Cancer Research Consortium of West Michigan
Committed to Community Cancer Research & Education

100 Michigan St NE, MC 12
Grand Rapids, MI 49503
616-391-1230
800-336-5079
F 616-391-6299
www.crcwm.org

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.
   - CBC w/differential indicative of a probable hematologic malignancy.

   • 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 histology must be confirmed to the coordinating site detailing the cancer diagnosis for patients enrolled based on the above criteria.
4. Patients with a newly diagnosed primary and/or metastatic solid tumor or hematologic malignancy for which they have not yet received treatment
5. Patients with a solid tumor or hematologic malignancy that is recurrent, newly metastasized, or progressing while on treatment indicated by:
   - radiographic evidence of tumor growth, re-growth and/or new metastases, OR
   - documentation by the treating physician of clinical disease progression, OR
   - CBC W/differential and/or flow cytometry for hematologic malignancies.
6. Patients currently undergoing treatment (adjuvant, neoadjuvant, etc.
   • 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.
   • Confirmation of viable residual malignancy and/or <90% tumor necrosis, fibrosis or hemorrhage must be confirmed to the NCI coordinating site, as indicated in the final post-operative/post-procedure pathology and/or flow cytometry report.
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 NCI 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

Note: Testing for bloodborne pathogens or other infections is not required for eligibility assessment and will be performed only if clinically indicated. Exclusion criteria for bloodborne pathogens and/or other infections is based on existing documentation in the medical record or patient report of such diagnosis at the time of eligibility assessment, if testing is not obtained for clinical indications.

1. Patients with cancer-like syndromes and/or blood disorders such as systemic mastocytosis, Langerhans cell histiocytosis, chronic eosinophilic leukemia/hypereosinophilic syndrome, lymphomatoid granulomatosis, or monoclonal gammopathy of undetermined significance (MGUS).
2. Patients with invasive fungal infections.
3. Patients with active and/or uncontrolled bacterial, fungal, or viral infections or who are still recovering from an infection.
    - Actively febrile patients with uncertain etiology of febrile episode
    - All antibiotics prescribed for the treatment of a bacterial infection should be completed at least 1 week (7 days) prior to collection.
        - Patients with a hematologic malignancy who are treated with an antibiotic, anti-fungal, and/or anti-viral medication for an active infection who then remain on the treatment for prophylaxis following resolution of the infection as assessed by the treating physician are not excluded.
    - No recurrence of fever or other symptoms related to infection for at least 1 week (7 days) following completion of antibiotics.
    - Patients receiving antibiotics, antifungals, and/or antivirals for prophylaxis are permissible.
    - Antibiotics being administered topically at a location distant from the planned tissue collection site or eye drops for a localized infection are permissible.

4. 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.
5. Patients with Hepatitis A as indicated by anti-HAV IgM reactivity.
    - Patients that are anti-HAV IgG reactive only are eligible.
6. 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).

Study Design