Interdisciplinary Approach to Research Biopsy Acquisition in Oncology Clinical Trials

Katy Schroeder, BSN, RN, OCN, CCRP; Jarrod Roessler, BS; Stacey Zindars, MS, CCRP; Mary Rau, BS; Elizabeth Polak, BSN, RN, CNOR; Jennifer Fleischman, RN, BBA, CCRP

Significance/Background

While image-guided tumor biopsies have been a main-stay 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) RN 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.

Interdisciplinary Team

CTO RN manager-Manages portfolio of oncology clinical trials; from trial activation to closure
ARP clinic-Manages new referral/consult services for patients who need image-guided procedures in radiology
OCRICC- The link between the investigators and/or their designees and the health system clinical business leaders for research projects using Froedtert resources
Medical College of Wisconsin Tissue Bank-Provides a secure storage facility for research samples as well as the structure to process research related tissue biopsy samples

Intervention

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

It was determined that a single communication template would properly contain the required information for each department, as well as the key information for the specific trial. The 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 initial draft of the guidance document is created by the CTO RN 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.

Guidance Document Template Example

PI: Smith; UB-16-0578-PANC; PRO 41027; OCRICC 19-0199

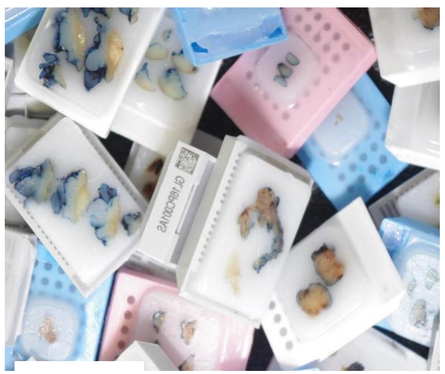
Biopsy Collection Plan

Lab Manual version 2.0 3-14-19

Instructions: Rename file to your study folder using OnCore® Protocol No, IRB PRO & OCRICC#. Delete all green instructions, examples and <insert> prompts and replace with purple, study-specific text. Black & red language is template. Delete template language that is not applicable.

Expected Biopsies: Example: This study wants 2 cores fresh frozen and 2 cores paraffin-embedded tissue blocks from intrahepatic lesion, pre and post SBRT (same lesion). Budget allows for ultrasound guided liver biopsies, but based on previous experience, guidance may vary by patient. We will allow for US and CT guidance, but US is preferred. Per PI, patients will not require routine biopsies at the same time as these research biopsies, so all biopsies per protocol will be billed to research.
Please seek permission from manager prior to exploring other biopsy types, as the cost may be prohibitive.

The template contains 5 steps where staff can edit (based on the colored language mentioned above) the content to match the specific needs of the trial.
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



For additional information please contact:
Katy Schroeder BSN, RN, OCN, CCRP
Froedtert & Medical College of Wisconsin Cancer Center
kbschroeder@mcw.edu
www.mcw.edu/departments/cancer-center

Evaluation and Challenges

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