NA-ACCORD Cancer Data Collection Instructions

Registry
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The NA-ACCORD Cancer Data Collection System is an Access database designed to capture and export information regarding cancer diagnoses to NA-ACCORD in the approved data format.

Section 1. Technical Details for Data Managers

Opening the database for data manager access:

The startup menu displays the logon form at entry and the database window is hidden by default. To see the database window along with full menus, forms, and tables -- hold down the shift key when you open the database. You will then have full access to all aspects of the database for adjustments or modifications needed for your site.

Configuring Access 2003/2007 to avoid extraneous windows from popping up:

If you do not routinely use Microsoft Access, you may wish to suppress action query confirmation messages as action queries are used extensively in this database. This will prevent a warning box every time you add, update, or delete data:

Microsoft Access 2003

1) Open the database while holding down the shift key to give you full data manager access.
2) Click on the *Tools* menu in bar across the top.
3) Select *Options* and then *Edit/Find*
4) Uncheck all 3 boxes under 'Confirm' in the top right corner of the box titled 'Record changes', 'Document deletions', and 'Action queries'.
5) Click *OK* button at the bottom of the window.

Microsoft Access 2007

1) Open the database while holding down the shift key to give you full data manager access.
2) Click on the *Office* button in upper left corner of the window.
3) Click on the *Access Options* button at the bottom of the opened box.
4) Click on 'Advanced'.
5) Under the 'Editing' header and 'Confirm' section uncheck all 3 boxes titled 'Record changes', 'Document deletions', and 'Action queries'.
6) Click *OK* button at the bottom of the window.

Adding reviewer names:

The database is set up to capture the name of the person reviewing a diagnosis. This name is entered in the log-in screen and added to each record that is entered in the database from that form. If you don't want to capture this information, choose "test reviewer" on the log-in form each time the database is opened. (Note: this information is never sent to NA-ACCORD). If you would like to capture who reviewed each diagnosis, open the tbl_values, find the row with the value_type of "reviewer", and change "test reviewer" to the name of the reviewer at your site. If you have multiple chart reviewers, add subsequent rows with the value_type of "reviewer", the value equal to the reviewer's name, sort order to capture the order you want the names to appear in the drop down menu, and do not check "NotActive". If you want to remove a reviewer from the list, check "NotActive".

Pre-loading Data:

The system allows for pre-loading diagnoses and cancer details from cancer registry (ICD-O-3) or ICD9 codes into the database prior to final review.

Cancer Registry Data

To pre-load diagnoses from your cancer registry, you will need to create an append query to append rows to the *Diagnosis*, *DxSupport*, and *Tumor* tables. Detailed information on how to convert, map, and append cancer registry variables map to NA-ACCORD variables is found in the file titled, 'NA-ACCORD_Cancer_Registry_Preload_Mapping'.

Since cancer registry information is coded using ICD-O-3, we have provided two documents for mapping ICD-O-3 codes to NA-ACCCORD diagnosis number (variable *DxListID*) (see file 'NA-ACCORD Cancer Registry Diagnosis Mapping') and histology number (variable *histocode*) (see file 'NA-ACCORD Cancer Registry Histology Mapping').

The NA-ACCORD_Cancer_Registry_Preload_Mapping.xls file contains a list of the fields that should be appended to each table. You will need to append data to the *Diagnosis* table first, to obtain the *DxId* (unique number that identifies each cancer diagnosis). This number is then used to enter data into the *DxSupport* and *Tumor* tables for each diagnosis.

ICD9 Codes
If you wish to pre-load diagnoses from ICD9 codes, you will need to create an append query to append rows to the *Diagnosis* table. PatientIdentify = local site id, DxDate should be the first diagnosis date of the cancer, DxListID is the ID number contained in the DxList table for each diagnosis. The *malignancy_icd9* table can be used to map your ICD9 codes to the DxList table. Diagnosis date precision should be set as day, month, year, or unknown. Diagnosis status should all be appended as "Incomplete". The addDate will default to the date the rows are appended.

Exporting Data:
Prior to exporting data, it may be helpful to run the Diagnosis Status report to check that the appropriate number of diagnoses have been completed and verified. You may also want to run the Export Report to check that the expected number of completed and verified diagnoses are available for export. If you do not feel that the numbers reported are correct, please check that all diagnoses have been verified, and that the NA_Accord_ID_tbl has been filled out appropriately.

To export data in NA-ACCORD standard form, click the "export data" button on the logon form. Type in the location of the folder to which you would like the data exported (e.g. C:\NA-ACCORD\Export). Do not include a final "\" or any quotes. The NA-ACCORD ID will be substituted for the local ID and data exported in csv files to the folder. Note that if the NA-ACCORD_ID_tbl is not filled out prior to this process, the export will fail.

The database contains the following tables:
NA-ACCORD_ID_tbl – sites should load this table with the NA-ACCORD ID and the local site ID. This allows reviewers to see the local ID for ease of reviewing a patient (local ID is not sent to NA-ACCORD), the NA-ACCORD ID is substituted when exporting data to NA-ACCORD.

Assessment: captures information on past or current exposure to tobacco and alcohol.

Diagnosis: captures information on patient identifier, diagnosis, diagnosis date, and status of diagnosis review.

DxList: contains the list of NA-ACCORD diagnoses labels. These labels populate the drop down list on the diagnosis tab, and are used to export data to NA-ACCORD. Please do not alter these labels unless asked to do so by the NA-ACCORD Data Management Core.

DxSupport: captures confirmatory data support types and dates for diagnoses.

DxSupportHistology: contains list of histology descriptions for entry of cancer histology into the tumor table (see below).

FamHx: captures information on family history of cancers.

FurtherReviewNotes: captures site specific information about the review process (e.g. if diagnosis needs further review, a note could be made here about what is missing). Note: this table is not exported to NA-ACCORD -- site specific information can be stored here.

Malignancy_ICD9: contains the mapping of ICD9 codes and diagnoses in the Diagnosis table. This is included to assist sites in pre-loading the diagnosis table if desired (see above description of pre-loading diagnoses).

Pap: captures information on pap smears for screening for anal and/or cervical cancer.

tbl_values: contains values used in drop down menus throughout the database.

Tumor: captures information on cancer grade, histology and staging.

TumorStagingSupport: contains information for drop down menus specific to tumor staging.

Verify_dx: for use in the diagnosis verification process (temporary holding table)

Section 2. Data Entry and Standard Operating Procedures

The NA-ACCORD Cancer Data Collection System is designed to facilitate capture of timely, comprehensive, and high quality information on cancers (both HIV and non-HIV associated) among all patients in NA-ACCORD.

- **We are only collecting information on MALIGNANT (INVASIVE) tumors or cancers. Do not collect information on tumors described as benign, in situ, dysplasia, pre-cancer or pre-malignant.**

- **We are collecting comprehensive information on the initial occurrence of all NEW (INCIDENT) cancers diagnosed while the patient was in care at your clinical site, after the date of entry into your cohort. DO NOT capture information on any recurrences, or second cancers of a given type (except Hematologic cancers, see Appendix below).**

- **In addition, we are collecting as much information as possible on cancer diagnoses preceding entry of a patient into care at your clinical site or preceding entry of a patient into your cohort. You are not required to gather additional data from outside of your medical record system for these diagnoses. However, any outside documentation in the medical record should be fully utilized during the review and data collection process. For remote or historical diagnoses (prior to a three month window preceding entry of a patient into care at your clinical site or into your cohort), it is permissible to capture only limited information (*Cancer type* and *Diagnosis date*). If the only documentation for these historical diagnoses is patient reported, use the support type of 'Patient Report Only' (see *Cancer Dx support* below). All data elements should be reviewed and entered as per the directions below with 'Unknown' entered for variables where information is not available.**

- **Every attempt should be made to label the PRIMARY site or location of cancer diagnosis. If this is unknown or the only information is that the patient had "Cancer", then the diagnosis is labeled as 'Other'.**

To accomplish this, we are asking you to review and enter particular information on cancer diagnosis events or occurrences. A patient may have more than one cancer diagnosis that requires review.

- **Data review and entry is structured in this database to capture information per diagnosis, not per patient.**

Since risk factors for malignancies are dynamic, this means that you may enter varying information for the same patient on different cancer diagnoses.

Before we get to the specifics of each part of the database, there are a few overall rules of data entry:

1) Data entry is REQUIRED in fields that are highlighted in **bold**.
2) All date fields should be entered in the MM/DD/YYYY format without any blanks.
3) If an entire date is unknown, then enter '01/01/1900' into the date field and select 'unknown' from the *Date Precision* field drop down menu.
4) If only the year is known then enter '01/01/YYYY' into the date field and select 'year' from the *Date Precision* field drop down menu.
5) If the month and year are known then enter 'MM/01/YYYY' into the date field and select 'month' from the *Date Precision* field drop down menu.
6) If the entire date is known then enter 'MM/DD/YYYY' into the date field and select 'day' from the *Date Precision* field drop down menu.
7) For any field requiring entry of a numeric value that is unknown, enter '-1'.

NA-ACCORD Cancer Logon:

Double-click on the NA-ACCORD cancer database icon to open the Access file. A small window will open titled "NA-ACCORD Cancer Logon." To logon and enter the database, select your name from the *Logon* field drop down menu and click the *Open Database* button. If you are a data manager and you would like to prepare files for export to NA-ACCORD core, click on the *Export Data* button (see Exporting Data section above). If you would like to exit the database, click on the *Exit Database* button.

NA-ACCORD Cancer Review Database:

After logging on, a larger window will open titled "NA-ACCORD Cancer Data Collection System." This is the main data entry interface organized by type of information collected using the following tabs – *Cancer Dx Support, Cancer Details, Pap Screening, Exposure Hx,* and *Other Hx,*.

Across the top of this window are fields pertaining to the overall cancer diagnosis and review process:

MR Number (required): Enter or pre-load this field with the patient's local medical record number. This number will not be sent to NA-ACCORD, but will be converted to NA-ACCORD number in the exporting process (see Exporting Data section above).

Cancer (required): Select or pre-load the type of cancer from the designated drop down list. Many diagnoses have been lumped together in broad categories based on type or anatomic location of the cancer.

- **Every attempt should be made to match the cancer to the most specific cancer type and/or location appearing on the drop-down list. *Make special note of certain cancers that require review for detailed information on anatomic location within that type (Biliary tract, Colon, Kaposi's sarcoma, Non-Hodgkin's lymphoma, and Oral cavity/pharynx).***

- **Don't forget… this field can be changed and you should select the PRIMARY site or location of cancer diagnosis.**

- **For example, if a diagnosis was initially captured or pre-loaded as 'Colon cancer, unspecified' , but it is found, after further review, that the diagnosis is 'Colon cancer, distal' then the label should be changed to the most accurate diagnosis description.**

- **However, if the diagnosis is entered or pre-loaded as a secondary site of diagnosis (or metastatic site) and the primary site is already captured as a separate diagnosis entry, then select 'Error' under *Review Status* for the secondary diagnosis. If the primary site was not already captured, then the label for the metastatic diagnostic site can be changed to the correct primary diagnosis site. In the later case, do not select 'Error' under *Review Status*.**

- **If the cancer is diagnosed at a metastatic site with unknown primary site, then change the Cancer label to 'Other' for this field.**

Diagnosis Date (required): See date rules above. Enter the date this NEW (incident) cancer was first diagnosed. If diagnosis date was pre-loaded, this field can be changed to reflect the most accurate date of diagnosis determined during the review process.

> ***Below are detailed instructions, based on SEER cancer data collection, to help you determined the most accurate cancer diagnosis date.***
>
> The diagnosis date refers to the first diagnosis by any recognized medical practitioner.

1. When the only information available is a positive pathology or cytology report, code the date the biopsy was done, not the date the report was dictated or transcribed.

2. The first diagnosis of cancer may be **clinical** (i.e. based on physical exam, scans or laboratory results for hematopoietic malignancies) -- *Do not change the date of diagnosis when a clinical diagnosis is confirmed later by positive histology or cytology.*

Example: On May 15, 2007, the physician states that the patient has lung cancer based on clinical findings. The patient has a positive biopsy of the lung in June 3, 2007. The date of diagnosis remains May 15, 2007.

3. If the patient receives first course treatment in the hospital, outpatient clinic or an infusion center, and there is no information about the date of diagnosis, use the first date of admission or clinic visit as the date of diagnosis.

4. If the patient receives first course of treatment in the hospital, outpatient clinic or an infusion center and there is no information about the date of diagnosis nor is there an admission or visit date, then use the date of first treatment as the date of diagnosis.

5. Positive **tumor markers** alone are not diagnostic of cancer. Use the date of clinical, histologic, or positive cytologic confirmation as the date of diagnosis. However, this information should be captured as a 'Laboratory Test' type of support., see below.

Example 1: The patient has an elevated PSA and the physical examination is negative. The physician documents only that the patient is referred for a needle biopsy of the prostate. The biopsy is positive for adenocarcinoma. The date of diagnosis is the date of the biopsy (do not code the date the procedure was dictated or transcribed). ***Example 2:*** The patient has an elevated PSA and the physical examination is negative. The physician documents that he/she suspects that the patient has prostatic cancer and is referring the patient for a needle biopsy. The needle biopsy is positive. The date of diagnosis is the date the physician documented that he/she suspects that the patient has prostatic cancer.

6. **Suspicious cytology only** (e.g., "suspicious of", "cannot rule out", "or "suggestive of" cancer) is not diagnostic of cancer. Use the date of clinical, histologic, or **positive** cytologic confirmation as the date of diagnosis.

7. If a recognized medical practitioner says that, in **retrospect**, the patient had cancer at an earlier date, code the date of diagnosis as the earlier date. If the original slides are reviewed and the pathologist documents cancer, code the diagnosis date as the date the original slides were made.

Example: The patient had an excision of a benign fibrous histiocytoma in January 2007. Six months later, a wide reexcision was positive for malignant fibrous histiocytoma. The physician documents in the chart that the previous tumor (benign fibrous histiocytoma) must have been malignant. Code the diagnosis date as January 2007.

8. If there is **no review** of previous slides with a revised diagnosis of cancer, and **no physician's statement** that, in retrospect, the previous tumor was malignant, or if information on the previous tumor is unclear, do not back-date the date of diagnosis.

Example: The patient had a total hysterectomy and a bilateral salpingo oophorectomy (BSO) in June 2007 with pathology diagnosis of papillary cystadenoma of the ovaries. In December 2007 the patient is diagnosed with widespread metastatic papillary cystadenocarcinoma. The slides from June 2007 are not reviewed and there is no physician statement saying the previous tumor was malignant. The date of diagnosis is December 2007.

9. Code the **date of death** as the date of diagnosis for: autopsy only cases, death certificate only cases, or if the case is found by **death certificate** and there is no mention of cancer in the medical records. If no additional information is gathered from another source code the date of death as the date of diagnosis.

10. **Estimate the date of diagnosis** if an exact date is not available.

a. Estimating the **month**

i. Code "spring of" to April
ii. Code "summer" or "middle of the year" to July
iii. Code "fall" or "autumn" as October
iv. For "winter of," try to determine whether the physician means the first of the year or the end of the year and code January or December as appropriate.
v. Code "early in year" to January
vi. Code "late in year" to December
vii. Use whatever information is available to calculate the month of diagnosis as per the date rules mentioned above.

Example 1: Admitted October 2007. History states diagnosed 7 months ago. Subtract 7 from the month of admit and code date of diagnosis to March 2007 . ***Example 2:*** Outpatient bone scan done January 2007 that states history of prostate cancer. The physician says the patient was diagnosed in 2007. Assume bone scan was part of initial work-up and code date of diagnosis to January 2007.

b. Estimating the **year**

i. Code "a couple of years" to two years earlier
ii. Code "a few years" to three years earlier
iii. Use whatever information is available to calculate the year of diagnosis as per the date rules mentioned above.
c. Estimating **both the month and year**: use whatever information is available to calculate the month and year of diagnosis as per the date rules as mentioned above.

Date Precision (required): See date rules above. Select the level of accuracy for this date from drop down list.

Review By (required): If a name was selected during the Logon process, then this field will be filled in automatically. If you need to change the name of the person who is reviewing this diagnosis, then select a name from the drop down list.

Review Start Date (required): Enter the date that the review and data collection process for this diagnosis began. For a new record, the current date is automatically filled into this field.

Review Status (required): Select the current status for the review and data collection process for this cancer diagnosis from the drop down list. For a new record and all pre-loaded records, this field is automatically filled in as 'Incomplete'. Below are explanations of the different options:

a. Incomplete – The review and data collection is in process and has not been completed.
b. Complete – Review and data collection has been completed on this diagnosis. The diagnosis has been confirmed with at least one support type (see *Diagnosis Support* tab explanation below).
c. Error – There is no information to support or confirm the diagnosis of a primary cancer (See *Diagnosis Support* tab explanation below). This may occur for various reasons including the following -- inaccurate pre-loaded diagnosis, alternative non-cancer diagnosis made, it is part of a differential or "rule-out" diagnosis list, cancer recurrence, cancer diagnosis was a second occurrence for a given site (see Appendix), or diagnosis of an in situ or pre-cancer tumor. If

possible, enter a brief reason for the diagnosis error by clicking on the *Additional Information/Note* button (see below). Do not select 'Error' if the review resulted in the diagnosis being changed from one primary cancer site to another or from a secondary site to a primary site (which should only occur if the primary site was not already captured).

d. Further Review – You have questions or uncertainty about any part of the review and data collection for this cancer diagnosis. This will flag the diagnosis to be reviewed by another member of the research staff at your site. If you select this option from the drop down list, place a brief comment in the *Additional Info/Notes* button to give details on why this diagnosis requires further review. This will allow the next reviewer to focus their efforts on the incomplete or questionable areas.

Additional Info/Notes – Click on this button to enter additional details about a diagnosis. This could be a question, comment, reason for error (see above) or reason for 'Further Review' (see above).

Verify Diagnosis –Click this button after completing data collection and review. This will generate a report detailing the status of required data for the cancer diagnosis. If there is missing information, please pursue further review of records and enter the appropriate data. If the report is complete and accurate, your review will be accepted and the diagnosis marked verified. If required information is not entered, the case will not be considered verified and will not be included in the database. Click on *Finalize Diagnosis* to complete the verification process.

Review and Data Collection Tabs:

Fields for data collection and review for each cancer diagnosis are organized by tabs across the top:

- ***For any cancer diagnoses found to be an 'Error' (no supporting information to confirm the diagnosis, recurrence or second occurrence of a given cancer type (except Hematologic cancers, see Appendix below)), do not proceed with collecting any of the information under the tabs.***

Cancer Dx Support:

This tab contains fields for collecting information that supports the diagnosis of cancer. For cancer registry sites, a cancer diagnosis must have at least two support types entered into the ***Histopathology/Cancer Registry Support*** section: 1) 'Cancer Registry' AND 2) 'Histopathology' or 'Histopathology not found'. If you enter 'Histopathology not found' under the ***Histopathology/Cancer Registry Support*** section, then make sure to enter all types of information that support the diagnosis under the section ***Other Diagnosis Support***. 'Cancer Registry' should NOT be the only support type listed for a diagnosis.

If you are unable to find supportive information or the information found does not support the diagnosis of an invasive or malignant tumor or cancer, then leave this section blank and enter 'Error' into the *Review Status* field. Additionally, place a brief comment by clicking on the *Additional Info/Notes* button.

Listed below are descriptions and data entry comments for each field contained in this tab:

Histopathology/Cancer Registry Support

Support Type: (required, unless the diagnosis is an 'Error'):

- **Histopathology information is essential for all cancers and the most reliable source of information for confirming a cancer diagnosis.**

Select from the following options in the drop down list – Histopathology, Outside histopathology, Histopathology not found, or Cancer Registry. For diagnoses pre-loaded or individually entered from cancer registry data, this field should be populated with 'Cancer Registry'. In this section, you also need to make a second entry for either 'Histopathology' or 'Histopathology not found', as detailed above.

Support Date (required, unless the diagnosis is an 'Error'): Enter the date histopathology was obtained and the date that the patient was entered into the cancer registry.

Other Diagnosis Support

Support Type: (required, unless the diagnosis is an 'Error'): Select every type of support you find during your record review for this cancer diagnosis from the drop down list. Laboratory tests and Procedures (imaging and endoscopy) are considered more reliable types of supporting information to confirm a cancer diagnosis, followed by Physical exam findings (PEX). When more than one *Support Type* exists, each type must be entered. If supporting information for the cancer is contained in documentation from an outside institution, select "Outside" for each support type.

- **The least reliable types of support are Clinician Documentation Only and Patient Report only. Select these support types when no other types of support for the cancer diagnosis are available (no histolopathology, cancer registry, lab test, procedure, or physical exam support).**

Below is an explanation of each choice in the drop down list:

a. Endoscopy: Laryngoscopy, esophagogastroduodenoscopy (EGD), bronchoscopy, colonoscopy, or colposcopy was performed with findings that supported this cancer diagnosis.
b. Laboratory Test: Patient body fluid or tissues sent for laboratory analysis (other than histopathology or cytology) yielded results that supported this cancer diagnosis.
c. CT Scan: A CT scan of the patient was performed with findings that supported this cancer diagnosis.
d. MRI: An MRI of the patient was performed with findings that supported this cancer diagnosis.
e. Ultrasound: An ultrasound of the patient was performed with findings that supported this cancer diagnosis.
f. X-Ray: An X-Ray of the patient was performed with findings that supported this cancer diagnosis.
g. Outside Endoscopy
h. Outside Laboratory Test
i. Outside CT Scan
j. Outside MRI
k. Outside Ultrasound
l. Outside X-Ray
m. PEX: A medical record generated from an outpatient or inpatient visit documents a provider within your medical center/site performed a physical examination with findings that supported this cancer diagnosis.
n. Outside PEX: same as above, but performed and documented by an outside provider.

- **Again, select from the following support types when no other type of support for the cancer diagnosis is available (no histolopathology, cancer registry, lab test, procedure, or physical exam support):**

o. Clinician Documentation Only: A medical record generated from an outpatient or inpatient visit by a clinician within your medical center/site documents that the diagnosis was made.
p. Outside Clinician Documentation Only: A medical record generated from an outpatient or inpatient visit by a clinician outside your medical center/site documents that the diagnosis was made.
q. Patient Report Only: A medical record generated from an outpatient or inpatient visit documents patient reported history of past or current cancer diagnosis.

- **For cancers that were distant historical diagnoses and you have no other information, enter 'Patient Report Only' in the *Other Diagnosis Support* section and 'Histopathology not found' in the *Histology/Cancer Registry Support* section.**

Support Date (required, unless the diagnosis is an 'Error'): Enter the date of the procedure, test or medical record for the *Support Type*.

Cancer Details:
Listed below are descriptions and data entry comments for each field contained in this tab:

Tumor Histopathology and *Other Histopathology, not listed* **(one of two entries required):** Select cancer histopathology from the drop down menu. If the histopathology is not found on the extensive drop-down list, then free text of the cancer histopathology can be entered into the *Other Histopathology, not listed* field.

- **It is essential that all available records be thoroughly reviewed to obtain histopathology information for every cancer.**

- **This information is usually obtained from histopathology, cytology, clinician notes, or outside documentation.**

- **Despite exhaustive record review, it is possible that this information is 'Unknown'. *For example, KS might be diagnosed by physical exam and no biopsy performed, in which case histopathology will be entered as 'Unknown' for this cancer.***

Tumor Grade (applicable for some cancers): Select the best description of the grade of the cancer or tumor.

- **This information is usually obtained from histopathology, cytology, clinical notes, or outside documentation.**

For Prostate cancer, enter the Gleason Score (from 2 to 9).

Staging: This is a complicated, but important part of the review and data collection process. As a guide, staging systems that are specific for each cancer diagnosis are automatically provided in the column under *Staging References*.

- **Staging information should be found and collected from clinician documentation.**

- **Ideally, staging has been performed and documented by an Oncology clinician either at your institution or an outside facility.**

The majority of cancers can be staged with a summary score of 0, I, II, III, IV or with a summary description of 'Localized', 'Regional, direct extension only', 'Regional, lymph nodes only', 'Regional, direct extension & lymph nodes', 'Regional, NOS', 'Distant metastases or systemic disease (Remote)' or 'Widespread'. In addition, for some cancers, there are sub-scores (i.e. IIA and IIB). In the records you might find only *TNM*, both *TNM* and summary score/description, or only a summary score/description. We ask that you review and collect all the staging information that you find for each diagnosis. For each of these staging categories, it is possible to enter 'Not Applicable', or 'Unknown'. 'Not Applicable' means the method of staging is not applicable to the cancer being reviewed (the *Staging References* column will give the applicable staging system). 'Unknown' means staging was not done or the results could not be found after exhaustive record review. If the staging summary score/description found in the records in not on the drop-down list or you have other details regarding the staging, then you can enter free text information into *Other stage or details.* If both a staging summary score (e.g., I, II, III, IV) and staging description (e.g., Localized, Remote, Widespread) are available, select the summary score from the drop down list in the *Summary Stage* field and enter free text of the staging description into the *Other stage or details* field.

In general, "solid" malignancies (breast, lung, colon, cervical, etc.) are staged using the detailed *TNM* system. Blood, lymph or "liquid" malignancies (leukemia, lymphoma, multiple myeloma, etc.) have either no staging or other staging systems (Ann Arbor, Rai, etc.) that are detailed in the *Staging References* column. If there is no staging for a diagnosis (i.e. Leukemia, acute monocytic) then select 'Not Applicable' under the *Summary Stage* field.

Tumor (T of TNM staging): Select the T (tumor size) of the *TNM* staging system for this cancer from the drop down menu. It is possible for you to enter: Not applicable, TX, Tis, T0, T1, T1a, T1a1, T1a2, T1b, T1c, T2, T2a, T2b, T2c, T3, T3a, T3b, T3c, T4, T4a, T4b, T4c, T4d, Unknown.

Nodes (N of TNM staging): Select the N (lymph node) of the *TNM* staging system for this cancer from the drop down menu. It is possible for you to enter: Not applicable, NX, N0, N1a, 1b, N2, N2a, N2b, N2c, N3, Unknown.

Metastasis (M of TNM staging): Select the M (metastasis) of the *TNM* staging system for this cancer from the drop down menu. It is possible for you to enter: Not applicable, MX, M0, 1, M1a, M1b, M1c, Unknown.

Summary Stage: Select summary staging information for this cancer from the drop down menu. This could be numeric staging from 0 to IV or staging descriptions such as 'Localized', 'Regional, NOS', 'Remote', or 'Widespread', as mentioned above. You should familiarize yourself with the options in the drop down menu prior to the review and data collection process. If the staging summary score/description found in the records in not on the drop-down list or you have other details regarding the staging, then you can enter free text information into *Other stage or details.* Again, if both a staging summary score (e.g., I, II, III, IV) and staging description (e.g., Localized, Remote, Widespread) are available, select the summary score from the drop down list in the *Summary Stage* field and enter free text of the staging description into the *Other stage or details* field.

Kaposi's sarcoma staging: Select information specific to staging of Kaposi's sarcoma (KS) from the drop down menu. Please review all clinical notes or charts available to determine the extent of KS disease and this staging. Do not rely only on biopsy site for this staging as it may not be accurate. Similarly, primary site ascertained from cancer registries may reflect the first source (i.e. biopsy, or clinical observation) and likely does not reflect the full extent of KS. However, if the only information available is a biopsy site or a cancer registry, then select from the drop down list the appropriate site in the *Kaposi's sarcoma staging* field and in the *Other stage or details* field enter free text of 'biopsy site only' or 'cancer registry'.

- **The list is hierarchical -- you only need to choose one description from this list. For example, if a patient has KS in the lung and all over the skin, you only need to choose 'Lung'. But if the patient only has a couple of lesions on the skin, then choose 'Skin only, few (<10) lesions'.**

<u>Pap Screening:</u>
Information should be captured on all pap smear screenings performed prior to the cancer diagnosis date only for patients with *Cervical cancer, invasive.*

Pap Screen Type: Select the type of pap screening (Anal or Cervical) from the drop down menu. If, after exhaustive review, you are unable to find any record of pap screening then enter 'None recorded' and enter '01/01/3000' into the *Pap Date* field.

Pap Date: Enter the date the pap screening was performed.

Date Precision: See date rules above. Select the level of accuracy for this date from the drop down list.

Pap Result: Select the results of the pap screening from drop down menu. There are two different ways to report pap smear results. If you find more than one result, then enter separate screening results, but use the same *Pap Date*.

Exposure Hx:

For the *Exposure Hx* section, review and collect information on tobacco and alcohol exposure from the record or assessment closest to the cancer *Diagnosis Date*.

- **The review of medical records to capture this information may need to include documentation from an initial intake visit, which may provide a more complete patient history than is present in documentation of a regular follow up visit.**

- **Review of consultation documentation and/or in-patient admission notes may be helpful as they frequently include a full review of a patient's medical and social history.**

- **Use all available records to perform a complete review to obtain tobacco and alcohol history assessments closest to the cancer that are *BEFORE AND UP TO SIX MONTHS AFTER THE CANCER DIAGNOSIS DATE.***

A review of the patient's medication history could show whether a patient was prescribed a medication to assist with smoking or alcohol cessation. Checking transcripts from the time period around initiating that medication might elicit a more detailed history of tobacco or alcohol use. Perusing medical records for referrals to treatment programs or smoking cessation classes can be beneficial in acquiring additional information or direction to other transcripts.

Listed below are descriptions and data entry comments for each field contained in this tab:

Tobacco Use (required): Select the category for this patient's tobacco use from the drop down list. It is possible for you to enter Never, Current, Past, Unknown.

Assessment Date: See date rules above. Enter the date when *Tobacco Use* was assessed. If *Tobacco Use* is 'Unknown' then enter '1/1/3000'. Capture the tobacco assessment **CLOSEST TO THE CANCER THAT IS BEFORE OR UP TO SIX MONTHS AFTER THE CANCER DIAGNOSIS.**

Level of use (current or past):

> *Packs per day:* Enter the number of packs per day that the patient currently smokes or smoked in the past. If the number of packs per day is unknown, then enter '-1'.
>
> *Years:* Enter the number of years that the patient smoked. If the number of years is unknown, then enter '-1'.
>
> *Pack-years:* Occasionally, the provider making the tobacco assessment calculates the pack-years of smoking and documents this number in the medical record. In this instance, enter the number of pack-years that the patient has smoked into this field. If the number of pack-years is unknown, then enter '-1'.

Alcohol Use (required): Select the category for this patient's alcohol use from the drop down list. It is possible for you to enter Never, Current, Past, Unknown

Assessment Date: See date rules above. Enter the date when *Alcohol Use* was assessed. If *Alcohol Use* is 'Unknown' then enter '1/1/3000'. Capture the alcohol assessment **CLOSEST TO THE CANCER THAT IS BEFORE OR UP TO SIX MONTHS AFTER THE CANCER DIAGNOSIS.**

Level of use (current or past): Quantitative, qualitative, both, or neither types of *Level of use* can be reviewed and collected here depending on the information documented in the patient's medical record.

> *Drinks per weeks (quantitative):* Enter the number of drinks per week that the patient has consumed. If the number of drinks per weeks is unknown, then enter '-1'.

Years: Enter the number of years that the patient has used alcohol. If the number of years is unknown, then enter '-1'.

(qualitative): Select the qualitative category for level of alcohol use from the drop down list. It is possible for you to enter: Social, Daily, Abuse, Dependence, Binge, Unknown

Other hx:

Listed below are descriptions and data entry comments for each field contained in this tab:

Family Hx/Relationship (required): Select whether the patient has a family history of cancer and the relationship (degree of separation) with the patient from the drop down list. It is possible for you to enter: None, First degree (mother, father, children, siblings), Second degree (grandparents, grandchildren, nieces, nephews, aunts, uncles), Other (anyone else), Unknown.

Cancer Type (required)*:* Select the type of cancer in the history of the family member selected above from the drop down list.

For Women, Number of Live Births: Enter the number of live births that the woman has had in her lifetime prior to the cancer diagnosis. If the number of live births is unknown or cannot be found in the medical record, then enter '-1'.

Verification:

Once all information has been entered for a diagnosis, click the 'Verify Diagnosis' button on the form header. If the Review Status is not 'Complete' you will be prompted to change the review status. If the Review Status is 'Complete', a form will appear will summary information about the data entered for the diagnosis. Note that if either HistoPresent or Staging Present are marked 'No', you will be unable to verify the diagnosis until an entry has been made in both of these fields. If no histopathology data were found after thorough record review, please choose 'Histopathology not found'. If no staging data were found after thorough record review, please choose 'Unknown' in the appropriate staging area for that type of cancer.

The verification form also indicates whether there are entries for family history, alcohol assessment and smoking assessment. These are not required fields.

Once all information has been entered, choose Finalize Diagnosis. A pop-up box indicating that the diagnosis has been finalized will appear.

Appendix: Definitions for Single and Subsequent Primaries for Hematologic Malignancies (from SEER program , NCI) (For full table and instructions see the following file – Appendix SEER subsequent primaries for hematologic cancer.pdf)

Cancer registrars are often faced with multiple pathology reports in patients with hematologic malignancies, and the diagnoses reported may require different morphology codes. This is due in part to the fact that more intensive diagnostic study may yield a more specific diagnosis, and in part due to the natural histories of hematopoietic diseases, which may progress from one diagnosis into another.

The following chart, provided to aid the registrar in determining single versus subsequent primaries, employs the following guidelines:

1. "Lymphoma" is a general term for hematopoietic solid malignancies of the lymphoid series. "Leukemia" is a general term for liquid malignancies of either the lymphoid or the myeloid series. While it is recognized that some malignancies occur predominantly (or even exclusively) in liquid or solid form, because so many malignancies can potentially arise as either leukemias or lymphomas (or both), all hematopoietic malignancies are assumed to have this potential.

2. Malignancies of the lymphoid series are considered to be different from those of the myeloid series. Therefore, a lymphoid malignancy arising after diagnosis of a myeloid malignancy (or myelodysplastic or myeloproliferative disorder) would be considered a subsequent primary; however, a myeloid malignancy diagnosed after a previous myeloid malignancy would not count as a subsequent primary. Histiocytic malignancies are considered different from both lymphoid and myeloid malignancies.

3. Hodgkin lymphoma is considered to be different from non-Hodgkin lymphoma (NHL). Among the NHLs, B-cell malignancies are considered different from T-cell/NK cell malignancies. Therefore, a B-cell malignancy arising later in the course of a patient previously diagnosed with a T-cell malignancy would be considered a subsequent primary; however, a T-cell malignancy diagnosed later in the same patient would not be considered a subsequent primary.

4. The sequence of diagnoses affects whether a diagnosis represents a subsequent primary. In some cases, the order of occurrence of the two diagnoses being compared is a factor in the decision whether the second diagnosis is a new primary.

To use the table (see separate PDF file), assign the ICD-O-3 code to the first diagnosis and find the row containing that code.
Assign the ICD-O-3 code for the second diagnosis and find the column containing that code. In the cell at the intersection of the first diagnosis row and the second diagnosis column, a "**S**" symbol indicates that the two diagnoses are most likely the **same** disease process (prepare/update a single abstract), and a "**D**" indicates that they are most likely **different** disease processes (prepare more than one abstract).

Note 1: If one of the two diagnoses is an NOS (not otherwise specified) term and the other is more specific and determined to be the same disease process, code the more specific diagnosis regardless of the sequence. For example, if a diagnosis of non-Hodgkin lymphoma, NOS is followed by a diagnosis of follicular lymphoma, assign the morphology code for the follicular lymphoma.

Note 2: The table "Single versus Subsequent Primaries of Lymphatic and Hematopoietic Diseases" (pages 2-6) and the "Complete Diagnostic Terms for Table (based on ICD-O-3)" (page 7) display only the ICD-O-3 primary (boldfaced) term associated with the code. Refer to the *International Classification of Diseases, Third Edition* (ICD-O-3) for a complete list of related terms and synonyms.