RESEARCH CONSENT FORM

Protocol Title: RESOURCE COLLECTION AND EVALUATION OF HUMAN TISSUES AND CELLS FROM DONORS WITH AN EPIDEMIOLOGY PROFILE FOR NCI CONTRACT # N02-RC-57700

Study No.: 42163

Principal Investigator: DEAN MANN, MD

Sponsor: NATIONAL INSTITUTES OF HEALTH

UMMS –Controls

BACKGROUND

We have invited you to join this National Cancer Institute study because we are recruiting men and women from the general population to participate in a study of cancer. You will provide information that we can compare to information we get from people with cancer. The Principal Investigator is Dr. Dean Mann.

PURPOSE OF STUDY

The purpose of this study is to see how people get cancer. We know some of the major causes of cancer but we do not know why some people get cancer, and why others do not. We are conducting a study to find out how certain factors are related to cancer and cancer risk.

PROCEDURES

A total of 6,450 subjects at 3 institutions will be asked to participate in this cancer study. You will be one of approximately 2,500 subjects to be asked to participate at this location.

Participants will be recruited from the following location(s): University of Maryland Baltimore, University of Maryland Medical System, VAMHCS, Other Sites.

If you join this study, we will:

- Conduct a one-time interview and ask you questions about your residential history, medical and family medical history, tobacco use, alcohol use, occupation, diet and, if applicable, questions about your lifestyle and sexual history.
- Read your medical records and record medical information. (Hospital Controls only)

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- Collect a maximum of 65 cc (four to five tablespoons) of blood from you. This will be collected by a needle stick in your arm.
- We may ask you to provide cheek swabs from the inside of both cheeks, or use a mouthwash to collect cheek cells, one time.
- Collect a one-time urine sample from you.

Specimens collected for this study will be sent to the National Institutes of Health. We will use your blood (or oral cells) and urine to study how genes and other factors affect the development of cancer. We will study one part of these samples for genes that we think are related to cancer, and to test for how your body repairs any damage to your genes. We also will measure chemicals in your blood and urine that come from your diet (nutrients and vitamins) and the environment, cigarette smoking, and chemicals that your body produces such as hormones.

You will not be informed of the results of studies done on your specimens. The tests performed will be done for research and they are not likely to be useful for clinical care. Therefore, we do not plan to send you test results from this research. If you would like to withdraw your samples at anytime please call the Principal Investigator. At that time we will stop collecting health information about you and we will not use health information already gathered.

Depending on the information you provide to us, or the results of the blood or urine, we might want to contact you for more information, or more blood or urine. At that time, you can refuse to provide any additional information, blood or urine. If you do not want us to contact you, please circle below.

I can be contacted in the future for more information, blood or urine:

Yes No (Please circle) Sign your initials here: _____

At the present time, the NCI is not studying genes where the results of the study will be clear-cut and have a large impact on a patient's cancer risk. Even if our single study indicates that there is an increased risk of cancer because of a specific test result, no single research study is final and other studies would have to be done to confirm our results. At the present time we are not releasing individual test results to study subjects. You have the right to withdraw your samples for further use at any time by contacting the Principal Investigator. At that time we will stop collecting health information about you and we will not use health information already gathered. Please initial below if you allow your tissue samples to be used for genetic testing.

_____ _____
INITIAL DATE

OPTIONAL STUDIES

We will store your left-over blood or urine and questionnaire data for later studies that are not part of this protocol of cancer factors that are found in the future. The specimens will be stored without identifiers. They are linked by a coded identification number. Will you give your permission for storage and use of your biological samples for future research studies?

Yes No (Please Circle) Sign your initials here:_____

POTENTIAL RISKS/DISCOMFORTS

There is minimal risk associated with participation in this study. There is a risk that you may develop a bruise on your arm from the needle stick, but there is no other risk involved in drawing this blood sample. There is also the risk that you may feel uncomfortable or embarrassed by some of the questions that the study staff will ask or that are in the questionnaires. You are free to not answer questions that make you feel uncomfortable or embarrassed. There is potential risk of breach of confidentiality. We are doing our best to protect your information and to minimize the risk. A few examples of how we protect our participants are that everyone is given a coded identification number and that all study data are stored in locked cabinets.

POTENTIAL BENEFITS

You will receive no direct benefit from participation in this study. However, your participation may help the investigators better understand factors which work to influence cancer risk.

ALTERNATIVES TO PARTICIPATION

This is not a treatment study. Your alternative is to not take part. If you choose not to take part, your healthcare at University of Maryland, Baltimore will not be affected

COSTS TO PARTICIPANTS

There are no costs to you as a consequence of your participation in this research study.

PAYMENT TO PARTICIPANTS

You will be paid $50.00 compensation for time and effort involved in participating in the study. You will receive the first $25.00 after you donate the blood and urine and receive the second $25.00 after you complete the questionnaire.

This institution does not plan to pay royalties to you if a commercial product is developed from blood or tissue obtained from you during this study.

CONFIDENTIALITY

The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

SUBJECT'S RIGHTS

Your participation in this study is voluntary. You may choose not to participate now or at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to stop participating in this study, if you have questions or concerns at any time, or if you need to report an injury related to the research, please contact: Dr. Dean Mann at 410-328-5512.

Your participation in this study in no way affects your employment and/or student status at the University of Maryland or the Veterans affairs Medical Center. If you are a veteran wanting to confirm that this study is in fact Institutional Review Board approved and is being conducted at the VAMHCS, you may contact Donna Perlmutter at 410-706-5129.

In addition to the risks described in this form, there may be unknown risks/discomforts involved in participating in the study. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study. The investigator Dr. Dean Mann or sponsor can decide to withdraw you from the study at any time. You could be removed from the study for reasons related solely to you. Also, the entire study may be stopped by the sponsor, the Investigator, the Institutional Review Board, the facility where the study is being carried out, or the University. The sponsor may also decide to stop the Investigator's participation in the study. In that case, your participation will end unless another investigator is identified and approved by the sponsor and the Institutional Review Board.

If you are injured because of study participation, you will receive emergency medical care if needed and you will receive assistance in getting other medical care as needed. You or your insurance carrier will be billed for the cost of care, just as you would be billed for any other medical care. If you incur uninsured medical costs, they are your responsibility. The study staff can give you more information about this if you have a study injury.

As a participant, you are not waiving any of your legal rights. You can seek legal compensation for any injury that may occur to you during the study as a result of an error by a member of the research staff, the sponsor, or others.

Members of the Institutional Review Board (IRB) or the Human Research Protections Office can answer your questions and concerns about your rights as a research subject. The IRB office number

is 410-706-5037.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University is committed to providing participants in its research all rights due to them under state and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.

The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland, Baltimore (UMB). The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.

If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staffs of the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland School of Medicine
Human Research Protections Office
BioPark I
800 W. Baltimore Street, Suite 100
Baltimore, MD 21201
410-706-5037

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

_____

Participant's Signature Date

_____

Investigator or Designee Obtaining Consent Date

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Site of Research:
Johns Hopkins Medical Institutions

Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **P53, Apoptosis Phenotypes in Lung Cancer- Persons with Lung Cancer**

Hospital and Population Controls Consent

Application No.: **NA_00029111**

Sponsor: **National Cancer Institute**
University of Maryland Medical School

Principal Investigator: Dr. Rex Yung

1 What you should know about this study:

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Please ask questions at any time about anything you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
- Ask your study doctor or the study team to explain any words or information in this informed consent that you do not understand.

2 Why is this research being done?

The purpose of this research study is to see how people get lung cancer. We know that the major cause of lung cancer is cigarette smoking, but we do not know why only some smokers get lung cancer, and why some non-smokers may get lung cancer. We also are interested in why people smoke cigarettes.

You are being asked to participate in this research study because you can provide information that we can compare to information we get from people with lung cancer.

How many people will be in this study?

From Johns Hopkins, we are expecting to enroll 2,500 participants in the study. In total, about 6,300 participants will take part in this study at all sites.

3 What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

- Ask you questions about your medical background and your family medical background. We will ask about your smoking habits and your alcohol use. We will also ask about your past work locations and where you have lived.
- Read your medical records and write down your medical information (Hospital Controls only).
- Collect from you about four to five tablespoons of blood; this will be done by a needle stick in your arm.
- Collect from you a urine sample (less than a half a cup).+
- We will ask you to use a mouthwash to collect cheek cells (oral cells) if we are not successful in collecting blood.

We will use your samples to study lung cancer and cigarette smoking risks with lab tests. Your samples will be delivered to the University of Maryland (our contractor) for processing and will ultimately arrive at the National Institute of Health (our sponsor) to conduct tests for the genetic portion of the study. After testing, any remaining samples will be stored at the National Institute of Health.

We will study one part of these samples now for genes that we think are related to cancer. We will also see how your body repairs any damage to your genes. The lab tests will also measure chemicals in your samples. The chemicals we measure may come from the food you eat, hormones, and the environment such as cigarette smoking.

Optional Storage of Leftover Samples for Future Genetic Testing

We would like to keep your leftover samples, and questionnaire data for possible future cancer studies. You will not be told of the results of studies done on your samples. These tests will only be used for research. The tests we use have not been through a review process that happens for clinical tests. The usefulness of the tests is not yet proven. However, we may learn something in the future that suggests that others may benefit from such tests. You do not give up any rights that you have regarding access to and disclosure of your records. Please indicate your preference by selecting the appropriate box below:

☐ YES – I DO agree to have the leftover samples stored for possible future cancer studies.

☐ NO – I DO NOT agree to have the leftover samples stored for possible future cancer studies.

Based on the information you give to us, or the results of the blood (or oral cells) and urine tests, we may want to collect more information or more blood or urine from you. If you want, you may refuse to give more information, blood (or oral cells), or urine. Please indicate your preference by selecting an appropriate box below:

☐ YES – I DO agree that you may contact me in the future to ask more questions or ask me to donate more blood or urine.

☐ NO – I DO NOT agree that you may contact me in the future about this research.

How long will you be in the study?

You will be in this study for ten years.

Future Contact

We would like your permission to contact you about other studies that you may be eligible for in the future. Please initial your choice below:

_____ Yes, you may contact me in the future about other studies.
_____ No, I do not want you to contact me about other studies

4. What are the risks or discomforts of the study?

Taking blood may cause discomfort, bleeding or bruising where the needle enters the body. In rare cases, it may result in fainting. There is a small risk of infection.

We will question you about topics such as smoking habits and alcohol use. We will ask about reproductive history (women only), medical information, and income. On average, the interview will take about 1–1.5 hours to complete. You may get tired or bored when we are asking you questions. You do not have to answer any question you do not want to answer.

If we visit you in your home, the research team will comply with Maryland law and will tell the local or state authorities if they suspect abuse or neglect of a child or dependent adult, or see other illegal activity.

To guard your privacy, all completed surveys (questionnaires) are stored in locked cabinets and used only by study staff. The study information is put into a computer file. This holds study ID numbers but no names or contact information. When the results of the study are presented or published, no names will be used. Every effort is made to keep the information you give safe. Yet the chance remains that others outside of this study could find out this private information.

5. Are there benefits to being in the study?

There is no benefit to you if you join this study. However, your participation will help the investigators to better understand how smoking and other factors work to influence lung cancer risk.

6. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

No.

8. Will you be paid if you join this study?

You will receive $50 either in cash or check for taking part in the study at the end of the interview.

9. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- If you leave the study early, Johns Hopkins may use or give out your health information that it already has if the information is needed for this study or any follow-up activities.

10. How will your privacy be protected?

Johns Hopkins has rules to protect information about you. Federal and state laws also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

Generally, only people on the research team will know that you are in the research study and will see your information. However, there are a few exceptions that are listed later in this section of the consent form.

The people working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may collect other information including your name, address, date of birth, and other details.

The research team will need to see your information. Sometimes other people at Johns Hopkins may see or give out your information. These include people who review the research studies, their staff, lawyers, or other Johns Hopkins staff.

People outside of Johns Hopkins may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and companies that sponsor the study.

We cannot do this study without your permission to use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Hopkins who receive your information may not be covered by this promise. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee this.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by calling the Johns Hopkins Privacy Officer at 410-735-6509 or by sending a letter to:

Johns Hopkins Privacy Officer
5801 Smith Avenue
McAuley Hall, Suite 310
Baltimore, MD 21209
Fax: 410 735-6521

Please be sure to include the name of the study doctor, the study number and your contact information.

If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

11. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

b. What do you do if you have questions about the study?

Call the study doctor, Dr. Rex Yung at (410) 955-3467. If you cannot reach the study doctor or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What happens to Data, Tissue, Blood and Specimens that are collected in the study?

Scientists at Johns Hopkins work to find the causes and cures of disease. The data, tissue, blood and specimens collected from you during this study are important to both this study and to future research.

If you join this study:

- You will not own the data, or the tissue, blood, or other specimens given by you to the investigators for this research.
- Both Johns Hopkins and any sponsor of this research may study your data and the tissue, blood or other specimens collected from you.
- If data, tissue, blood, or other specimens are in a form that identifies you, Johns Hopkins may use them for future research only with your consent or IRB approval.
- You will not own any product or idea created by the researchers working on this study.
- You will not receive any financial benefit from the creation, use or sale of such a product or idea.

d. What are the Organizations that are part of Johns Hopkins?

Johns Hopkins includes the following:

- The Johns Hopkins University
- The Johns Hopkins Hospital
- Johns Hopkins Bayview Medical Center
- Howard County General Hospital
- Johns Hopkins Community Physicians.

12. What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study
- You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

_____
Print name of Participant

_____
Signature of Participant Date

_____
Signature of Person Obtaining Consent Date

(This section should be completed when the participant is unable to read or write.)
If this consent has been read and explained to you and you have been given the chance to ask any questions now or later, please sign or make your mark below.

Print Name of Participant:
NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL

_____ _____
Participant's Mark or Signature Date

_____ _____
Signature of Person Obtaining Consent Date

_____ _____
Signature of Witness Date
(Must be different from the person obtaining consent.)

INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; AND, IF APPROPRIATE A COPY OF THE CONSENT FORM MUST BE PLACED IN THE PARTICIPANT 'S MEDICAL RECORD.