8.11 Form 130 – Report of 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 – Report of Cancer Outcome* and a copy of the supporting documents to the Cancer Adjudicator.

Administrative Questions

Date Completed: Date the Cancer Adjudicator completed the form.

Adjudicator Code: 3-digit ID for the Cancer Adjudicator

Central Case No.: Case number assigned by WHIX

Case Copy No.: Copy number assigned by WHIX

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 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.

Qx. 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-0-2 (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'.

Qx. 3 – ICD-0-2

A numeric ICD-0-2 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'.

Qx. 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; 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 (code 3)
- Unknown (code 9)

Tips for Tumor Behavior:

- Code '3' is only used for ovary.

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 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)

Qx. 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 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
- Grade: 3 - poorly differentiated

Qx. 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.

Qx. 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)

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)
- Lobular invasive plus ductal in-situ (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 4)
- Unknown/Not done (code 5)

Qx.12.1 – Date

Indicate the date the tissue was 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 4)
- Unknown/Not done (code 5)

Qx. 13.1 – Date

Indicate the date the tissue was 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

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)

Qx. 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 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.

Figure 8.10
Form 130 – Report of Cancer Outcome

WHI **Form 130 – Report of Cancer Outcome** **Ver. 8.2**

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.)***

_____

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Figure 8.10 (continued)
Form 130 – Report of Cancer Outcome

WHI **Form 130 – Report of Cancer Outcome** **Ver. 8.2**

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

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Figure 8.10 (continued)
Form 130 – Report of Cancer Outcome

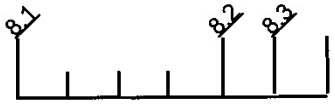
WHI **Form 130 – Report of Cancer Outcome** **Ver. 8.2**

Complete Questions 7–10 for Main Cancer Outcomes only.

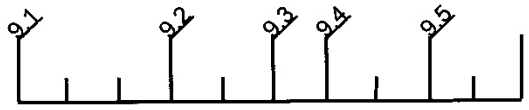
7. Laterality: ***(Mark one only.)***

- ☐ 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

R:\DOC\EXT\FORMS\ENG\CURR\F130V8_2.DOC 7/15/06 3 of 4

Figure 8.10 (continued)
Form 130 – Report of Cancer Outcome

WHI **Form 130 – Report of Cancer Outcome** **Ver. 8.2**

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: __

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