

WOMEN'S INTERAGENCY HIV STUDY QUESTION-BY-QUESTION SPECIFICATIONS FORM QCCD: CANCER DIAGNOSIS REVIEW FORM
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A QCCD form is to be completed for every WIHS cancer case that is selected for review. The WIHS Cancer/Pathology Working Group and WDMAC will provide direction on which cancer cases should be reviewed and in what priority. Prior to a Cancer Diagnosis Review, the WIHS site, in some manner, should confirm the cancer case. For instance, a participant may self-report a cancer, but the case would not be eligible for review until the cancer diagnosis has been confirmed via some mechanism such as medical record abstraction/ascertainment or cancer registry match.

The Cancer Diagnosis Review process is the final step in confirming or disputing a cancer diagnosis within the WIHS cohort.

General Instructions:

1. Use the form version dated **04/01/04**.
2. All dates should be recorded in MM/DD/YY format.

Completing the Form:

- A1. Record the 8-digit WIHS ID number for the participant cancer case in review.
- A3. Record the date the QCCD form was completed.
- A4. Record the initials of the person completing the QCCD form.
- B1. Record the cancer diagnosis, as indicated on the source document that identified the cancer.
- B2. Indicate the initial source(s) of the cancer diagnosis (i.e., how did WIHS first confirm the cancer?) by circling "1" (YES) or "2" (NO) for each of subquestions a through f, and enter the date of diagnosis, if applicable. More than one answer may apply.
 - a. CNCR: Cancer was confirmed via the cancer registry match and recorded on the CNCR form. If "NO," skip to subquestion B2b.
 - b. CORE: Cancer was confirmed via WIHS medical record abstraction/ascertainment and recorded on a Clinical Outcomes Reporting Form. If "NO," skip to subquestion B2c.
 - c. L15: Cancer was confirmed on the L15 Biopsy Form, transcribed from a pathology report. If "NO," skip to subquestion B2d.
 - d. L14: Cancer was identified and recorded during a participant colposcopy on the L14 Colposcopy form. If "NO," skip to subquestion B2e.
 - e/f. Other: If cancer was confirmed via any mechanism other than the above sources, please specify the source. If "NO," skip to question C1.
- C1. Different types of cancer may be reviewed by WIHS for different reasons. Please specify if the cancer case is being reviewed for routine quality assurance/quality control, for specific use in a manuscript/consent sheet, or for another reason. If the review is being done for routine QA/QC, skip to question C2. If for a manuscript/concept sheet, specify the WDMAC README number in question C1a and skip to question C2. If for another reason, specify the reason in question C1b, then proceed to question C2.
- C2. Record who did the cancer case review and at which institution.
 - a. NAME: Record the name of the pathologist conducting the WIHS cancer review.
 - b. INSTITUTION: Record the institution/hospital where the reviewer/pathology resides.
 - c. CITY, STATE: Record the city and state of the institution/hospital.

- C3. Record the date that the cancer case was reviewed by the pathologist noted in C2.
- C4. Circle “1” (YES) for each source of information or mechanism used in the cancer case review. More than one answer may apply.
- a. TISSUE/SAMPLE: Pathologist reviewed actual and original diagnostic tissue/sample.
 - b. PATHOLOGY REPORT: The original pathology report was reviewed.
 - c. OTHER MEDICAL RECORDS: Other medical records (other than original pathology report) were reviewed.
 - d. CONTACT W/ PERSON: The reviewer discussed the case with the person who made the original diagnosis of cancer.
 - e/f. OTHER: Please clearly specify any other sources/mechanisms used in review.
- D1. Indicate the findings of the review. Does the reviewer agree or disagree with the original cancer diagnosis that was indicated in question B1 and on the original source document?
- NOT INVASIVE/MALIGNANT CANCER: Circle “1” if the **original** cancer diagnosis (in question B1) was invasive/malignant, but the reviewer judges the case to be **NON**-invasive/malignant. The reviewer disagrees with the diagnosis in B1 and finds no malignancy. Skip to question E1.
 - CANCER, AS ORIGINALLY DOCUMENTED: Circle “2” if the reviewer **agrees** with the original diagnosis documented in B1. Skip to question E1.
 - CANCER, BUT OTHER THAN ORIGINALLY DOCUMENTED: Circle “3” if the reviewer judged the case to be cancerous but **disagrees** with the original cancer diagnosis documented in B1. Specify the new diagnosis.
- E1. The reviewer is encouraged to include other comments related to the review process and findings that will help identify the reasons for concurrence or, especially, disagreement with the original cancer diagnosis.

Processing the Form and Disseminating the Results:

1. The pathologist conducting the review should return any tissue specimens to the original WIHS site or institution of origin, per the instruction of those providing the specimen for review.
2. The reviewer should forward the QCCD form to the participant’s WIHS site, usually to the Project Director of the WIHS site, or the reviewer’s contact person at WIHS. A copy of the QCCD must be returned to the participant’s WIHS site.
3. The WIHS site staff, usually the Project Director, should report the QCCD results to the chair of the WIHS Cancer/Pathology Working Group and WDMAC.
4. The QCCD should be entered in Apollo at the WIHS site of the participant under review.