University of North Carolina-Chapel Hill
Consent for Storing Biological Specimens and Data
Adult Subjects Biomedical Form

IRB #09-0605

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Title: UNC Health Registry

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What are some general things you should know about research?

You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason.

Research is designed to obtain new knowledge that may help other people in the future. You may not receive any direct benefit from being in this research effort. There also may be risks to being involved in research.

Deciding not to be involved in this research or leaving this research effort before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in this research in order to receive health care.

Details about this research are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research. 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 research at any time.

What is the purpose of this research?

The purpose of this research is to collect information and biologic specimens from a large group of people who are seeking care at UNC. Research with specimens (blood, tissue or body fluids) can help researchers understand how the human body works. Studies of large groups of people over long periods of time help researchers understand causes, treatments and methods for disease prevention. You are being asked to participate because you are a patient with an appointment in the NC Hospitals.

Sometimes many specimens are collected and stored together for use in different kinds of research; this is called a specimen "biobank." The purpose of this biobank is to obtain information (data) and specimens (such as blood, tissue or saliva) to serve as a resource for future research. Researchers use specimens and data from participants to study how genes, lifestyle and our environment may lead to disease and to study what things may affect how people do after they are treated. Genetic material (for example, DNA) obtained from your specimens will be used to search for genes that may cause or increase risk or severity of disease. It is hoped that someday this research will be used to prevent disease as well as improve early detection, diagnosis and treatment.

How many people will take part in this research?

If you decide to participate, you will be one of many thousands of people identified over the course of many years. Approximately 10,000 people will be followed annually.

How long will your part in this research last?

The initial participation visit will require up to approximately 2 hours, if you participate in all components of this research. We may re-contact you each year to follow-up on your health.

What will happen if you take part in this research?

If you volunteer to participate in this research, we will ask you to do the following things.

As being part of this research our research staff will obtain information (data) from your doctor or his/her office records. You will be asked to provide permission to contact your non-UNC doctors for additional medical record information. Some of the information in your medical records may include identifying information (for example, your name or address). This data from medical records will be linked together with your biologic specimens. It may also be matched with existing records in other datasets. A unique research ID will be used for this linkage and only authorized research staff will have access to your identifying information.

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. You agree to allow research staff to use specimens that were already collected for research purposes. Only tissue needed as deemed necessary for your regular medical care will be taken. No additional tissue will be collected as part of this research. These biological specimens are used first to help plan your care, but if extra is available, you will allow a research staff member to work with your doctor to collect and store some of the extra tissue for research. For example, when a person has a biopsy or surgery there may be some tissue or biologic specimen left over after the doctors have completed their review. Instead of letting the left over specimens go to waste, you will be asked to allow Lineberger Comprehensive Cancer Center (LCCC) to keep some for future research. Genetic material called DNA from these specimens is often used for genetic research. There is no time limit on how long your specimens may be stored. You may also be asked to provide permission to contact your non-UNC doctors for additional specimens that were collected outside of UNC.

Our research staff will obtain a sample of blood (about 2-3 tablespoons) from your arm in the clinic or may request a saliva sample (about 2 mls). The saliva sample can be collected by you in your home and returned by mail to the Health Registry in a pre-paid envelop that will be provided to you. Your blood or saliva will be processed, stored, and used later for many different analyses. There is no time limit on how long your specimens may be stored. DNA that is obtained from your blood or saliva will be used to search for genes that may affect treatment or increase the risk or severity of disease. If the blood or saliva specimen collected does not provide usable data, you may be asked to provide an additional sample.

Part of your blood specimen may be used to grow immortal cell lines (those which grow indefinitely) so researchers will not have to obtain more blood from you. These cell lines will be stored indefinitely.

We do not plan to report tests done with your data and specimens for research nor do we plan to give them to your doctor or put them in your health record. This is because research can take a long time and must use specimens from many people before results are known. These results may not be ready for many years. Although these tests may not affect your care right now, they may be helpful to people like you in the future.

Participants may also be asked to complete a questionnaire by a trained staff member. The questionnaire will ask for information about your quality of life, family and medical histories, general characteristics, and lifestyle factors. The questionnaire may be completed in several segments and will take up to a total of about 1 ½ hours to complete. You may skip any questions that you do not want to answer.

You may be asked to allow investigators to contact you in the future. For example, you may be invited to participate in other research studies. You are not required to participate in these studies and your medical care will in no way be affected if you choose not to participate. You may also be contacted yearly to follow-up on your quality of life, family and health histories and lifestyle habits. You may ask us to stop contacting you at any time.

What will happen to the biologic specimens and your data?

Researchers from UNC and other universities, hospitals, and health organizations conducting research using biologic specimens and data may contact the LCCC for their studies. A variety of research studies may use your specimens and some involve genetic research. Your blood, saliva, and tissues contain genes which are made of DNA that is unique to you. Your specimens and some medical information may be shared with the researchers at the other institutions. The specimen(s) and data will be given only to researchers approved by oversight committees. These committees are to protect your interests in any future medical studies.

The LCCC will distribute the specimens and data to the researcher, labeled only with a unique research code number. Your name, phone number and anything else that could directly identify you will be removed. Only authorized research staff will be able to identify you and link your specimens with your data. This coded information and information from more detailed analyses will be put into a controlled-access database available only to researchers with approval from the UNC IRB and LCCC data sharing committee. One of these research groups may include The National Institutes of Health (NIH) who has established a national database that will hold information from many individuals across the country, including medical information and genetic information. If coded information about you is sent to this national database, access will be controlled and limited to other researchers. The remaining portions of your specimens will be stored for an unlimited period of time for future use in research.

What are the possible benefits from being in this research?

Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research. However, the information you provide will help researchers better understand the causes, treatments and prevention of disease, as well as ways to improve health care and quality of life. Future generations may benefit from the results and knowledge gained from this research.

What are the possible risks or discomforts involved with being in this research?
There are minimal risks to participating in this research.

There is a small risk of breach of confidentiality. However, all research staff will be instructed to keep data in strict confidence and information related to this research will be stored under conditions designed to protect the privacy of research participants. The link between your identifying and research information will be kept secure.

There is a slight chance of minor bruising or fainting associated with obtaining the blood specimen. To decrease the chance of this happening, a trained and skilled phlebotomist will perform the blood collection. Prior to the blood draw, you will be asked about bleeding tendencies, anticoagulant (blood thinner) use and use of other medications. Other biologic specimen collection will occur as part of your care and will not involve additional burden to you.

There are minimal known risks associated with completing the questionnaire, although some of the questions are of a personal nature and may make you uncomfortable. You may skip any questions that you do not want to answer.

In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems to the researchers.

How will your privacy be protected?
All information collected about you by this research will be kept confidential. All electronic data will be stored on a password-protected, restricted-access database. All paper forms will be stored in locked cabinets at the LCCC or an approved secure facility. The link between your identifying and research information will be kept secure. You will not be identified in any report or publication about this research.

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.

A Federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for

information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

You will be asked to sign a separate form ("HIPAA authorization") to allow researchers to review your medical records. All research staff are trained to maintain strict confidence. All information obtained for research is stored and released under conditions designed to protect the privacy of participants.

A copy of this consent form may go in to your medical record. This will allow the doctors caring for you to know that you are part of this research.

Will researchers seek approval from you to do future studies involving the specimens?
By signing this consent form, you are giving your permission for researchers to use your specimens as described above. Current and future research is overseen by a committee called the 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.

What if you want to stop participating in this research?
You may withdraw from this research at any time without penalty. If you choose to withdraw from this research contact the researcher listed on the first page of this consent form. Your current or future medical treatment at the University of North Carolina will not be affected if you withdraw from this research.

Can you withdraw the specimens from 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 analysis in progress at the time of your request or already performed prior to your request being received by the researcher will continue to be used as part of this research. Once the researchers have been notified, your remaining specimens would be destroyed. 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.

Will you receive anything for being in this research?
You will receive two 1 hour parking vouchers for your participation in the study.

Will you receive results from research involving your specimens and data?
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.

Will it cost you anything to be in this research?
There will be no cost to you to participate in this research other than your time.

Who is sponsoring this research?
This research is funded by the North Carolina General Assembly's University Cancer Research Fund (UCRF). The researchers do not have a direct financial interest in the final results of this research.

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 being in this research. 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 owns the specimens?
UNC will own the specimens that you donate. This includes any cell lines made from your blood specimen. By signing this consent form, you indicate that you are donating your specimens to the University of North Carolina - Lineberger Comprehensive Cancer Center. This means that the Lineberger Comprehensive Cancer Center will also own anything that is made from your specimens. They may retain, preserve or dispose of these specimens and may use these specimens for research that may result in commercial products. There are no plans to provide you with any compensation in the event that any future value is found for the specimens.

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, or if a research-related injury occurs, 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 email to IRB_subjects@unc.edu.

Subject'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.

_____	_____
Signature of Research Subject	Signature of Person Obtaining Consent
_____	_____
Printed Name of Research Subject	Printed Name of Person Obtaining Consent
_____ Date	_____ Date