

PDM 9846: Patient-Derived Models Tissue Procurement Protocol for the National Cancer Institute (NCI)

Fast Facts

Inclusion Criteria

1. Patients 18 year of age or older who are being evaluated, treated or enrolled in a clinical trial for cancer at participating sites.
2. Patients with a histologically or cytologically confirmed diagnosis of cancer.
3. Patients without histologically or cytologically confirmed diagnosis of cancer, but for whom approval has been requested and received from the Coordinating Site Study Coordinator.
 - Requests for Coordinating Site approval should only be made if the patient's existing work-up at the time of the request demonstrates a combination of two or more of the following indicating the greater likelihood of a cancerous process in the assessment of the treating physician:
 - radiographic imaging (CT, MRI, etc.),
 - elevated tumor markers,
 - clinical symptoms,
 - documented risk factors, known genetic changes (mutation, deletion, fusion, etc.), and/or known familial cancer history or syndrome.
 - If the patient will be undergoing surgical resection at a later time and will be accessible to approach for study participation at that time, resected material following cancer diagnosis confirmation is preferred.

Important: Additional medical, genetic and/or demographic work-up should not be obtained solely for determination of eligibility for protocol 9846 by these criteria. Once available, final redacted pathology confirmation must be provided to the coordinating site detailing the confirmed cancer diagnosis for patients enrolled based on the above criteria.
4. Patients with a newly diagnosed solid tumor, lymphoma or multiple myeloma malignancy for which they have not yet received treatment
5. Patients with a previously treated solid tumor, lymphoma or multiple myeloma malignancy that is now recurrent or currently progressing on treatment indicated by:
 - radiographic evidence of tumor growth and/or new metastases, OR
 - documented evidence by the treating physician of signs/symptoms of clinical disease progression.
6. Patients currently undergoing treatment (adjuvant, neoadjuvant, etc.), are within a maximum of the first two (2) cycles of treatment, and for whom disease response has not yet been assessed.
 - In this circumstance, specimen collection should occur as distant in time from the most recent drug administration as possible (e.g., after completion of a treatment cycle and immediately prior to initiation of the next cycle).
 - Specimens should not be collected from patients between doses within a single treatment cycle.
7. Patients with ongoing partial response (PR) or stable disease (SD) are eligible.
 - Confirmation of viable malignancy and/or <90% tumor necrosis must be confirmed to the coordinating site, as indicated in the final postoperative/ post-procedure pathology report.
8. Ability to understand and willingness to sign a written informed consent document indicating their willingness to have their tissue or biologic fluid specimens used for research as outlined in this protocol.

Exclusion Criteria

1. Patients with invasive fungal infections.
2. Patients with active and/or uncontrolled infections or who are still recovering from an infection.
 - Actively febrile patients with uncertain etiology of febrile episode
 - All antibiotics should be completed at least 1 week (7 days) prior to collection
 - No recurrence of fever or other symptoms related to infection for at least 1 week (7 days) following completion of antibiotics.
- Note: Use of antibiotics for pre-operative prophylaxis is not an exclusion.
3. Patients with Human Immunodeficiency Virus (HIV), active or chronic hepatitis (i.e., quantifiable HBV-DNA and/or positive HbsAg, quantifiable HCV-RNA) or known history of HCV, HBV or HIV. Testing for HBV, HCV, HIV or other infections will be performed only if clinically indicated.
4. Patients with Hepatitis A as indicated by anti-HAV IgM reactivity.
 - Patients that are anti-HAV IgG reactive only are eligible.
5. Specimen collections from patients with benign tumors including but not limited to desmoid tumors, carcinoma in situ, or ongoing evidence of complete disease response (CR) based on imaging.

Study Design

