North Carolina Tissue Consortium
Brody School of Medicine at East Carolina University
600 Moye Boulevard
Greenville, NC 27834
Phone: 252-744-2616 Fax: 252-744-5777

RESEARCH AGREEMENT

(Use of NCTC for Studies Classified as Not Human Subject Research)

Thank you for your interest in the North Carolina Tissue Consortium at East Carolina University, Brody School of Medicine. Enclosed you will find an application packet. The North Carolina Tissue Consortium (NCTC), an IRB-approved tissue bank, is supported by the University Cancer Research Fund which was established by the NC General Assembly to accelerate the battle against cancer. The objective of the NCTC is to facilitate cancer-related research by providing a means through which normal and malignant tissue specimens are procured, processed, stored, and distributed to researchers while protecting the rights and confidentiality of participants. We also provide consultations on an as needed basis to help identify and target specimen collection so as to meet the specific research needs of investigators at ECU.

We have developed and implemented strict policies that address medical and legal issue and protect patient privacy and confidentiality. Specific policy criteria include the following:

1. Specimens will be procured only after the patient has been properly informed and has signed the appropriate consent form.

2. Tissue will only be procured after the amount of specimen needed for diagnostic purposes has been determined. Preparations of fresh, snap-frozen, and formalin-fixed paraffin-embedded tissue, and H&E-stained slides are available. Blood or other body fluid samples may also be procured upon request by investigators. Samples may be annotated with patient demographics, such as age or age range, gender, race, height, weight etc. A de-identified pathology report may be provided, if available and requested.

3. The NCTC may obtain blood samples from patients. Patients will be targeted for these samples upon request.

4. Specimens will be distributed only after a final diagnosis on the quality control sections has been received from pathology. This is to ensure that appropriate and representative diagnostic tissue is procured and distributed to any researcher for research use. Fresh tissue is received by NCTC personnel after the pathologist has determined that a sufficient quantity of tissue has been submitted for diagnostic purposes.

5. Specimens collected for the NCTC IRB-approved study are not distributed for germline studies (studies of inherited characteristics). Specimens can be collected and distributed for germline DNA studies if the NCTC has pre-approved procurement for the specific IRB-approved germline study and the investigator has obtained informed consent from the participant.

6. Specimens distributed to investigators will not be sold to or shared with a third party. All collaborators must be listed on the NCTC application.

7. Specimens are marked with an ID number assigned by the NCTC laboratory. No identifying information will be distributed.

8. NCTC personnel and investigators must be vigilant in protecting patient confidentiality.

North Carolina Tissue Consortium
Brody School of Medicine at East Carolina University
600 Moye Boulevard
Greenville, NC 27834
Phone: 252-744-2616 Fax: 252-744-5777

9. Specimens will be distributed only after the investigator submits documentation of IRB review and agreement that the study is classified as not human subject research. This may be accomplished via an email from the PI to the UMCIRB with a brief project description and rationale for this classification (18 HIPAA identifiers will not be collected). Submission of IRB determination should accompany the initial request.

10. Investigators and collaborators must agree to abide by policies and procedures of the NCTC and sign a letter of research agreement for ethical conduct of their research that utilizes any specimen obtained from the facility.

11. Prior to any directed procurement, the investigator will meet with the NCTC study coordinator and/or director to assess the needs of the investigator. Specifications include type and number of specimens required, conditions for procurement, transport, storage, and application. All investigators must submit a written proposal to the facility detailing the need and use of the NCTC, including an abstract of the study, documentation of IRB determination, and a current account and PID number for billing. The Use Committee will review the proposal for feasibility and scientific integrity.

I, the undersigned, have read, understood and agree to comply with all policies and procedures of the North Carolina Tissue Consortium. Specifically, I agree that any specimen or information from the NCTC will not be used for germline DNA research (research of heritable traits), nor will any specimen be sold to or shared with any third party. I agree to keep all information received on this specimen strictly confidential and understand that I will receive the sample(s) identified by a unique number assigned by the NCTC lab. I will not receive any information regarding the identity of the individual(s) to whom the coded private information or specimens pertain. I am prohibited from receiving the key to the coded sample(s) received.

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

P.I. _____ Date _____

Collaborators

_____ Date _____

_____ Date _____

The PI and recipient shall acknowledge the North Carolina Tissue Consortium (NCTC) as the source of material in any publications, posters and presentations that result from the use of specimens received from NCTC.

Please include the following statement in the acknowledgement section: This project used the North Carolina Tissue Consortium (NCTC) shared resource which is supported in part by the University Cancer Research Fund (UCRF).

North Carolina Tissue Consortium

Brody School of Medicine at East Carolina University
600 Moye Boulevard
Greenville, NC 27834
Phone: 252-744-2616 Fax: 252-744-5777

Request Form

Principal Investigator

Name _____ Date _____

Institution _____

Address _____

Telephone _____ Department _____

Email _____

Contact Person (Only fill out if different from Principal Investigator, listed above)

Name _____

Telephone _____ Email _____

IRB Determination

Institution: ☐ East Carolina University ☐ UNC-Chapel Hill

☐ Not Human Subject Research (NHSR)
☐ Exempt
☐ Expedited Review and Approval

Materials Requested

Anatomic Site of Tissue Sample(s): _____

☐ Normal ☐ Metastatic Tumor ☐ Primary Tumor

Dx: _____

Approximate number of specimens requested: _____

Methods of Storage:
☐ Snap frozen in liquid nitrogen
☐ Fresh in media (directed procurement)
☐ Fixed in formalin

North Carolina Tissue Consortium
Brody School of Medicine at East Carolina University
600 Moye Boulevard
Greenville, NC 27834
Phone: 252-744-2616 Fax: 252-744-5777

Request Form (Continued)

Number of blocks: Number of sections per block:

Thickness: ☐ 5µm ☐ 10µm ☐ Other

Quantity: Stained slides: Unstained slides:

Blood samples requested: ☐ Yes ☐ No
Note: NCTC will target patients upon request

☐ Whole blood ☐ Serum ☐ Plasma ☐ Buffy Coat

Approximate number of samples needed:

Vacutainer® tube preference:

Background Information Requested

☐ Age range ☐ Gender ☐ Race ☐ Tumor Staging

☐ Other Clinical Background:

Billing

ECU Account Number

UNC Account Number

FedEx Account Number

Required attachments:

☐ IRB Determination
☐ Study Description

North Carolina Tissue Consortium

Brody School of Medicine at East Carolina University
600 Moye Boulevard
Greenville, NC 27834
Phone: 252-744-2616 Fax: 252-744-5777

Use of NCTC for Studies Classified as Not Human Subject Research

Date

Principle Investigator

Study Title

Collaborators (Name and Department)

I, the undersigned, have read, understood and agree to comply with all policies and procedures of the North Carolina Tissue Consortium. Specifically, I agree that any specimen or information from the NCTC will not be used for germline DNA research (research of heritable traits), nor will any specimen be sold to or shared with any third party. I agree to keep all information received on this specimen strictly confidential and understand that I will receive the sample(s) identified by a unique number assigned by the NCTC lab. I will not receive any information regarding the identity of the individual(s) to whom the coded private information or specimens pertain. I am prohibited from receiving the key to the coded sample(s) received.

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

P.I. Date

Collaborators

Date

Date

The PI and recipient shall acknowledge the North Carolina Tissue Consortium (NCTC) as the source of material in any publications, posters and presentations that result from the use of specimens received from NCTC.

Please include the following statement in the acknowledgement section: This project used the North Carolina Tissue Consortium (NCTC) shared resource which is supported in part by the University Cancer Research Fund (UCRF).