

Interdisciplinary Approach to Research Biopsy Acquisition in Oncology Clinical Trials

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1. Background

While imaging-guided tumor biopsies have been a mainstay for the histologic diagnosis of cancer, fresh tumor research biopsies in clinical trials are a more recent requirement.

Since each clinical trial sponsor has unique guidelines that can vary greatly on the acquisition and processing of these samples, the Froedtert & Medical College of Wisconsin interdisciplinary team, including: Advanced Radiology Procedures (ARP) clinic, Office of Clinical Research and Innovative Care Compliance (OCRICC), Medical College of Wisconsin Tissue Bank, and the Clinical Trials Office (CTO) manager, found that there was no consistent communication plan, and with each biopsy that was being performed there was often last minute planning. This led to frustration among team members, the potential risk for error, and concern for patient safety.

2. Goals

Since communication between departments was pivotal in developing a formal process, the CTO manager met with the interdisciplinary team to understand the capabilities and needs of each department.

It was determined that a single communication guidance document would properly contain the required information for each department, as well as the key information for the specific trial.

3. Solutions and Methods

It was determined that the initial draft of the guidance document is to be created by the CTO manager/staff and reviewed by each department during the planning phase of the trial. Once approved, the document is sent out in the final activation packet from OCRICC to all departments. This approval has to be granted before the trial can be activated at the site.

The template guidance document includes:

1. Naming convention (each trial is named using the OnCore® ID, IRB PRO number, and the OCRICC number)
2. Expected samples needed and the type of biopsy allowed (helps the staff understand what type of biopsy can be ordered based on the contracted budget)
3. Contact and communication information for each department
4. Specific instructions from the trial specific lab manual for the collection and processing

The template guidance document contains 5 steps where staff can add and edit the content to match the specific needs of the trial. However, the template also includes language that must remain present regardless of the type of procedure.

Category: Trial Start Up/Closure – Completed Project

Step 1: DETERMINE IF BIOPSY PROCEDURE WILL BE DONE AS ROUTINE CARE or RESEARCH

Step 2: NAMING CONVENTION FOR RESEARCH BIOPSY

Step 3: NOTIFICATION OF GROUP(S) INVOLVED

Step 4: COMMUNICATE PRIOR TO PROCEDURE DATE, REGARDLESS OF BIOPSY SITE OR GUIDANCE

Step 5: INSTRUCTIONS FOR COLLECTION AND PROCESSING

4. Outcomes and Future Directions

With a single communication tool encompassing the needs of each department created prior to the activation of each trial, the last minute planning of these biopsies no longer occurs. This organization provides a guidance to the staff to appropriately manage these research biopsies and also a tool to educate trial participants on the process.

Challenges that remain include:

1. Investigators requesting routine tissue samples along with research samples during the same procedure.
2. Utilizing the correct naming convention at the time of ordering the biopsy (often done by Investigators)
3. Managing amendments if the biopsy process changes