

The UNIVERSITY OF CHICAGO  
The Division of the Biological Sciences • The University of Chicago Hospitals

CONSENT BY SUBJECT FOR PARTICIPATION IN A RESEARCH PROTOCOL

Protocol Number: 14104B      Name of Subject: \_\_\_\_\_  
Medical History Number: \_\_\_\_\_

STUDY TITLE: BIOMARKERS IN HEALTH AND DISEASE  
Dr. Meltzer Study Amendment

Doctors Directing Research: Nancy J. Cox, PhD  
Address: University of Chicago  
5841 S. Maryland Ave.  
MC 6091  
Chicago, IL 60637  
Telephone Number: (773) 834-1001

You are being asked to participate in a research study. A member of the research team will explain what is involved in this study and how it will affect you. This consent form describes the study procedures, the risks and benefits of participation, as well as how your confidentiality will be maintained. Please take your time to ask questions and feel comfortable making a decision whether to participate or not. This process is called informed consent. If you decide to participate in this study, you will be asked to sign this form.

**WHY IS THIS STUDY BEING DONE?**

**Background:**

We, as a society, have invested a great deal in research to develop markers (like, for example Type A, B, AB and O blood) to better understand disease risks and improve the treatment of disease. These markers help determine the make up and functioning of our body. The next stage of this research is to test these markers in large samples of healthy individuals as well as individuals with different diseases.

**The purpose of this study is** to identify biological markers that can help to predict the risk of common diseases and their course over time. Examples of biological markers include blood type, like A, B, O or AB and other proteins in blood. By studying these markers, scientists hope to improve their ability to predict, effectively treat, and ultimately prevent common diseases.

**HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?**

We estimate that 5000 people will take part in this study in one year at the University of Chicago.

**WHAT IS INVOLVED IN THE STUDY?**

In this study we will ask you to donate an additional blood sample for research purposes only during an already scheduled blood draw.. The blood sample used for research will not require you to undergo any additional procedures, and will not affect the accuracy of any routine tests that are to be conducted today for your medical care.

The blood sample will be part of a routine blood draw, so that no extra needle stick is needed. A small additional amount of blood will be removed (approximately 1½ tablespoons) for each blood draw.

You will also be asked questions, including information on your race/ethnicity, current diagnoses, and medications taken over the past year. We will also record the clinic and the physician that you were visiting as well as your sex, birth date and two assigned numbers (the University Medical Record # and a unique number that will ultimately link to your clinical data).

The samples we obtain will be used for performing special research tests and, in some cases, these tests may be performed years later. These tests could include genetic testing. Genes are the material passed from parent to child that determines the make-up of the body and mind. The doctors conducting these studies will utilize the results of these tests for the purposes of their research. However, no genetic information or results will be placed in your medical records or given to you. These tests may provide additional information that will be helpful in understanding your general health. If you participate, you give approval for the performance of these tests on these specimens. Although there are no specific plans at this time, it is possible that blood samples obtained from you in the course of this study may be used to develop products that could be used and sold.

**Data Gathered for This Study:**

Your sample will be stored with information that identifies you. This information includes your name, medical history number, date of birth, race, name of the physician you are visiting, information about your sample (date and type of sample, location, tracking numbers to locate sample easily), your diagnosis (stage, pathological diagnosis), medical history, clinic in which samples was collected, date of consent and the medications you are taking. Please note that if you are HIV positive this information will be collected as part of the study data as well. To ensure that we have the most accurate and current medical information for future studies, this information will be updated on a regular basis based on your medical record.

This information will be kept in a computer database that can only be accessed by the study staff or people following the study staff's specific instructions. Each time we perform a test on your sample, we may need to access your information in this database. For certain specific questions we may also access your medical records, if this question has been reviewed and approved by a panel of medical experts and laypeople (called the institutional review board (IRB)). E.g. one sample question could be: 'Are patients with ulcers more likely to have type A blood?' This information would be obtained from your medical record if our institutional review board (IRB) agreed that this is an appropriate question. Please note that we will not ask you for permission to use your sample and/ or to access your medical information (including your medical record) each time we wish to do so in the future if the purpose of the investigation has been approved.

In order to answer new research questions, data from this study may also be used in combination with data about you from other studies that you agree to, or have already agreed to participate in at the University of Chicago. We may not always ask your permission to combine this study data if the purpose of the investigation has been approved by our IRB.

**Data from Other Studies in Which You May be Participating:**

If you have agreed to participate in Dr. Meltzer's study # 13930B, Cardiology Quality of Care Study

we would like your permission to use the data collected for Dr. Meltzer's study in conjunction with your blood sample and data collected under this study (#14104B Biomarkers in Health and Disease), for future research.

The data collected as part of this study could be used in future research studies that examine the progression, treatment and prevention of diseases. To do this, your data from study #13930B would be combined with biological information provided by your blood sample, as well as any data collected under this protocol #14104B Biomarkers in Health and Disease.

Data collected as part of Dr. Meltzer's study #13930B will be controlled by Dr. Meltzer. However, Dr. Meltzer could decide to share your data with other doctors for future research studies.

Please indicate whether or not you give your permission to use your study data from study # 13930B, Cardiology Quality of Care Study, in conjunction with the samples and data collected under this study, #14104B Biomarkers in Health and Disease:

Yes, you may combine my study data in this manner

No, you may not combine my study data in this manner

#### **HOW LONG WILL I BE IN THE STUDY?**

Your active participation in the study will end at the conclusion of the blood draw. However, your information may be accessed for future research indefinitely.

You may choose to withdraw from this study at any time. If you withdraw, any information and samples that have not already been used in a research study will be discarded

#### **WHAT ARE THE RISKS OF THE STUDY?**

There is some risk that individuals could know some of your personal medical information other than your doctor and other caregivers. Every effort will be made to prevent this from occurring. There are no additional physical risks.

The blood will be drawn as part of your routine blood draw. No additional needle stick is required. With blood draw there is a minor risk of momentary discomfort, bruising, bleeding, inflammation, or (rarely) infection at the site of needle insertion for blood drawing. On rare occasion, fainting can occur as well. Care will be taken to avoid these risks.

#### **ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?**

You will not gain any direct personal benefit from participation in this study. Information can be gained from these studies, which could provide future benefit for the prediction, treatment or prevention of common diseases.

#### **WHAT OTHER OPTIONS ARE THERE?**

There is no treatment as part of this study. You may choose not to participate in this study. The decision whether or not you wish to participate in this study will not affect your care at the University of Chicago Hospitals.

### **WHAT ARE THE COSTS?**

The extra samples we obtain are for research purposes only and you will not be charged for them. Since you may be required to have blood drawn today, the costs associated with this procedure will be billed to you or your insurance company as usual and there is no additional cost beyond what you would have been charged.

### **WILL I BE PAID FOR MY PARTICIPATION?**

You will not be paid for your participation in this study.

### **WHAT ABOUT CONFIDENTIALITY?**

Study records that identify you will be kept confidential. Only study staff will have access to this information. Your study records will contain your name, medical history number, date of birth, race, name of the physician you are seeing today, information about your sample (type of sample, location, tracking numbers to locate sample easily), your diagnosis (stage, pathological diagnosis), medical history, clinic in which sample was collected, date of consent and the medications you are taking, and will be available to the study doctor, research nurse, and data coordinator. The data collected for this study will be continually updated. Your study records will be secured in locked offices. Neither your name nor other personally identifying information will be used in any publication resulting from the research study.

The data collected in this study will be used for the purpose described in the form. By signing this form, you are allowing the research team access to your medical records, which include Protected Health Information. Protected Health Information (PHI) consists of any health information that is collected about you, which could include your medical history and new information collected as a result of this study. The research team includes the individuals listed on this consent form and other personnel involved in this study at the University of Chicago.

Your data may be shared with other investigators who are conducting research regarding disease diagnosis, progression, treatment and prevention. These investigators may or may not be affiliated with the University of Chicago. If your study information is shared with investigators outside of the University of Chicago, your name and medical record number will not be included. You will be identified by a study code instead. The data that could be shared include date of birth, race, ethnicity, your diagnosis (stage, pathological diagnosis), any medical history, date of consent and the medications you are taking. This data will be continually updated based on your medical record to ensure that the most accurate and current information is used for future research studies.

Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research including the Food and Drug Administration (FDA) and Office of Human Research Protections (OHRP). In addition, representatives of the University of Chicago including the Institutional Review Board, a committee that oversees the research at the University of Chicago, may also view the records of the research. If your research record is reviewed by any of these groups, they may also need to review your entire medical record.

During your participation in this study, you will have access to your medical record. Dr. Nancy Cox is not required to release to you research information that is not part of your medical record.

The study results will be kept in your research record and be used by the research team forever. Any research information in your medical record will be kept indefinitely. Data from this study may be used in medical publications or presentations. **Your name and other identifying information will be removed before these data elements are used.** If we wish to use identifying information in publications, we will ask for your approval at that time. This consent form will be kept by the research team for at least six years.

Parts of your blood sample may be provided to collaborators to perform certain tests that we cannot perform at the University of Chicago. The provided material / information will be de-identified and results will be returned to us for evaluation as described previously.

### **WHAT ARE MY RIGHTS AS A PARTICIPANT?**

Taking part in this study is voluntary. If you choose not to participate in this study, your care at the University of Chicago/University of Chicago Hospitals will not be affected.

You may choose not to participate at any time during the study. Leaving the study will not affect your care at the University of Chicago/University of Chicago Hospitals.

If you choose to no longer be in the study and you do not want any of your future health information to be used, you must inform Dr. Nancy Cox in writing at the address on the first page. Dr. Nancy Cox may still use your information that was collected prior to your written notice. We will tell you about significant new information that may affect your willingness to stay in this study.

You will be given a signed copy of this document. This consent form does not have an expiration date.

### **WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

You have talked with research staff at the University of Chicago about this study and you had the opportunity to ask questions concerning any and all aspects of the research. If you have further questions about the study, you may call Dr. Nancy Cox, (773) 834-1001. Additionally, you may visit the study website at: <http://tridom.bsd.uchicago.edu>.

If you have any questions concerning your rights in this research study you may contact the Institutional Review Board, which is concerned with the protection of subjects in research projects. You may reach the Committee office between 8:30 am and 5:00 pm, Monday through Friday, by calling (773) 702-6505 or by writing: Institutional Review Board, University of Chicago, 5751 S. Woodlawn Ave., McGiffert Hall, Chicago, Illinois 60637 .

## **CONSENT**

### **SUBJECT**

The research project and the procedures associated with it have been explained to me. The experimental procedures have been identified and no guarantee has been given about the possible results. I will receive a signed copy of this consent form for my records.

I agree to participate in this study. I am aware that my participation is voluntary and that I do not have to sign this form if I do not want to be part of this research study.

**Signature of Subject:** \_\_\_\_\_

**Date:** \_\_\_\_\_ **Time:** \_\_\_\_\_ **AM/PM (Circle)**

**PERSON OBTAINING CONSENT**

I have explained to \_\_\_\_\_ the nature and purpose of the study and the risks involved. I have answered and will answer all questions to the best of my ability. I will give a signed copy of the consent form to the subject.

**Signature of Person Obtaining Consent:** \_\_\_\_\_

**Date:** \_\_\_\_\_ **Time:** \_\_\_\_\_ **AM/PM (Circle)**

**INVESTIGATOR/PHYSICIAN:**

**Signature of Investigator/Physician** \_\_\_\_\_

**Date:** \_\_\_\_\_ **Time:** \_\_\_\_\_ **AM/PM (Circle)**