Instructions for Submitting IRB Applications for Research that Includes the Collection of Human Biologic Specimens

These instructions cover any human tissue, blood, urine, saliva, semen, other body fluid, or stool being collected prospectively for research purposes. (N.B.: Excess tissue from existing specimens that were collected for clinical purposes, if obtained without personal identifiers, may be exempt from these instructions. See the Short Form application on the website under Forms.)

A. Specimens collected for tests excluding genetic tests that will be done as part of the protocol that is being submitted. (No specimens will be stored for tests to be done after termination of this protocol.)

The protocol and consent form must disclose, at a minimum, the general type of tests that will be done, e.g., blood cell counts, liver function tests, bacterial cultures, etc.

B. Specimens collected for tests including genetic tests that will be done as part of the protocol being submitted. (No specimens will be stored for tests to be done after termination of this protocol.)

The protocol and consent form must disclose as specifically as possible the type of genetic information that will be sought, tell whether the information may be of value to the individual subject and, if so, provide opportunity in the consent form for the subject to choose whether (s)he wishes to receive the test results and appropriate genetic counseling.

C. Specimens collected and stored for as-yet-undesignated tests, but specifically excluding genetic tests.

The protocol and consent form must disclose, at a minimum, that genetic tests will not be performed on the stored specimens, that the specimens will be used only for studies that have been approved by a human subjects protection committee, and that no information will be released to other researchers that could enable them to connect any subject's name to the specimens.

D. Specimens collected and stored for as-yet-undesignated purposes that may include genetic testing.

1. If any personal identifiers or code are retained with the specimens:

(a) Use the *Consent for Storing Blood, Tissue or Body Fluid with Identifying Information* as an addendum to the usual consent form. (If part of a multicenter study, a similar consent form addendum or insert may be substituted.)

(b) Provide each subject with a copy of *Information About Storage and Use of Specimens With Identifying Information*.

2. If no personal identifiers or code linking the specimen to any subject are retained:

(a) Use *Consent for Storing Tissue, Blood or Body Fluid without Identifying Information* as an addendum to the usual consent form. (If part of a multicenter study, a similar consent form addendum or insert may be substituted.)

(b) Provide each subject with a copy of *Information About Storage and Use of Specimens Without Identifying Information.*

UNC-CH SCHOOL OF MEDICINE / UNC HOSPITALS
INFORMATION ABOUT STORAGE AND USE OF SPECIMENS
WITH IDENTIFYING INFORMATION

This brochure provides information that may help you decide whether to allow some of your blood, tissue and/or body fluid (specimens) which will be collected as part of this research study to be stored and used for future medical research.

WHAT WILL HAPPEN TO THE SPECIMEN?

The specimens will be processed for storage, catalogued and placed in a secured facility at the UNC-CH School of Medicine, UNC Hospitals, or another site. All identifying information, including your name and medical record number, will be removed from the specimens. The specimens will be given a unique identifier (code).

The researcher in this study and his/her associates will have access to the specimens and the code which links the specimens to you.

WILL RESEARCH RECORDS AND PERSONAL INFORMATION BE KEPT PRIVATE?

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of those records, including personal information about you. When disclosure is required, the UNC School of Medicine and/or UNC Hospitals will take all steps allowable by law to protect the privacy of your personal information.

IS THERE ANY COST FOR STORAGE OF THE SPECIMENS?

There is no cost to you or your insurance company for the storage and use of the specimens.

WHO OWNS THE SPECIMENS?

By signing the consent form, you will donate the specimens for medical research purposes. Your donation does not entitle you to compensation from any commercial use of the products that may be derived from the specimens.

HOW WILL THE SPECIMENS BE USED IN THE FUTURE?

The research studies in which the specimens may be used have not yet been determined. The studies may involve genetic research. Genetic research is about finding the specific location of genes, learning how genes work, and developing treatments and cures for diseases which are genetically based.

Before any research involving the specimens is conducted, a committee at the UNC School of Medicine called The Committee on the Protection of the Rights of Human Subjects will review and approve the research proposal. The Committee includes scientists and non-scientists, including community representatives. The purpose of the Committee is to assure that the interests of individuals participating in research studies are well protected.

WILL RESEARCHERS SEEK CONSENT TO DO FUTURE STUDIES INVOLVING THE SPECIMENS?

In some cases, the Committee may require that you be contacted and asked for your consent to participate in the specific research study in which the specimens will be used. You have the right not to participate in any research study for which your consent is sought. Refusal to participate will not jeopardize your medical care or result in loss of benefits to which you are entitled.

WILL YOU RECEIVE STUDY RESULTS OF RESEARCH INVOLVING YOUR SPECIMENS?

There may be times when the Committee will require that you be notified about the results of a research study in which your specimens were used. You have the right to be told of the results and their meaning, or to decide not to be told of those results, or to have the information sent directly to your personal physician.

HOW WILL RESEARCHERS FIND YOU IN THE FUTURE?

If you decide to allow the specimens to be stored and used in future medical research studies, you will be asked to provide your social security number. Your social security number will be used by the researchers and their associates in this study when it is necessary to contact you to seek your consent to participate in a specific research study or to notify you about the results of that study.

If you allow your specimens to be stored with identifying information, you will be asked to choose, at the time you sign the consent form, a course of action that will be taken in the event that the researchers are unable to locate you in the future, even with your social security number. The options include allowing continued storage and use of your specimens with the identifying code remaining, continued storage and use of the specimens after removing the identifying code, and disposing of the specimens according to standard medical procedures.

WILL THE SPECIMENS BE SHARED WITH OTHER INSTITUTIONS?

The specimens may be shared with researchers from other institutions. Research studies may be conducted at several locations at the same time.

No identifying personal information about you will be provided to researchers from other institutions who will use the specimens.

HOW LONG WILL THE SPECIMENS BE STORED?

The specimens will be stored indefinitely. Specimens may also be disposed of at any time at the discretion of the investigators, using standard medical procedures. If in the future you should decide that you no longer wish for the specimens to be stored, you may contact the researcher and/or his/her associates on the study in which you are participating. You may also contact The Committee on the Protection of the Rights of Human Subjects at (919) 966-1344 and request that the specimens be disposed of.

Consent For Storing Blood, Tissue or Body Fluid
With Identifying Information

Addendum to Consent for Participation in:
GCRC #2067
Physiological Changes in Adults With Metabolic Syndrome Exposed to Concentrated Chapel Hill Ultrafine Air Particles
Donald Graff, Pharm.D. (PI)

You are asked to give permission for some of your blood, tissue or body fluid (collectively referred to as "specimens") which will be collected in this research study to be stored for future medical research studies.

The specimens will be stored at the UNC School of Medicine, UNC Hospitals, or another site. All identifying information including your name and medical record number will be removed from the specimens and replaced with a code. Dr. Graff and his associates will have access to the specimens and the code which links the specimen to you. There is no cost to you or your insurance company for the storage and use of the 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 those records, including personal information about you. When disclosure is required, the UNC School of Medicine and/or UNC Hospitals will take all steps allowable by law to protect the privacy of your personal information.

By signing this form, you will donate the specimens for medical research purposes. Your donation does not entitle you to compensation from any commercial use of the products that may be derived from the specimen. The research studies in which the specimens may be used have not yet been determined, but they may involve genetic research. Before any research involving the specimens is conducted, a committee at the UNC School of Medicine called The Committee on the Protection of the Rights of Human Subjects will review and approve the research proposal.

In some cases, the Committee may require that you be contacted and asked for your consent to participate in the specific research study in which the specimens will be used. You have the right not to participate in any research study for which your consent is sought. Refusal to participate will not jeopardize your medical care or result in loss of benefits to which you are entitled.

In other cases, the Committee may require that you be notified about the results of a research study in which the specimens were used. You have the right to be told the results and their meaning, or to decide not to be told of those results, or to have the information sent directly to your personal physician.

You are asked to provide your social security number and agree that it may be used by Dr. Graff and his associates if it necessary to contact you to ask your consent to participate in a specific research study or to notify you about the results of the study.

The specimens may be shared with other institutions and research studies may be conducted at several locations at the same time. Non-identifying personal information about you will be provided to investigators from other institutions.

If in the future you should decide that you no longer wish for the specimens to be stored, you may contact Dr. Graff and/or his associates at The University of North Carolina at Chapel Hill at (919) 843-5155 or The Committee on the Protection of the Rights of Human Subjects at (919) 966-1344 and request that the specimens be disposed of according to standard medical research procedures. If you do not make such a request, the specimens will be stored indefinitely. They may be disposed of at any time at the discretion of the investigators.

Before signing this consent form, please read the brochure entitled ***Information About Storage and Use of Specimens With Identifying Information*** that is designed to answer your questions.

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Please check which course of action is to be followed in case, even with your social security number, the investigators cannot find you after reasonable time and effort:

_____I agree to allow the specimens to continue to be stored with identifying information, for as-yet-undesignated purposes that may include genetic research.

_____I request that the identifying code be removed from the specimens; after that is done, the specimens may continue to be stored and used for as-yet-undesignated purposes that may include genetic research.

_____I request that the identifying code be removed from the specimens; after that is done the specimens may continue to be stored and used for as-yet-undesignated purposes NOT INCLUDING genetic research.

_____I request that the specimens be disposed of.

I consent to the donation and storage of the specimens, as described above.

_____ _____

Name of Subject Date

_____

Social Security Number

UNC-CH SCHOOL OF MEDICINE / UNC HOSPITALS
INFORMATION ABOUT STORAGE AND USE OF SPECIMENS
WITHOUT IDENTIFYING INFORMATION

This brochure provides information that may help you decide whether to allow some of your blood, tissue and/or body fluid (specimens) which will be collected as part of this research study to be stored and used for future medical research.

WHAT WILL HAPPEN TO THE SPECIMEN?

The specimen will be processed for storage, catalogued and placed in a secured facility at the UNC-CH School of Medicine, UNC Hospitals, or another site. All identifying information, including your name and medical record number, will be removed from the specimen and will not be retained. As a result, it will be impossible to connect you with the specimen. Some basic information such as your age, gender and diagnosis may be retained with the specimen.

IS THERE ANY COST FOR STORAGE OF THE SPECIMEN?

There is no cost to you or your insurance company for the storage and use of the specimen.

WHO OWNS THE SPECIMEN?

By signing the consent form, you will have donated the specimen for medical research purposes. Your donation does not entitle you to compensation from any commercial use of the products that may be derived from the specimen.

HOW WILL THE SPECIMEN BE USED IN THE FUTURE?

The research studies in which the specimen may be used have not yet been determined. Some studies may involve genetic research. Genetic research is about finding the specific location of genes on chromosomes, learning how genes work, and developing treatments and cures for diseases which are genetically based. If you sign the consent form, you may choose whether or not to allow the specimen to be used in genetic research.

Because it will be impossible to connect you with the specimen, you will not be contacted in the future about any planned studies involving the specimen. However, all such studies must be reviewed and approved by a committee of the UNC-CH School of Medicine called the Committee on the Protection of the Rights of Human Subjects. The Committee includes scientists and non-scientists, including community representatives. The purpose of the Committee is to assure that the interests of individuals participating in research studies are well protected.

The specimen may be shared with researchers from other institutions. Research studies may be conducted at several locations at the same time.

WILL I RECEIVE STUDY RESULTS OF RESEARCH INVOLVING THE SPECIMEN?

Because it is impossible to connect you with the specimen, you will be unable to learn about the studies in which the specimen was used and any findings from those studies which relate to the specimen. This is true for all research on the specimen, including any genetic research.

HOW LONG WILL THE SPECIMEN BE STORED?

The specimen will be stored indefinitely.

Consent For Storing Blood, Tissue or Body Fluid
Without Identifying Information

Addendum to Consent for Participation in:

(*Identify here by IRB number, title and name of the principal investigator the protocol to which this will be added)*

You are asked to give permission for some of your blood, tissue or body fluid (collectively referred to as "specimens") which will be collected in this research study to be stored for future medical research studies.

The specimens will be stored at the UNC-CH School of Medicine, UNC Hospitals, or another site. All identifying information including your name and medical record number will be removed from the specimens and will not be retained. As a result, it will be impossible to connect you with the specimens. This means that you will be unable to learn about the studies in which the specimen was used and any findings of those studies which relate to the specimens. There is no cost to you or your insurance company for the storage and use of the specimens.

By signing this form, you will donate the specimens for medical research purposes. Your donation does not entitle you to compensation from any commercial use of the products that may be derived from the specimens. The research studies in which the specimens may be used have not yet been determined. The specimens may be shared with other institutions and research studies may be conducted at several locations at the same time.

The specimens will be stored indefinitely.

Before signing this consent form, please read the brochure entitled ***Information About Storage and Use of Specimens Without Identifying Information*** that is designed to answer your questions.

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Check one below:

___ I consent to the donation and storage of the specimens, as described above, for as-yet-undesignated purposes that may include genetic research.

___ I consent to donation and storage of the specimens as described above, for as-yet-undesignated purposes **NOT INCLUDING** genetic research.

_____ _____

Name of Subject Date