Valid from 2/16/2018 to 2/15/2019

University of North Carolina at Chapel Hill
Consent and HIPAA Authorization for Storing Biological Specimens With Identifying Information for Patients with Solid Tumor Tissue

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IRB Study # 90-0573 (90-SURG-253-ORC)
Consent Form Version Date: 12-20-2017

Title of Study: LCCC Procurement of Biospecimens-**for Patients with Solid Tumor Tissue**
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Funding Source and/or Sponsor: NCI Core Grant, Breast and GI SPOREs, CTSA, UCRF

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What are some general things you should know about research?
Research is designed to gain scientific information that may help other people in the future. You may not receive any direct benefit from participating. There also may be risks.

You may refuse to take part in research. If you are a patient with an illness, you do not have to be in research in order to receive treatment.

Details are discussed below. It is important that you understand this information so that you can make an informed choice. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this specimen repository or "biobank?"
Sometimes many specimens are collected and stored together for use in different kinds of research; this is called a specimen repository or "biobank." The purpose of this biobank is to obtain specimens (such as blood, body fluids, or tissue) and information (data) to serve as a resource for future research. The specimens are collected and stored by the UNC Lineberger Comprehensive Cancer Center Tissue Procurement Facility (TPF), which is a biobank. Only adults, legally able to give informed consent, are eligible for this study.

Many different kinds of studies use our specimens (blood, tissue, or body fluids). Some researchers investigate what causes cancer or other non-cancer diseases, how to prevent them, how to treat them, and how to cure them.

Your specimens and data may be used for genetic research. Genetic research performed on your specimens may include genetic material that you were born with and can pass down to your children (inherited) or may include the study of genetic changes that may have occurred after you were born. For example, genetic material obtained from your specimens may be used to:
1) search for genes that may cause or increase risk or severity of disease; 2) look for relationships between genes, the environment, people's habits, diet, and different diseases; 3) identify genes that may help predict individual responses to therapy.

How will the specimens be collected?

If you participate in this research you will be asked to allow the research staff to collect biological specimens that may be taken at any time as part of medical care. After your tissue has been removed during a biopsy or surgery as part of your medical care, a research staff member will work with your doctor or other doctors and medical staff who handle your tissue to collect some of the excess tissue, if present. By signing this consent form, a blood sample (about 2-3 tablespoons) will be collected at one of your clinic visits, or when you return for surgery. Other body fluid specimens might be collected when available, like urine or ascites.

What will happen to the specimens and data?

The specimens will be stored in the Lineberger Comprehensive Cancer Center (LCCC) Tissue Procurement Facility at UNC, or if needed, in a secure off-site storage facility, until it is released to an approved researcher. There is no time limit on how long your specimens may be stored.

Each specimen is assigned a unique code number. The specimen samples will be distributed to the researcher labeled with the unique code number. No identifying information will be on the specimen label. You will not be identified by name or other identifiable information (such as your medical record number) to the researcher, unless the researcher has IRB-approval for access to this information or your medical record.

Data obtained from your medical record by authorized TPF-associated research staff will be entered into secure, controlled-access databases in the Tissue Procurement Facility and the Lineberger Comprehensive Cancer Center Data Warehouse. TPF-associated research staff, LCCC Bioinformatics staff who support the TPF database and the LCCC Data Warehouse, and researchers with IRB-approval for access to your medical information will have access to the identifying information stored in these databases and will be able to link your specimens with your data.

Will specimens and data be shared with other researchers?

Approved researchers from UNC and from other universities, hospitals, health organizations and industry conducting research using biologic specimens and data may contact the TPF for their studies. Your specimens may be used in a variety of research studies, including genetic research. Your specimens and some medical information related to the specimen, such as anatomic site and diagnosis, may be shared with the researchers at UNC or researchers at other institutions such as universities, hospitals, health organizations and industry. All identifying information will be removed from the specimens prior to sharing with other researchers unless researchers obtain IRB approval, allowing them access to your information or your medical record.

GWAS (Genome Wide Association Studies)

The National Institutes of Health has established a central repository for genotype information (DNA information, including sequences obtained from blood or other tissue) and phenotype information (such as age, signs and symptoms of illness, response to therapy). Your genotype and phenotype information may be included in this national database and shared with many researchers. The idea is that the greatest public benefit is served if the information is shared with a large number of researchers.

What are the possible benefits to you?

Benefits to you are unlikely. Studies that use specimens from this repository may provide additional information that will be helpful to others in the future by understanding what causes cancer and other diseases, how to prevent them, how to treat them, and how to cure them.

What are the possible risks or discomforts involved with the use of your specimens?

There are minimal physical risks to participating in this research. There is a slight chance of bruising or fainting from the drawing of blood.

The greatest risk to you is breach of confidentiality. There is a possibility that coded information about you may be accessed or inadvertently released to members of the public, insurers, employers and law enforcement agencies. When data are stored electronically, there is also a risk of breach of computer security. Since you and your relatives and other members of your ethnic group share some of the same genetic make-up, there is a small chance for breach of their privacy, as well.

There may be risks that at this time are unknown. You should report any problems that might occur to the researcher.

What are the ways to minimize these risks?

There are several ways to minimize risk of harm to you and your family. These include:
1) coding specimens and associated information that are distributed to researchers; 2) making sure that the link that connects the code to your identity is protected and is only accessible by the TPF and authorized LCCC bioinformatics staff or an IRB-approved investigator; 3) federal and state laws.

A new federal law, called GINA (Genetic Information Non-discrimination Act) prohibits health insurers and most employers from discriminating against you based on your genetic information. This law generally will protect you in the following ways:

Health insurance companies and group plans may not request genetic information from this research;
Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums;
Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote or fire you or when setting the terms of your employment.

Employers must follow this law beginning November 21, 2009; Health insurance companies and group plans must follow this law beginning May 21, 2010.GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance or long-term care insurance. GINA does not protect you against discrimination based on an already diagnosed genetic condition or disease.

Will there be any cost to you for storage of the specimens?
There will be no cost to you for the storage and use of the specimens for research purposes.

Will you receive anything for the use of your specimens?
You will not receive anything for taking part in this study.

Who owns the specimens?
Any blood, body fluids, or tissue specimens obtained for this biobank become the exclusive property of the University of North Carolina at Chapel Hill. The researchers may retain, preserve or dispose of these specimens. The researchers may use these specimens to develop new diagnostic tests, detect new markers of disease activity, or discover new treatment approaches to various diseases. Some of these discoveries may be used to develop commercial products or improve existing ones. You will not be compensated for any commercial use of these specimens or any related discoveries.

How will your privacy be protected?
Your specimen will only be distributed to researchers labeled with a unique code number. It will not be labeled with your name or other identifying information. The link between your identity and research information will be kept secure but may be released to researchers with IRB-approval for access to this information.

Information from your medical records may be stored along with your specimens(s).

All electronic data will be stored in a password-protected, restricted-access database. All paper forms will be stored in locked cabinets or rooms in the TPF or an LCCC-approved secure facility.

You will not be identified in any report or publication about research using your specimens. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

1. If you sign this consent form, you are giving your permission for the following people or groups to give the researchers certain information about you (described below):

Any health care providers or health care professionals or health plans that have provided health services, treatment, or payment for you such as physicians, clinics, hospitals, home health

agencies, diagnostics centers, laboratories, treatment or surgical centers, including but not limited to the UNC Health Care System, health insurance plans, and government health agencies.

2. If you sign this form, this is the health information about you that the people or groups listed in #1 may give to the researchers to use in the biobank and associated studies:

Any information in your medical records that relates to your participation in this biobank and studies which use specimens you have donated.

These records might include information about mental health, drug or alcohol use, HIV/AIDS or other communicable diseases, or genetic testing. Most often, the information needed by the biobank includes: your age and gender, the history and diagnosis of your disease including your pathology results, specific information about the treatments you received, including previous treatment(s) you may have had, results of relevant radiology or lab tests , information about other medical conditions, data that may be related to tissue and/or blood samples that will be collected from you, numbers or codes that will identify you, for example, your medical record number and your pathology number.

3. The HIPAA protections that apply to your medical records will not apply to your information when it is in the research biobank records. Your information in the research biobank records may also be shared with, used by or seen by collaborating researchers including approved researchers from UNC and from other universities, hospitals, health organizations and industry, the sponsor of the research study, the sponsor's representatives, and certain employees of the university or government agencies (like the FDA) if needed to oversee the research study. HIPAA rules do not usually apply to those people or groups. If any of these people or groups reviews your research record, they may also need to review portions of your original medical record relevant to the situation. The informed consent document describes the procedures in this research study that will be used to protect your personal information. You can also ask the researchers any questions about what they will do with your personal information and how they will protect your personal information in this research study.

4. Medical information derived from studies using your specimens donated to the biobank will not go into your medical record.

5. If you want to participate in this research study, you must sign this consent form to allow the people or groups listed in #1on this form to give access to the information about you that is listed in #2. If you do not want to sign this consent form, you cannot participate in this research study. However, not signing the form will not change your right to treatment, payment, enrollment or eligibility for medical services outside of this research study.

6. This HIPAA authorization will not stop unless you stop it in writing.

7. You have the right to stop this HIPAA authorization at any time. You must do that in writing. You may give your written stop of this HIPAA authorization directly to the Principal Investigator or researcher or you may mail it to the department mailing address listed at the

top of this form, or you may give it to one of the researchers in this study and tell the researcher to send it to any person or group the researcher has given a copy of this HIPAA authorization. Stopping this HIPAA authorization will not stop information sharing that has already happened.

Will researchers seek approval from you to do future studies involving the specimens or data?

By signing this consent form, you are giving your permission for researchers to use your specimens and data as described above. Current and future research is overseen by a committee called the Institutional Review Board (IRB). The role of the IRB is to protect the rights and welfare of research participants. In some cases, the IRB may require that you be re-contacted and asked for your consent to use your specimens in a specific research study. You have the right, at that future time, not to participate in any research study for which your consent is sought. Refusal to participate will not affect your medical care or result in loss of benefits to which you are entitled.

Will you receive results from research involving your specimens?

Most research with your specimens is not expected to yield new information that would be meaningful to share with you personally. There are no plans to re-contact you or other subjects with information about research results.

Can you end your participation in the research repository?

If you decide that you no longer wish for the specimens to be stored, you should contact the researchers on the front page of this form. It is best to make your request in writing.

Any specimens remaining in the bank will be destroyed or returned to the pathology department, if needed. Any specimens already given out to researchers cannot be returned. Any analysis already performed by a researcher on your specimen prior to your request being received by TPF will continue to be used as part of the researcher's study. If you do not make such a request, the specimens may be stored forever. The researchers may choose to destroy the specimens at any time.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from having your specimen collected. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. However, by signing this form, you do not give up any of your legal rights.

Who is sponsoring this research?

This biobank is supported by the UNC Lineberger Comprehensive Cancer Center through funding it receives from the North Carolina General Assembly's University Cancer Research Fund (UCRF) and the National Cancer Institute. The biobank researchers do not have a direct financial interest with the sponsor supporting the biobank

However, some researchers who use samples from this biobank may have a financial interest in the tests or technologies that are developed from these samples. If their research or approach is successful, it is possible that those researchers and/or UNC-Chapel Hill may receive financial benefits. If you would like more information, please ask the researchers listed on the first page of this form.

What if you have questions about this research? You have the right to ask, and have answered, any questions you may have about this research. If you have questions, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research subject?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by e-mail to IRB_subjects@unc.edu.

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Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate. I agree to my specimen(s) being stored with the identifying code(s).

_____ _____
Signature of Research Participant Date

_____
Printed Name of Research Participant

_____ _____
Signature of Staff Member Obtaining Consent Date

_____
Printed Name of Staff Member Obtaining Consent