Supporting Statement B

Attachment 13

OS Adjudicator Forms

ADJUDICATOR FORMS

Report of Cardiovascular Outcome

Report of Fracture Outcome

Report of Death (Final)

Summary of Hospitalization Diagnosis

Report of Cancer Outcome

Report of Stroke Outcome

Form 121 - Report of Cardiovascular Outcome Ver. 8.1

OMB# 0925-0414 Exp: 5/09

COMMENTS	-Affix label here- Member ID: __ __ __ __ - ___ ___ ___ - __
To be completed by Physician Adjudicator Date Completed: ☐☐-☐☐-☐☐ (M/D/Y) Adjudicator Code: ☐☐-☐☐☐	Central Case No.: ☐☐☐☐☐☐ Case Copy No.: ☐☐

(For items 1-8, 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 death [hospitalized], and coronary revascularization

1. ECG pattern: ***(Mark the one category that applies best.)***

- ☐ 1 Evolving Q-wave and evolving ST-T abnormalities
- ☐ 2 Equivocal Q-wave evolution; or evolving ST-T abnormalities; or new left bundle branch block
- ☐ 3 Q-waves or ST-T abnormalities suggestive of an MI and not classified as code 1 or 2 above
- ☐ 8 Other ECG pattern, ECG uncodable, or normal ECG pattern
- ☐ 9 ECG not available

2. Cardiac enzyme information available?

- ☐ 0 No ⟶ ***Skip to Question 3 on page 2.***
- ☐ 1 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.*)

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

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

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

If CK-MB not available:

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

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.)**

- ☐ 1 Troponin C
- ☐ 2 Troponin I
- ☐ 3 Troponin T
- ☐ 4 Troponin, not specified
- ☐ 9 Troponin not available → ***Skip to Question 3 below.***

2.2.1 Results ***(Mark the one category that applies best.)*** 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.

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

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.)*

- ☐ 1 Present
- ☐ 2 Absent
- ☐ 9 Unknown/Not recorded

Yes ☐ 1 **No** ☐ 0 **4. Definite, probable, or aborted myocardial infarction (See excerpts from *Table 8.5.1 – Definition of Criteria for Diagnosis of Myocardial Infarction* and *Table 8.5.2 – 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.)***

- ☐ 1 Myocardial infarction not occurring as a result of or during a procedure → ***Skip to Question 4.3 on the next page.***
- ☐ 2 Myocardial infarction during or resulting from a procedure, i.e., within 30 days of any procedure.

↓

4.2.1. Type of Procedure ***(Mark one.)***

- ☐ 1 A myocardial infarction that followed a cardiac procedure within 24 hours (for example, diagnostic coronary catheterization, percutaneous coronary intervention, CABG, pacemaker insertion, or cardioversion).
- ☐ 2 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).
- ☐ 3 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).

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 Q6. Non-emergent revascularization procedures are coded only under Q6. Examples of thrombolytic agents are streptokinase, reteplase (Retavase), tenecteplase (TNKase), alteplase tPA (Activase).

☐ 0 No
☐ 1 Yes
☐ 9 Unknown

4.4. Was the myocardial infarction fatal? ***(Mark one.)***

☐ 0 No
☐ 1 Yes ***(Complete Question 5 below [for hospitalized deaths only] and Form 124 - Final Report of Death.)***

For <u>hospitalized</u> deaths only:

Yes ☐ 1 **No** ☐ 0 **5. Coronary death *(Complete Form 124 - Final Report of Death.*)**

5.1. Date of Death: ___ - ___ - ___ (M/D/Y)

5.2. Diagnosis: _____

Yes ☐ 1 **No** ☐ 0 **6. Coronary revascularization**

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

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

☐ 1 Coronary artery bypass graft (CABG)
☐ 2 Percutaneous transluminal coronary angioplasty (PTCA), coronary stent, or coronary atherectomy

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

☐ 0 No
☐ 1 Yes
☐ 2 Unknown

Yes ☐1 **No** ☐0 **7. Carotid artery disease requiring and/or occurring during hospitalization.** Disease must be **symptomatic and/or requiring intervention** (i.e., vascular or surgical procedure).

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

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

☐1 Carotid artery occlusion and stenosis without documentation of cerebral infarction

☐2 Carotid artery occlusion and stenosis with documentation of cerebral infarction

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

☐1 Symptomatic disease with carotid artery disease listed on the hospital discharge summary

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

☐3 Vascular or surgical procedure to improve flow to the ipsilateral brain

Yes ☐1 **No** ☐0 **8. Peripheral arterial disease (aorta, 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 or abdominal aortic aneurysm).

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

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

☐1 Lower extremity claudication

☐2 Atherosclerosis of arteries of the lower extremities

☐3 Arterial embolism and/or thrombosis of the lower extremities

☐4 Abdominal aortic aneurysm (AAA)

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

☐1 Ultrasonographically- or angiographically-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

☐2 Absence of pulse by doppler in any major vessel of lower extremities

☐3 Exercise test that is positive for lower extremity claudication

☐4 Surgery, angioplasty, or thrombolysis for peripheral arterial disease

☐5 Amputation of one or more toes or part of the lower extremity because of ischemia or gangrene

☐6 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

☐7 Ultrasonographically- or angiographically-demonstrated abdominal aortic aneurysm

☐8 Surgical or vascular procedure for abdominal aortic aneurysm

_____

Responsible Adjudicator Signature

Table 1
Definition of Criteria for Diagnosis of Myocardial Infarction

	Cardiac Enzyme Interpretation (see *Table 8.8* below)			
	Abnormal	**Equivocal**	**Incomplete**	**Normal**
ECG Pattern/Symptoms				
Cardiac pain present:				
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
Cardiac Pain absent:				
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

		Interpretation	
Cardiac Enzyme	**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
Toponin (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.

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COMMENTS	**-Affix label here-** Member ID: __ __ __ __ - ___ ___ ___ - __
To be completed by Physician Adjudicator: Date Completed: ⌊__⌋⌊__⌋-⌊__⌋⌊__⌋-⌊__⌋⌊__⌋ (M/D/Y) Adjudicator Code: ⌊__⌋⌊__⌋-⌊__⌋⌊__⌋⌊__⌋	Central Case No.: ⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋ Case Copy No.: ⌊__⌋⌊__⌋

Use a separate form for each fracture.

Yes ☐ 1 No ☐ 0

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.*)**

☐ 1 Neck of femur (transcervical, cervical)
☐ 2 Intertrochanteric fracture
☐ 3 Greater trochanter
☐ 4 Unspecified part of proximal femur

1.3. Side of hip fracture: **(*Mark the one that applies best.*)**

☐ 1 Right
☐ 2 Left
☐ 3 Both sides
☐ 9 Unknown

1.4. Hip fracture based on: **(*Mark the one category that applies best.*)**

☐ 1 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

☐ 2 Radiologist's report confirms a proximal femur fracture, but the hospital discharge summary does not (or is equivocal or missing)

☐ 3 All of the following:
   1) hospital discharge summary listing fracture of the proximal femur, femoral neck fracture, intertrochanteric fracture, trochanteric fracture, or hip fracture;
   2) equivocal written radiology report of the hip (e.g., "possible" or "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

☐ 4 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.*)**

☐ 0 No ☐ 1 Yes ☐ 2 Possible

_____

Responsible Adjudicator Signature

RV_____K_____V_____

OMB #0925-0414 Exp: 5/09

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

1. Date of death: ___-___-___ (M/D/Y)

2. Cause of death:

		ICD-9-CM/ICD-10-CM Codes	**CCC use only**
2.1.	**Underlying cause:** (Disease or injury that initiated events resulting in death.)		
	_____	2.2. ___.___	2.3. ___
	_____		
	Contributory cause(s) of death. (Contributory causes do not have to be listed in the hierarchical order.)		
2.4.	_____	2.5. ___.___	2.6. ___
	_____		
2.7.	_____	2.8. ___.___	2.9. ___
	_____		
2.10.	_____	2.11. ___.___	2.12. ___
	_____		
2.13.	**Immediate cause:** (Final disease or condition resulting in death.)		
	_____	2.14. ___.___	2.15. ___
	_____		

RV K V

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

- ☐ 1 Breast
- ☐ 2 Ovarian
- ☐ 3 Endometrial
- ☐ 4 Colon
- ☐ 5 Rectosigmoid junction
- ☐ 6 Rectum
- ☐ 7 Uterus
- ☐ 10 Lung
- ☐ 8 Other Cancer _____
- ☐ 9 Unknown cancer site

Cardiovascular disease

- ☐ 11 Definite Coronary Heart Disease (CHD)
  (No known non-CHD cause and at least one of the following: (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.)
- ☐ 14 Possible Coronary Heart Disease (CHD)
  (No known non-CHD cause, and death certificate consistent with CHD as the underlying cause.)

→ **If box 11 or 14 marked, complete Question 6 on the next page.**

- ☐ 12 Cerebrovascular disease
- ☐ 13 Pulmonary Embolism
- ☐ 18 Other cardiovascular disease
- ☐ 19 Unknown cardiovascular disease

Accident/Injury

- ☐ 21 Homicide
- ☐ 22 Accident
- ☐ 23 Suicide
- ☐ 28 Other injury

"Other" Cause of Death

- ☐ 31 Alzheimer's Disease
- ☐ 32 COPD
- ☐ 33 Pneumonia
- ☐ 34 Pulmonary Fibrosis
- ☐ 35 Renal Failure
- ☐ 36 Sepsis
- ☐ 88 Another cause of death, known
- ☐ 99 Unknown cause of death

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

☐ 0 No
☐ 1 Yes
☐ 9 Unknown

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

☐ 1 Medical records documentation (current case only)
☐ 2 Report of autopsy findings
☐ 3 Death certificate
☐ 4 ER record
☐ 5 EMS report
☐ 6 Informant interview
☐ 7 *Form 120 – Initial Notification of Death*
☐ 9 **NDI Search (CCC use only)**
☐ 10 Coroner's report
☐ 8 Other _____ (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.)***

☐ 1 Hospitalized myocardial infarction within 28 days of death
☐ 2 Previous angina, myocardial infarction, or revascularization procedure and no known potentially-lethal non-coronary disease process
☐ 3 Coronary heart disease (CHD) diagnosed as cause of death at post-mortem examination
☐ 4 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*]**
☐ 8 Other (none of the above)

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

☐ 1 Definite fatal MI: no known non-atherosclerotic cause (and death within 28 days of definite MI) or autopsy evidence of acute MI
☐ 2 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
☐ 3 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.)**

☐ 1 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
☐ 2 Rapid death: death occurs within 1-24 hours of symptom onset
☐ 3 Other coronary death (Does not fulfill criteria for sudden or rapid coronary death.)

_____
Responsible Adjudicator Signature

NOTE: If this is a hospitalized death, or an autopsy report is available, adjudicate any WHI outcomes using the appropriate outcomes form.

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COMMENTS	-Affix label here- Member ID: __ __ __ __-__ __ __ __-__ First Name _____ M.I._____ Last Name _____
Date Completed: ___-___-___ (M/D/Y)	*To be completed by Outcomes Coordinator:* Staff person: ___-___ Adjudication Case No.: ___

Complete a separate form for each hospitalization.

Record the hospitalization information below. The admission and discharge date/date of death should match the dates on the attached medical documentation and corresponding provider visit entered in the WHIX database. Items 1 through 4 to be completed by Outcomes Coordinator.

Hospital

Hospital/Facility Name: _____

Address: _____

_____

City State Zip Code

Admission Date: _____(M/D/Y)

Discharge Date/Date of Death: _____(M/D/Y)

Patient's Hospital ID: _____

ICD-9-CM/ICD-10-CM Discharge Diagnosis Codes:

1. Record all ICD-9-CM/ICD-10-CM diagnosis codes in the order they are listed on the hospital face sheet, physician attestation sheet or other documentation listing diagnosis codes. If there are more diagnosis codes than space available, record on a separate page and append to this form. (Do not report codes with a V prefix.)

1. ___.___	5. ___.___	9. ___.___	13. ___.___
2. ___.___	6. ___.___	10. ___.___	14. ___.___
3. ___.___	7. ___.___	11. ___.___	15. ___.___
4. ___.___	8. ___.___	12. ___.___	16. ___.___

ICD-9-CM/ICD-10-CM Procedure Codes:

2. Record all ICD-9-CM/ICD-10-CM procedure codes in the order they are listed on the hospital face sheet, physician attestation sheet or other documentation listing procedure codes. If there are more procedure codes than space available, record on a separate page and append to this form.

1. ___.___	5. ___.___	9. ___.___	13. ___.___
2. ___.___	6. ___.___	10. ___.___	14. ___.___
3. ___.___	7. ___.___	11. ___.___	15. ___.___
4. ___.___	8. ___.___	12. ___.___	16. ___.___

RV_____K_____V_____

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Discharge Diagnoses:

3. If the ICD-9-CM/ICD-10-CM discharge codes are not available, write out all discharge diagnoses in the order they are listed on the hospital face sheet or other sources. If there are more diagnoses than space available, record on a separate page and append to this form.

3.1. Discharge diagnoses recorded below? ☐$_0$ No ☐$_1$ Yes

1. _____	9. _____
2. _____	10. _____
3. _____	11. _____
4. _____	12. _____
5. _____	13. _____
6. _____	14. _____
7. _____	15. _____
8. _____	16. _____

Procedures:

4. If the ICD-9-CM/ICD-10-CM procedure codes are not available, record all procedures in the order they are listed on the hospital face sheet or other sources. If there are more procedures than space available, record on a separate page and append to this form.

4.1. Procedures recorded below? ☐$_0$ No ☐$_1$ Yes

1. _____	9. _____
2. _____	10. _____
3. _____	11. _____
4. _____	12. _____
5. _____	13. _____
6. _____	14. _____
7. _____	15. _____
8. _____	16. _____

OMB #0925-0414 Exp: 5/09

COMMENTS	**- Affix label here-** Member ID: __ __ __ __ - ___ ___ ___ - __ #___
To be completed by CCC Cancer Coder: Date Completed: ☐☐-☐☐-☐☐ (MM/DD/YY) Adjudicator Code: ☐☐-☐☐☐	Central Case No.: ☐☐☐☐☐☐☐ Case Copy No.: ☐☐

Use a separate form for each new diagnosis.

1. Date of Diagnosis: ☐☐-☐☐-☐☐ (MM/DD/YY)

2. Primary cancer site: ***(Mark the one that applies best.)***

Main WHI Cancer Outcomes

- ☐ 50 Breast → **Questions 1–3, 5–14 required.**
- ☐ 56 Ovary
- ☐ 54 Corpus uteri, endometrium
- ☐ 18 Colon (excludes appendix, see below)
- ☐ 20 Rectum
- ☐ 19 Rectosigmoid junction

→ **Questions 1–3, 5–10 required.**

Other Cancer Outcomes → **Questions 1–6 required.**

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

_____

3. ICD-0-2 Code: **Complete for Main Cancer site or "Other Cancer" site not already specified in Question 2. (Note to ancillary study coder, complete as requested by CCC.)**

   ☐☐☐.☐

4. Tumor Behavior: **Complete only for an "Other Cancer" diagnosis.** ***(Mark one only.)***

   ☐ 1 Invasive; malignant; infiltrating; micro-invasive

   ☐ 2 In situ; intraepithelial; non-infiltrating; non-invasive; intraductal

   ☐ 3 Borderline malignancy; low malignant potential; uncertain whether benign or malignant; indeterminate malignancy

   ☐ 9 Unknown

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

   ☐ 1 Hospital inpatient

   ☐ 2 Hospital outpatient/radiation or chemotherapy facility, surgical center, or clinic

   ☐ 3 Laboratory only (hospital or private) including pathology office

   ☐ 4 Physician's office/private medical practitioner

   ☐ 5 Nursing/convalescent home/hospice

   ☐ 6 Autopsy only

   ☐ 7 Death certificate only

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

   Microscopically Confirmed:

   ☐ 1 Positive histology (pathology)

   ☐ 2 Positive exfoliative cytology, no positive histology

   ☐ 3 Positive histology (pathology), regional or distant metastatic site only

   ☐ 4 Positive microscopic confirmation, method not specified

   Not Microscopically Confirmed:

   ☐ 5 Positive laboratory test/marker study

   ☐ 6 Direct visualization without microscopic confirmation

   ☐ 7 Radiography and other imaging techniques without microscopic confirmation

   ☐ 8 Clinical diagnosis only (other than 5, 6 or 7 above)

   Confirmation Unknown:

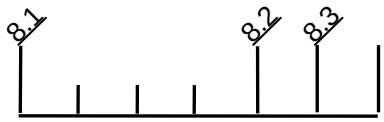
   ☐ 9 Unknown if microscopically confirmed

Complete Questions 7–10 for Main Cancer Outcomes only.

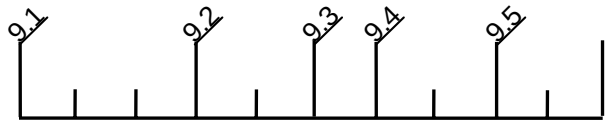
7. Laterality: ***(Mark one only.)***

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

8. Morphology:



9. EOD (SEER):



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

- ☐ 1 In situ
- ☐ 2 Localized
- ☐ 3 Regional
- ☐ 4 Distant
- ☐ 9 Unknown

Complete Questions 11–14 for Breast Cancer Only.

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

- ☐ 0 Not applicable
- ☐ 1 Ductal in situ plus lobular in situ
- ☐ 2 Ductal invasive plus lobular in situ
- ☐ 3 Ductal invasive plus lobular invasive
- ☐ 4 Lobular invasive plus ductal in situ
- ☐ 5 Invasive cancer, ductal and lobular nos

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

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

12.1. Date:
__-__-__
(MM/DD/YY)

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

- ☐ 1 fmol/mg protein
- ☐ 2 ICC/IHC
- ☐ 8 Other:_____
- ☐ 9 Unknown

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

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

13.1. Date:
__-__-__
(MM/DD/YY)

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

- ☐ 1 fmol/mg protein
- ☐ 2 ICC/IHC
- ☐ 8 Other:_____
- ☐ 9 Unknown

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

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

14.1. Date:
__-__-__
(MM/DD/YY)

_____
Coder Signature

15. Editor Code: ___

COMMENTS	**-Affix label here-** Member ID: __ __ __ __ - ___ ___ ___ - __
To be completed by Physician Adjudicator: Date Completed: ☐☐-☐☐-☐☐ (M/D/Y) Adjudicator Code: ☐☐-☐☐☐	Central Case No.: ☐☐☐☐☐☐ Case Copy No.: ☐☐

Yes ☐1 **No** ☐0 **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

☐1 Subarachnoid hemorrhage

☐2 Intraparenchymal hemorrhage

☐3 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.)***

☐4 Occlusion of cerebral or pre-cerebral arteries with infarction (cerebral thrombosis, cerebral embolism, lacunar infarction)

Other

☐5 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.)**

☐0 No

☐1 Yes

☐9 Unknown

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

☐0 No

☐1 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_____

1.5. Oxfordshire Classification ***(Mark the <u>one</u> category that applies best.)***

☐ 1 Total anterior circulation infarct (TACI)

☐ 2 Partial anterior circulation infarct (PACI)

☐ 3 Lacunar infarction (LACI)

☐ 4 Posterior circulation infarct (POCI)

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

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

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

☐ 1 Rapid onset of neurological deficit and CT or MRI scan shows acute focal brain lesion consistent with neurological deficit and without evidence of blood (except mottled cerebral pattern)

☐ 2 Rapid onset of localizing neurological deficit with duration ≥ 24 hours but imaging studies are not available

☐ 3 Rapid onset of neurological deficit with duration ≥ 24 hours and the only available CT or MRI scan was done early and shows no acute lesion consistent with the neurologic deficit

☐ 4 Surgical evidence of ischemic infarction of brain

☐ 5 CT or MRI findings of blood in subarachnoid space, intra-parenchymal, or intraventricular hemorrhage consistent with neurological signs or symptoms

☐ 6 Positive lumbar puncture (for subarachnoid hemorrhage)

☐ 7 Surgical evidence of subarachnoid or intra-parenchymal hemorrhage as the cause of a clinical syndrome consistent with stroke

☐ 8 None of the above (e.g., fatal strokes where no imaging studies or clinical evidence are available; or CT/MRI does not show lesion consistent with the neurologic deficit)

1.8. If stroke fatal: ***(Mark all that apply.)***

☐ 1 Hospitalized stroke within 28 days of death

☐ 2 Previous stroke and no known potentially lethal non-cerebrovascular disease process

☐ 3 Stroke diagnosed as cause of death at post-mortem examination

☐ 4 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 <u>one</u> category that applies best.)

*Participant may be discharged from the Emergency Department, hospital, or physician's office.

☐ 1 Good recovery – Patient can lead a full and independent life with or without minimal neurological deficit

☐ 2 Moderately disabled – Patient has neurological or intellectual impairment but is independent

☐ 3 Severely disabled – Patient conscious but dependent on others to get through daily activities

☐ 4 Vegetative survival – Has no obvious cortical functioning

☐ 5 Dead

☐ 6 Unable to categorize stroke based on available case packet documentation (for limited use only when adjudicator is unable to categorize above).

Yes ☐ 1 **No** ☐ 0 **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 ☐ 1 **No** ☐ 0 **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.)***

☐ 1 Carotid artery occlusion and stenosis without documentation of cerebral infarction

☐ 2 Carotid artery occlusion and stenosis with written documentation of cerebral infarction

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

☐ 1 Symptomatic disease with carotid artery disease listed on the hospital discharge summary

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

☐ 3 Vascular or surgical procedure to improve flow to the ipsilateral brain

_____
Responsible Adjudicator Signature