Supporting Statement B

Attachment 14

OS Adjudicator Form Instructions

ADJUDICATOR FORMS

INSTRUCTIONS

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**

Version: 8 – October 1, 2005

Description: 5-page form filled out by the Physician Adjudicator after the diagnosis of one or more cardiovascular outcomes. Key-entered at the CCC, as appropriate.

When used: Completed when the Physician Adjudicator confirms that a WHI Extension Study participant (Clinical Trial [CT] or Observational Study [OS]) has experienced a WHI Extension Study-defined cardiovascular outcome requiring a hospitalization. The form must also be completed to confirm an outpatient PTCA/revascularization procedure.

Purpose: To provide confirmation of a WHI Extension Study cardiovascular outcome.

GENERAL INSTRUCTIONS

1. A Physician Adjudicator must complete this form when a participant is confirmed as having had one or more of the WHI Extension Study cardiovascular outcomes listed below:

   - Definite or probable myocardial infarction
   - Coronary death
   - Coronary revascularization (including outpatient coronary revascularization)
   - Carotid artery disease requiring hospitalization
   - Peripheral arterial disease requiring hospitalization

2. Obtain all available required documentation before filling out the form. (See *Table 8.2.2 - Documentation Requirements for WHI Extension Study Outcomes*.)

3. CCC Outcomes staf will place the participant's barcode label in the space provided at the top of the form and route the form and a copy of the supporting medical record documents to the Physician Adjudicator for completion and signature.

4. Record ECG and cardiac enzyme criteria for any confirmed MI, coronary death, or coronary revascularization procedure.

5. When the Physician Adjudicator returns the completed form, the CCC Outcomes staff will review the form for completeness and discuss any questions with the Physician Adjudicator. Send to data entry for key-entry.

6. Data Entry: Key-enter the form and initial the first page of the form after key-entry.

7. File a copy of the adjudication case packet [outcomes form(s)] and a copy of all documentation used in the adjudication] in the participant’s outcome file at the CCC.

8. For additional details on adjudicating cardiovascular outcomes, refer to *Section 8.5 - Outcomes Classification: Cardiovascular Outcomes*.

Item Instructions

	Date completed	Month, day, year. Date that the form is completed by the Physician Adjudicator.
	Adjudicator code	The 5-digit WHI Extension Study ID code for the Physician Adjudicator.
	Adjudication case	The adjudication case number assigned in the WHIX database.
1.	ECG pattern	Mark the one category that best describes the serial evolution of ECG pattern based on as many of the following ECG records as are available. Note that enzymes are to be coded for the timing of the event or symptoms, not just if collected for routine monitoring. Box 1 and box 2 require serial ECGs. **Complete ECG information for a confirmed MI, coronary death, and coronary revascularizations.** **Left bundle branch block (LBBB)**: select box 2 - "equivocal Q-wave evolution; or evolving ST-T abnormalities; or <u>new</u> LBBB" if there is documentation in the medical record indicating the LBBB is new. Otherwise, select box 8-"Other ECG pattern or ECG uncodable."
2.	Cardiac Enzyme information?	Yes/No. If the cardiac enzyme information is not available anywhere in the medical records, select box - 0 "No", and skip to question 3 – "Myocardial Infarction (MI)."
2.1	Serum creatine kinase	If MB is available, do not classify total CK. For options referring to "normal limits," use the limits specified by the laboratory that conducted the test. If creatine kinase was not measured or if no result is available, mark box – 99 "CK result not available." Data Entry: Key-enter each box checked.
2.2	Troponin Lab Test	Mark the <u>one</u> category that applies best. Indicate Troponin C, I, T, or Troponin not specified. If more than one Troponin test was conducted, indicate the type that was most elevated.
2.2.1	Troponin Lab Results	Mark the <u>one</u> category that applies best. 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 hospital laboratory that conducted the test. Troponin values should be coded using the upper limit of normal (UNL) and not the upper limit of indeterminate/indecisive as the reference values. Thus, if 2 cutpoints are given, choose the lower cutpoint of the upper limit of normal. If Troponin was not measured or if no result is available, mark "Troponin not available" and skip to Question 3 - "Other cardiac-specific lab test."
3.	Cardiac pain	Present/Absent/Unknown. Refers to an acute episode of pain, discomfort or tightness in the chest, arm, throat, or jaw.
4.	Definite, probable, or aborted MI	Yes/No. Using *Table 8.5.1 – Definition of Criteria for Diagnosis of Myocardial Infarction*, mark the appropriate box and complete Questions 4.1. to 4.4.
4.1.	Date of admission	The **admit date** on the hospital medical records.

4.2.	Diagnosis	Mark the one category that corresponds best to the Physician Adjudicator's final diagnosis. If the myocardial infarction occurred during or resulted from a procedure, mark the appropriate box listed under 4.2.1.
4.2.1.	Type of procedure	Mark the <u>one</u> category that applies best: 1. A MI that followed a <u>cardiac</u> procedure within 24 hours. 2. A MI that followed a <u>cardiac</u> procedure within 2-30 days. 3. A MI that followed a <u>non-cardiac</u> procedure within 30 days.
4.3.	Thrombolytic agent or procedure	No/Yes/Unknown. Mark one. If “No”, skip to Question 3.5 – “Was the MI fatal.” Mark "Yes" if medical record shows administration of streptokinase, reteplase (Retavase), tenecteplase (TNKase), alteplase tPA (Activase); or a procedure (e.g., angioplasty) conducted soon after admission.
4.4.	MI fatal	No/Yes. Complete Question 5 – “Coronary Death.”
5.	Coronary death *[hospitalized deaths only*]	Yes/No. Note that Q.1 - ECG and Q.2 - enzyme information must be completed. Complete *Form 124 – Report of Death (Final)* also.
5.1.	Date of death	The discharge date on the hospital medical records or the date on the death certificate.
5.2.	Diagnosis	State the type of coronary death in words, e.g., definite CHD death, possible CHD death, fatal MI, fatal CABG. Data Entry: Do not key-enter this text.
6.	Coronary revascularization (hospitalized/non-hospitalized)	Yes/No. Mark the appropriate box and complete Questions 6.1 to 6.2 to confirm the procedure to improve the patency of one or more coronary arteries. Note that Q.1 - ECG and Q.2 - enzyme information must be completed.
6.1.	Date of admission	Use the date of admission as the date of procedure, even if more than one procedure was done.
6.2.	Type of procedure	Mark all that apply. If multiple procedures of the same type (e.g., two PTCA’s) are conducted during a single hospital admission, only record the first procedure.
6.3	Second MI	Mark one. Mark only if a second MI not already reported in Question 4 – “Definite, probable or aborted MI” occurred at this admission as a result of, or during the coronary revascularization procedure. Answer ‘No’ if enzymes were drawn after the revascularization and there is no evidence for an MI. Answer ‘Yes’ if enzymes were drawn after the revascularization and there <u>was</u> evidence for an MI. Answer ‘Unknown’ if no enzymes were drawn after the procedure.
7.	Carotid artery disease requiring hospitalization	Yes/No. Mark the appropriate box and complete Questions 7.1 to 7.3 to confirm the carotid artery disease. Note that participant must be hospitalized (and symptomatic or requiring intervention).

7.1.	Date of admission	The **admit date** on the medical records.
7.2.	Diagnosis	Mark the one box that corresponds best to the Physician Adjudicator's final diagnosis.
7.3.	Criteria for diagnosing carotid artery disease	Mark all that apply. Note that participant must be hospitalized (and symptomatic or requiring intervention).
8.	Peripheral arterial disease requiring hospitalization	Yes/No. Mark the appropriate box and complete Questions 8.1 to 8.3 to confirm the peripheral arterial disease. This diagnosis refers to disease in aorta, iliac arteries or below that is symptomatic and/or requiring intervention; and requires or occurs during a hospitalization. Includes abdominal aortic aneurysm but exludes aortic dissection.
8.1.	Date of admission	The **admit date** on the hospital medical records.
8.2.	Diagnosis	Mark the one box that corresponds to the Physician Adjudicator's final diagnosis.
8.3.	Criteria for diagnosing peripheral arterial disease	Mark all that apply.
	Responsible Adjudicator Signature	The Physician Adjudicator should sign 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, and that **other** WHI Extension Study outcomes (e.g., hospitalization) have been investigated and adjudicated.

FORM: **123 - REPORT OF FRACTURE OUTCOME**

Version: 8 – October 1, 2005

Description: 2-page form filled out by UCSF Bone Density Center Physician Adjudicator. Key-entered at the CCC.

When used: Completed as the UCSF Bone Density Center Physician Adjudicator confirms that a WHI Extension Study participant (Clinical Trial [CT] or Observational Study [OS]) has experienced a WHI Extension Study-defined hip fracture outcome.

Purpose: To provide confirmation of a hip fracture outcome.

GENERAL INSTRUCTIONS

1. This form must be completed by a UCSF Physician Adjudicator only when a participant (in the CT or OS) is confirmed as having had a WHI Extension Study-defined hip fracture.

2. Obtain all available supporting documentation before filling out the form. (See *Table 8.2.2 – Documentation Requirements for WHI Extension Study Outcomes*.)

3. The CCC Outcomes staff will place the participant's barcode label in the space provided at the top of the form and route the form and a copy of the supporting medical record documents to Physician Adjudicator for completion and signature.

4. Complete Question 1, items 1.1. - 1.5. for a confirmed hip fracture.

5. When the completed form is returned by Physician Adjudicator, the CCC Outcomes staff will review the form for completeness and discuss any questions with the Physician Adjudicator. Send to data entry for key-entry.

6. Data Entry: Key-enter the form and initial the first page of the form after key-entry.

7. File a copy of the adjudication case packet (form and a copy of all supporting documentation used in the adjudication) in the participant's outcomes file at the CCC.

8. For additional details on adjudicating a hip fractures outcome, refer to *Section 8.6 - Outcomes Classifications: Hip Fractures*.

Item Instructions

	Date completed	Month, day, year. Date that the form is completed.
	Adjudicator code	The 5-digit WHI Extension Study employee ID for the Physician Adjudicator.
	Adjudication case no.	The adjudication case number assigned in the WHIX database.
1.	Hip fracture	Yes/No. Mark the appropriate box and complete items 1.1. to 1.5. for a report of a confirmed hip fracture.
1.1.	Date of diagnosis	Month, day, year. The date of hospital admission for radiologic confirmation of the hip fracture or the date of radiologic confirmation if no hospitalization occurred.
1.2.	Fracture site	Mark the one category that best describes the hip fracture site.
1.3.	Side of hip fracture	Mark one.
1.4.	Criteria used for diagnosis	Mark one. The items are arranged in hierarchical order from the strongest to the weakest evidence of hip fracture, so mark the <u>first</u> item that applies.
1.5.	Pathologic fracture	Mark one. Choose "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. Choose "Yes" if the fracture was associated with a documented underlying bone abnormality including a bone tumor, bone cyst, Paget's disease (of bone), cancer metastasis, or occurred at a pre-existing hip replacement site. Choose "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.
	Responsible adjudicator signature	The Physician Adjudicator should sign the form only when (s)he is satisfied that the relevant items have been filled in as completely and accurately as possible on the basis of the information available.

FORM: **124 - REPORT OF DEATH (Final)**

Version: 8 – October 1, 2005

Description: 3-page form filled out by the Physician Adjudicator after a participant death. Key-entered at the CCC.

When used: Completed as the Physician Adjudicator confirms that a WHI Extension Study participant (CT or OS) has died and her cause of death is determined.

Purpose: To provide confirmation of a death and/or cause of death information.

GENERAL INSTRUCTIONS

1. This form must be completed by a Physician Adjudicator when a participant has died.
2. Obtain all available supporting documentation before filling out the form.
3. The CCC Outcomes staff will place the participant's barcode label in the space provided at the top of the form and route the appropriate outcome form and a copy of the supporting documents to the Physician Adjudicator for completion and signature.
4. When the completed form is returned by the Physician Adjudicator, the CCC Outcomes staff will review the form for completeness and discuss any questions with the Physician Adjudicator. Send to data entry for key-entry.
5. File a copy of the form and a copy of all supporting documentation in the participant's outcome file at the CCC.
6. For additional details on adjudicating deaths, refer to *Section 8.7 - Fatal Events.*

Item Instructions

	Date complete	Month, day, year. Date that the form is completed by the Physician Adjudicator.
	Adjudicator code	The 5-digit WHI Extension Study ID for the Physician Adjudicator.
	Adjudication case	The adjudication case number assigned in the WHIX database.
1.	Date of death	Month, day, year. The date of hospital discharge or the date on the death certificate.
2.	Cause of death	
2.1.	Underlying cause	The underlying cause is the disease or injury that initiated events resulting in death. Include the precise diagnosis in words.
2.2.	Underlying cause ICD-9-CM or ICD-10-CM code	The ICD-9-CM or ICD-10-CM code corresponding to the underlying cause of death as documented in the medical records. If the underlying cause of death is the result of an accident/injury and the corresponding ICD-9-E-code or ICD-10-E-code is available, record the E-code in Question 3 - *Subclassification of underlying cause of death, Accident/Injury*.
2.3.	Contributory cause(s) of death	Under 2.3.1, 2.3.3, and 2.3.5, indicate the events that contributed to the death but did not directly cause the death. List only the top three. Hierarchical order not required. Under 2.3.2, 2.3.4, 2.3.6, indicate the ICD-9-CM or ICD-10-CM code corresponding to the contributory cause of death. If the immediate cause of death is the result of an accident/injury and the corresponding ICD-9-E-code or ICD-10-E-code is available, record the E-code in Question 3 - *Subclassification of underlying cause of death, Accident/Injury*.
2.4.	Immediate cause	The immediate cause is the final disease or condition resulting in death. Include the precise diagnosis in words.
2.5.	Immediate cause ICD-9-CM or ICD-10-CM code	The ICD-9-CM or ICD-10-CM code corresponding to the immediate cause of death as documented in the medical records. If the immediate cause of death is the result of an accident/injury and the corresponding ICD-9-E-code or ICD-10-E-code is available, record the E-code in Question 3 - *Subclassification of underlying cause of death, Accident/Injury*.
3.	Subclassification of underlying cause of death **(Required)**	Mark one. Subclassification of death includes cancer, cardiovascular disease, accident/injury, other/known, and other/unknown. If the subcategory of accident/injury is selected, record the appropriate E-Code listed on the hospital face sheet or physician attestation and enter the E-Code into the WHIX database. Only report a code with the prefix "E" (the external cause of injury and poisoning). E-codes are used for classifying environmental events, circumstances, and conditions as the cause of injury, poisoning, and other adverse effects. ***Note*: Identification of a death outcome (in the WHIX database) requires this question to be completed.**
4.	Autopsy	Mark one. No/Yes/Unknown

5.	Documentation available for adjudication	Mark all that apply. Record all documentation present in case packet used to adjudicate the death. Sources include medical records, autopsy findings, death certificate, ER record, EMS report, informant interview, *Form 120 – Initial Notification of Death*, and Coroner's report. NDI search option is for CCC use only.
6.	Coronary Death	Cause(s), subclassification and timing of coronary death. Complete for both in or out of hospital coronary death. For all in-hospital coronary deaths, complete *Form 121 – Report of Cardiovascular Outcome*.
6.1.	Criteria for diagnosing coronary death	Mark all that apply. Classification for which the coronary death is based.
6.2.	Coronary death subclassification	Mark the <u>one</u> category that applies best. Definite fatal MI/definite fatal CHD/possible fatal CHD.
6.3.	Timing of coronary death	Mark one. If the timing of the coronary death is unknown, or the participant "drops dead", select Box 3 – Other coronary death.
	Responsible adjudicator signature	The Physician Adjudicator should sign the form only when (s)he is satisfied that the relevant items have been filled in as completely and accurately as possible, on the basis of the information available.

FORM: **125 - SUMMARY OF HOSPITALIZATION DIAGNOSIS**

Version: 8 – October 1, 2005

Description: 2-page form filled out by Field Center (FC) staff and reviewed/approved by the Physician Adjudicator or CCC Outcomes Liaison. Key-entered at the CCC.

When used: Completed after the FC receives the hospital face sheet or physician attestation that a WHI Extension Study participant (Clinical Trial [CT] or Observational Study [OS]) has had a hospitalization.

Purpose: To provide confirmation of a hospitalization. To document the hospital discharge diagnosis to determine the degree to which the WHI Extension Study is interested in the hospitalization.

GENERAL INSTRUCTIONS

1. This is completed by the FC Outcomes Coordinator and then confirmed by the Physician Adjudicator or CCC Outcomes liaison when a participant is identified as having had a hospitalization.

2. Obtain available supporting documentation before filling out the form.

3. Hospitalization contact information, including date of admission and discharge is required. These items will be key-entered.

4. The FC Outcomes Coordinator will place the participant's barcode label in the space provided at the top of the form and transcribe the ICD-9-CM or ICD-10-CM codes (or text) onto the form. The form and a copy of the supporting documents are sent to the CCC. The CCC Outcomes Liaison reviews the codes and/or text and forwards to the Physician Adjudicator when appropriate. The Physician Adjudicator should adjudicate the outcomes case packet for any WHI Extension Study outcomes including an outcome not self-reported by the participant. The Physician Adjudicator should then sign the form.

5. When the completed form is returned by the Physician Adjudicator, CCC outcomes staff will review the form for completeness and discuss any questions with the Physician Adjudicator. Send to data entry for key-entry.

6. Data Entry: CCC staff will key-enter the form and initial the first page of the form after key-entry. Because the data entry procedures for this form are not standard, please refer to WHIX documentation for detailed form entry instructions.

    - Note: WHIX may not always accept the ICD codes indicated on the medical records documentation. If this happens, double check to ensure the code was data-entered correctly. Ocassionally, a code may need to be truncated before the code is accepted by WHIX. In this case, drop one or two of the terminal digits. Start by eliminating one digit, then a second if the first process is unsuccessful. For example, 410.09 would be truncated to 410.0 or 410.
    - Please notify the CCC of any truncated codes so the CCC can track them.

7. File a copy of the form and a copy of all supporting documentation in the participant's outcome file at the CCC.

Item Instructions

	Date completed	Month, day, year. Date that the form is completed.
	Adjudicator code	The 5-digit WHI Extension Study ID for the Physician Adjudicator.
	Staff person code	5-digit WHI Extension Study employee ID.
	Adjudication case	The adjudication case number assigned in the WHIX database.
	Hospital/facility name	The name, city, state, and zip code of the hospital/facility where the participant was hospitalized.
	Admission date	Month, day, year. The date of hospital admission.
	Discharge date/date of death	Month, date, year of the hospital discharge or date of death.
	Patient's hospital ID	The hospital ID number for the patient's medical records. (optional)
1.	ICD-9-CM or ICD-10-CM discharge diagnosis codes	Record all ICD-9-CM or ICD-10-CM diagnosis codes in the order they are listed on the hospital Face Sheet, Physician Attestation or other diagnosis code sheet. If there are more diagnosis codes than space available, record on a separate page and append to this form. Do <u>not</u> report codes with a V prefix. Do not add, delete, or alter the ICD-9 or ICD-10-CM codes provided in the hospital documentation.
2.	ICD-9-CM or ICD-10-CM procedure codes	Record all ICD-9-CM or ICD-10-CM procedure codes in the order they are listed on the hospital Face Sheet, Physician Attestation or other procedure code sheet. If there are more procedure codes than space available, record on a separate page and append to this form. Do not add, delete, or alter the ICD-9 or ICD-10-CM procedure codes provided in the hospital documentation.
3.	Handwritten discharge diagnoses	
3.1.	Discharge diagnoses recorded?	Mark one. No/Yes. If the ICD-9-CM or ICD-10-CM diagnosis codes are not available, write out the discharge diagnoses in the order they are listed on the hospital Face Sheet, Physician Attestation Sheet, or other diagnoses code sheet. If there are more diagnoses than space available, record on a separate page and append to this form. Data Entry: Key-enter the marked box code only.
4.	Handwritten procedures	
4.1.	Procedures recorded?	Mark one. No/Yes. If the ICD-9-CM or ICD-10-CM procedure codes are not available, write out the procedures in the order they are listed on the hospital Face Sheet, Physician Attestation or other procedure code sheet. If there are more procedures than space available, record on a separate page and append to this form. Data Entry: Key-enter the marked box code only.

5.	Additional outcomes associated with hospitalization	Mark one. No/Yes. While reviewing the case documentation, were any unexpected outcomes discovered, i.e., any that were not reported by the participant? If yes, adjudicate all WHI Extension Study outcomes using the appropriate outcomes forms. Note: This question is <u>not</u> data entered.
	Responsible adjudicator/CCC Outcomes Liaison signature	The Physician Adjudicator or Outcomes Liaison should sign this form only when s/he is satisfied that all questions have been filled in as completely and accurately as possible on the basis of all available information.

FORM: **130 - REPORT OF CANCER OUTCOME**

Version: 8.2 – October 30, 2008

Description: 4-page form filled out by the CCC Cancer Coder after the diagnosis of a new cancer or hematoproliferative or lymphoproliferative malignancy. Do NOT complete the form if the cancer is a relapse, recurrence, or metastatic site of a cancer first diagnosed prior to entry into the study or a cancer reported previously. Key-entered at CCC.

When used: Completed when the Cancer Coder confirms that a WHI Extension Study participant (Clinical Trial [CT] or Observational Study [OS]) has had a cancer diagnosed (excluding non-melanoma skin cancer).

Purpose: To provide confirmation of each newly-diagnosed (incident) cancer outcome.

The CCC Outcomes staff places the participant's barcode ID label in the space provided at the top of the form and routes the *Form 130* and a copy of the supporting documents to the Cancer Adjudicator.

GENERAL INSTRUCTIONS

1. This form must be completed by a CCC Cancer Coder when a WHI Extension Study participant (in the CT or OS) is confirmed as having had a newly-diagnosed cancer or malignancy (excluding non-melanoma skin cancer).

2. Only complete this form for newly-diagnosed primary cancers.

3. Obtain all available supporting documentation before filling out the form.

4. Use a separate form for each primary cancer site.

5. The CCC Outcomes Staff will place the participant's barcode label with ID number on the front page of the form and route the form and a copy of the supporting documents to the CCC Cancer Coder for completion and signature.

6. When the completed form is returned by the Cancer Coder, the CCC Outcomes Staff will review the form for completeness and discuss any data questions with the Cancer Coder. Send to data entry for key-entry.

7. Data Entry: Key-enter the form and initial the first page of the form after key-entry.

8. File a copy of the adjudication case packet (form and a copy of all supporting documentation) in the participant's outcome file at the CCC.

9. For additional details on adjudicating cancer outcomes, refer to *Vol. 8, Section 4 - Outcome Classifications: Cancer Outcomes*.

Item Instructions

	Date completed	Month, day, year. Date the Cancer Adjudicator completed the form
	Adjudicator code	3-digit ID for the Cancer Adjudicator.
	Center Case No.	Case number assigned by WHIX.
	Case Copy No.:	Copy number assigned by WHIX
1.	Date of Ddiagnosis	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 when the initial biopsy of the cancer is done. If no tissue was obtained to make the diagnosis, use the date of the first cytology diagnosis. **Tips for Date of Diagnosis:** • Oftentimes for leukemia cases, the first diagnosis may be made with a peripheral blood smear. • 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 the best approximation**.**
2.	Primary Cancer Site	Mark one primary cancer site. If a case has multiple cancer sites, complete a *Form 130* 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 'Other Cancer Outcomes' or is an unknown site, mark 'Box 00 - Other' and hand write the site or indicate 'unknown' in the space provided. **Tips for primary cancer site:** • For the 'Main WHI Cancer Outcomes', breast only, complete the required questions, Qx.1-3 and Qx.5-14. • For the other 'Main WHI Cancer Outcomes' (ovary, corpus uteri/endometrium, colon, rectum, rectosigmoid/rectosigmoid junction), complete the required questions, Qx.1-3 and Qx.5-10. • For the 'Other Cancer Outcomes', complete the required questions, Qxs.1-6, to capture the fact of cancer. Note: Extension Study goal is to apply SEER coding to all 'Other Cancer Outcomes' sites for WHI and Extension Study primary sites. • If the primary cancer site is listed under 'Other Cancer Outcomes', check the box provided in Qx.2 but do not enter a site code for Qx.3. • Do not code primary cancer site as the secondary or metastatic site of the cancer. • If 'Box 00 - Other' is marked, a corresponding ICD-O-2 (International Classification of Diseases for Oncology, Second Edition) must be entered in Qx3. • Refer to *Form 130* for the list of the 'Main WHI Cancer Outcomes' and the 'Other Cancer Outcomes'.

3. ICD-O-2-Code

A numeric ICD-O-2 code is recorded for the primary cancer site indicated in Qx. 2 for the 'Main WHI Cancer Outcomes' sites and those primary sites handwritten in the 'specify' field for 'Box 00 – Other'.

4. Tumor Behavior

This item is completed only when a primary site list under 'Other Cancer Outcomes' in Qx. 2 is checked.

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

- Invasive; malignant; infiltraing; 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 (code 3)
- Unknown (code 9)

Tips for Tumor Behavior:

- Code '3' is only used for ovary.

5. Reporting Source

This is a hierarchical field, lower numbers 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)

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 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)

7. Laterality

Mark the one laterality that is applicable for the primary site.

- 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)

8. Morphology

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 differenctiation 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
- Grade: 3 - poorly differentiated

9. EOD (SEER)

The EOD (extent of disease) is an estimate of the extent of disease based on all the evidence available during the first couse of treatment (4 months from date of diagnosis), 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:

- Refer to appropriate SEER coding scheme for details of the codes.

10. Summary Stage (SEER)

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)

Items 11-14 are completed for breast cancer only.

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) • Lobular invasive plus ductal in-situ (code 4) • Invasive cancer, ductal and lobular NOS (code 5)
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 4) • Unknown/Not done (code 5)
12.1	Date	Indicate the date the tissue was excised (that was used for the ERA).
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)
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 4) • Unknown/Not done (code 5)
13.1	Date	Indicate the date the tissue was excised (that was used for the PRA).
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)
14.	Her 2/Neu	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 4) • Unknown/Not done (code 5)

14.1	Date	Indicate the date the tissue was excised (that was used for the Her 2/Neu). **Tips for ERA/PRA/Her 2/Neu assays:** • The ERA/PRA/Her 2/Neu assays are generally done on an invasive tumor. • Do not code the assay results if the tissue that was submitted was either lymph nodes or metastatic sites. • Code assay results from the primary site tissue. • A FISH assay will overide the the Her 2/Neu since it will provide a more specific result. • If Qxs 12, 13, or 14 are coded '9-unknown/not done', do not code 12.1, 12.2, 13.1, 13.2 or 14.1, respectively.
15.	Editor Code	ID of the CCC Cancer Coder who edited the form, if appropriate.
	Cancer Coder Signature	The CCC Cancer Coder should sign the form only when the relevant items have been filled in as completely and accurately as possible on the basis of the information available.

FORM: **132 - REPORT OF STROKE OUTCOME**

Version: 8 – October 1, 2005

Description: 3-page form filled out by the CCC Stroke Adjudicator after the diagnosis of a cerebrovascular outcome. Key-entered at the CCC, as appropriate.

When used: Completed when the CCC Stroke Adjudicator confirms that a WHI Extension Study participant (Clinical Trial [CT] or Observational Study [OS]) has experienced a WHI Extension Study-defined cerebrovascular outcome. The form must also be completed to confirm a TIA or hospitalized carotid artery disease.

Purpose: To provide confirmation of a WHI Extension Study cerebrovascular outcome.

GENERAL INSTRUCTIONS

1. A CCC Stroke Adjudicator must complete this form when a participant is confirmed as having had WHI Extension Study cerebrovascular outcome.

2. Obtain all available required documentation before filling out the form. (See *Table 8.2.2 - Documentation Requirements for WHI Extension Study Outcomes*.)

3. CCC Outcomes staff will place the participant's barcode label in the space provided at the top of the form and route the form and a copy of the supporting medical record documents to the CCC Stroke Adjudicator for completion and signature.

4. When the CCC Stroke Adjudicator returns the completed form, the CCC Outcomes staff will review the form for completeness and discuss any questions with the CCC Stroke Adjudicator. Send to data entry for key-entry.

5. Data Entry: Key-enter the form and initial the first page of the form after key-entry.

6. File a copy of the adjudication case packet [outcomes form(s)] and a copy of all documentation used in the adjudication] in the participant's outcomes file at the CCC.

7. For additional details on adjudicating cardiovascular outcomes, refer to *Section 8.5 - Outcomes Classification: Cardiovascular Outcomes*.

Item Instructions

	Date completed	Month, day, year. Date that the form is completed by the Physician Adjudicator.
	Adjudicator code	The 5-digit WHI Extension Study employee ID code for the Physician Adjudicator.
	Adjudication case	The adjudication case number assigned in the WHIX database.
1.	Stroke	Yes/No. If non-fatal, complete Questions 1.1 to 1.7 and 1.9. If fatal, complete Questions 1.1 to 1.9.
1.1	Date of admission or diagnosis	The **admit date** on the hospital or outpatient medical records.
1.2	Diagnosis	Mark the one category that corresponds best to the CCC Stroke Adjudicator's final diagnosis.
1.3	Stroke during or resulting from a procedure	Yes/No/Unknown. Mark one.
1.4	Stroke requiring hospitalization	Yes/No. Mark one.
1.5	Oxfordshire classification	Mark the <u>one</u> category that applies best. A stroke assessment scale completed by a Stroke Neurologist.
1.6	TOAST classification	Mark the <u>one</u> category that applies best. Trial of Org 10172 in Acute Stroke Treatment (TOAST) classification. To be completed by the Stroke Neurologist.
1.7	Criteria for diagnosing stroke	Mark the <u>one</u> category that applies best.
1.8	Criteria for diagnosing fatal stroke	Mark all that apply and complete *Form 124 – Final Report of Death*. Indicate on the Investigation Documentation Summary (IDS) Report that the death needs to be adjudicated by the CVD Adjudicator.
1.9	Participant's functional status at hospital discharge (Glasgow Outcome Scale)	Mark the <u>one</u> 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. 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."
2.	TIA requiring hospitalization	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.
2.1	Date of admission	The **admit date** on the hospital outpatient medical records.
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).

3.1	Date of admission	The **admit date** on the medical records.
3.2	Diagnosis	Mark the one box that corresponds best to the Physician Adjudicator's final diagnosis.
3.3	Criteria for diagnosing carotid artery disease	Mark all that apply. Note the participant must be hospitalized (and symptomatic or requiring intervention).
	Responsible adjudicator signature	The Physician Adjudicator should sign the form only when (s)he is satisfied that the relevant items have been filled in as completely and accurately as possible on the basis of the information available.