

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 <i>Form 130</i> for each cancer site.
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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; 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.
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 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
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 course 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 override 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.