>0</sub> 5. Coronary revascularization. Categories A, C, D

5.1 Date of Admission/Procedure:  -  -  (M/D/Y)

5.2 Type of procedure: Any one of the following procedures aimed at improving cardiac status (*Mark all that apply.*)

<sub>1</sub> Coronary artery bypass graft (CABG)

<sub>2</sub> Percutaneous transluminal coronary angioplasty (PTCA), coronary stent, or coronary atherectomy, percutaneous coronary intervention (PCI)

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5.2.1 Coronary artery interventions (*Mark all that apply.*)

<sub>1</sub> Left main coronary artery

<sub>2</sub> Left anterior descending artery or branches

<sub>3</sub> Left circumflex artery or marginal branches

<sub>4</sub> Right coronary artery or branches

<sub>5</sub> Any vein bypass graft treated by PCI

<sub>6</sub> Internal thoracic (left or right internal mammary) artery (RIMA or LIMA) graft treated by PCI

<sub>8</sub> Other (Specify: \_\_\_\_\_)

<sub>9</sub> Information not available

5.3 Second myocardial infarction (MI) (i.e., second MI not already reported in Question 4) occurring as a result of or during the revascularization procedure. (*Mark one.*)

<sub>0</sub> No <sub>9</sub> Unknown

<sub>1</sub> Yes

↓

5.3.1 For PCI, were enzyme levels at least 3X ULN (99th percentile)?

<sub>0</sub> No <sub>1</sub> Yes <sub>9</sub> Unknown

5.3.2 For CABG, were enzyme levels at least 5X ULN (99th percentile) and Q-Wave, new LBBB or evidence for graft closure found?

<sub>0</sub> No <sub>1</sub> Yes <sub>9</sub> Unknown

Figure 8.4 (continued)

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Categories A, C, D

Yes <sub>1</sub> No <sub>0</sub>

6. **Carotid artery disease** requiring and/or occurring during hospitalization. Disease must be symptomatic and/or requiring intervention (i.e., vascular or surgical procedure).

6.1 Date of Admission:  -  -  (M/D/Y)

6.2 Diagnosis: (Mark one.)

<sub>1</sub> Carotid artery occlusion and stenosis without documentation of cerebral infarction

<sub>2</sub> Carotid artery occlusion and stenosis with documentation of cerebral infarction

6.3 Carotid artery disease based on (Hospitalization plus one or more of the following): (Mark all that apply.)

<sub>1</sub> Symptomatic disease with carotid artery disease listed on the hospital discharge summary

<sub>2</sub> Symptomatic disease with abnormal findings (≥ 50% stenosis) on carotid angiogram, MRA, or Doppler flow study

<sub>3</sub> Vascular or surgical procedure to improve flow to the ipsilateral brain

Categories A, C, D

Yes <sub>1</sub> No <sub>0</sub>

7. **Peripheral arterial disease** (iliac arteries or below) requiring and/or occurring during hospitalization. Symptomatic disease including intermittent claudication, ischemic ulcers, or gangrene. Disease must be symptomatic and/or requiring intervention (e.g., vascular or surgical procedure for arterial insufficiency in the lower extremities).

7.1 Date of Admission:  -  -  (M/D/Y)

7.2 Diagnosis: (Mark the one category that applies best.)

<sub>2</sub> Atherosclerosis of arteries of the lower extremities

<sub>3</sub> Arterial embolism and/or thrombosis of the lower extremities

7.3 Peripheral arterial disease based on (hospitalization plus one or more of the following): (Mark all that apply.)

<sub>1</sub> Ultrasonographically, angiographically, or MRI-demonstrated obstruction, or ulcerated plaque (≥ 50% of the diameter or ≥ 75% of the cross-sectional area) demonstrated on ultrasound or angiogram of the iliac arteries or below

<sub>2</sub> Absence of pulse by Doppler in any major vessel of lower extremities

<sub>3</sub> Exercise test that is positive for lower extremity claudication

<sub>4</sub> Surgery, angioplasty, or thrombolysis for peripheral arterial disease

<sub>5</sub> Amputation of one or more toes or part of the lower extremity because of ischemia or gangrene

<sub>6</sub> Exertional leg pain relieved by rest and at least one of the following:

(1) claudication diagnosed by physician, or

(2) ankle-arm systolic blood pressure ratio ≤ 0.8

Categories A, C, D, E

Yes <sub>1</sub> No <sub>0</sub>

8. **Congestive heart failure** requiring and/or occurring during hospitalization. (Physician diagnosis of new-onset or worsened congestive heart failure on this admission.)

8.1 Date of Admission:  -  -  (M/D/Y)



Figure 8.4 (continued)

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- 8.2 Congestive heart failure based on one or more of the following: *(Mark all that apply.)*
- <sub>1</sub> Congestive failure diagnosed by physician and receiving medical treatment for CHF on this admission (e.g., diuretic, digitalis, vasodilator and/or angiotensin-converting enzyme inhibitor)
  - <sub>2</sub> Congestive failure diagnosed by physician and receiving medical treatment on this admission **plus** current medical record documents a history of an imaging procedure showing impaired systolic or diastolic LV function
  - <sub>3</sub> Pulmonary edema/congestion by chest X-ray on this admission
  - <sub>4</sub> On this admission, dilated ventricle or poor left (or right-side) ventricular function (e.g., wall motion abnormalities) by echocardiography; radionuclide ventriculogram (RVG)/multigated acquisition (MUGA), or other contrast ventriculography, or evidence of left ventricular diastolic dysfunction

Categories A, C, D

Yes <sub>1</sub> No <sub>0</sub>

9. Aortic aneurysm Requires a hospitalization of one night or more. Disease must be symptomatic and/or requiring intervention (e.g., vascular or surgical procedure).

9.1 Date of Admission:  -  -  (M/D/Y)

9.2 Diagnosis: *(Mark one.)*

- <sub>1</sub> Ultrasonographically- or angiographically-demonstrated (by any imaging modality) aortic aneurysm
- <sub>2</sub> Surgical or vascular procedure for aortic aneurysm

9.3 Location: *(Mark one.)*

- <sub>1</sub> Ascending aortic aneurysm (arising anywhere from the aortic valve to the left subclavian artery)
- <sub>2</sub> Descending aortic aneurysm (thoracic aorta from the left subclavian artery to the diaphragm)
- <sub>3</sub> Thoracoabdominal aortic aneurysm (descending aorta extending below the diaphragm)
- <sub>4</sub> Abdominal aortic aneurysm (AAA) (abdominal aorta below the renal arteries only)
- <sub>8</sub> Other (Specify: \_\_\_\_\_)
- <sub>9</sub> Unknown, not specified

Categories A, C, D

Yes <sub>1</sub> No <sub>0</sub>

10. Aortic dissection Requires a hospitalization of one night or more.

10.1 Date of Admission:  -  -  (M/D/Y)

10.2 Diagnosis: *(Mark one.)*

*DeBakey Classification*

- <sub>1</sub> Type I (Dissection of the ascending and descending thoracic aorta)
- <sub>2</sub> Type II (Dissection of the ascending aorta)
- <sub>3</sub> Type III (Dissection of the descending aorta)

If DeBakey classification cannot be determined, complete the following:

- <sub>4</sub> Stanford Type A (Dissection involving the ascending aorta, regardless of the site of the primary tear)
- <sub>5</sub> Stanford Type B (Dissection of the descending aorta)
- <sub>6</sub> Not able to be classified with available documents

Figure 8.4 (continued)

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Category A, C

Yes <sub>1</sub> No <sub>0</sub>

11. **Heart Valve Disease** Requires a hospitalization of one night or more. Moderate to severe valvular disease involving one or more valves that requires medical treatment; surgical repair or replacement; or interventional procedure to treat stenosis or regurgitation.

11.1 Date of Admission:  -  -  (M/D/Y)

11.2 Which valve(s) involved (causing symptoms, hospitalization, treatment, or complications) are specified?

Which valves? (Mark No or Yes for each valve. If valve not known, mark Valve NOS (Not Otherwise Specified - i.e., not identified in available records). If you mark Yes, mark the one corresponding diagnosis.

		Diagnosis							
		No	Yes	Stenosis	Insufficiency	Both	Unknown		
11.2.1	Aortic	<input type="checkbox"/> <sub>0</sub>	<input type="checkbox"/> <sub>1</sub>	→	11.2.1.1	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>9</sub>
11.2.2	Mitral	<input type="checkbox"/> <sub>0</sub>	<input type="checkbox"/> <sub>1</sub>	→	11.2.2.1	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>9</sub>
11.2.3	Pulmonic	<input type="checkbox"/> <sub>0</sub>	<input type="checkbox"/> <sub>1</sub>	→	11.2.3.1	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>9</sub>
11.2.4	Tricuspid	<input type="checkbox"/> <sub>0</sub>	<input type="checkbox"/> <sub>1</sub>	→	11.2.4.1	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>9</sub>
11.2.5	Valve NOS	<input type="checkbox"/> <sub>0</sub>	<input type="checkbox"/> <sub>1</sub>	→	11.2.5.1	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>9</sub>

11.3 Was a procedure or operation performed?

<sub>0</sub> No  
<sub>1</sub> Yes  
 ↓

11.3.1 On which valve was the procedure or operation performed? (Mark all that apply.)

- <sub>1</sub> Aortic
- <sub>2</sub> Mitral
- <sub>3</sub> Pulmonic
- <sub>4</sub> Tricuspid
- <sub>9</sub> Unknown

\_\_\_\_\_  
 Responsible Adjudicator Signature

Figure 8.4 (continued)

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Table 1  
Definition of Criteria for Diagnosis of Myocardial Infarction

	Cardiac Enzyme Interpretation (see Table 2 below)			
	Abnormal	Equivocal	Incomplete	Normal
<b>ECG Pattern/Symptoms</b>				
<b>Cardiac pain present:</b>				
Evolving Q wave and evolving ST-T abnormalities	Definite MI	Definite MI	Definite MI	Definite MI
Equivocal Q wave evolution; or evolving ST-T abnormalities, or new left bundle branch block	Definite MI	Definite MI	Probable MI	No MI
Q waves or ST-T abnormalities suggestive of an MI and not classified above	Definite MI	Probable MI	No MI	No MI
Other ECG, ECG absent or uncodable	Definite MI	No MI	No MI	No MI
<b>Cardiac Pain absent:</b>				
Evolving Q wave and evolving ST-T abnormalities	Definite MI	Definite MI	Definite MI	Probable MI
Equivocal Q wave evolution; or evolving ST-T abnormalities; or new left bundle branch block	Definite MI	Probable MI	No MI	No MI
Q waves or ST-T abnormalities suggestive of an MI and not classified above	Probable MI	No MI	No MI	No MI
Other ECG, ECG absent or uncodable	No MI	No MI	No MI	No MI

Table 2  
Algorithm for Enzyme Diagnostic Criteria\*\*\*

Cardiac Enzyme	Abnormal*	Interpretation	
		Equivocal	Normal
Creatine kinase MB fraction (CK-MB)	≥ 2x ULN (as %, index, or units)	1-2x ULN (as %, index, or units)	WNL
Troponin (C, I, or T)**	Troponin ≥ 2x ULN	Troponin 1-2x ULN	Troponin is WNL
Total creatine kinase (CK) (no MB available)	N/A	Total CK ≥ 2x ULN	Total CK is 1-2x ULN or WNL

ULN = upper limit of normal  
WNL = within normal limits

- \* If both CK-MB and Troponin are available, Troponin must be elevated to be considered abnormal; if only CK-MB is available, abnormal levels are enough to code enzymes as abnormal, i.e., WHI considers Troponin as the most accurate indicator of myocardial injury.
- \*\* Code Troponin levels using the ULN and not Upper limit of undeterminate/indecisive as the reference value. Thus, if 2 cut points are given, choose the lower cut point for the ULN.
- \*\*\* For procedure related MI – also code 5.3.1 or 5.3.2 with these definitions: 3X ULN (99th percentile) for PCI and 5X ULN (99th percentile) and Q-Wave, new LBBB or evidence for graft closure found for CABG.

Figure 8.4 (continued)

WHI

Form 121 - Report of Cardiovascular Outcome

Ver. 10

AS355 COSMOS only	
Table 3 Universal Classification of Myocardial Infarction	
<b>Type 1: Spontaneous myocardial infarction</b>	
	Spontaneous myocardial infarction related to atherosclerotic plaque rupture, ulceration, fissuring, erosion, or dissection with resulting intraluminal thrombus in one or more of the coronary arteries leading to decreased myocardial blood flow or distal platelet emboli with ensuing myocyte necrosis. The patient may have underlying severe CAD but on occasion non-obstructive or no CAD.
<b>Type 2: Myocardial infarction secondary to an ischaemic imbalance</b>	
	In instances of myocardial injury with necrosis where a condition other than CAD contributes to an imbalance between myocardial oxygen supply and/or demand, e.g., coronary endothelial dysfunction, coronary artery spasm, coronary embolism, tachy-/brady-arrhythmias, anemia, respiratory failure, hypotension, and hypertension with or without LVH.
<b>Type 3: Myocardial infarction resulting in death when biomarker values are unavailable</b>	
	Cardiac death with symptoms suggestive of myocardial ischemia and presumed new ischemic ECG changes or new LBBB, but death occurring before blood samples could be obtained, before cardiac biomarker could rise, or in rare cases cardiac biomarkers were not collected.
<b>Type 4a: Myocardial infarction related to percutaneous coronary intervention (PCI)</b>	
	Myocardial infarction associated with PCI is arbitrarily defined by elevation of cTn values >5 x 99th percentile URL in patients with normal baseline values (≥ 99th percentile URL) or a rise of cTn values >20% if the baseline values are elevated and are stable or falling. In addition, either (i) symptoms suggestive of myocardial
<b>Type 4b: Myocardial infarction related to stent thrombosis</b>	
	Myocardial infarction associated with stent thrombosis is detected by coronary angiography or autopsy in the setting of myocardial ischemia and with a rise and/or fall of cardiac biomarkers values with at least one value above the 99th percentile URL.
<b>Type 5: Myocardial infarction related to coronary artery bypass grafting (CABG)</b>	
	Myocardial infarction associated with CABG is arbitrarily defined by elevation of cardiac biomarker values >10 x 99th percentile URL in patients with normal baseline cTn values (≥ 99th percentile URL). In addition, either (i) new pathological Q waves or new LBBB, or (ii) angiographic documented new graft or new native coronary artery occlusion, or (iii) imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.

### 8.8.6 *Form 132 – Report of Stroke Outcomes*

This form must be completed to confirm a stroke or hospitalized carotid artery disease.

#### Qx. 1 – Stroke

Stroke is defined as the rapid onset of a persistent neurologic deficit attributed to an obstruction or rupture of the brain arterial system (including stroke occurring during or resulting from a procedure). The deficit is not known to be secondary to brain trauma, tumor, infection, or other cause. The deficit must last more than 24 hours unless death supervenes or there is a demonstrable lesion compatible with an acute stroke on CT, CT perfusion, MRI, or other future validated imaging modalities. A stroke is defined as procedure-related if it occurs within 24 hours after any procedure or within 30 days after a cardioversion or invasive cardiovascular procedure (e.g., any surgical intervention, heart catheterization, open heart surgery, PFO closure, pace maker insertion).

The diagnosis of stroke will be made by the Stroke Adjudicators based on medical records documentation demonstrating that a stroke has occurred. WHI ES strokes will include those occurring during surgery or procedures, those aborted by thrombolytic therapy\* (streptokinase, TPA, etc.), and those occurring in the outpatient setting. Central retinal artery infarction is also classified as a stroke.

*\*Note:* If TPA is given and ultimately TIA and stroke are ruled out and another cause is confirmed (e.g., seizure), do not code to stroke just because TPA was administered.

The definition of a stroke **excludes**:

- Headache alone and no demonstrated blood by lumbar puncture, CT, or MRI scan.
- Bell's palsy or labyrinthine disease.
- Metabolic problems (such as diabetic, uremic, or hepatic coma) as a cause of altered consciousness.
- Brain tumor as found or diagnosed by hospital course, CT or MRI scan, angiography, biopsy, or autopsy.
- Trauma as diagnosed by history, CT or MRI scan, or angiography.
- Infection (encephalitis, abscess) as diagnosed by CT or MRI scan, lumbar puncture, or absence of fever.
- Old stroke by CT or MRI scan. This is usually diagnosed if the location of the infarct is inappropriate to explain the findings or when there is nearby focal ventricular enlargement. Recent infarcts often have edema or show distortion of the brain, are enhanceable, or show progression between serial CT or MRI scans.
- Seizures with status and post-ictal paralysis (Todd's) ruled out by history or observation **and** history of past seizures. Sometimes when a stroke causes seizure, CT or MRI scan or angiogram can confirm the stroke.
- All venous infarcts
- All epidural hematomas including those documented as non-traumatic.
- All subdural hematomas, including those documented as non-traumatic
- All traumatic subarachnoid hemorrhages
- Hysteria, which can usually be differentiated by inconsistencies on examination and evidence of secondary gain.
- Arterial stenosis or dissection without corresponding neurological symptoms, non-ruptured aneurysms with mass effect (e.g., cranial nerve palsy).

#### Qx. 1.1 – Date of admission or diagnosis

The **admission date** to the acute care hospital or **date of visit** to an outpatient facility.

#### Qx. 1.2 – Diagnosis

Stroke outcomes will be divided into 3 subtypes: **Hemorrhagic**, **Ischemic**, and **Other**. Mark the one category that corresponds best to the Stroke Adjudicator's final diagnosis.

**Stroke terminology and definitions**

**Rapid onset:** Symptoms arising within minutes to hours and occasionally days. Symptoms that progress for more than 1 week are less likely to be associated with stroke.

**Mottling:** High density (blood) within a low density infarction.

**Bloody Cerebral Spinal Fluid (CSF):** A non-traumatic lumbar puncture positive for subarachnoid hemorrhage with  $> 100$  cells/mm<sup>3</sup>. Counts in the last tube are similar to those in the first tube (no clearing) or xanthochromia is present when the specimen is spun down.

**Focal neurologic deficit:** Signs/symptoms localized to one or a few locations.

**Compatible with:** Can explain the neurologic deficit.

**Hemorrhagic stroke** (codes 1-3)

Hemorrhagic stroke is categorized into the following three categories:

- Subarachnoid hemorrhage (SAH) (code 1)
- Intraparenchymal hemorrhage (IPH) (code 2)
- Other or unspecified hemorrhage intracranial (e.g., isolated intraventricular hemorrhage) (code 3)

**Note:** If both SAH and IPH are in the differential diagnosis, use clinical judgment to determine the best category option.

A diagnosis of hemorrhagic stroke requires one of the following criteria:

- Blood in subarachnoid space or intraparenchymal hemorrhage by CT or MRI scan. (Intraparenchymal blood must be dense and not mottled--mixed hyperdensity and hypodensity.)
- **Or** bloody spinal fluid by lumbar puncture plus neurologic signs and symptoms consistent with stroke.
- **Or** death from stroke within 24 hours of symptom onset **and** no lumbar puncture, CT or MRI scan, or autopsy is available. (Death within 24 hours of onset of stroke is nearly always due to hemorrhage.)
- **Or** surgical or autopsy evidence of hemorrhage as the cause of a clinical syndrome consistent with a stroke.

**Ischemic stroke** (code 4): Occlusion of cerebral or pre-cerebral arteries with infarction (cerebral thrombosis, cerebral embolism, lacunar infarction)

A diagnosis of stroke due to ischemic infarction requires one of the following criteria:

- Focal neurologic deficit as shown by CT scan, MRI scan, CT perfusion, or future validated imaging modalities.
- **Or** CT or MRI scan with mottled cerebral pattern or showing decreased density in a location compatible with reported symptoms and signs.
- **Or** Surgical or autopsy evidence of ischemic infarction (cerebral thrombosis or cerebral embolism).

**Note:** Anterior spinal cord infarcts (extremely rare) are coded to ischemic strokes (JL)

**Other** (code 5): Acute, but ill-defined, cerebrovascular disease (select this option only if unable to code as hemorrhagic or ischemic)

- Inadequate information to categorize as hemorrhagic or ischemic infarction, but satisfies criteria for stroke.

**Qx. 1.3 – Stroke during or resulted from a procedure**

Stroke occurred or resulted from a procedure within 24 hours after any procedure or within 30 days after a cardioversion or invasive cardiovascular/cerebrovascular procedure. Mark one response.

**Qx. 1.4 – Diagnosed or managed as outpatient**

The outpatient setting includes any emergency department or observation unit admission, short stays of less than 24 hours duration, or a direct admission to a rehab facility without an associated admission to an acute care hospital.

**Qx. 1.5 – Oxfordshire classification**

Oxfordshire Classification is based on clinical symptomatology, not on vascular distribution/imaging.

<b>Total anterior circulation infarct (TACI): (code 1) Must have all 3 components</b>	
<b>Clinical Features:</b>	
1) Combination of higher cerebral dysfunction	<ul style="list-style-type: none"> <li>• Aphasia</li> <li>• Dyscalculia</li> <li>• Visuospatial dysfunction</li> <li>• Neglect</li> </ul>
2) Visual defect	<ul style="list-style-type: none"> <li>• Homonymous hemianopsia</li> </ul>
3) Motor or sensory deficit	<ul style="list-style-type: none"> <li>• Ipsilateral motor deficit (at least 2 areas involved, face, arm, leg)</li> <li>• Ipsilateral sensory deficit (at least 2 areas involved, face, arm, leg)</li> </ul>
<b>Partial anterior circulation infarct (PACI): (code 2) Must meet one of the following 3 criteria (1-3) in a participant with no drowsiness, or 4 or 5.</b>	
<b>Clinical Features:</b> 2 of 3 criteria of total anterior circulation infarction (TACI)	
1) New higher cerebral dysfunction	<ul style="list-style-type: none"> <li>• Dysphasia</li> <li>• Dyscalculia</li> <li>• Visuospatial dysfunction</li> <li>• Neglect</li> </ul>
2) Visual defect	<ul style="list-style-type: none"> <li>• Homonymous hemianopsia</li> </ul>
3) Motor and/or sensory deficit	<ul style="list-style-type: none"> <li>• Ipsilateral motor deficit</li> <li>• Ipsilateral sensory deficit</li> </ul>
<i>or</i> 4) Higher cerebral dysfunction alone (e.g., dysphasia)	
<i>or</i> 5) Motor/sensory deficit more restricted than those classified as Lacunar Syndrome (LACI), e.g., confined to one limb	
<b>Lacunar infarction (LACI): (code 3) Must have all 3 components.</b>	
<b>Clinical Features:</b>	
1) Lacunar syndrome - Any of the following:	<ul style="list-style-type: none"> <li>• Pure motor stroke (2 of 3 areas must be involved, face, arm, leg)</li> <li>• Pure sensory stroke (2 of 3 areas must be involved, face, arm, leg)</li> <li>• Sensory-motor stroke (2 of 3 areas must be involved, face, arm, leg)</li> <li>• Ataxic hemiparesis</li> </ul>
2) Absence of cortical deficit	
3) Absence of brainstem signs	

**Posterior circulation infarct (POCI): (code 4)** Any of the following:

**Clinical Features:**

- Ipsilateral cranial nerve deficit and contralateral motor deficit
- Ipsilateral cranial nerve deficit and contralateral sensory deficit
- Bilateral motor deficit
- Bilateral sensory deficit
- Disorder of conjugate eye movement
- Cerebellar dysfunction
- Isolated homonymous visual defect

**Notes:** Code a comatose patient to TACI (JL)  
Central retinal artery occlusion is coded to PACI (JL)

**Qx. 1.6 – TOAST classification**

Mark the one category that applies best (from: Trial of Org 10172 in Acute Stroke Treatment (TOAST) classification).

**Probable vs. possible categories**

- A “probable” diagnosis is made if the clinical findings, neuroimaging data, and results of diagnostic studies are consistent with one subtype and other etiologies have been excluded.
- A “possible” diagnosis is made when the clinical findings and neuroimaging data suggest a specific subtype but other studies are not done.

**Large artery atherosclerosis (embolus/thrombosis) – Codes 1 and 5**

Mark if any of the following are reported:

- Carotid lesions (extracranial) greater than or equal to 50% stenosis and ipsilateral to the lesion
- Vertebral lesions (extracranial) are relevant only in cases of brain stem infarction
- Ischemic stroke with infarction referable to greater than or equal to 50% stenosis in any of the following vessels: intracranial ICA, M1, A1, P1, intracranial vertebral arteries, and basilar artery

**Note:** Large artery atherosclerosis is restricted to the above vessels only. Both intracranial and extracranial large artery atherosclerosis can be chosen as options on *Form 132 – Report of Stroke Outcome* when there are tandem lesions.

**Cardioembolism (high-risk/medium risk) – Codes 2 and 6**

Mark if any of the following are reported:

- Mechanical prosthetic heart valve
- Atrial fibrillation
- Sick-sinus syndrome
- Myocardial infarction (MI) within 4 weeks: as stated
- Dilated cardiomyopathy: as stated per history
- Atrial myxoma: as described by studies prior to admission (usually echocardiogram)
- Infective endocarditis
- Akinetic left ventricular segment
- Left ventricular thrombus: Score this item if at any time in the patient’s history they were found to have a thrombus in the left ventricle. Score even if the patient has completed their recommended course of anticoagulation or if currently taking anticoagulants. Score even if echocardiogram on current admission fails to find thrombus.
- MI > 4 weeks ago but < 6 months ago: as documented in the medical record or by prior WHI adjudication
- Congestive heart failure: Score if recorded in patient’s history at any time. Score regardless of patient’s current medication regimen or echocardiographic findings on present admission. An



- ejection fraction of  $\leq$  35% should be considered a low enough level to be classified HF for cardioembolic risk when there is no mention of clinical heart failure. (OAC, Oct. 2011)
- Left ventricular aneurysm: as recorded in history
- Atrial flutter: Score if this rhythm recorded at any time. Score even if the patient is being treated with anticoagulation (e.g., coumadin), antiarrhythmics (e.g., digoxin, calcium channel blockers, beta-blockers), has a pacemaker, or has been successfully undergone cardioversion in the past.
- Bioprosthetic heart valve: Score as recorded in patient's history.
- Mitral stenosis without atrial fibrillation: as recorded in history and/or current echocardiogram
- Mitral valve prolapse: as recorded in history and/or current echocardiogram
- Mitral annular calcification: as recorded in history and/or current echocardiogram
- Atrial septal defect: as recorded in history. Do NOT record if patient has undergone surgical closure of defect.
- Patent foramen ovale: as recorded in history or prior/current echocardiogram. Do NOT record if patient has undergone surgical closure of defect.
- Interatrial septal aneurysm: as recorded in history or prior echocardiograms
- Nonbacterial endocarditis: as recorded in history. This would include marantic or Libman-Sacks endocarditis.

**Note:** Lambl's excrescences is not considered high/medium risk cardioembolic stroke.

**Note:** The WHI Steering Committee reviewed and declined the request to remove mitral valve prolapse (MVP) and mitral annular calcification (MAC) from the above list at this point in the Extension. Instead, *Form 132 – Report of Stroke Outcome* has an additional follow-up question asking if the only reason for coding to cardioembolic was based on either MVP or MAC (Steering Committee, Sept. 30, 2011).

### **Small vessel occlusion (lacune) – Codes 3 and 7**

Mark if any of the following are reported with an appropriate imaging correlate and comparable in size to a lacune infarct.

- Pure motor (hemiparesis/hemiplegia): New onset weakness of the face, arm and leg. All should be involved on the same side of the body, usually but not always to the same degree. Dysarthria is frequently present. Sensory findings and poor coordination inappropriate for muscle weakness should not be present.
- Pure Sensory: New onset sensory findings occurring on one side of the body, involving at least two of our three body areas (face, arm, leg). Objective findings of sensory loss are not required--sensory symptoms (e.g., numbness) in the above noted distributions qualify. Motor and cerebellar findings should be absent.
- Mixed sensorimotor: Motor and sensory findings simultaneously located in at least 2 out of 3 body areas (face, arm and leg). Tongue deviation and dysarthria may be present.
- Ataxic Hemiparesis: Ipsilateral cerebellar ataxia and hemiparesis. Gait ataxia may be present, and the presence or absence of sensory findings on the same side of the body is variable. The face need not be involved, and arm and leg may be weak to varying extents.
- Dysarthria-Clumsy hand: Severe dysarthria, clumsy ataxic hand (especially on writing); facial weakness; tongue deviation may or may not be present, as may ipsilateral hyper-reflexia and Babinski sign.

**Note:** Unlike clinical practice, a lacunar mechanism diagnosis is not a diagnosis of exclusion. If there is a lacunar syndrome and appropriate imaging correlate with AF then the coding should state 2 or more causes identified (code 11).

**Stroke of other determined etiology – Codes 4 and 10**

Mark if any of the following are reported:

Activated protein C resistance (e.g. Factor V Leiden)	Fabry's Disease	Paroxysmal nocturnal hemoglobinuria
Amyloid angiopathy	Fibromuscular dysplasia	Platelet hyperaggregability
Anticardiolipin antibody	Granulomatous angiitis of the CNS	Polyarteritis nodosa
Aortic arch atheroma	Hematologic	Polycythemia rubra vera
Arterial dissection	Hemoglobin SC disease	Post-irradiation vasculopathy
Behcet's syndrome	Herpes encephalitis	Pseudoxanthoma elasticum
CADASIL	HIV	Relapsing polychondritis
Cardiac procedure (post operative)	Homocysteinemia	Rickettsioses (e.g., Rocky Mountain Spotted Fever)
Churg-Strauss syndrome	Lupus anticoagulant	Schistosomiasis
Coagulation factor deficiencies: Antithrombin III, protein C, protein S, plasminogen, factor VIII (hemophilia), factor XII, C2, Prekallikrein, heparin cofactor II)	Malaria	Scleroderma
Congenital connective tissue disorders	Marfan's syndrome	Severe Anemia
Cryoglobulinemia	MELAS	Sickle cell disease
Degos-Kohlmeier Disease	Moya moya	Sjogren's syndrome
Disseminated intravascular coagulation	Mucormycoses	Sneddon's syndrome
Dolichoectasia	Mycoses	Systemic lupus erythematosus
Drug induced (amphetamine, cocaine, heroin, LSD, PCP, ecstasy)	Myeloproliferative disorders	Takayasu's disease
Drug induced vasculitis	Neoplastic angioendotheliosis	Thalassemias
Eale's disease	Neuroborreliosis (Lyme disease)	Thrombotic thrombocytopenic purpura (TTP)
Ehler's-Danlos syndrome	Neurobrucellosis	Trichinosis
Essential thrombocythemia	Neurosarcoidosis	Typhus
	Neurosyphilis	Vasospasm
	Neurotuberculosis	Vitamin K therapy
	Oral contraceptive induced hypercoagulability	Waldenstrom's macroglobulinemia
	Osler Weber Rendu Syndrome	Wegener's granulomatosis
	Other non-inflammatory vasculopathies	
	Paraneoplastic syndrome	

**Stroke of undetermined etiology**

- Two or more causes identified (Code 11)
- Negative evaluation (Code 12)
- Incomplete evaluation (Code 13)

**Note:** Incomplete evaluation (code 13) should be used only if we cannot get a “possible” mechanism diagnosis. For example, if patient has AF but carotid studies were not done, then it would be possible cardioembolism and not incomplete mechanism. Negative evaluation is used if the required tests were done (as stated below) and no mechanism was found.

To be a complete evaluation, the following 3 areas must be evaluated.

- 1) Neuroimaging
  - CT scan
  - MRI scan
- 2) Carotid and intracranial vessel evaluation (any of the following) [a complete evaluation of the relevant arterial distribution, e.g., carotid, vertebral, basilar system]
  - Carotid Dopplers
  - CTA
  - MRA
  - Cerebral angiography
- 3) Cardiac evaluation
  - Transthoracic Echocardiogram
  - Transesophageal Echocardiogram

**Note:** A carotid study done within 12 months can be used to answer Qx 1.6 if there was no carotid study done during the current admission.

An echocardiogram may be used for adjudication of TOAST classification if performed within the period of 2 weeks before or 2 weeks after the index stroke. Echocardiograms performed beyond those time windows should be referred to the Stroke Committee for review.

### Qx. 1.7 – Stroke diagnosis based on

Mark the one category that applies best

- Rapid onset of neurological deficit and imaging shows acute focal brain lesion consistent with neurological deficit and without evidence of blood (except mottled cerebral pattern) (code 1)
- Rapid onset of localizing neurological deficit with duration  $\geq$  24 hours but imaging studies are not available (code 2)
- Rapid onset of neurological deficit with duration  $\geq$  24 hours and the only available imaging was done early and shows no acute lesion consistent with the neurologic deficit (code 3)
- Surgical evidence of ischemic infarction of brain (code 4)
- Imaging findings of blood in subarachnoid space, intra-parenchymal, or intraventricular hemorrhage consistent with neurological signs or symptoms (code 5)
- Surgical evidence of subarachnoid or intra-parenchymal hemorrhage as the cause of a clinical syndrome consistent with stroke (code 7)
- None of the above (e.g., fatal strokes where no imaging studies or clinical evidence are available; or imaging does not show lesion consistent with the neurologic deficit; Retinal artery stroke based on retinal imaging alone (code 8)

**Note:** A negative DWI stroke is counted as a stroke if it meets WHI stroke definition. It is estimated that 10-20% strokes are DWI negative in the first 24 hours of small brain stem infarcts.

### Qx. 1.8 – If stroke fatal

Mark all that apply. Complete *Form 124 – Report of Death (Final)*. Indicate on the IDS Report that the death needs to be adjudicated by the CVD Adjudicator.

- Hospitalized stroke within 28 days of death (code 1) [Participant may also be considered “hospitalized” if admitted to the Emergency Department and dies of a stroke, regardless of discharge to hospice or inpatient admit.]
- Previous stroke and no known potentially lethal non-cerebrovascular disease process (code 2)
- Stroke diagnosed as COD at post-mortem examination (code 3)
- Stroke listed as underlying COD on death certificate (code 4)

Occasionally, the death certificate is the only available document. In this case, code the underlying cause as mentioned on the death certificate. If the cause of death is incorrectly ordered on the death certificate, the PA may code according to what he/she thinks should be the sequence of events leading to death. In instances where this is the only documentation available it should be considered the most accurate determination of the COD.

- It is possible to code Box 1 – Hospitalized stroke with 28 days of death without checking Box 4 – Stroke listed as the underlying COD [e.g., the immediate or a contributory COD].
- Box 4 – Stroke listed as the underlying COD on the death certificate is not required to be checked in order to mark *Qx. 1.9 – Functional Status*, Box 5 – Dead.

### Qx. 1.9 – Participant’s functional status at time of discharge (Glasgow Outcome Scale)

Mark the one category that applies best. Complete the Glasgow Outcome Scale at the time of discharge from the medical service, using only current medical records documentation provided in the case packet. The participant may be discharged from the Emergency Department, hospital, or physician’s office. Do not request additional medical records to determine the Glasgow Outcomes Scale. If, based on currently available medical records, you are unable to categorize the participant, mark Box 6 – “Unable to

categorize participant based on available case packet documentation.” (For limited use only when adjudicator is unable to otherwise categorize.)

- Good recovery – Participant can lead a full and independent life with or without minimal neurological deficit. Participant should have a normal neurological examination or a single neurological deficit (code 1)
- Moderately disabled – Participant has neurological or intellectual impairment but is independent. Participant has neurological deficit but does not rely on others for activities of daily living (code 2) [If participant enters acute rehab but particular information exists that clearly states the participant’s functional ability at the time of discharge is consistent with independent function, the adjudicator may choose Code 2 – Moderately Disabled.]
- Severely disabled – Participant conscious but dependent on others to get through daily activities (code 3) [For participants entering acute rehab, use code 3 when there are A) clearly stated functional deficits or B) when the medical record does not provide clear or enough information to determine deficits. **Note:** For participants discharged to a skilled nursing facility, the minimum coding would be a Code 3 – Severely Disabled.]
- Vegetative survival – Participant has no obvious cortical functioning. Participant may have eye opening, reactive pupils, limb movement, decorticate or decerebrate posturing, and semi-purposeful movements, but there is no purposeful avoidance of/withdrawal from painful stimuli (code 4)
- Dead (code 5)  
**Note:** Do not code to deceased if presumed to have died but no records available that confirm this status.
- Unable to categorize stroke based on available case packet documentation (for limited use only when adjudicator is unable to categorize above) (code 6)

#### Qx. 2 – Transient ischemic attack (TIA)

Transient ischemic attack is defined as the rapid onset of a neurologic deficit attributed to an embolus or an obstruction of the arterial system that is not known to be secondary to brain trauma, tumor, infection, or other cause. In the WHI ES, TIA is only collected by self-report on *Form 33* (i.e., the report of TIA does not require procurement of medical records). However, in instances where the self-report of stroke is denied by the CCC Stroke Adjudicator and determined to be a TIA based on the criteria below, a *Form 132 – Report of Stroke Outcome* is completed.

Yes/No. Mark the appropriate box and complete Question 2.1 if the participant has evidence of TIA. Mark “Yes” for a report of an acute neurologic event that does not satisfy the definition of a stroke but satisfies the definition given for a TIA.

- A participant has a diagnosis of TIA if she has one or more episodes of a focal neurologic deficit lasting more than 30 seconds and no longer than 24 hours in the absence of head trauma immediately preceding the onset. There must have been rapid evolution of the symptoms to the maximal deficit in less than 5 minutes with complete resolution within 24 hours. There should be no evidence of clonic jerking, conjugate eye deviation, prolonged Jacksonian march, scintillating scotoma, or headache with nausea and vomiting. Conditions to be ruled out include seizures, hypoglycemia, migraine, drug intoxication, tumor, infection, orthostatic hypotension, and generalized cerebral ischemia. Discovery of an infarct by CT or MRI scan in a location compatible with the symptoms, even if the symptoms cleared in less than 24 hours, shall be diagnosed as a stroke, not a TIA.

**Note:** Amaurosis fugax is considered a TIA.

Disorders not typically considered TIA:

- |                              |   |
|------------------------------|---|
| • March of a sensory deficit | • Confusion alone   |
| • Vertigo alone              | • Amnesia alone   |
| • Dizziness alone            | • Drop attacks alone  |
| • Dysphagia alone            | • Unconscious without other signs of posterior circulation symptoms |
| • Dysarthria alone           | • Tonic or clonic activity  |
| • Diplopia alone             |   |

- Incontinence of bowel or bladder
- Loss of vision associated with alteration of level of consciousness
- Focal symptoms associated with migraine
- Transient global amnesia
- Prolonged march of symptoms over several areas of the body
- Scintillating scotoma

There must be clear and convincing evidence to diagnose TIA in individuals with these symptoms, otherwise individuals with these symptoms should be classified not TIA. (Reference: Classification of cerebrovascular diseases III. Stroke 21: 637-676, 1990.)

#### **Qx. 2.1 – Date of admission or diagnosis**

The hospital admit date or date of diagnosis on the outpatient medical records.

#### **Qx. 3 – Carotid artery disease requiring hospitalization**

Yes/No. Mark the appropriate box and complete Question 3.1 to 3.3 to confirm the carotid artery disease. Note the participant must be hospitalized (and symptomatic or requiring intervention).

Confirmation of carotid artery disease is limited to carotid arteries only and does not include the larger arteries, e.g., brachio-cephalic or innominate arteries.

#### **Qx. 3.1 – Date of admission**

The admit date on the medical records.

#### **Qx. 3.2 – Diagnosis**

Mark the one box that corresponds best to the PA's final diagnosis.

- Carotid artery occlusion and stenosis without documentation of cerebral infarction (code 1)
- Carotid artery occlusion and stenosis with written documentation of cerebral infarction (code 2)

#### **Qx. 3.3 – Carotid artery disease based on**

Mark all that apply. Note the participant must be hospitalized (and symptomatic or requiring intervention).

- Symptomatic disease with carotid artery disease listed on the hospital discharge summary or documented in the medical records (code 1)
- Symptomatic disease with abnormal findings ( $\geq 50\%$  stenosis) on carotid angiogram, MRA, CTA. or doppler flow study (code 2)
- Vascular or surgical procedure to improve flow to the ipsilateral brain (code 3)

**Note:** For strokes that occur due to admission for Right CEA, they should be coded according to the evaluation. There should be a work-up for stroke, including echo, carotid imaging, and brain imaging. If this was complete then the stroke may be referable to the carotid which should be coded as LAA. But if the stroke is in a different vascular territory or lacunar syndrome, then this should be adjudicated accordingly.

Admission for right carotid endarterectomy for asymptomatic stenosis:

- 3.2 Carotid artery occlusion and/or stenosis without documentation of cerebral infarction
- 3.3 Vascular or surgical procedure to improve flow to the brain

Admission for right carotid endarterectomy for asymptomatic stenosis and post-operative stroke due to carotid artery:

- 3.2 Carotid artery occlusion and/or stenosis with written documentation of cerebral infarction
- 3.3 May include all 3

**Responsible Adjudicator Submission**

The PA should submit the form only when s/he is satisfied that the questions on the stroke outcomes being reported have been filled in as completely and accurately as possible on the basis of all available information, including documents from query requests.

**Figure 8.5  
Form 132 – Report of Stroke Outcome**

**WHI Form 132 - Report of Stroke Outcome Ver. 9**

<b>COMMENTS</b>	<b>-Affix label here-</b>
	Member ID: ____ - ____ - ____ - ____ - ____
<i>To be completed by Physician Adjudicator:</i> Date Completed: _____ (M/D/Y)	Central Case No.: _____
Adjudicator Code: _____	Case Copy No.: _____

**Yes**    **No**  
<sub>1</sub>    <sub>0</sub>

**1. Stroke:** Rapid onset of a persistent neurologic deficit attributable to an obstruction or rupture of the arterial system (including stroke occurring during **or resulting from** a procedure).\* Deficit is not known to be secondary to brain trauma, tumor, infection, or other cause. Deficit **must** last more than 24 hours, unless death supervenes or there is a demonstrable lesion compatible with acute stroke on CT or MRI scan.

\*A stroke is defined as procedure-related if it occurs within 24 hours after any procedure or within 30 days after a cardioversion or invasive cardiovascular procedure.

1.1. Date of Admission or diagnosis: \_\_\_\_\_ (M/D/Y)

1.2. Diagnosis: **(Mark the one category that applies best.)**

**Hemorrhagic Stroke**

- <sub>1</sub> Subarachnoid hemorrhage
- <sub>2</sub> Intraparenchymal hemorrhage
- <sub>3</sub> Other or unspecified intracranial hemorrhage (e.g., isolated intraventricular hemorrhage)

**Ischemic Stroke (If selected, complete questions 1.5 – Oxfordshire and 1.6 - TOAST Classification on the next page.)**

- <sub>4</sub> Occlusion of cerebral or pre-cerebral arteries with infarction (cerebral thrombosis, cerebral embolism, lacunar infarction)

**Other**

- <sub>5</sub> Acute, but ill-defined, cerebrovascular disease (select this option only if unable to code as hemorrhagic or ischemic)

1.3. Stroke occurred during or resulted from a procedure (defined above)\*. **(Mark one.)**

- <sub>0</sub> No
- <sub>1</sub> Yes
- <sub>9</sub> Unknown

1.4. Was the stroke diagnosed or managed as an outpatient?\*

- <sub>0</sub> No
- <sub>1</sub> Yes

\*The outpatient setting includes any emergency department or observation unit, short hospital stays of less than 24 hours duration or a direct admission to a rehab facility without an associated admission to an acute care hospital.

RV \_\_\_\_\_ K \_\_\_\_\_ V \_\_\_\_\_

Figure 8.5 (continued)

WHI

Form 132 - Report of Stroke Outcome

Ver. 9

1.5. Oxfordshire Classification **(Mark the one category that applies best.)**

- <sub>1</sub> Total anterior circulation infarct (TACI)
- <sub>2</sub> Partial anterior circulation infarct (PACI)
- <sub>3</sub> Lacunar infarction (LACI)
- <sub>4</sub> Posterior circulation infarct (POCI)

1.6. Trial of Org 10172 in Acute Stroke Treatment (TOAST) Classification **(Mark the one category that applies best.)**

**Large artery atherosclerosis follow-up question:**

**Mark all that apply.**

- Intracranial atherosclerosis
- Extracranial atherosclerosis

	Probable	Possible
Large artery atherosclerosis (embolus/thrombosis)	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>5</sub>
Cardioembolism (high-risk/medium risk)	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>6</sub>
Small vessel occlusion (lacune)	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>7</sub>
Stroke of other determined etiology	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>10</sub>
Stroke of undetermined etiology		
Two or more causes identified	<input type="checkbox"/> <sub>11</sub>	
Negative evaluation	<input type="checkbox"/> <sub>12</sub>	
Incomplete evaluation	<input type="checkbox"/> <sub>13</sub>	

**Cardioembolic follow-up question:**

Was the only reason for coding cardioembolic based on either mitral valve prolapse or mitral valve calcification?  
 Yes  No  (9/30/11 edit)

1.7. Stroke diagnosis based on: **(Mark the one category that applies best.)**

- <sub>1</sub> Rapid onset of neurological deficit and imaging shows acute focal brain lesion consistent with neurological deficit and without evidence of blood (except mottled cerebral pattern)
- <sub>2</sub> Rapid onset of localizing neurological deficit with duration ≥ 24 hours but imaging studies are not available
- <sub>3</sub> Rapid onset of neurological deficit with duration ≥ 24 hours and the only available imaging was done early and shows no acute lesion consistent with the neurologic deficit
- <sub>4</sub> Surgical evidence of ischemic infarction of brain
- <sub>5</sub> Imaging findings of blood in subarachnoid space, intra-parenchymal, or intraventricular hemorrhage consistent with neurological signs or symptoms
- <sub>7</sub> Surgical evidence of subarachnoid or intra-parenchymal hemorrhage as the cause of a clinical syndrome consistent with stroke
- <sub>8</sub> None of the above (e.g., fatal strokes where no imaging studies or clinical evidence are available; or imaging does not show lesion consistent with the neurologic deficit)



Figure 8.5 (continued)

WHI

Form 132 - Report of Stroke Outcome

Ver. 9

- 1.8. If stroke fatal: **(Mark all that apply.)**
- <sub>1</sub> Hospitalized stroke within 28 days of death
  - <sub>2</sub> Previous stroke and no known potentially lethal non-cerebrovascular disease process
  - <sub>3</sub> Stroke diagnosed as cause of death at post-mortem examination
  - <sub>4</sub> Stroke listed as underlying cause of death on death certificate
- 1.9 Participant's functional status at the time of discharge\* (Glasgow Outcome Scale):  
**(Mark the one category that applies best.)**  
 \*Participant may be discharged from the Emergency Department, hospital, or physician's office.
- <sub>1</sub> Good recovery – Patient can lead a full and independent life with or without minimal neurological deficit
  - <sub>2</sub> Moderately disabled – Patient has neurological or intellectual impairment but is independent
  - <sub>3</sub> Severely disabled – Patient conscious but dependent on others to get through daily activities
  - <sub>4</sub> Vegetative survival – Has no obvious cortical functioning
  - <sub>5</sub> Dead
  - <sub>6</sub> Unable to categorize stroke based on available case packet documentation (for limited use only when adjudicator is unable to categorize above).

Yes <sub>1</sub> No <sub>0</sub>

2. **Transient ischemic attack:** One or more episodes of a focal neurologic deficit lasting more than 30 seconds and no longer than 24 hours. Rapid evolution of the symptoms to the maximal deficit in less than 5 minutes, with subsequent complete resolution. No head trauma occurring immediately before the onset of the neurological event.

2.1. Date of Admission or diagnosis:  -  -  (M/D/Y)

Yes <sub>1</sub> No <sub>0</sub>

3. **Carotid artery disease requiring and/or occurring during hospitalization.** Disease must be **symptomatic and/or requiring intervention** (i.e., vascular or surgical procedure).

3.1. Date of Admission:  -  -  (M/D/Y)

3.2. Diagnosis: **(Mark one.)**

- <sub>1</sub> Carotid artery occlusion and stenosis without documentation of cerebral infarction
- <sub>2</sub> Carotid artery occlusion and stenosis with written documentation of cerebral infarction

3.3. **Carotid artery disease based on** (Hospitalization plus one or more of the following):  
**(Mark all that apply.)**

- <sub>1</sub> Symptomatic disease with carotid artery disease listed on the hospital discharge summary
- <sub>2</sub> Symptomatic disease with abnormal findings (≥ 50% stenosis) on carotid angiogram, MRA, CTA, or Doppler flow study
- <sub>3</sub> Vascular or surgical procedure to improve flow to the ipsilateral brain

\_\_\_\_\_  
 Responsible Adjudicator Signature

## 8.9 **Form 126 – Report of Venous Thromboembolic Disease**

Venous thromboembolic includes both 1) deep vein thrombosis, either hospitalized or managed as an outpatient and 2) pulmonary embolism requiring hospitalization. Both are adjudicated for MRC participants using *Form 126 – Report of Venous Thromboembolic Disease*. This outcomes was previously adjudicated in HT participants only but was expanded to MRC participants in the WHI 2010-2015 ES. This outcome is collected only as a self-report for SRC participants.

### **Qx. 1 – Deep vein thrombosis (DVT)**

The presence of thrombus within a deep vein and the accompanying inflammatory response in vessel wall is termed deep vein thrombosis. In the WHI 2010-2015 ES, only deep vein thrombosis of the lower extremity, pelvis, or IVC is of interest. Deep vein thrombosis in other locations such as the upper extremity is not adjudicated. DVT excludes superficial veins (e.g., the saphenous) even if clinically treated with anticoagulation therapy.

#### **Qx. 1.1 – Date of diagnosis/admission**

If hospitalized DVT, the admission date on the hospital medical records.  
If outpatient DVT, the date of the procedure or test that first diagnosed the DVT.

#### **Qx. 1.2 – Diagnosis**

Mark the one category that corresponds best to the PA's final diagnosis.

- DVT of lower extremities not resulting from a procedure within 60 days (code 1)
- DVT of lower extremities during or following a procedure within 60 days (code 2)

#### **Qx. 1.3 – Diagnosis of DVT based on**

Mark all that apply. The diagnosis of DVT can be made when the diagnosis is present in the discharge summary (code 1) **or any** of the following are recorded:

- Hospital discharge summary with a diagnosis of deep vein thrombosis (code 1)
- Positive findings on a venogram, defined as presence of a filling defect (code 2)
- Positive findings using impedance plethysmography, indicating a flow defect (code 3)
- Positive findings on doppler duplex examination, ultrasound, sonogram, or other non-invasive test examination, demonstrating a flow velocity disturbance (code 4)
- Positive findings on isotope scan (e.g., I<sup>125</sup> fibrinogen scan) (code 5)

#### **Qx. 1.4 – Diagnosis DVT reporting source**

Mark one. The categories are listed in hierarchical order - if more than one category applies, mark the first applicable category.

- Hospital inpatient (code 1)
- Hospital outpatient facility or clinic (code 2)
- Radiology or imaging facility (code 3)
- Physician's office/private medical practitioner (code 4)
- Nursing/convalescent home/hospice (code 5)
- Autopsy only (code 6)
- Death certificate only (code 7)
- Other (code 8)

#### **Qx. 1.5 – Work-up for PE performed**

Mark one: yes, no, unknown.

**Qx. 2 – Pulmonary embolism (PE) requiring hospitalization****Qx. 2.1 – Date of diagnosis/admission**

The admission date on the hospital medical records.

**Qx. 2.2 – Diagnosis**

Mark the one category that corresponds best to the PA's final diagnosis.

- PE not resulting from a procedure within 60 days (code 1)
- PE during or following a procedure within 60 days (code 2)

**Qx. 2.3 – Diagnosis based on**

Mark all that apply. Pulmonary embolism (PE) is defined as present if one of the following is present:

- Pulmonary embolism reported as a diagnosis in the discharge summary (code 1)
- Report of a positive findings on appropriate diagnostic studies, including:
  - a) Pulmonary ventilation/perfusion (V/Q) report describing a "high" probability of deficit. Moderate, intermediate, or low probability on a V/Q lung scan will not be considered confirmation of a PE (code 2)
  - b) Pulmonary angiography report or spiral CT describing either "cut off" of a vessel or "filling defect" (code 3)
- Diagnosis of deep vein thrombosis (DVT) based on  $\geq 1$  DVT criteria (see *Section 8.9 – Deep Vein Thrombosis*) plus signs and symptoms of PE (i.e., acute chest pain, dyspnea, tachypnea, hypoxemia, tachycardia, or chest X-ray findings suggestive of PE) (code 4)
- Other, including autopsy (code 8)

**Responsible Adjudicator Submission**

The PA should submit the form only when s/he is satisfied that the questions on the DVT and PE are being reported have been filled in as completely and accurately as possible on the basis of all available information, including documents from query requests.

**Figure 8.6**  
**Form 126 – Report of Venous Thromboembolic Disease**

**WHI**

**Form 126 - Report of Venous Thromboembolic Disease**

**Ver. 8.2**

<b>COMMENTS</b>	-Affix label here-
	Member ID: _____
<i>To be completed by Physician Adjudicator:</i>	
Date Completed: _____ (M/D/Y)	Central Case No.: _____
Adjudicator Code: _____	Case Copy No.: _____

Yes <sub>1</sub>    No <sub>0</sub>

1. **Deep vein thrombosis (DVT)**
  - 1.1 Date of Diagnosis/Admission: \_\_\_\_\_ (M/D/Y)
  - 1.2 Diagnosis: **(Mark the one category that applies best.)**
    - <sub>1</sub> Deep vein thrombosis of lower extremities **not resulting from a procedure** within 60 days
    - <sub>2</sub> Deep vein thrombosis of lower extremities **during or following a procedure** within 60 days
  - 1.3 Diagnosis of deep vein thrombosis is based on: **(Mark all that apply.)**
    - <sub>1</sub> Hospital discharge summary with a diagnosis of deep vein thrombosis
    - <sub>2</sub> Positive findings on a venogram
    - <sub>3</sub> Positive findings using impedance plethysmography
    - <sub>4</sub> Positive findings on doppler duplex, ultrasound, sonogram, or other non-invasive test examination
    - <sub>5</sub> Positive findings on isotope scan
  - 1.4 Diagnosis of deep vein thrombosis reporting source: **(Mark one. If more than one category applies, mark the first applicable category.)**
    - <sub>1</sub> Hospital inpatient
    - <sub>2</sub> Hospital outpatient facility or clinic
    - <sub>3</sub> Radiology or imaging facility
    - <sub>4</sub> Physician's office/private medical practitioner
    - <sub>5</sub> Nursing/convalescent home/hospice
    - <sub>6</sub> Autopsy only
    - <sub>7</sub> Death Certificate only
    - <sub>8</sub> Other
  - 1.5 Was a work up for pulmonary embolism performed?
    - <sub>1</sub> Yes    <sub>0</sub> No    <sub>8</sub> Unknown

RV \_\_\_\_\_ K \_\_\_\_\_ V \_\_\_\_\_

Figure 8.6 (continued)

WHI

Form 126 - Report of Venous Thromboembolic Disease

Ver. 8.2

Yes <sub>1</sub> No <sub>0</sub>

2. Pulmonary embolism (PE) requiring hospitalization:

2.1 Date of Diagnosis/Admission:  (M/D/Y)

2.2 Diagnosis: *(Mark the one category that applies best.)*

<sub>1</sub> Pulmonary embolism not resulting from a procedure within 60 days

<sub>2</sub> Pulmonary embolism during or following a procedure within 60 days

2.3 Diagnosis of pulmonary embolism is based on:

*(Mark all that apply.)*

<sub>1</sub> Hospital discharge summary with a diagnosis of pulmonary embolism

<sub>2</sub> High probability on ventilation-perfusion lung scan (exclude moderate, intermediate, or low probability on ventilation-perfusion lung scan)

<sub>3</sub> Positive findings on pulmonary angiogram or spiral CT

<sub>4</sub> Diagnosis of deep vein thrombosis (DVT) based on ≥1 DVT criteria in 1.3. plus signs and symptoms suggestive of PE (e.g., acute chest pain, dyspnea, tachypnea, hypoxemia, tachycardia, or chest X-ray findings suggestive of PE)

<sub>8</sub> Other, including autopsy

\_\_\_\_\_  
Responsible Adjudicator Signature

## 8.10 Fracture Outcomes Adjudication

Hip fractures are a primary outcome of the Calcium and Vitamin D (CaD) trial, and a secondary outcome of the Hormone Trial (HT) and Dietary Modification (DM) trials. In the WHI 2010-2015 ES, a self-report of hip fracture by a MRC participant is the only type of fracture requiring investigation and adjudication. All other fractures will be collected for both MRS and SRC participants by self-report on *Form 33 – Medical History Update*.

### 8.10.1 Fracture Definition

**Hip Fracture** is defined as a fracture of the proximal femur, including femoral neck, intertrochanteric region, greater trochanter, and other – not specified. See *Figure 8.8 – Fracture of Hip Views*.

**Other fractures collected only by self-report on *Form 33* include the following:**

- pelvis
- knee (patella or tibial plateau)
- lower leg (tibia and/or fibula) or ankle (very distal tibia/fibula and/or talus)
- foot (not toes)
- tailbone (sacrum and/or coccyx)
- spine or back (vertebra)
- lower arm or wrist (radius, ulna, and/or one or more carpal bones)
- hand (not finger) (one or more metacarpal bone[s])
- elbow (lower end of humerus, upper radius and/or ulna)
- upper arm or shoulder (humerus)
- collarbone; all clavicular and scapular fractures
- ribs
- chest/sternum/breast bone
- skull/face, including nose and jaw
- fingers
- toes

### 8.10.2 First vs. Subsequent Report of Hip Fractures

On June 24, 2015, the Outcomes Adjudication Committee (OAC) lifted the subsequent condition rule for Hip fracture; these events will be fully investigated and adjudicated. Adjudication of all hip fractures is to ensure the hip fracture is captured post randomization for two new ancillary study (AS)-intervention trials launching in 2015: AS355 - Randomized Trial of Cocoa Extract and Multivitamins for CVD and Cancer Prevention (COSMOS) and AS360 - Physical activity to improve cardiovascular health in women: A pragmatic trial (WHISH). Implementation of this revised procedure will result in little or no additional clinic or adjudicator work.

Prior to June 2015, the hip fracture subsequent condition rule was as follows: only the first occurrence of a hip fracture post randomization or enrollment was investigated and adjudicated. If a participant was hospitalized multiple times for one fracture site, only the first occurrence was adjudicated. If a subsequent hip fracture resulted in a hospital stay of two nights or more, the fracture would not be adjudicated (i.e., *Form 123 – Report of Fracture Outcome* would not be completed), but the hospitalization would have required completion of *Form 125 – Summary of Hospitalization Diagnosis*. A subsequent report of a hip fracture where the hospital stay was only one night was not investigated in the WHI 2010-2015 ES.

### 8.10.3 Identification of Fractures from Medical Records, Discovery

Occasionally, a hip fracture not reported by the MRC participant will be identified from medical records obtained while investigating other outcomes. When a hip fracture is identified in this manner, the PA should return the case and request investigation of the fracture. The OC should investigate the outcome and obtain the required supporting documentation.

## 8.10.4 Form 123 – Report of Fracture Outcome

### Qx. 1 – Confirmed hip fracture

Radiographically-confirmed fractures of the proximal femur, including fractures of the femoral neck, intertrochanteric region, greater trochanter, and hip fracture – site not specified. Fractures of the subtrochanteric region are not included as proximal femur fractures.

The report must meet the following criteria:

- One or more of the following phrases must appear in the report: “fracture,” “definite fracture,” “break,” “hairline fracture,” “stress fracture,” or “healing fracture.”
- **And** the confirmatory report does not contain any of the following phrases: “possible fracture,” “suspicious fracture,” “probable fracture,” “suspected fracture,” or similar language indicating the diagnosis of fracture is “**uncertain.**”

Situations where the Fracture Adjudicator needs to request more documents:

- a) If the preoperative X-ray report indicates a hip fracture, and the X-ray was not evaluated by a radiologist, or if the radiology report is missing, the Fracture Adjudicator may confirm the fracture by review of X-ray reports or other documentation such as the operative or other orthopedist reports.
- b) If the radiologist's report from a preoperative hip radiograph is negative or equivocal (“uncertain”) but the hospital discharge summary indicates a proximal femur fracture, then the Fracture Adjudicator needs to request a written radiologist's report of either a bone scan, MRI, or CT scan that unequivocally describes the presence of a new, acute, or healing fracture of a proximal femur before confirming the hip fracture.
- c) If the radiologist's report from a preoperative hip radiograph is equivocal (“uncertain”), or if the radiology report is missing, the Fracture Adjudicator needs to request a copy of the preoperative X-ray and/or other imaging studies, radiology reports, or clinical findings from the hospital record before confirming the hip fracture.

### Qx. 1.1 – Date of diagnosis

Date of hospital admission for radiology confirmation of the hip fracture or the date of radiologic confirmation if no hospitalization occurred.

### Qx. 1.2 – Fracture site

Base the fracture site for confirmed hip fractures on the information provided in the X-ray report. Refer to *Figure 8.8 – Fracture of Hip Views*.

- Neck of femur (transcervical, cervical) (code 1)
- Intertrochanteric fracture (code 2)
- Greater trochanter (code 3)
- Unspecified part of proximal femur (code4)
- In instances where fractures extend from one location to another (as defined on *Form 123 – Report of Fracture Outcome*), for example, an intertrochanteric/subtrochanteric fracture, the first location mentioned in the radiology report will be considered the primary fracture site.
- In instances where the usual documentation (hospital discharge summary, operative report and radiology report), do not agree on the fracture location, final determination will be based on radiology report. In the case of equivocal radiology report, the Fracture Adjudicator may review the available films to make a final determination or request the Fracture Committee review the case.

### Qx. 1.3 – Side of hip fracture

Mark one: Right, left, both sides, unknown.

**Qx. 1.4 – Hip fracture based on**

Criteria used for diagnosis. The items are arranged in hierarchical order from the strongest to the weakest evidence of hip fracture. Mark the one category that applies best.

- Written report of hip fracture by a radiologist based on a preoperative radiograph and documenting the presence of a new, acute, or healing fracture of the proximal femur (or one of its regions: the femoral neck or intertrochanteric region). Fracture confirmation may include a written report not by a radiologist and based on a review of a radiograph, if the Fracture Adjudicator deems it appropriate (code 1).
- Radiologist's report confirms a proximal femur fracture, but the hospital discharge summary does not (or is equivocal or missing). The X-ray report alone confirms a proximal femur fracture (code 2).
- All of the following (code 3):
  - 1) Hospital discharge summary listing fracture of the proximal femur, femoral neck fracture, intertrochanteric fracture, trochanteric fracture, or hip fracture; and
  - 2) An equivocal written radiology report of the hip (e.g., "possible," "probably," or "suspected" hip fracture); and
  - 3) a written radiologist's report of either a bone scan or MRI scan unequivocally stating that a new hip fracture or healing hip fracture is present
- Hip fracture diagnosed in discharge summary, or other written report, but no radiology report available or radiograph not read by radiologist. This includes a hospital discharge summary or face sheet listing fracture of the proximal femur, femoral neck, intertrochanteric region or hip (code 4).

**Qx. 1.5 – Pathologic hip fracture**

Pathologic hip fractures are adjudicated, though they will be excluded from the primary fracture endpoint.

Pathologic Hip Fractures: Those resulting from anatomic compromise due to bone tumors or cysts, Paget's disease, bone or joint prostheses, or surgical manipulation. Confirmation is obtained from the preoperative radiograph and/or the radiologic and operative reports or post-operatively from the pathology report.

- Mark "No" if the fracture occurred as a result of trauma sufficient to cause a fracture in normal healthy bone (e.g., a fall from a height or a motor vehicle accident) and no underlying bone abnormality was noted.
- Mark "Yes" if the fracture was associated with a documented underlying bone abnormality or anatomic compromise related to bone tumor, bone cyst, Paget's disease (of bone), cancer metastasis, bone or joint prostheses, occurred at a pre-existing hip replacement site, or surgical manipulation. When present, these conditions are usually evident on the preoperative radiograph, and are noted in the radiologic report and the operative report. For example, a typical radiologic report will note "fracture of proximal femur adjacent to lytic lesions consistent with tumor. Cannot rule out underlying metastatic lesions." For fractures due to bone tumors, confirmation is usually available from a pathology report. Read the radiologic, operative, and pathology reports carefully for indications of pathologic fracture. However, these will be rare (< 2% of hip fractures).
  1. Periprosthetic fractures will be the most common type of pathologic hip fracture.
  2. An osteoporotic fracture is not considered a pathologic fracture
- Mark "Possible" if the incident leading to the fracture does not seem sufficient to cause a fracture in normal healthy bone, but there is no unequivocal evidence of an underlying bone abnormality. Fractures of the proximal femur during or subsequent to hip replacement procedures are coded as pathologic hip fractures and the location coded as "Unspecified Part of the Proximal Femur".

**Responsible Adjudicator Submission**

The PA should submit the form only when s/he is satisfied that the questions on the fracture outcomes being reported have been filled in as completely and accurately as possible, including documents from query requests.



**Figure 8.7**  
**Form 123 - Report of Fracture Outcome**

**WHI** **Form 123 - Report of Fracture Outcome** **Ver. 8.2**

<b>COMMENTS</b>	-Affix label here-
<i>To be completed by Physician Adjudicator:</i>	Member ID: _____
Date Completed:     _____ (M/D/Y)	Central Case No.: _____
Adjudicator Code:    _____	Case Copy No.: _____

**Use a separate form for each fracture.**

Yes    No  
<sub>1</sub>    <sub>0</sub>

1. **Confirmed hip fracture:** Fracture of the proximal femur, including fractures of the femoral neck, intertrochanteric region, and greater trochanter
  - 1.1. Date of Diagnosis: \_\_\_\_\_ (M/D/Y)
  - 1.2. Fracture site: **(Mark the one that applies best.)**

<input type="checkbox"/> <sub>1</sub> Neck of femur (transcervical, cervical)	<input type="checkbox"/> <sub>3</sub> Greater trochanter
<input type="checkbox"/> <sub>2</sub> Intertrochanteric fracture	<input type="checkbox"/> <sub>4</sub> Unspecified part of proximal femur
  - 1.3. Side of hip fracture: **(Mark the one that applies best.)**

<input type="checkbox"/> <sub>1</sub> Right	<input type="checkbox"/> <sub>3</sub> Both sides
<input type="checkbox"/> <sub>2</sub> Left	<input type="checkbox"/> <sub>9</sub> Unknown
  - 1.4. Hip fracture based on: **(Mark the one category that applies best.)**

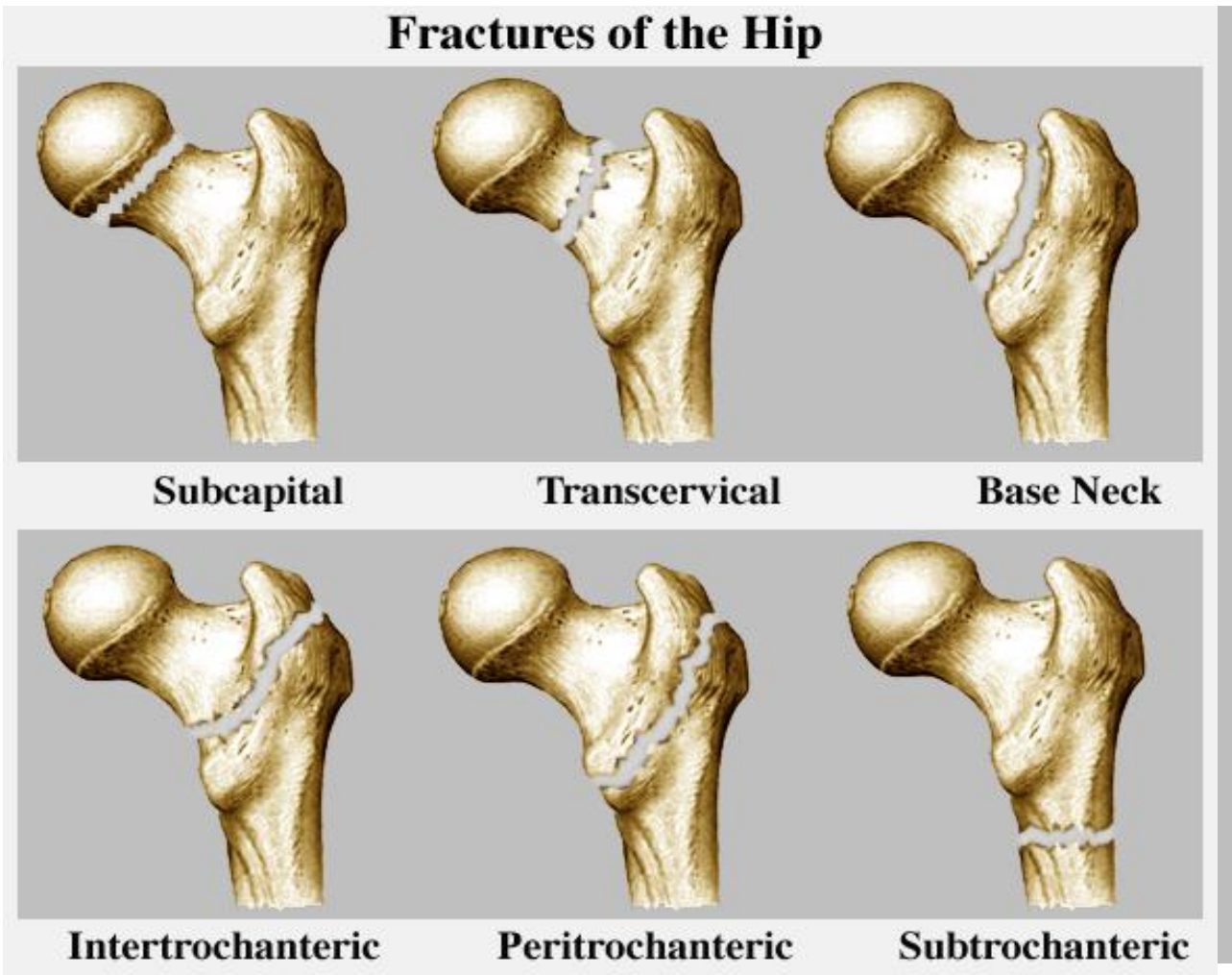
<input type="checkbox"/> <sub>1</sub> Written radiology report that is read by a radiologist and identifies the presence of a new, acute, or healing fracture of the proximal femur (femoral neck, intertrochanteric region, or the greater trochanter region) and documented on a discharge summary
<input type="checkbox"/> <sub>2</sub> Radiologist's report confirms a proximal femur fracture, but the hospital discharge summary does not (or is equivocal or missing)
<input type="checkbox"/> <sub>3</sub> <u>All of the following:</u> <ol style="list-style-type: none"> <li>1) hospital discharge summary listing fracture of the proximal femur, femoral neck fracture, intertrochanteric fracture, trochanteric fracture, or hip fracture;</li> <li>2) equivocal written radiology report of the hip (e.g., "possible" or "probably" or "suspected" hip fracture); <u>and,</u></li> <li>3) a written radiologist's report of either a bone scan, MRI, or CT scan unequivocally stating that a new hip fracture or healing hip fracture is present</li> </ol>
<input type="checkbox"/> <sub>4</sub> Hip fracture diagnosed in discharge summary, or other written report, but no radiology report available or radiograph not read by radiologist
  - 1.5. Pathologic hip fracture: fracture resulting from bone tumors or cysts, Paget's disease, bone or joint prostheses, or surgical manipulation. Osteoporotic fracture is not considered a pathologic fracture. **(Mark the one category that applies best.)**

<input type="checkbox"/> <sub>0</sub> No	<input type="checkbox"/> <sub>1</sub> Yes	<input type="checkbox"/> <sub>2</sub> Possible
--	---	--

\_\_\_\_\_  
Responsible Adjudicator Signature

RV \_\_\_\_\_ K \_\_\_\_\_ V \_\_\_\_\_

**Figure 8.8**  
**Fracture of Hip Views**



## 8.11 Form 130 – Report of Cancer Outcome

### Qx. 1 – Date of diagnosis

Date of diagnosis is a required field and must be completed. Record the date of the first tissue diagnosis for a new cancer. Generally, the first tissue diagnosis will be the initial biopsy of the cancer. If no tissue was obtained to make the diagnosis, use the date of the first cytology diagnosis. The first diagnosis of cancer may also be clinical, based on physical exam, scan or laboratory results, i.e., peripheral blood smear for leukemia.

#### Tips for Date of Diagnosis:

- Do not code '99 – Unknown' for day, month, or year of diagnosis. Currently, July is used as the default month and the 15th as the default day. If the year of diagnosis is unknown, use whatever information is available to calculate the month, day and year of diagnosis.

### Qx. 2 – Cancer site

Mark one primary cancer site in which the primary tumor originated, even if it extends into/onto an adjacent subsite. If a case has multiple cancer sites, complete a *Form 130 – Report of Cancer Outcome* for each cancer site.

The primary cancer site is the applicable organ or tissue site where the cancer originated. This question lists the 'Main WHI Cancer Outcomes' sites separate from the 'Other Cancer Outcomes' sites.

If the primary cancer site is not listed under *Qx. 2 - Other Cancer Outcomes* or is an unknown site, mark 'Box 00 - Other' and write or type the site or indicate 'unknown' in the space provided.

#### Tips for cancer site:

- For the 'Main Cancer Outcomes', breast only, complete the required questions, *Qx. 1-14*.
- For the other 'Main Cancer Outcomes' (ovary, corpus uteri/endometrium, colon, rectum/rectosigmoid junction), complete the required questions, *Qx. 1-10*.
- For the 'Other Cancer Outcomes', complete the required questions, *Qxs. 1-6*, to capture the fact of cancer and *Qxs. 1-10* if SEER coding.
- Do not code primary cancer site as the secondary or metastatic site of the cancer.
- If 'Box 00 - Other' is marked. A corresponding ICD-0-2 (International Classification of Diseases for Oncology, Second Edition) must be entered in *Qx. 3*.
- Code the last digit of the primary site code to '8' when a single tumor overlaps an adjacent subsite of an organ and the point of origin cannot be determined.
- Refer to *Appendix C – Coding Reference* for a list of site codes.

### Qx. 3 – ICD-0 code

A numeric ICD-0-2 code is recorded for the primary cancer site indicated in *Qx. 2* for the 'Main Cancer Outcomes', sites 'Other Cancer Outcomes', and those primary sites written or typed in the 'specify' field for 'Box 00 – Other'.

### Qx. 4 – Tumor behavior

Complete the tumor behavior for the cancer site checked in *Qx. 2*.

Select *only one* category to classify the behavior of the tumor.

- Invasive; malignant; infiltrating; micro-invasive (code 1)
- In-situ, intraepithelial; non-infiltrating; non-invasive; intraductal (code 2)
- Borderline malignancy; low malignant potential; uncertain whether benign or malignant; indeterminate malignancy (use code 3 only for ovary)
- Unknown (code 9)

**Qx. 5 – Reporting source**

This is a hierarchical field, lower numbers (e.g., code 1) take precedence over higher numbers. Select the first applicable category.

- Hospital inpatient (code 1)
- Hospital outpatient/radiation or chemotherapy facility, surgical center, or clinic (code 2)
- Laboratory only (hospital or private) including pathology office (code 3)
- Physician’s office/private medical practitioner (code 4)
- Nursing/convalescent home/hospice (code 5)
- Autopsy only (code 6)
- Death certificate only (code 7)

**Qx. 6 – Diagnostic confirmation status**

This item indicates the nature of the best evidence available on the diagnostic confirmation of the cancer. This is a hierarchical field, lower numbers (e.g., code 1) take precedence over higher numbers. Select the first applicable category under the 3 headings ‘(Microscopically Confirmed’, ‘Not Microscopically Confirmed’, ‘Confirmation Unknown’).

Microscopically Confirmed:

- Positive histology (pathology) (code 1)
- Positive exfoliative cytology, no positive histology (code 2)
- Positive histology (pathology), regional or distant metastatic site only (code 3)
- Positive microscopic confirmation, method not specified (code 4)

Not Microscopically Confirmed:

- Positive laboratory test/marker study (code 5)
- Direct visualization without microscopic confirmation (code 6)
- Radiography and other imaging techniques without microscopic confirmation (code 7)
- Clinical diagnosis only (other than 5, 6, or 7 above) (code 8)

Confirmation Unknown:

- Unknown if microscopically confirmed (code 9)

**Qx. 7 – Laterality**

Mark the one laterality on which the primary site originated.

- Not a paired site (code 0)
- Right: origin of primary (code 1)
- Left: origin of primary (code 2)
- Only one side involved, right or left origin unspecified (code 3)
- Bilateral involvement, lateral origin unknown: stated to be single primary (code 4)
- Paired site, but no information concerning laterality; midline tumor (code 5)

**Qx. 8 – Morphology (ICD-0)**

The morphology code is a 6-digit code that includes the 4 digits of a common root code for a particular cell type, the 5th digit indicating the behavior code, and the 6th digit indicating the grading and/or differentiation of the cancer. The morphology coding for this field is from the ICD-O-2

Example: A malignant poorly differentiated adenocarcinoma is coded as 814033:

- Root code: 8140 - adenocarcinoma
- Behavior code: 3 – malignant/invasive
- Grade: 3 - poorly differentiated

**Qx. 9 – Extent of disease (EOD)**

The EOD (extent of disease) is an estimate of the extent of disease based on all the evidence available during the first course of treatment (4 months from date of diagnosis or prior to the start of neoadjuvant treatment), in addition to the strictly clinical impression and any other evidence derived from the complete work-up of the participant. The coding for these EOD fields is site-specific.

The coding for EOD is broken into the following categories:

- Qx. 9.1 – size of primary tumor
- Qx. 9.2 – extension of tumor
- Qx. 9.3 – lymph node status
- Qx. 9.4 – number of regional nodes positive
- Qx. 9.5 – number of regional nodes examined

Tips for EOD:

- Each primary site has a site-specific coding scheme. Note the above coding scheme does not apply to hematologic or lymphatic cancer sites (all categories) or to melanoma or mycosis Fungoides of skin or vulva (Qx. 9.1 only).

**Qx. 10 – Summary stage**

The summary stage is the grouping of cases with similar prognoses into broad extent of disease categories, e.g., in-situ, localized, regional, distant, and unknown spread. The staging is done in accordance with the SEER site-specific summary staging schemes.

After the review of all evidence, mark the one appropriate stage of disease:

- In-situ (code 1)
- Localized (code 2)
- Regional (code 3)
- Distant (code 4)
- Unknown (code 9)

**Questions 11-14 are completed for breast cancer only.****Qx. 11 – Complete the subclassification for Breast Histology 8522**

Mark the one subclassification for the histology code 8522 – infiltrating duct and lobular carcinoma.

- Not applicable (code 0)
- Ductal in-situ plus lobular in-situ (code 1)
- Ductal invasive plus lobular in-situ (code 2)
- Ductal invasive plus lobular invasive (code 3)
- Ductal in-situ plus lobular invasive (code 4)
- Invasive cancer, ductal and lobular NOS (code 5)

**Qx. 12 – Estrogen receptor assay**

Mark the one category to indicate the result of the Estrogen Receptor Assay (ERA), if it was ordered but the results are not available, or if it is unknown if done or not done.

- Positive (code 1)
- Negative (code 2)
- Borderline (code 3)
- Ordered/Results not available (code 8)
- Unknown/Not done (code 9)

**Qx. 12.1 – Date**

Indicate the date the tissue was biopsied or excised (that was used for the ERA).

**Qx. 12.2 – Type of assay**

Mark the one category to indicate the type of ERA that was done.

- fmol/mg protein (code 1)
- ICC/IHC (code 2)
- Other, specify (code 8)
- Unknown (code 9)

**Qx. 13 – Progesterone receptor assay**

Mark the one category to indicate the result of the Progesterone Receptor Assay (PRA), if it was ordered but the results are not available, or if it is unknown if done or not done.

- Positive (code 1)
- Negative (code 2)
- Borderline (code 3)
- Ordered/Results not available (code 8)
- Unknown/Not done (code 9)

**Qx. 13.1 – Date**

Indicate the date the tissue was biopsied or excised (that was used for the PRA).

**Qx. 13.2 – Type of assay**

Mark the one category to indicate the type of PRA that was done.

- fmol/mg protein (code 1)
- ICC/IHC (code 2)
- Other, specify (code 8)
- Unknown (code 9)

**Qx. 14 – Her 2/Neu receptor**

Mark the one category to indicate the result of the Her 2/Neu, or that it was not done or unknown if done.

- Positive (code 1)
- Negative (code 2)
- Borderline (code 3)
- Ordered/Results not available (code 8)
- Unknown/Not done (code 9)

**Qx. 14.1 – Date**

Indicate the date the tissue was biopsied or excised (that was used for the Her 2/Neu).

**Tips for ERA/PRA/Her 2/Neu Assays:**

- If ER/PR/Her2 are done on both in situ and invasive components of the same primary, record the results from the invasive cancer.
- Record the results only on the primary tumor. If testing is done on a regional or metastatic site, code Qxs 12, 13, and 14 as “Unknown/Not Done”.
- A favorable result for ER/PR is positive and for Her2, it is negative. If results differ between the biopsy and surgical specimens, record the procedure date with the favorable results. For example, ER is positive, **PR is negative**, Her2 is negative on biopsy. At surgery, **PR is positive**. Record the date of biopsy for ER and Her2 and the date of surgery for PR.

- Additional testing (such as FISH/CISH/DISH) for a Her2 result for override the IHC test result since it provides a more specific result.
- If Qxs 12, 13, or 14 are coded as “Unknown/Not Done”, do not code 12.1, 12.2, 13.1, 13.2 or 14.1 respectively.

**Editor Code**

If there is an editor for the case, the second Cancer Adjudicator enters the assigned editor code.

Figure 8.9  
Form 130 – Report of Cancer Outcome

WHI Form 130 – Report of Cancer Outcome Ver. 9

<b>COMMENTS</b>	- Affix label here-
	Member ID: ____ - ____ - ____ # ____
<i>To be completed by CCC Cancer Coder:</i>	
Date Completed: [ ][ ]-[ ][ ]-[ ][ ] (MM/DD/YY)	Central Case No.: [ ][ ][ ][ ][ ][ ][ ][ ][ ]
Adjudicator Code: [ ][ ][ ][ ][ ][ ][ ][ ]	Case Copy No.: [ ][ ][ ]

Use a separate form for each new diagnosis.

- Date of Diagnosis: [ ][ ]-[ ][ ]-[ ][ ] (MM/DD/YY)
- Cancer site: *(Mark the one that applies best.)*

**Main Cancer Outcomes**

- <sub>50</sub> Breast
- <sub>56</sub> Ovary
- <sub>54</sub> Corpus uteri, endometrium
- <sub>18</sub> Colon (excludes appendix)
- <sub>20</sub> Rectum
- <sub>19</sub> Rectosigmoid junction

**Other Cancer Outcomes (listed alphabetically)**

- |   |   |  |
|---|---|--|
| <input type="checkbox"/> <sub>31</sub> Accessory sinuses  | <input type="checkbox"/> <sub>15</sub> Esophagus  | <input type="checkbox"/> <sub>06</sub> Oral (mouth) parts of [other/unspecified]                       |
| <input type="checkbox"/> <sub>74</sub> Adrenal gland  | <input type="checkbox"/> <sub>69</sub> Eye and adnexa   | <input type="checkbox"/> <sub>05</sub> Palate  |
| <input type="checkbox"/> <sub>21</sub> Anus and anal canal  | <input type="checkbox"/> <sub>23</sub> Gallbladder  | <input type="checkbox"/> <sub>25</sub> Pancreas  |
| <input type="checkbox"/> <sub>86</sub> * Appendix   | <input type="checkbox"/> <sub>57</sub> Genital organs, female [other/unspecified; excludes vagina, labia, and vulva]                      | <input type="checkbox"/> <sub>07</sub> Parotid gland (Stensen's duct)                                  |
| <input type="checkbox"/> <sub>24</sub> Biliary tract, parts of [other/unspecified]                      | <input type="checkbox"/> <sub>64</sub> Kidney (excludes renal pelvis)   | <input type="checkbox"/> <sub>47</sub> Peripheral nerves & autonomic nervous system                    |
| <input type="checkbox"/> <sub>67</sub> Bladder  | <input type="checkbox"/> <sub>32</sub> Larynx   | <input type="checkbox"/> <sub>12</sub> Pyriform sinus  |
| <input type="checkbox"/> <sub>40</sub> Bones, joints & articular cartilage of limbs                     | <input type="checkbox"/> <sub>42</sub> Leukemia [hematopoietic & reticuloendothelial systems [includes blood; excludes multiple myeloma]] | <input type="checkbox"/> <sub>39</sub> Respiratory system and intrathoracic organs [other/unspecified] |
| <input type="checkbox"/> <sub>41</sub> Bones, joints & articular cartilage [other/unspecified]          | <input type="checkbox"/> <sub>22</sub> Liver  | <input type="checkbox"/> <sub>08</sub> Salivary glands, major [other/unspecified]                      |
| <input type="checkbox"/> <sub>71</sub> Brain  | <input type="checkbox"/> <sub>34</sub> Lung (bronchus)  | <input type="checkbox"/> <sub>17</sub> Small intestine   |
| <input type="checkbox"/> <sub>72</sub> Central Nervous System (excludes brain)                          | <input type="checkbox"/> <sub>77</sub> Lymph nodes  | <input type="checkbox"/> <sub>16</sub> Stomach (includes GE junction)                                  |
| <input type="checkbox"/> <sub>53</sub> Cervix   | <input type="checkbox"/> <sub>83</sub> * Lymphoma, Hodgkin's  | <input type="checkbox"/> <sub>73</sub> Thyroid   |
| <input type="checkbox"/> <sub>49</sub> Connective, subcutaneous & other soft tissues (includes sarcoma) | <input type="checkbox"/> <sub>82</sub> * Lymphoma, non-Hodgkin's  | <input type="checkbox"/> <sub>02</sub> Tongue, parts of [other/unspecified]                            |
| <input type="checkbox"/> <sub>75</sub> Endocrine glands & related structures [other/unspecified]        | <input type="checkbox"/> <sub>44</sub> Melanoma of the skin   | <input type="checkbox"/> <sub>55</sub> Uterus, not otherwise specified                                 |
|   | <input type="checkbox"/> <sub>85</sub> * Multiple myeloma <sup>1</sup>  | <input type="checkbox"/> <sub>00</sub> Other ( <i>Specify site. Enter site code in Qx. 3.</i> )        |

\* See WHI Extension Manual, Appendix C, Coding Reference  
<sup>1</sup> Includes plasma cell leukemia and plasmacytoma/extramedullary



Figure 8.9 (continued)

WHI

Form 130 – Report of Cancer Outcome

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3. ICD-0 Code:

\_\_\_\_ . \_\_\_\_

4. Tumor Behavior: **(Mark one only.)**

- <sub>1</sub> Invasive; malignant; infiltrating; micro-invasive
- <sub>2</sub> In situ; intraepithelial; non-infiltrating; non-invasive; intraductal
- <sub>3</sub> Borderline malignancy; low malignant potential; uncertain whether benign or malignant; indeterminate malignancy. **(Use only for ovary site.)**
- <sub>9</sub> Unknown

5. Reporting Source: **(Mark one only. If more than one category applies, mark the first applicable category.)**

- <sub>1</sub> Hospital inpatient
- <sub>2</sub> Hospital outpatient/radiation or chemotherapy facility, surgical center, or clinic
- <sub>3</sub> Laboratory only (hospital or private) including pathology office
- <sub>4</sub> Physician's office/private medical practitioner
- <sub>5</sub> Nursing/convalescent home/hospice
- <sub>6</sub> Autopsy only
- <sub>7</sub> Death certificate only

6. Diagnostic Confirmation Status: **(Mark one only. If more than one category applies, mark the first applicable category.)**

**Microscopically Confirmed:**

- <sub>1</sub> Positive histology (pathology)
- <sub>2</sub> Positive exfoliative cytology, no positive histology
- <sub>3</sub> Positive histology (pathology), regional or distant metastatic site only
- <sub>4</sub> Positive microscopic confirmation, method not specified

**Not Microscopically Confirmed:**

- <sub>5</sub> Positive laboratory test/marker study
- <sub>6</sub> Direct visualization without microscopic confirmation
- <sub>7</sub> Radiography and other imaging techniques without microscopic confirmation
- <sub>8</sub> Clinical diagnosis only (other than 5, 6 or 7 above)

**Confirmation Unknown:**

- <sub>9</sub> Unknown if microscopically confirmed

Figure 8.9 (continued)

WHI

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7. Laterality: **(Mark one only.)**

- <sub>0</sub> Not a paired site
- <sub>1</sub> Right: origin of primary
- <sub>2</sub> Left: origin of primary
- <sub>3</sub> Only one side involved, right or left origin unspecified
- <sub>4</sub> Bilateral involvement, lateral origin unknown: stated to be single primary
- <sub>5</sub> Paired site, but no information concerning laterality; midline tumor

8. Morphology: (ICD-0)

9. Extent of disease

10. Summary Stage: **(Mark one only.)**

- <sub>1</sub> In situ
- <sub>2</sub> Localized
- <sub>3</sub> Regional
- <sub>4</sub> Distant
- <sub>9</sub> Unknown

Figure 8.9 (continued)

WHI

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Complete Questions 11–14 for Breast Cancer Only.

11. Complete the subclassification for Breast Histology 8522: **(Mark one only.)**

- |  |   |
|--|---|
| <input type="checkbox"/> <sub>0</sub> Not applicable                       | <input type="checkbox"/> <sub>3</sub> Ductal invasive plus lobular invasive   |
| <input type="checkbox"/> <sub>1</sub> Ductal in situ plus lobular in situ  | <input type="checkbox"/> <sub>4</sub> Ductal in situ plus lobular invasive    |
| <input type="checkbox"/> <sub>2</sub> Ductal invasive plus lobular in situ | <input type="checkbox"/> <sub>5</sub> Invasive cancer, ductal and lobular nos |

12. Estrogen Receptor Assay:  
**(Mark one only.)**

- <sub>1</sub> Positive
- <sub>2</sub> Negative
- <sub>3</sub> Borderline
- <sub>8</sub> Ordered/Results not available
- <sub>9</sub> Unknown/Not done

12.1. Date:

\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
(MM/DD/YY)

12.2. Type of assay:  
**(Mark one only.)**

- <sub>1</sub> fmol/mg protein
- <sub>2</sub> ICC/IHC
- <sub>8</sub> Other: \_\_\_\_\_
- <sub>9</sub> Unknown

13. Progesterone Receptor Assay:  
**(Mark one only.)**

- <sub>1</sub> Positive
- <sub>2</sub> Negative
- <sub>3</sub> Borderline
- <sub>8</sub> Ordered/Results not available
- <sub>9</sub> Unknown/Not done

13.1. Date:

\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
(MM/DD/YY)

13.2. Type of assay:  
**(Mark one only.)**

- <sub>1</sub> fmol/mg protein
- <sub>2</sub> ICC/IHC
- <sub>8</sub> Other: \_\_\_\_\_
- <sub>9</sub> Unknown

14. Her 2/Neu Receptor:  
**(Mark one only.)**

- <sub>1</sub> Positive
- <sub>2</sub> Negative
- <sub>3</sub> Borderline
- <sub>8</sub> Ordered/Results not available
- <sub>9</sub> Unknown/Not done

14.1. Date:

\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
(MM/DD/YY)

\_\_\_\_\_  
Coder Signature

15. Editor Code:

\_\_\_\_\_

**Table 8.9  
History of WHI Outcomes/Adjudication**

Outcome	Extension 1			Extension 2								
	2005-2010 F33, ver 8.1			2010-2015 F33, ver 11 combined			2015-2020 F33, ver 12 combined			2015-2020 F33, ver 13 combined		
	SR QX #	Central Adj	Subsequent Condition	SR QX #	Central Adj	Subsequent Condition	SR QX #	Central Adj	Subsequent Condition	SR QX #	Central Adj	Subsequent Condition
<b>Cardiovascular</b>	3											
<b>Inpatient for one or more nights</b>												
MI	3.1	X	1st	18	MRC	1 <sup>st</sup>	18	MRC	All > 6/24/15	10	MRC	All
Angina	3.3	-	-	4	-	-	4	-	-	5	-	-
CABG	3.4	X	1st	20	MRC	1st	20	MRC	All > 6/24/15	12	MRC	All
CHF	3.2	MRC cases (retro pull)	-	19	MRC	All	19	MRC	All	11	MRC	All
PAD	3.11	X	1st	28	MRC	1st	28	MRC	All > 6/24/15	16	MRC	All
Carotid (CAD)	3.8	X	All until 1st stroke	27	MRC	All until 1st stroke	27	MRC	All until 1st stroke	15	MRC	All
PE	3.10	HT	All	24	MRC	All	24	MRC	All	17	MRC	All
TIA	3.1.7	Balance of DM+OS (retro pull)	-	4	-	-	4	-	-	5	-	-
Stroke (WHI; Ext.1 and 2 below)	3.1.6	Balance of DM+OS (retro pull)	-	-	-	-	-	-	-	-	-	-
Atrial Fibrillation	-	-	-	22	MRC	All	22	MRC stopped 5/2017	-	19	-	-
Heart valve disease	-	-	-	21	MRC	All	21	MRC	All	13	MRC	All
Aortic aneurysm	-	-	-	23	MRC	1st	23	MRC	1st	14	MRC	All
Other cardiovascular	3.88			29	MRC	All	29	MRC	All	21	-	Stopped 7/2018

**Table 8.9**  
**History of WHI Outcomes/Adjudication (continued)**

Outcome	Extension 1			Extension 2								
	2005-2010 F33, ver 8.1			2010-2015 F33, ver 11 combined			2015-2020 F33, ver 12 combined			2015-2020 F33, ver 13 combined		
	SR QX #	Central Adj	Subsequent Condition	SR QX #	Central Adj	Subsequent Condition	SR QX #	Central Adj	Subsequent Condition	SR QX #	Central Adj	Subsequent Condition
<b>Cardiovascular (cont'd)</b>												
<b>Inpatient admits for one or more nights and Outpatient visits</b>												
Stroke (Ext.1 and 2; WHI above)	3.6	X; AS196-HT only	1st	17	MRC	1st	17	MRC	All > 6/24/15	9	MRC	
PTCA, stent, laser (SR=CHD)	3.5	X	All until MI & 1st post MI	26	MRC	All until MI & 1st post MI	26	MRC	All > 6/24/15	20	MRC	
DVT	3.9	HT	All	25	MRC	All	25	MRC	All	18	MRC	
<b>Fracture</b>	5			8,10,43			8,10,43			29, 30		
Hip/upper leg, uncertain hip	5.1	X	1st	8.10	MRC	1st	8,10,43	MRC	All > 6/24/15	29	MRC	
Other fractures	5.1		-	8			8			30	-	-
<b>Cancer</b>	4			44			44			28		
Breast**		X	All	44.10	X	All	44.10	X	All	28.10	X	All
Colon\rectum**		X	1st	44.60	X	1st	44.60	X	1st	28.60	X	1st
Endometrium**		X	1st	44.30	X	1st	44.30	X	1st	28.33	X	1st
Ovary**		X	1st	44.20	X	1st	44.20	X	1st	28.20	X	1st
Metastatic sites for breast cancer (brain, bone, liver, lung)	-	-	-	-	-	-	-	-	-	-	-	-

**Table 8.9**  
**History of WHI Outcomes/Adjudication (continued)**

Outcome	Extension 1			Extension 2								
	2005-2010 F33, ver 8.1			2010-2015 F33, ver 11 combined			2015-2020 F33, ver 12 combined			2015-2020 F33, ver 13 combined		
	SR QX #	Central Adj	Subsequent Condition	SR QX #	Central Adj	Subsequent Condition	SR QX #	Central Adj	Subsequent Condition	SR QX #	Central Adj	Subsequent Condition
<b>Cancer (cont'd)</b>												
Other Cancer		X	1st	44.88	X	1st	44.88	X	1st	28.88	X	1st
Cervix				44.40	X	1st	44.40	X	1st	28.40	X	1 <sup>st</sup>
Other female genital organs (not ovary, endo, or cervix)				44.50	X	1st	44.50	X	1st	28.50	X	1 <sup>st</sup>
Bladder				44.70	X	1st	44.70	X	1st	28.70	X	1 <sup>st</sup>
Brain				44.80	X	1st	44.80	X	1st	28.80	X	1 <sup>st</sup>
Esophagus				44.90	X	1st	44.90	X	1st	28.90	X	1 <sup>st</sup>
Gallbladder/bile ducts				44.10	X	1st	44.10	X	1st	28.100	X	1 <sup>st</sup>
Hodgkin's lymphoma				44.11	X	1st	44.11	X	1st	28.11	X	1 <sup>st</sup>
Non-Hodgkin's lymphoma				44.12	X	1st	44.12	X	1st	28.12	X	1 <sup>st</sup>
Kidney				44.13	X	1st	44.13	X	1st	28.13	X	1 <sup>st</sup>
Leukemia				44.14	X	1st	44.14	X	1st	28.14	X	1 <sup>st</sup>
Liver				44.15	X	1st	44.15	X	1st	28.15	X	1 <sup>st</sup>
Lung				44.16	X	1st	44.16	X	1st	28.16	X	1 <sup>st</sup>
Melanoma				44.17	X	1st	44.17	X	1st	28.17	X	1 <sup>st</sup>
Multiple Myeloma				44.18	X	1st	44.18	X	1st	28.18	X	1 <sup>st</sup>
Pancreas				44.19	X	1st	44.19	X	1st	28.19	X	1 <sup>st</sup>
Skin cancer (not melanoma)	-	-		44.20	X	1st	44.20	X	1st	28.200	X	1 <sup>st</sup>
Stomach				44.21	X	1st	44.21	X	1st	28.21	X	1 <sup>st</sup>
Thyroid				44.22	X		44.22	X	1st	28.22	X	1 <sup>st</sup>

**Table 8.9**

**History of WHI Outcomes/Adjudication (continued)**

Outcome	Extension 1			Extension 2								
	2005-2010 F33, ver 8.1			2010-2015 F33, ver 11 combined			2015-2020 F33, ver 12 combined					
	SR QX #	Central Adj	Subsequent Condition	SR QX #	Central Adj	Subsequent Condition	SR QX #	Central Adj	Subsequent Condition	SR QX #	Central Adj	Subsequent Condition
<b>Death</b>		X	N/A		MRC	N/A		MRC	N/A		MRC	N/A
<b>Hysterectomy</b>	8.10	HT	N/A	3.7	-	-	3.7	-	-	4.7	-	-
<b>Hospitalization 1+</b>	2	X	All	-	-	-	-	-	-	-	-	-
<b>Hospitalization 2+</b>				16,47	MRC	All	16,47	MRC stopped 6/6/18	-	-	-	-
<b>ER/Outpatient</b>										-	-	-

1. X = All participants based on the self-report (SR)
2. Inpatient stay: Admitted to an acute care hospital for one night or more (depends on outcome type)
3. Self-Report (SR) drives central adjudication case selection. Locally confirmed and denied cases are centrally reviewed for all major WHI outcomes.
4. Subsequent condition: The number of times a particular outcome is adjudicated
5. Carotid disease is centrally adjudicated by both CVD and Stroke committees (carotid alone is reviewed by the CVD Committee; carotid + stroke by the Stroke Committee) x
6. Started SEER coding other cancers in Ext. 1 (2005-2010)
7. Medical Record Cohort (MRC): HT, African American and Hispanic participants consented to Ext. 2
8. HF/Venous Thromboembolic (VTE) (MRC only): Added to Form 33 Ver. 10, Oct 30, 2009; Retrospective pull of MRC HF cases not previously sent to CCC [N=~5,000]
9. Ext. 2, collect SR of one night hospital stay but only collect medical records for 2 or more nights
10. ER/Outpatient: Collected as a SR in WHI and is adjudicated for the specific outcomes of interest
11. June 24, 2015: The Subsequent Condition Rule was lifted for MRC CVD and Hip fracture outcomes to ensure the first incident CVD (e.g., MI, stroke and/or revascularization) is captured post randomization for two new ancillary study (AS)-intervention trials launching in 2015: AS455 – COSMOS and AS360 - WHISH.
12. March 31, 2016: Completed central adjudication of 5000 retrospective DM/OS strokes
13. May, 2017: Discontinued investigation and adjudication of atrial fibrillation
14. June 6, 2018: Discontinued investigation and adjudication of stand-alone 2-night hospital stays collected on routine *Form 33s*

**Table 8.10  
Self-Reported Outcomes**

	Extension #1		Extension #2					
	2005-2010 F33, ver 8.1		2010-2015 Combined F33/33D		2015-2020 Combined F33/33D through version 12		2015-2020 Combined F33/33D Version 13	
Self-Report on Form 33	SR Qx #		SR Qx #		SR Qx #		SR Qx #	
Cataracts	--		--				-	-
Colorectal polyps	7.2		4.8		4.8		5.9	
COPD	--		4.1	new	4.1	new	5.1	
Dementia, Alzheimer's	7.6	new	4.6		4.6		5.7	
Diabetes ever	Form 134		--		--		-	
Fainted/black out	--		--		--		-	
Falls	--	Not in Ext 1	7		7		8	
Fractures (non-hip)			8		8		30	
Gallbladder disease/stones	--		--		--		-	
Glaucoma	--		--		--		-	
Kidney/bladder stone	--		--		--		-	
Macular degeneration	7.4	new	4.5		4.5		5.5	
Osteoarthritis	7.1		4.4		4.4		5.4	
Osteoporosis	--		--		--		-	
Parkinson's	7.5	new	4.7		4.7		5.8	
Rheumatoid Arthritis (RA)	--		--		--		-	
Systemic Lupus Erythematosus (SLE)	7.3		4.9		4.9		-	



**Table 8.10**  
**Self-Reported Outcomes (continued)**

	Extension #1		Extension #2					
	2005-2010 F33, ver 8.1		2010-2015 Combined F33/33D		2015-2020 Combined F33/33D through version 12		2015-2020 Combined F33/33D Version 13	
Self-Report on Form 33	SR Qx #		SR Qx #				SR Qx #	
<b>Exams/Procedures</b>								
Barium enema	8.8		--		--		-	
Blood in stool	8.6		3.5		3.5		4.5	
Blood pressure	--		--		--		-	
Bone density scan	8.12	new	3.9		3.9		-	
Breast biopsy	8.3		3.3		3.3		4.3	
Breast exam	8.1		3.1		3.1		4.1	
Breast exam, other (MRI/ultrasound)	8.4	new	3.4		3.4		4.4	
Cholesterol	--		--		--		-	
D&C	8.9		--		--		-	
ECG	--		--		--		-	
Endometrial Bx	8.11		3.8		3.8		4.8	
Eye exam	--		--		--		-	
FlexSig/colonoscopy	8.7		3.6		3.6		4.6	
Hysterectomy*			3.7	SR only	3.7	SR only	4.7	
Mammogram	8.2		3.2		3.2		4.2	
PAP	--		--		--		-	
Physical Exam	--		--		--		-	
PTCA*	3.1		2.6		2.6		20	
Rectal Exam	8.5		--				-	