



**CAP Cancer Protocol and CAP Electronic Cancer Checklist (eCC)
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1. Background

Since 1986, the CAP cancer protocols have served as a resource and reference for complete reporting of malignant tumors, including American Joint Committee on Cancer (AJCC) staging and the World Health Organization (WHO) histologic type standard elements. The production and maintenance of these important reference resources and cancer reporting tools is performed by the expert pathologists on the CAP Cancer Committee. The protocols have grown in number and scope over the past several years, and have influenced important global efforts such as the International Collaboration on Cancer Reporting (ICCR) datasets.

The move to integrate the cancer protocols into the pathologist AP-LIS workflow came in 2007 with the release of the CAP electronic Cancer Checklists (eCC), and the Pathology Electronic Reporting (PERT) Committee was created to manage this product and process. Uptake and use of the CAP eCC has grown significantly since its inception, with over 3500 licensed pathologists in the US and Canada, and incorporation into all of the major AP-LIS vendor systems.

The Cancer Biomarker Reporting Committee (CBRC) was formed in 2013 to standardize cancer biomarker reporting, with a charge to produce the cancer biomarker reporting templates to complement the cancer protocols. Like the protocols, these templates are produced in both document (Word/PDF) and electronic (eCC) format.

2. What is a cancer protocol?

The cancer protocols are created by a multidisciplinary team of expert medical professionals, led by the members of the College of American Pathologists Cancer Committee, to facilitate comprehensive pathology reporting of a cancer specimen. Protocols can be utilized for a variety of procedures and tumor types for clinical care purposes. For accreditation purposes, only the definitive primary cancer resection specimen is required to have the core and conditional data elements reported in a synoptic format.

Each cancer protocol is composed of two parts:

Case Summary (i.e. the 'synoptic report' data elements) contains:

- Core data elements are required in reports to adequately describe appropriate malignancies. For accreditation purposes, essential data elements must be reported in all instances, even if the response is “not applicable” or “cannot be determined”.
- Conditional data elements are only required to be reported if applicable as delineated in the protocol. For instance, the total number of lymph nodes examined must be reported, but only if nodes are present in the specimen.
- Optional data elements are identified with “+” and although not required for CAP accreditation purposes, may be considered for reporting as determined by local practice standards.

Explanatory Notes provide brief educational material to facilitate accurate completion of the Case Summary



3. When are the protocols revised?

The CAP's Cancer Committee and Cancer Protocol Review Panels are charged with developing new protocols and revising the existing CAP cancer protocols on a routine basis. Revisions to the protocols are initiated by updates in clinical standards, such as the AJCC and WHO, and by user submitted issues evaluated by the Committee. Updates of the CAP electronic Cancer Checklists (CAP eCC), which are available from CAP to license for your institution, are coordinated with cancer protocol releases.

4. When new or revised cancer protocols are released, how soon should they be adopted?

In June 2017 the CAP released 52 revised cancer protocols that contain AJCC 8th edition staging system content that should be reported beginning January 1, 2018. Pathologists and vendors should use the existing cancer protocols with AJCC 7th edition staging content for the remainder of 2017, and should be prepared to report cancer cases using the 8th edition content on January 1, 2018.

CAP accredited laboratories should use the AJCC 8th edition cancer protocols on January 1, 2018 and may be deficient for inspection purposes if these protocols are not in use by March 2018.

5. How can I know that I am using the most current version of the protocols?

The most up-to-date protocols and background documentation may be downloaded from the CAP website and integrated into your practice. The release date and version appears near the top of the title page of current protocols.

6. What tumor and specimen types should be reported using cancer protocols?

Cancer protocols should be used to report the definitive primary cancer resection specimen. The cancer protocols include tables that outline the tumor types that should be reported using the cancer protocol. The tables also include a small list of tumor types that should not be reported used the protocol and indicated alternate protocols when applicable.

When should a cancer protocol be used?

- A. Reporting biopsy specimens using case summaries is optional and not required for accreditation purposes.
- B. For patients that require multiple operative procedures to accomplish definitive resection, only the primary operative procedure (defined as the definitive surgical resection) requires reporting the cancer protocol required elements.
- C. For some cancer resection reports, such as skin melanoma, it may be appropriate to include elements from a previous biopsy specimen, even though these observations are from a separate specimen.
- D. For accreditation purposes, **the cancer protocols are NOT required for use in:**
 - Biopsy specimens
 - Primary (definitive) resection in which NO residual tumor is present



- Additional operative procedures performed after the definitive resection such as re-excision of surgical margins, biopsy or excision of metastatic lesion, lymph node dissection or sentinel node biopsy.
- Resection after neoadjuvant therapy in which no tumor is present
- Resection for recurrent disease
- Resection *without an invasive component* for in situ disease, dysplasia without malignancy, or non-invasive tumors, **with the exception of DCIS.**
- Resection of a metastatic lesion if performed as separate procedure from the definitive primary tumor resection (e.g. liver resection of metastatic colon carcinoma performed as a separate procedure from the colectomy).

For clinical care purposes:

Some cancer protocols contain case summaries for biopsies and other procedures. Organizations may choose to use these summaries for clinical management across the entire episode of care, including biopsies and re-excisions. These cases will not be reviewed during accreditation inspections and should not be included in internal audits.

Many organizations use the cancer protocols to provide a composite report; e.g. reporting the definitive resection with information from the biopsy and prior procedures. Adding information from the biopsy to the case summary of the definitive resection is allowable for accreditation purposes, as long as the case summary contains all of the required elements and is in the appropriate synoptic format.

7. What cancer protocol should be used for instances where there are multiple primary tumors?

In cases where multiple tumors need to be staged separately, the report should include separate synoptic case summaries for each tumor. For sites where multiple tumors are staged together (i.e. using the 'm' modifier for T classification), the required elements for the multiple tumors may be reported together in one synoptic case summary.

Many of the cancer protocols address reporting of multiple tumors. Additionally, the AJCC Cancer Staging Manual 8th Edition covers the topic in detail in Chapter 1 and in many of the site-specific chapters and may be a valuable reference in these cases.

8. If a previously excised cancer recurs locally and a re-excision is performed, should a cancer case summary be included in the pathology report of the re-excision?

There is no requirement that case summaries be used for tumors that recur; however, hospitals and pathology groups may find the templates useful in reporting such tumors.

9. Should pathologists assign the pathologic prognostic stage group?

No, according to the AJCC 8th edition (chapter 1) "Only the managing physician can assign the patients stage, because only (s)he routinely has access to all the pertinent information from physical examination, imaging studies, biopsies, diagnostic procedures, surgical finding and pathology reports." In breast this also includes the results of genomic testing.



10. Do I need to list the data elements and responses exactly as they are stated in the cancer protocols?

The data element should be represented in the report as it is listed in the case summary. Laboratories are allowed to alter the exact wording as long as it still conveys the meaning of the data element. The response for any data element may be modified from those listed in the case summary, including "Cannot be determined" if appropriate.

11. What are the CAP accreditation program requirements for the cancer protocols?

The CAP requires that all accredited laboratories include in their pathology reports the required data elements from the applicable cancer protocols for definitive cancer resection specimens with invasive tumor or DCIS. These data elements must be reported in a synoptic format to achieve laboratory accreditation.

Additionally, The Joint Commission has requires the use of cancer protocols as a part of their Laboratory Accreditation Program. Pathologists reporting breast specimens in a program accredited by the National Accreditation for Breast Centers (NAPBC) are required to use CAP synoptic reporting and to include ER, PR and Her2 results in the report. Please refer to each organization's website for details.

12. What does the American College of Surgeons Commission on Cancer (CoC) program require?

The most current information regarding CoC accreditation requirements is available on the CoC website.

CoC Standard 2.1

Each calendar year, 95 percent of the eligible cancer pathology contain all required data elements of the College of American Pathologists (CAP) protocols and are structured using the [synoptic reporting format](#) as defined by the CAP Cancer Committee.

Definition and Requirements:

The CoC requires that 95 percent of eligible pathology reports that include a cancer diagnosis are formatted using synoptic reporting and incorporate the required data elements outlined in the current applicable surgical case protocols and summary checklists of the College of American Pathologists (CAP) publication, Reporting on Cancer Specimens. Synoptic pathology reporting uses discrete data field format (i.e., each required data element has a specific place and format in the report).

For CoC-accredited programs, the CAP protocols apply to the following:

- Pathology reports created by the program from resected specimens with a diagnosis of invasive cancer.
- Pathology reports created by the program from resected specimens with a diagnosis of ductal carcinoma in situ (DCIS).
- Diagnostic biopsy specimens, cytology specimens, special studies, and reports of carcinoma in situ (except for ductal carcinoma in situ) are **excluded**.

At a minimum, a random sample of 10 percent of pathology reports eligible for the CAP protocols or a maximum of 300 cases are reviewed each year to document compliance with this standard. The cancer committee may delegate this quality control activity to the pathologists who report the quality control activity and a summary of findings regularly to the cancer committee, or to other physicians on the cancer committee.



13. What is a synoptic report?

The CAP has established a guidance document and definition for 'synoptic reporting' within a surgical pathology report on cancer specimens. Synoptic reporting minimizes the variability between institutions and is presented in such a way that clinicians can easily and quickly find the pertinent information in the surgical pathology report, and ensures that the appropriate data needed for patient care is provided.

Additional information and examples of synoptic reports can be found at the **CANCER PROTOCOL RESOURCES PAGE** at www.cap.org.

14. How can I implement the cancer protocols into my pathology reports?

The cancer protocols are tools used to assist the pathologists in providing clinically useful and relevant information when reporting surgical specimen examinations of surgical specimens. The "Surgical Pathology Cancer Case Summary" portion of the protocols lists the reporting elements that CAP considers essential in the surgical pathology report. How an institution implements this is at the discretion of that institution, as long as it meets the requirements identified above for synoptic reporting. We recommend that format development for the surgical pathology report for cancer specimens at individual institutions or healthcare systems occurs as a multidisciplinary or organizational process.

There are various ways to incorporate the checklist portion of the cancer protocols into your surgical pathology reports. Some institutions have templated the entire checklist for each specimen and are using that in their diagnostic field. Other institutions still report out their diagnosis using a traditional format but have incorporated the synoptic reporting piece either elsewhere in the diagnostic field or in the comment field or even in the microscopic description field. Whatever format that an institution chooses to use, the synoptic reporting piece should be easily identifiable and distinct from other data included in the report, and must contain the required elements as identified in the cancer protocols. Additionally, the entire synoptic reporting portion of the surgical pathology report must be reported in a single place in the report, i.e., you cannot break up this portion and put it in various areas of the surgical pathology report.

15. Can I include multiple required data elements on one line?

Two data element names may not be listed on the same line, with the following exceptions:

- Anatomic site and/or specimen, laterality, and procedure
- Negative margins. For example, for colorectal carcinoma resection specimens, negative proximal, distal, radial, and any other specified margins may be listed on one line.
- Pathologic staging: pT, pN, and pM categories may be listed on one line. It is not necessary to include definitions of the pT, pN, and pM categories in the report.

Otherwise, only multiple values pertaining to the same data element may be listed on the same line.

16. Do I need to include required data elements in the report if I don't have all the information or it is not applicable?

Yes required core data elements must be reported in the synoptic portion of the report even if you don't have information. Using "not available" or "not applicable" or similar wording is appropriate. Conditionally required data elements must be reported only if applicable or present in the specimen.



17. Are tools available to ensure compliance?

The CAP offers the CAP electronic Cancer Checklists (eCC) and the CAP eFRM software to help pathologists and laboratories incorporate the protocols directly into their workflow and AP-LIS vendor software. The CAP eCC is supported by all major AP-LIS systems, and provides automatic updates of protocol content through your vendor. Please refer to WWW.CAP.ORG/CAPECC or email us at CAPECC@CAP.ORG for more information.

Additionally, the CAP offers a summary of required elements containing concise lists of the required cancer reporting elements, which can be found at <http://capatholo.gy/cancerprotocols-accreditation>.

18. What are the Cancer Biomarker Reporting Templates?

The cancer biomarker reporting templates are produced to establish reporting guidance for commonly ordered biomarkers, create stand-alone reporting templates, and improve consistency and completeness of results reporting to assist tumor registrars and others involved in data collection, exchange, and surveillance. These reporting templates are intended to encompass all important data elements for routinely assessed tumor markers and are designed to be incorporated into electronic reporting systems. Completion of the template is the responsibility of the laboratory performing the biomarker testing and/or providing the interpretation.

19. Is use of the cancer biomarker reporting templates required by accreditation?

Use of the cancer biomarker reporting templates is entirely optional and is currently not a requirement for laboratory accreditation. At this time, only the breast template includes required elements (in accordance with CAP/ASCO reporting guidelines), the results of which need be present somewhere in your pathology report. All elements found in the other biomarker reporting templates are currently optional, although this may change in future versions as new evidence emerges.

20. If hormone receptor and HER2 testing is performed on a previous breast biopsy specimen do those results need to be included in the breast resection pathology report?

The CAP does not require labs to re-report the markers in resection specimens if they were performed on a previous biopsy specimen. It is at the laboratories discretion whether to include these results in the resection report. The National Accreditation Program for Breast Centers (NAPBC) now requires the results of ER/PgR and HER2 testing be included in the synoptic report of the definitive cancer resection specimen, even if the testing was done on an earlier needle biopsy or at an outside institution, but this requirement only applies to facilities that are accredited by NAPBC.

21. How can I get more information on the CAP electronic Cancer Checklists (CAP eCC)?

Please contact us at CAPECC@CAP.ORG or visit us online at WWW.CAP.ORG/CAPECC for further information about using the CAP eCC or the CAP eFRM software to help you with cancer reporting at your institution.

22. How can I get copies of the cancer protocols and biomarker reporting templates?

The cancer protocols and biomarker reporting templates are available free of charge and can be downloaded from the CAP website www.cap.org/cancerprotocols.



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23. How can I comment on the cancer protocols and cancer biomarker reporting templates?

Feedback from cancer protocol and biomarker reporting template users is invited and encouraged. You may provide feedback via CPROTOC@CAP.ORG.

For feedback on the CAP electronic Cancer Checklists (eCC), please go to WWW.CAP.ORG/CAPECC and complete and return the feedback form in the upper right side of the webpage.