

**HEALTH ABC
CANCER ADJUDICATION PROTOCOL
(Revised November 2005)**

I. Definitions

1) Cancer endpoint

- Malignant neoplasm including solid tumors and hematologic malignancies such as leukemias
- Invasive and in situ cancers but not “pre-cancerous” or “pre-malignant” lesions
- We will not include non-melanoma skin cancers, specifically skin squamous cell carcinomas and basal cell carcinomas. Any melanoma will be an endpoint.

2) Metastasis

- Spread tumor beyond the primary site, including any involvement of lymph nodes
- Metastatic disease may be inferred from a consistent clinical picture without pathologic confirmation of distant involvement (e.g., confirmed colon cancer with nodules on chest x-ray).

3) New (incident) vs. recurrent malignancy

Only information on newly diagnosed incident cancers, or first recurrences, are of interest in this study. Each reported cancer must be classified by clinic staff as new (incident) or recurrent. Recurrent cancers do not require completion of the cancer-specific forms (although recurrent cancers may result in hospitalization or death that do require record collection and completion of appropriate forms). Recurrent cancers should trigger a review of the existing records to be sure that the cancer is listed as prevalent disease.

4) Pathologically confirmed

Defined as a pathology report that clearly states the diagnosis in specific terms that are synonymous with cancer (e.g., malignancy, malignant tumor, malignant neoplasm, carcinoma, CA, or a specific histology that defines malignant tumor morphology). Ambiguous terms or conclusions in the report should be classified as follows:

- ACCEPT as cancer: “probable, suspect, suspicious, compatible with, most likely , and consistent with.”
- DO NOT ACCEPT as cancer: “questionable, possible, suggests, worrisome, equivocal.”

II. Ascertainment of Cancers during Surveillance

Study participants may report cancers during any of the following contacts:

1) Semi annual telephone interview

- 2) Annual clinic visit
- 3) Scheduling of annual clinic visits
- 4) Proxy, spouse, relative, or friends contact field center to report hospitalization
- 5) Hospital medical records from later event indicate a cancer event occurred.
- 6) HCFA tape review
- 7) Obituary

If a participant reports cancer at any of these times, it is important to determine the details of the cancer and to obtain the information necessary for requesting documentation needed for cancer adjudication.

Cancers can also be reported by proxy respondents and other informants, by contacts with health care professionals and others when attempting to trace participants who have missed regular follow-up contacts, and from hospital discharge records and death certificates of participants who have died. Documentation and adjudication of these cancers should proceed as outlined below, to the extent possible.

III. Health ABC Data Collection Forms to be Completed by Examiners and Events Coordinators (or their designates) at the Field Centers

- 1) Data collection forms required for all cancers
 - a. Health ABC Event Form
 - b. Cancer Adjudication Report
- 2) If cancer diagnosis made during a hospitalization, also complete
 - a. Discharge Abstract Form
 - b. Local Adjudication Report
- 3) If cancer diagnosis resulted in death or was discovered at autopsy, also complete the following:
 - a. Report of Death
 - b. Decedent Proxy Interview
 - c. Informant Interview for Out-of-Hospital Deaths (if appropriate)
 - d. Final Death Adjudication Report (at central adjudication)

IV. Documentation to be Requested for Cancers by Events Coordinator (or their designates)

- 1) Pathologic or cytologic reports from biopsy, surgery or other method of collection.

- 2) Additional cancer-specific documents to request (if appropriate) for all confirmed cancers
 - a. Face sheet or physician attestation with ICD codes and Discharge Summary (if hospitalized)
 - b. Written report from radiologic or other non-invasive tests such as CT or MR scans, bone scans, x-rays, angiograms, etc.
 - c. Other supportive laboratory data, such as PSA (prostate specific antigen), tests of liver function, etc.
 - d. Other written reports by a physician
 - clinic notes indicating that a cancer is present or related to its treatment
 - progress notes from a hospitalization
 - operative reports from surgical procedures related to diagnosis (i.e., excisional biopsy) or therapy, even if outpatient.
 - discharge summary from hospitalization where cancer is mentioned.
 - e. Autopsy reports if participant died

V. Procedures

Once a cancer is identified in a Health ABC participant, the following protocol should be followed:

- 1) An Event Form is completed by examiner or Event Coordinator at the local field center once notified of cancer. Check the appropriate box under "Section II: Cancer, Fracture, and Pneumonia." Record the location and histologic type if known after "Please specify type" (e.g., brain glioblastoma, or renal carcinoma).
- 2) If hospitalized, complete Discharge Abstract Form and Local Adjudication Report.
- 3) The completed Event Form scanned into data system.
- 4) A copy of the Event Form is forwarded to the Event Coordinator at the local field center.
- 5) The Event Coordinator enters tracking information into the web-based D and D tracking system.
- 6) Event Coordinator requests:
 - a) pathologic or cytologic reports
 - b) cancer-specific documentation (refer to Section IV.2 above)
- 7) The Event Coordinator notes first request for documentation in the D and D tracking system.
- 8) If necessary, the Event Coordinator makes second request for documentation.
- 9) The Event Coordinator notes second (and all additional) requests for documentation in the D and D tracking system.

- 10) All documentation received is noted in the D and D tracking system. Once all documentation is received, the Cancer Adjudication Report is completed.
- 11) Event Coordinator notes the date the event packet is completed (documentation received and all appropriate data collection forms filled out) in the D and D tracking system.

VI. Completing the Cancer Adjudication Report

Question #1: Record the Health ABC Event Form reference number from the lower left-hand corner of the Event Form.

Question #2: Record the date that the cancer was first diagnosed by a physician. Typically, this will be the date on the pathologic or cytologic report, and if not confirmed pathologically, the date of the first abnormal laboratory test or physical exam finding. If diagnosis made at autopsy, the date of death is used. Note that this date may simply be the best guess of the person reporting the event.

Question #3: Record if the needed reports are attached, and if not, indicate if other records are attached.

Question #4: Mark the primary cancer site. Pick the one category that best describes the initial location of the cancer. For cancers that have spread beyond the initial site, attempt to identify where the cancer began. If the primary site cannot be determined, mark "unknown."

Question #5: Indicate if the cancer has been confirmed by a pathologic/cytologic report, written reports from laboratory or radiographic reports, or other written reports from a physician. When these indicate that no malignancy is present, mark "no" and stop. When review of these documents does not convince the adjudicator that a malignancy is highly likely, mark "uncertain." Note that the decision mark "yes" vs. "uncertain" is based on review of all available documentation.

Question #6: Indicate the cell type as described in the pathologic, cytologic or other reports. If the cell type is not recorded on any of the reports or supporting documents, record "unknown."

Question #7: Indicate if any of the supporting documents state that the malignancy has metastasized.

Question #8: Indicate the most reliable level of documentation reviewed to adjudicate the event. From most reliable to least reliable these include:

- Written pathology report of cytologic, histologic, gross anatomy (includes autopsy).
- Written report for other laboratory or radiographic testing.

- Written notes from a physician summarizing the cancer diagnosis or procedures related to the diagnosis.

VII. Decision rules

- 1) Multiple cancers diagnosed simultaneously.
 - If tissue origin of cancers differ, report separately.
 - If tissue origin of cancer is the same (e.g., two breast cancers diagnosed at the same time) only record the most advanced neoplasm (typically the largest and/or most invasive).
- 2) Cytologic report of malignancy but histologic report in negative.
The final diagnosis should reflect the histological report unless there is compelling evidence that the histologic report is incorrect.
- 3) Villous adenomas should be classified as neoplasms that are not cancer.
- 4) If a cancer is suspected without pathologic confirmation (ex. radiologic evidence of tumor) and it is presumed to be the primary site, mark the primary site as that location (question 4). Indicate in question 5 (Is cancer confirmed?) as 'yes'. If the event is an inpatient hospitalization, indicate on the Local Adjudication Report 'yes' for question 4p.
- 5) If a cancer is suspected without pathologic confirmation but the primary site is unknown (ex. radiologic evidence appearing as mets), mark the primary site (question 4) as 'Unknown'. Indicate in question 5 (Is cancer confirmed?) as 'yes'. If the event is an inpatient hospitalization, indicate on the Local Adjudication Report 'yes' for question 4p.