Cancer Institute Tumor Bank

UNIVERSITY OF Cincinnati

STANDARDIZATION OF CONSENT PRACTICES AT THE UCCITB: CHALLENGE IN BIOBANKING

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Abstract

While intense labor is focused on biospecimen processing and storage conditions to obtain high quality samples, standardization of consent practices may be overlooked. To unify our banking procedures for multiple PI-initiated projects, the University of Cincinnati Cancer Institute Tumor Bank (UCCITB) developed and implemented standard operating procedures (SOP), not only governing all aspects of sample handling but also addressing subject consenting. Due to internal staffing limitations, we encourage medical personnel to consent their subjects. Our challenge is to expand banking efforts by involving more people in consenting while maintaining high quality consenting practices. In order to implement internal consenting procedures among clinical staff, we utilized various resources to introduce and follow-up on consent practices. First, consent documentation for new and existing banking projects was standardized. Providing a uniform presentation of critical information and questions for the subject ensures collection of key subject preferences regarding usage of biospecimens and associated protected health information. The standardized consent form was approved by the University of Cincinnati institutional review board. Second, a user-friendly one-page "Consenting Quick Reference" was developed to reinforce guidelines for appropriate consenting practices. This form was disseminated by e-mail to all consenters and published in our monthly electronic newsletter. It emphasizes how to identify and approach a potential participant, what information must be presented during consenting and how to keep standardized record notes in the electronic medical record. These procedures allow us to efficiently monitor newly consented subjects and alert all clinical staff about patient enrollment in specimen banking. Third, we developed an internal audit checklist for assessing compliance with our consenting SOP. Ultimately, excellent communication between clinical staff and tumor bank personnel is the key to successfully implementing our consenting SOP. Strong working relationships

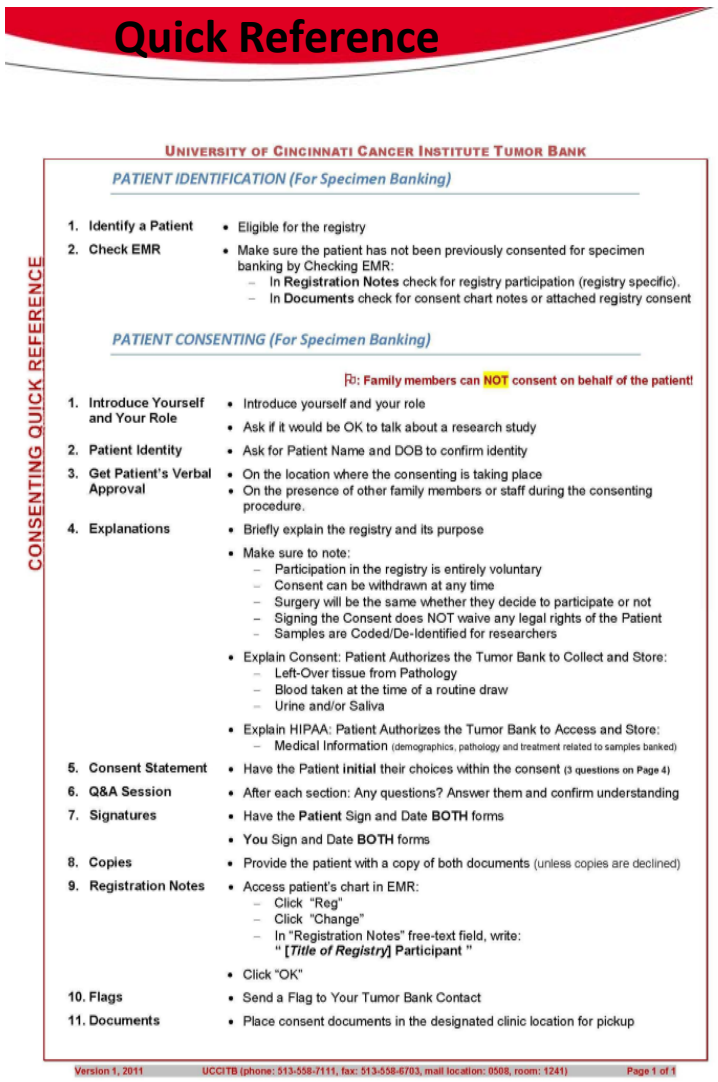
Informed Consent

Informed consent must be obtained before identifiable specimens may be collected for banking purposes. It is an active process of sharing information between the consenter and the potential participant. This process should ensure that all critical information about a study is completely disclosed, and that potential participants adequately understand the research so that they can voluntarily decide whether or not to participate as a research subject. CITB developed and implemented standard operating procedures that govern all aspects from subject consenting to sample handling and releasing in order to maintain high quality practices.

Informed Consent cont'd

For our consenting procedures, we introduced standardized consent documentation for new and existing banking projects that provides a uniform presentation of critical information. To ensure uniformity and consistency of our consenting practices, we implemented a user-friendly one-page "Consenting Quick Reference" (Figure 1). In addition, we developed an internal audit checklist for assessing compliance with our consenting SOP (Figure 2).

Quick Reference



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CONSENTING QUICK REFERENCE

PATIENT IDENTIFICATION (For Specimen Banking)

1. **Identify a Patient**
   - Eligible for the registry
2. **Check EMR**
   - Make sure the patient has not been previously consented for specimen banking by Checking EMR:
     - In **Registration Notes** check for registry participation (registry specific).
     - In **Documents** check for consent chart notes or attached registry consent

PATIENT CONSENTING (For Specimen Banking)

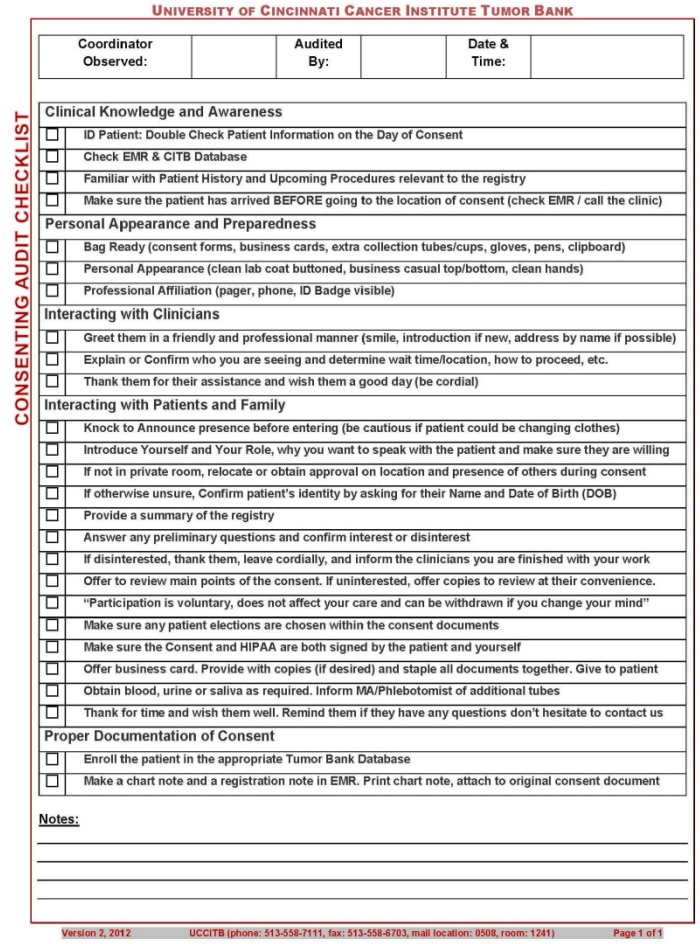
!: Family members can NOT consent on behalf of the patient!

1. **Introduce Yourself and Your Role**
   - Introduce yourself and your role
   - Ask if it would be OK to talk about a research study
2. **Patient Identity**
   - Ask for Patient Name and DOB to confirm identity
3. **Get Patient's Verbal Approval**
   - On the location where the consenting is taking place
   - On the presence of other family members or staff during the consenting procedure.
4. **Explanations**
   - Briefly explain the registry and its purpose
   - Make sure to note:
     - Participation in the registry is entirely voluntary
     - Consent can be withdrawn at any time
     - Surgery will be the same whether they decide to participate or not
     - Signing the Consent does NOT waive any legal rights of the Patient
     - Samples are Coded/De-Identified for researchers
   - Explain Consent: Patient Authorizes the Tumor Bank to Collect and Store:
     - Left-Over tissue from Pathology
     - Blood taken at the time of a routine draw
     - Urine and/or Saliva
   - Explain HIPAA: Patient Authorizes the Tumor Bank to Access and Store:
     - Medical Information (demographics, pathology and treatment related to samples banked)
5. **Consent Statement**
   - Have the Patient **initial** their choices within the consent (3 questions on Page 4)
6. **Q&A Session**
   - After each section: Any questions? Answer them and confirm understanding
7. **Signatures**
   - Have the **Patient** Sign and Date **BOTH** forms
   - You Sign and Date **BOTH** forms
8. **Copies**
   - Provide the patient with a copy of both documents (unless copies are declined)
9. **Registration Notes**
   - Access patient's chart in EMR:
     - Click "Reg"
     - Click "Change"
     - In "Registration Notes" free-text field, write:
       " ***[Title of Registry]*** **Participant** "
   - Click "OK"
10. **Flags**
    - Send a Flag to Your Tumor Bank Contact
11. **Documents**
    - Place consent documents in the designated clinic location for pickup

Version 1, 2011 UCCITB (phone: 513-558-7111, fax: 513-558-6703, mail location: 0508, room: 1241) Page 1 of 1

Figure 1: Consenting Quick Reference is a user-friendly one-page document used to reinforce guidelines for uniformity and consistency of our consenting practices.

Audit Checklist



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CONSENTING AUDIT CHECKLIST

Coordinator Observed:		Audited By:		Date & Time:	

Clinical Knowledge and Awareness	
☐	ID Patient: Double Check Patient Information on the Day of Consent
☐	Check EMR & CITB Database
☐	Familiar with Patient History and Upcoming Procedures relevant to the registry
☐	Make sure the patient has arrived BEFORE going to the location of consent (check EMR / call the clinic)
Personal Appearance and Preparedness	
☐	Bag Ready (consent forms, business cards, extra collection tubes/cups, gloves, pens, clipboard)
☐	Personal Appearance (clean lab coat buttoned, business casual top/bottom, clean hands)
☐	Professional Affiliation (pager, phone, ID Badge visible)
Interacting with Clinicians	
☐	Greet them in a friendly and professional manner (smile, introduction if new, address by name if possible)
☐	Explain or Confirm who you are seeing and determine wait time/location, how to proceed, etc.
☐	Thank them for their assistance and wish them a good day (be cordial)
Interacting with Patients and Family	
☐	Knock to Announce presence before entering (be cautious if patient could be changing clothes)
☐	Introduce Yourself and Your Role, why you want to speak with the patient and make sure they are willing
☐	If not in private room, relocate or obtain approval on location and presence of others during consent
☐	If otherwise unsure, Confirm patient's identity by asking for their Name and Date of Birth (DOB)
☐	Provide a summary of the registry
☐	Answer any preliminary questions and confirm interest or disinterest
☐	If disinterested, thank them, leave cordially, and inform the clinicians you are finished with your work
☐	Offer to review main points of the consent. If uninterested, offer copies to review at their convenience.
☐	"Participation is voluntary, does not affect your care and can be withdrawn if you change your mind"
☐	Make sure any patient elections are chosen within the consent documents
☐	Make sure the Consent and HIPAA are both signed by the patient and yourself
☐	Offer business card. Provide with copies (if desired) and staple all documents together. Give to patient
☐	Obtain blood, urine or saliva as required. Inform MA/Phlebotomist of additional tubes
☐	Thank for time and wish them well. Remind them if they have any questions don't hesitate to contact us
Proper Documentation of Consent	
☐	Enroll the patient in the appropriate Tumor Bank Database
☐	Make a chart note and a registration note in EMR. Print chart note, attach to original consent document

Notes:

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Figure 2: Audit Checklist is a one-page form developed as a tool to consistently and periodically monitor each consenter's adherence to, or variation from, established consenting guidelines. Based on each audit, CITB is able to review variations and determine if modifications in individual training or SOP should be made, as well as ensuring consistency in the information presented to each patient.

Acknowledgments

The Key to our successful expansion of tumor banking operations lies in all our Cancer Institute members who have been enthusiastic and extremely helpful. This process has and will continue to be a monumental team effort that we could not have achieved without the support of the UC Cancer Institute and the collaboration of the surgeons, nurses and pathologists as well administrators at University of Cincinnati and University Hospital.