

<p>COMMENTS</p>	<p align="center">-Affix label here-</p> <p>Clinical Center/ID: _____ - _____ - _____</p> <p>First Name _____ M.I. _____</p> <p>Last Name _____</p>
<p><i>To be completed by Physician Adjudicator</i></p> <p>Date Completed: _____-_____-_____ (M/D/Y)</p> <p>Adjudicator Code: _____</p>	<p><i>To be completed by Outcomes Specialist:</i></p> <p>Staff person: _____</p> <p>Adjudication Case No.: _____</p>

(For items 1-11, each question specifies “mark one” or “mark all” that apply.)

Complete ECG and cardiac enzyme information for the following WHI outcomes:

Myocardial infarction (MI), coronary death [hospitalized], angina, CHF, 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 3.)**
- 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

No units or % index given for CK-MB:

- ₇ CK-MB reported as "present" without quantification
- ₈ CK-MB reported as "weakly present" without quantification

RV _____ KE _____

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. Serum lactate dehydrogenase (LDH): **(Mark the one category that applies best.) (Complete only if no other cardiac enzymes are available.)**

If LDH1 and LDH2 available:

- ₁ LDH1 \geq LDH2
- ₂ LDH1 < LDH2

If LDH1 available and LDH2 missing or absent:

- ₃ LDH1 at least 2x upper limit of normal
- ₄ LDH1 greater than upper limit of normal but less than 2x upper limit of normal
- ₅ LDH1 within normal limits

If LDH1 not available:

- ₆ Total LDH at least 2x upper limit of normal
- ₇ Total LDH greater than upper limit of normal but less than 2x upper limit of normal
- ₈ Total LDH within normal limits
- ₉ LDH result not available

- 2.3. 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 ₄ Troponin, not specified
- ₂ Troponin I ₉ Troponin not available **(Skip to Question 2.4 below.)**
- ₃ Troponin T

- 2.3.1 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

- 2.4. "Other" cardiac-specific lab: (write in) _____

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

- ₁ At least 2x upper limit of normal
- ₂ Greater than upper limit of normal but less than 2x upper limit of normal
- ₃ Within normal limits
- ₉ Other

Yes ₁ No ₀

3. **Definite, probable, or aborted myocardial infarction (See MOOP Vol. 8, Table 5.1 – Definition of Criteria for Diagnosis of Myocardial Infarction.)**

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

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

₁ Myocardial infarction not occurring as a result of or during a procedure*

₂ Myocardial infarction during or resulting from a procedure*

*An MI is defined as procedure-related if it occurs within 30 days after any procedure. This includes any vascular procedure (regardless of type of anesthesia) plus all other procedures requiring more than local anesthesia.

3.3. 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

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

*An emergent revascularization is conducted within 12 hours of symptom onset; code both here and in Q7. Non-emergent revascularization procedures are coded only under Q7. Examples of thrombolytic agents are streptokinase, tPA, reteplase (Retavase), tenecteplase (TNKase), alteplase tPA (Activase).

₀ No **(Skip to Question 3.5 below.)**

₁ Yes

₉ Unknown

3.4.1 Was the myocardial infarction aborted? *(Diagnosis of an aborted MI requires: symptoms and ECG evidence for acute MI at presentation; intervention [thrombolytic therapy or a procedure] followed by resolution of ECG changes; and all cardiac enzymes within normal limits.)*

₀ No

₁ Yes

₉ Unknown

3.5. Was the myocardial infarction fatal?

₀ No

₁ Yes **(Complete Question 4 below [for hospitalized deaths only] and Form 124 - Final Report of Death.)**

For hospitalized deaths only:

Yes ₁ No ₀

4. **Coronary death (Complete Form 124 - Final Report of Death.)**

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

4.2. Diagnosis: _____

- Yes ₁ No ₀ 5. **Angina pectoris (including unstable angina) requiring and/or occurring during hospitalization.** Chest pain, tightness, or shortness of breath produced by myocardial ischemia that does not result in infarction (usually caused by coronary insufficiency).
- 5.1. Date of Admission - - (M/D/Y)
- 5.2. **Angina pectoris (including unstable angina) based on: (Mark all that apply.)**
- ₁ Physician diagnosis of angina and receiving medical treatment at discharge, for angina on this admission (e.g., nitrate, beta-blocker, or calcium-channel blocker)
- ₂ Physician diagnosis of angina and receiving medical treatment for angina on this admission **plus** current medical record documenting a history of coronary heart disease by previous catheterization or revascularization procedure
- ₃ CABG surgery or other revascularization procedure on this admission. **(Complete Question 7 also.)**
- ₄ 70% or greater obstruction of any coronary artery on angiography on this admission
- ₅ Horizontal or down-sloping ST-segment depression or abnormal ST elevation ≥ 1 mm on exercise or pharmacological stress testing with pain on this admission
- ₆ Scintigraphic or echocardiographic stress test positive for ischemia on this admission
- ₇ Resting ECG shows horizontal or down-sloping ST depression or abnormal ST elevation ≥ 1 mm with pain that is not present on ECG without pain on this admission
- Yes ₁ No ₀ 6. **Congestive heart failure requiring and/or occurring during hospitalization.** (Physician diagnosis of new-onset or worsened congestive heart failure on this admission.)
- 6.1. Date of Admission - - (M/D/Y)
- 6.2. Congestive heart failure based on one or more of the following: **(Mark all that apply.)**
- ₁ 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)
- ₂ 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
- ₃ Pulmonary edema\congestion by chest X-ray on this admission
- ₄ 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
- 6.3. Was the congestive heart failure fatal? (Mark one.)
- ₀ No, non-fatal
- ₁ Yes, fatal **(Complete Question 4 on page 3 of this form and Form 124 - Final Report of Death.)**

Yes ₁ No ₀

7. **Coronary revascularization on this admission**7.1. Date of Admission: - - (M/D/Y)7.2. **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 atherectomy7.3. Second myocardial infarction (MI) (i.e., second MI not already reported in Question 3) occurring as a result of or during the revascularization procedure. **(Mark one.)**₀ No₁ Yes₂ Unknown

Yes ₁ No ₀

8. **Stroke requiring and/or occurring during hospitalization:** 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.

8.1. Date of Admission: - - (M/D/Y)8.2. Diagnosis: **(Mark the one category that applies best.)****Hemorrhagic Stroke**₁ Subarachnoid hemorrhage not resulting from a procedure₂ Intraparenchymal hemorrhage not resulting from a procedure₃ Other or unspecified intracranial hemorrhage (not resulting from a procedure) (nontraumatic epidural hemorrhage or subdural hemorrhage)**Ischemic Stroke**₄ Occlusion of cerebral or pre-cerebral arteries with infarction not resulting from a procedure (cerebral thrombosis, cerebral embolism, lacunar infarction)**Other**₅ Acute, but ill-defined, cerebrovascular disease not resulting from a procedure₆ Central nervous system complications during or resulting from a procedure

8.3. **Stroke diagnosis based on: (Mark the one 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 \geq 24 hours but imaging studies are not available
- ₃ Rapid onset of neurological deficit with duration \geq 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 or intra-parenchymal 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)

8.4. **If stroke fatal: (Mark all that apply.) (Complete Form 124 - Final Report of Death.)**

- 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

8.5. **Participant's functional status at the time of hospital discharge (Glasgow Outcome Scale): (Mark the one category that applies best.)**

- 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

Yes ₁ No ₀

9. **Transient ischemic attack requiring and/or occurring during hospitalization:** 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.9.1. Date of Admission - - (M/D/Y)

Yes ₁ No ₀

10. **Carotid artery disease requiring and/or occurring during hospitalization.** Disease must be symptomatic and/or requiring intervention (i.e., vascular or surgical procedure).10.1. Date of Admission: - - (M/D/Y)

10.2. 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

10.3. **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 ($\geq 50\%$ stenosis) on carotid angiogram or doppler flow study
₃ Vascular or surgical procedure to improve flow to the ipsilateral brain

Yes ₁ No ₀

11. **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).

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

11.2. 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)

11.3. **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 ($\geq 50\%$ of the diameter or $\geq 75\%$ 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

NOTE: If this is a hospitalized event, Form 125 - Summary of Hospitalization Diagnoses must be completed and any other WHI outcomes adjudicated