9001 Consented Cases

Letter of Research Agreement

Thank you for your interest in the Tissue Procurement Facility (TPF) of the University of North Carolina Lineberger Comprehensive Cancer Center. Enclosed you will find an application packet. TPF functions to support and enhance translational and clinical research by providing Lineberger Cancer Center Members (or non-members who have an LCCC member sponsor) a centralized, quality controlled, quality assured facility for the procurement, processing, storage, analysis, distribution and database management of normal and malignant tissue specimens and corresponding blood specimens. We have developed and implement strict policies that address medical and legal issues and protect patient privacy and confidentiality. Specific policy criteria include the following:

1. Tissue is only procured after the pathologist has obtained the appropriate specimen information for the patient care (e.g. diagnosis, inking of margins, etc). TPF personnel must receive the specimen or receive approval for the specimen from the attending pathologist.

2. No specimen is distributed to any investigator until a final diagnosis has been received from pathology.

3. No specimen is procured unless the patient has been appropriately informed and signed a consent form for such procurement. (Note: for some protocols, this consent may be the same as a clinical trial consent form).

4. Specimens collected by TPF are not distributed for germline studies (studies of inherited characteristics). Specimens can only be collected or distributed for germline DNA studies if the investigator has obtained a separate and specific informed consent from the patient and TPF has consent on file. IRB approval for the study must also be on file with TPF before distribution of any specimen.

5. Specimens distributed to investigators are not to be sold or shared with any third party or other investigator. If there are other collaborators on the study for which specimens are being procured, those investigators need to be listed as collaborators on the original study (include information in letter of research agreement).

6. Specimens are distributed with a unique identification number generated by the TPF laboratory. No patient identifying information is distributed with any sample.

7. Patient privacy and confidentiality are essential and the investigator and TPF personnel must take all precautions to ensure compliance of our policies and protect against violation of patient privacy and confidentiality.

8. The investigator must provide documentation of IRB review and approval of their study before any specimens are distributed.

9. The investigator must agree to abide by policies and procedures of TPF and sign a letter of research agreement for ethical and appropriate conduct of their research that utilizes any specimen obtained from TPF.

10. Prior to any directed procurement, the investigator will meet with the tissue procurement coordinator to assess the needs of the investigator including type and number of specimens required, conditions for procurement; transport, storage, and application. All investigators must first submit a 1-2 page proposal to the facility detailing the need and use of the core facility, including an abstract of the study, a copy of the IRB review/approval, and a current account and PID number for billing of services. The medical director, laboratory director, facility pathologist, faculty advisor and coordinator review all proposals submitted at least monthly for appropriateness, completeness, feasibility and scientific integrity.

I, the undersigned have read, understood and agree to comply with all policies and procedures of the Tissue Procurement Facility (TPF). Specifically, I agree that any specimen or information from TPF will not be used for germline DNA research, nor will any specimen be shared with or sold to any other third party. I agree to keep all information received on this specimen strictly confidential and understand that I will receive the sample(s) identified only by a unique number assigned by TPF.

By signing below, I indicate that I am fully responsible for research performed using the material obtained from TPF and have provided truthful information on the nature and IRB review of my research study.

Signature: _____ Date: _____

Collaborators: _____ Date: _____

_____ Date: _____

General Information

Contact Information

Principal Investigator: Title

Department: UNC PID#:

Campus Address:

Phone: Pager: Email:

Is the Principal Investigator also the primary or secondary study contact? ◯ Primary ◯ Secondary ◯ Neither

Primary Contact: Title

Department:

Campus Address:

Phone: Pager: Email:

Secondary Contact: Title

Department:

Campus Address:

Phone: Pager: Email:

Study Information

Study Title:

Protocol Alias (LCCC#, if unknown, the alias will be PI initials/ Study-Specific #):

Date of Form Submission to TPF: Is PI an LCCC Member: ◯ Yes ◯ No

IRB # Approval Date: Expiration Date: Comment:

Account Number: Billing Contact:

Funding Source

Length of study (months):

Please attach IRB approval letter and a brief description of your project. Please direct your questions or concerns to the appropriate personnel listed below.

Mei Huang, PhD, TPF Manager
Email: mei_huang@med.unc.edu
Tel: (919) 843-8477 Fax: (919) 843-9501

Tissue Request Details

Select categories applicable to your study. Free-typing is allowed for most fields, including drop-downs.
Scrolling over many of the form headers will reveal comments with additional instructions. Contact TPF for any further clarifications.

Desired Number of Cases: Frequency, if applicable:

Patient Criteria	Are specific patient criteria required?	◯ Yes	◯ No
Solid Tissue Request	Do you want solid tissue?	◯ Yes	◯ No
Blood Products Request	Do you want blood products?	◯ Yes	◯ No
DNA/RNA Request	Do you want DNA/RNA purified?	◯ Yes	◯ No
Histology Request	Do you want histology?	◯ Yes	◯ No
Data Request	Do you have a request for data?	◯ Yes	◯ No

Patient Criteria Are specific patient criteria required? ◯ Yes ◯ No Gender: ◯ Male ◯ Female ◯ Either

Other Patient Criteria:

Solid Tissue Request Do you want solid tissue? ◯ Yes ◯ No Number of tissue schema: − + 1

Additional Ins

Blood Products Request ◯ Yes ◯ No Required? ◯ Yes ◯ No Check desired products: ☐ Plasma

Additional Instructions:

DNA/RNA Request ◯ Yes ◯ No Number of DNA/RNA sources: − + 1

Anatomic Site(s):

Nucleic Acid	Source		Requested Amt. (ug)	Minimum Amt. (ug)

Additional Instructions:

Histology Request ◯ Yes ◯ No Number of histology sources: − + 1

Anatomic Site(s):

Source		Slide Type	# of Slides	Sections/Slide	Thickness (um)	Stain	For RNA?

Additional Instructions:

Tissue Request Details

Data Request ◯ Yes ◯ No Number of Data Requests: − + 1

Data Request	Additional Instructions

Additional Instructions, all data requests:

Ensure that all relevant information is complete. Sign and date the Letter of Research Agreement electronically, or print, sign, and scan. Save a copy for your records. You may submit the form by email as an attachment to mei_huang@med.unc.edu or by using the "Submit by Email" button below. Rename the file with your protocol alias and the date of submission. Append IRB approval letter and brief description. To submit using button, must be logged in to email client (Outlook) before email will be sent.

Print Form Submit by Email