

Prospective Biospecimen Collection Protocol

Ovarian Cancer

v1.2

Overview

The Clinical Proteomic Tumor Analysis Consortium (CPTAC) sponsored by the NCI Office of Cancer Clinical Proteomics Research is a comprehensive and coordinated effort to accelerate the understanding of the molecular basis of cancer through the application of robust, quantitative, proteomic technologies and workflows. The overarching goal of CPTAC is to improve our ability to diagnose, treat and prevent cancer. To achieve this goal in a scientifically rigorous manner, the NCI launched CPTAC to systematically identify proteins that derive from alterations in cancer genomes and related biological processes, and provide this data with accompanying assays and protocols to the public.

CPTAC consists of a network of Proteome Characterizations Centers (PCC) and a Data Coordinating Center (DCC) serving as a hub and central repository for all CPTAC data. CPTAC will be expanded to include a 1) network of Tissue Source Sites (TSS) to obtain clinical specimens for proteomic and genomic analysis, 2) a Biospecimen Core Resource (BCR) to serve as a repository for tissue and associated, de-identified clinical data submitted to the program, and 3) a Genomic Characterization Center (GCC) dedicated to the genomic analysis of CPTAC specimens.

Purpose

The purpose of this protocol is to establish the minimum procurement parameters for high-grade serous ovarian, fallopian tube, and peritoneal cancer specimens to be submitted to the CPTAC for proteomic and genomic analysis. The tissue source will be from newly diagnosed, untreated patients undergoing definitive surgery for ovarian cancer.

The protocol builds on CPTAC experience with human tissues obtained from the TCGA programs and specifically aims for:

- Minimized specimen processing and ischemia time with the ischemia time recorded.
- Sufficient total material from each patient divided into multiple samples suitable for independent processing for proteomic and genomic analysis.
- Independent samples suitable for histopathological analysis with frozen sections obtained at the BCR.
- Improved determination of weights of individual samples for improved estimates of protein yield.

Scope

The protocol applies to any samples submitted by a SAIC-F subcontractor to the CPTAC BCR.

Requirements

Patient Inclusion Criteria

- Newly diagnosed, untreated patients undergoing primary cytoreductive surgery for serous ovarian cancer.
- Tumor from ovary, pelvic mass or omentum only (other anatomic sites not acceptable).

Patient Exclusion Criteria

- Prior history of other malignancies within the past 12 months except non-melanomatous skin cancer and in situ cervical cancer.
- Other malignancies at the time of surgery.
- Prior systemic treatment (cytotoxic or molecular) for any malignancy.
- Prior radiation therapy for any prior malignancy that involves treatment to the abdomen or pelvis.
- Prior hormonal therapy within the last five years for cancer.
- Patients who are found to have low-grade (grade 1) or low stage (stage I or II) serous ovarian, fallopian tube, or peritoneal cancer based on final pathology (typically 5-10 days after surgery).

Regulatory (before procurement)

- IRB approval received and documented with the CPTAC BCR.
- MTA/DUA agreement received and documented with the CPTAC BCR.

Tissue Procurement and Shipping

- Signed patient consent (maintained at the tissue source site, copy to CPTAC BCR not required).
- Cancer tissue per protocol.
- Normal fallopian tube fimbriae if possible (per Crum protocol).
- Blood per SOPs.
- Shipping Manifest completed and accompanying tissue shipment.
- CPTAC Tissue Submission Form (contains details regarding procurement such as warm ischemia times along with minimal patient information) completed and electronically submitted within 1-2 working days after tissue procurement.
- Adherence to BCR shipping instructions (the BCR will provide the shipping cryoport and cover the cost of shipping).

Patient Data

- CPTAC Baseline Case Report Form containing the patient's history and status at surgery along with diagnostic information (specific data to be collected to be determined) completed and electronically submitted prior to tissue shipment.
- Pathology Report (de-identified) submitted prior to tissue shipment.
- FFPE H&E diagnostic slides/images (at least one that is representative of the diagnosis in the pathology report; slides will be returned) submitted prior to tissue shipment.
- CPTAC One-Year Case Report Form with updated history and status one year after completion of the initial treatment regimen (specific data to be collected to be determined).

- CPTAC Five-Year Case Report Form with updated history and status five years after completion of the initial treatment regimen (specific data to be collected to be determined).

Tumor Specimen Inclusion Criteria

- Greater than 300 mg total of all samples obtained from a patient.
- Greater than 60% tumor cell nuclei.
- Less than 20% necrosis.
- Less than 10 minutes warm ischemia time.

Tissue Procurement Procedure

Tumor Tissue

- Identify a 1-2 cc nodule that appears to be mostly tumor, with little or no intervening normal tissue.
- Dissect free from surrounding attachments leaving main blood supply intact for as long as possible unless specimen is to be excised immediately from within a larger tumor mass.
- Start timer when blood supply transected.
- Take nodule off operating field onto back table, bisect to confirm apparent tumor.
- Cut at least three strips of tumor each measuring 8-10 mm x 2-3 mm x 2-3 mm (~100 mg each) for submission to the BCR.
- Additional samples may be obtained for local use.
- Place each piece destined for the BCR into a pre-labeled cryovial and freeze in liquid nitrogen vapor. Pre-weighed cryovials will be supplied by the CPTAC BCR.
- Record time when samples are placed in the liquid nitrogen vapor.

Normal Tissue (Fallopian tube submitted for SEE-FIM sectioning)

- Record the time of excision.
- If a fallopian tube grossly appears normal after SEE-FIM, collect 2-3 individual fimbria from that tube.
- Place each piece destined for the BCR into a pre-labeled cryovial and freeze in liquid nitrogen vapor. Pre-weighed cryovials will be supplied by the CPTAC BCR.
- Record time when samples are placed in the liquid nitrogen vapor.

Blood Collection Procedure

- Obtained preoperatively.
- 10ml lavender top vacutainer with blood processed per SOP.