



**CAP Cancer Protocol and CAP Electronic Cancer Checklist (eCC)  
Frequently Asked Questions**

1.	Background	<a href="#">Go To Text</a>
2.	What is a cancer protocol?	<a href="#">Go To Text</a>
3.	What tumor and specimen types should be reported using cancer protocols?	<a href="#">Go To Text</a>
4.	What cancer protocol should be used for instances where there are multiple primary tumors?	<a href="#">Go To Text</a>
5.	If a cancer is excised and then recurs locally and is re-excised, should a template and pathologic stage be provided with the pathology report of the re-excision?	<a href="#">Go To Text</a>
6.	Should pathologists assign the pathologic prognostic stage group?	<a href="#">Go To Text</a>
7.	Do I need to list the data elements and responses exactly as they are stated in the cancer protocols?	<a href="#">Go To Text</a>
8.	What are the CAP accreditation program requirements for the cancer protocols?	<a href="#">Go To Text</a>
9.	What does the American College of Surgeons Commission on Cancer (CoC) program require?	<a href="#">Go To Text</a>
10.	What is a synoptic report?	<a href="#">Go To Text</a>
11.	Do I need to include required data elements in the report if I don't have all the information or it is not applicable?	<a href="#">Go To Text</a>
12.	How can I implement the cancer protocols into my pathology reports?	<a href="#">Go To Text</a>
13.	When are the protocols revised?	<a href="#">Go To Text</a>
14.	When new or revised cancer protocols are released, how soon should they be adopted?	<a href="#">Go To Text</a>
15.	How can I know that I am using the most current version of the protocols?	<a href="#">Go To Text</a>
16.	Are tools available to ensure compliance?	<a href="#">Go To Text</a>
17.	How can I get more information on the CAP electronic Cancer Checklists (CAP eCC)?	<a href="#">Go To Text</a>
18.	What are the cancer biomarker reporting templates?	<a href="#">Go To Text</a>
19.	Is use of the cancer biomarker reporting templates required by accreditation?	<a href="#">Go To Text</a>
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?	<a href="#">Go To Text</a>
21.	How can I get copies of the cancer protocols and biomarker reporting templates?	<a href="#">Go To Text</a>
22.	How can I comment on the cancer protocols and biomarker reporting templates?	<a href="#">Go To Text</a>



## 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.

## 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 CAP Cancer and PERT Committees, 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 must be reported whether applicable or not. Conditional data elements only need to be reported if applicable; 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. 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.

For accreditation purposes, **the cancer protocols are NOT required for use in:**

- Cancer for which no CAP Cancer Protocol is available
- Additional surgical procedures performed after definitive surgical resection such as excision for positive margins or lymph node sampling
- Definitive resection specimens that do not contain cancer (eg, following neoadjuvant chemotherapy)
- Diagnostic biopsy, cytology specimens, or other diagnostic procedures done prior to definitive surgical therapy
- Metastatic tumors or resections for recurrent tumors
- Special studies, including biomarker testing performed in another laboratory

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.

**4. 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.

**5. 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.

**6. 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.

**7. 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.



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

The CAP requires that all required data elements in applicable CAP Cancer Protocols are included with appropriate responses using a synoptic format in at least 90% of the surgical pathology reports from definitive resection specimens for primary invasive malignancies, as well as cases of ductal carcinoma in situ of the breast (DCIS). A self-audit is performed annually to ensure that all required elements are included.

Additionally, The Joint Commission 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.

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

The Commission on Cancer does have requirements for use of the CAP Cancer Protocols for CoC-accredited organizations. The most current information regarding CoC accreditation requirements is available on the CoC website.

**10. 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.

The synoptic component of the cancer reports meets the following four key criteria:

1. All core elements must be reported whether applicable or not. Elements identified in the Cancer Protocols as 'core-conditional' or "conditional" only need to be reported if applicable.
2. All data elements and responses must be reported in an element response pair format, ie, defined as data element followed by its response (eg, Histologic type: Invasive lobular carcinoma).
3. Each element response pair must be listed on a separate line or in a tabular format to achieve visual separation. Two or more data elements may NOT be listed together on one line with the following exceptions:
  - Anatomic site or specimen, laterality, and procedure
  - Pathologic Staging Tumor Node Metastasis (pTNM) staging elements
  - Negative margins, as long as all negative margins are specifically enumerated where applicable
4. All required data elements must be listed together in one location in the pathology report and may be listed in any order. Additional items may be added within the synoptic report as needed.

Additional information and examples of synoptic reports can be found at the **CANCER PROTOCOL RESOURCES PAGE** at [www.cap.org](http://www.cap.org).



**11. 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.

**12. 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.

**13. 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.

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

The CAP Laboratory Accreditation Program allows a period of 8 months from the posting dates of new and revised protocols before laboratories are at risk of an accreditation deficiency.

**15. 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.



**16. 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](http://WWW.CAP.ORG/CAPECC) or email us at [CAPECC@CAP.ORG](mailto: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>.

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

Please contact us at [CAPECC@CAP.ORG](mailto:CAPECC@CAP.ORG) or visit us online at [WWW.CAP.ORG/CAPECC](http://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.

**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 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](http://www.cap.org/cancerprotocols).

The free download authorization does not extend to reproduction or other use of any substantial portion of these protocols for commercial purposes. The cancer protocols and biomarker reporting templates are protected by copyright and cannot be used in an information system without a license. Please read the copyright, disclaimer and authorized use licensing model for terms and conditions. This information is printed on the second or third page of every cancer protocol and biomarker reporting template. For commercial use of the protocols, contact [CAPECC@CAP.ORG](mailto:CAPECC@CAP.ORG) or 847-832-7700.

**22. 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 [CPROTUC@CAP.ORG](mailto:CPROTUC@CAP.ORG).

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