PLCO SCREENING TRIAL
PROTOTYPE "SCREENING" (**Main combined with ESC**) CONSENT FORM
Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial
NAME OF CLINICAL CENTER

DESCRIPTION OF STUDY

I have been asked to take part in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial sponsored by the National Cancer Institute, LOCAL CLINICAL CENTER, and nine other centers across the country. The purpose of this study is to determine if certain screening tests can reduce deaths from prostate cancer, lung cancer, ovarian cancer, and cancers of the colon and rectum. [Some doctors believe that screening for these cancers will extend lives, others do not believe that it will. A large, carefully controlled scientific study is necessary to resolve this debate.] Nationwide, this study will enroll 148,000 men and women between the ages of 55 and 74.

Four specific questions to be addressed in this study are:

- Does screening with flexible sigmoidoscopy reduce deaths from cancers of the colon and rectum?
- Does screening with chest x-rays reduce deaths from lung cancer?
- In men, does screening with digital rectal examinations plus a blood test for serum prostate-specific-antigen (PSA) reduce deaths from prostate cancer?
- In women, does screening with transvaginal ultrasound of the ovaries, and testing the blood for CA-125, reduce deaths from ovarian cancer?

The PLCO Trial will also look for factors that may cause these cancers.

STUDY PROCEDURES

By agreeing to participate in the PLCO Trial, I agree to be assigned by a random statistical process to either a screened group or a usual care group. I understand that I have an equal chance of being in either group.

Regardless of which group I am assigned to, I will be asked questions about my personal and family medical history for these cancers and about my overall risk of developing cancer.

If I am assigned to the usual care group, I will follow my normal health care routine. I will be asked to give information about my health and factors related to my health (collected by mail or telephone) once a year for at least 13 years.

If I am assigned to the screened group, the following tests will be carried out on an annual basis for up to 6 years:

Males:

- Digital rectal exam (annually for the first four (4) years)
- Serum PSA blood test (annually for six (6) years)
- Chest x-ray (annually for the first four (4) years in current and former smokers; first three (3) years in people who never smoked)

Females:

- Transvaginal ultrasound (annually for the first four (4) years except for women without ovaries; a tampon-sized probe is inserted into the vagina and images of the ovaries are made using sound waves)
- CA-125 blood test (annually for six (6) years)
- Chest x-ray (annually for first four (4) years in current and former smokers; first three (3) years in people who never smoked)

At the first and sixth screening visit, the following test will be performed on both male and female participants:

- Flexible sigmoidoscopy

The flexible sigmoidoscopy involves the insertion to about 20-24 inches of a thin flexible lighted instrument to examine the colon and the rectum. Preparation for this test consists of two Fleets enemas one hour before the test.

The blood draw for the PSA or CA-125 test will include the collection of up to 45-ml (3 tablespoons) of blood from my arm. Blood not used for the PSA or CA-125 will be stored for future research purposes.

By agreeing to participate in this study, I agree to have all of the screening tests performed as required by the study. The examinations that are part of this trial are well-established tests that doctors use frequently to diagnose problems in patients with certain symptoms. Their effectiveness in early detection of cancer is being tested in this study. It is unknown if these tests will provide any benefit to me.

For quality control, some participants will be asked to have a screening test repeated to test the accuracy of certain measures.

I further agree to provide specific information about my health and factors related to my health (collected by mail or telephone) once a year for at least 13 years.

In addition to evaluating screening tests, the PLCO Trial also seeks to study factors that may cause these cancers to develop and progress. Additional research on cancer and other diseases that occur in your age group will be carried out among PLCO participants who volunteer for these additional studies. We are requesting your consent to participate in these additional studies of cancer and other diseases that occur in you age group.

ADDITIONAL STUDY PROCEDURES

If I am selected to be in the screened group and I volunteer for these additional studies, blood not used for the prostate cancer screening test (PSA) or the ovarian cancer screening test (CA-125II) test will be stored and used in future medical research. (If I am a woman without ovaries and will not receive the CA-125II, or a man without a prostate and will not receive the PSA I may still choose to participate in this additional medical research by signing this document.) These future studies will include investigations to determine if genetic (inherited) factors and chemicals in blood, such as dietary nutrients and hormones, are related to the risk of developing cancer and other diseases that occur in your age group.

If I am assigned to the usual care group and I volunteer for these additional studies, I will provide a sample of saliva which will be stored and used in future medical research. Such studies will include investigations to determine if genetic (inherited) factors are related to the risk of developing cancer and other diseases that occur in your age group. Briefly, the collection of saliva requires that, at home, I rinse with a small sample of mouthwash (less than a tablespoon), spit the saliva into a small cup, and then seal the cup tightly. I will be provided with a kit and instructions for the collection and pre-paid return mailing of this sample to the researchers.

If I volunteer for these additional studies and I later have surgery for diagnosis or treatment of cancer or a related condition, the study investigators may then ask my doctors and the hospitals where I was treated to provide a small sample of the surgical material. This material may be used by the study investigators only for medical research about genetic (inherited) factors and chemical changes that lead to the development of cancer and other diseases that occur in my age group.

These materials will be stored at a National Cancer Institute research storage facility for up to 25 years and used to help scientists learn what causes cancer and how to prevent its progression. It is believed that cancer may be caused by both environmental and genetic factors. Therefore, the samples, which I contribute, may be used in biochemical and genetic studies to identify these causes.

BENEFITS

I understand that I will receive free cancer screening tests. I further understand that if I develop prostate, colorectal, lung, or ovarian cancer it is possible that the cancer may be detected at an early stage. Early diagnosis may prolong my life, however, this cannot be guaranteed.

[If this study shows that screening for prostate, lung, colorectal, or ovarian cancer decreases the chances of dying from these cancers, then screening for these cancers will become common practice in the future. If this study shows that the screening tests do not decrease the chances of dying of these cancers, doctors will know not to use them, saving me and others unnecessary inconvenience and expense.]

BENEFITS OF ADDITIONAL STUDIES

The additional studies will not provide direct benefit to me other than the satisfaction of participating in this research for the possible benefit of future generations. However, my participation in these additional studies will help answer questions related to the health and longevity of persons in my age group and will help establish a scientific understanding of the factors, which influence the development, and progression of cancer.

RISKS

I understand that there are certain risks and discomforts that might be associated with the screening procedures.

There may be some discomfort from the physical exam of the rectum, or the sigmoidoscopic exam.

- Very rarely a perforation of the bowel occurs during sigmoidoscopy (less than once in every 10,000 to 50,000 examinations). If this would occur, medical treatments consisting of antibiotics and, in a very rare instance, surgical correction could occur.

- A small amount of radiation is received as part of the chest x-ray. This amount is smaller than that of a normal chest x-ray and poses no measurable risk.

- There may be discomfort involved from the transvaginal ultrasound. There is a very rare chance of a vaginal tear with the probe.

- When blood is drawn, there may be local bruising or bleeding at the puncture site. There may also be uneasiness associated with needles.

I understand that it is possible that the cancers detected by these screening tests may be very slow growing. It is possible that diagnosis (and treatment) of cancers detected in this trial may not prolong my life. Additionally, it is possible that the screening tests may falsely suggest that I have cancer. In this case, it is possible that I may suffer pain, anxiety, and expense that could have been avoided if I had never undergone the screening tests.

RISKS OF ADDITIONAL STUDIES

There are certain risks and discomforts that might be associated with the additional procedures. When blood is drawn I may feel a little discomfort as the needle goes through the skin. There may be local bruising or bleeding at the puncture site. Pressing hard on the spot for 1 to 2 minutes after the needle is removed will help prevent a bruise. There may also be uneasiness associated with needles. Very rarely, the arm may become infected. The risk is the same as that of having blood drawn at my doctor's office or clinic.

- When saliva is collected, (by rinsing with mouthwash) there may be slight irritation or stinging in the mouth from the mouthwash.

NOTIFICATION AND COSTS

I understand screening results will be sent to me as soon as they become available. If I have indicated a primary physician, he/she will receive the results. If the results indicate a potential medical problem, I will also be offered a referral to a physician specialist of my choice from whom I can receive further medical evaluation, if I so choose. The costs of diagnostic tests beyond screening will not be covered by the study and must come from insurance or other sources.

If I am diagnosed with cancer, I may be referred to a cancer specialist of my choice, if I so request. The costs of cancer treatment will not be covered by this study.

The additional biologic samples are for medical research only and the research results are not suitable for use as clinical tests for my medical care. The scientific studies require only looking at all lab results together. Therefore, the results of these additional studies will not be available to me.

COMPENSATION FOR RESEARCH-RELATED INJURIES

In the unlikely event of physical injury resulting from my participation in this study, I will be provided with immediate medical treatment. I understand, however, that no payment of medical treatment is available from the National Cancer Institute for any such injury.

EXCLUDED PROCEDURES

This trial includes only the screening tests listed above. Other medical procedures are not part of this trial. This includes a biopsy that might be done if abnormalities are found during the flexible sigmoidoscopy.

INFORMATION ON NEW FINDINGS

I understand that any significant new findings about screening for these cancers discovered during the term of the study will be given to me if that information will make a difference in my willingness to continue in the study.

CONFIDENTIALITY

Information concerning my participation in the study will be kept private under the Privacy Act and used only for scientific purposes, in accordance with applicable state and federal laws. As the tests to be carried are for research purposes only, no results from these tests will be placed in my medical records or linked to my name. In order to protect the privacy of my samples, they will be stored and used for medical research by code number only and no one who has access to my name will have access to the coded test results for me. No individual will be identified in any report.

RIGHT TO WITHDRAW

My participation in the additional medical research is voluntary and I may refuse to participate and/or withdraw my consent and discontinue participation at any time without penalty or loss of benefits to which I am otherwise entitled. I may participate in the screening part of the PLCO Trial and yet decline to have biologic samples stored for research purposes. Further, if I initially decide to have my biologic samples stored for research purposes, but later change my mind by written notification of Dr. _____ at _____ University Medical Center, whatever remains of my biologic samples will then be destroyed. My decision will not affect my care.

PERMISSION TO REVIEW MEDICAL RECORDS

I understand that, by agreeing to participate, I give permission for my doctors and hospitals where I have been seen to release my medical records to the study investigators.

CERTIFICATION

I have read this form or it has been read to me and I understand its contents. Any questions concerning the research or the rights of the participants involved have been and will be answered by NAMES, TITLES, PHONE NUMBERS.

A copy of this consent form has been given to me. My signature below means that I freely agree to participate in this study.

Please read the two sentences below and circle your responses (Yes/No).

By signing this document, I agree to have biologic samples (some of my blood or saliva and possibly surgical tissue) stored for future research on cancer.

YES **NO**

By signing this document, I agree to have biologic samples (some of my blood or saliva and possibly surgical tissue) stored for future research **on diseases and conditions other than cancer** that affect my age group.

YES **NO**

_____

PARTICIPANT'S NAME (PRINT)

_____

PARTICIPANT'S SIGNATURE DATE

Witness (if necessary)

_____

WITNESS SIGNATURE

[ ] = Optional Phrase

Attachment 7 (continued)

Sample Authorization to Obtain Information from Medical Records

OMB#: 0925-0407
Expiration Date: XX/XX/XXX

(Letterhead Of Screening Center)

ASSURANCE OF PRIVACY - All information which would provide identification of the individual will be kept private under the Privacy Act, will be used only for study purposes, and will not be disclosed or released to other than the study team, unless required by law.

AUTHORIZATION TO OBTAIN INFORMATION

FROM MEDICAL RECORDS

I, _____hereby authorize the release of information from medical records and staff of a health care facility where I have been seen. This information will be used for a cancer screening trial being conducted by NAME OF SCREENING CENTER and the National Cancer Institute. I understand that I may revoke this consent at any time except to the extent that action has already been taken. I also understand that this authorization expires one year from the date of signature. I further understand that all information obtained will be held private under the Privacy Act, and will not be disclosed to anyone but the researchers conducting this study, except as otherwise required by law.

_____
Signature of Subject

_____
Print Name

_____
Date

PLCO CENTRALIZED FOLLOW-UP PARTICIPANT COVER LETTER

<PARTICIPANT NAME>
<PARTICIPANT ADDRESS>
<CITY STATE ZIP>

Dear Mr./Mrs./Ms.:

We <Screening Center> want to thank you for your participation in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial. Your participation has been an important contribution to the success of this national study. We are writing to you today to inform you that the National Cancer Institute has decided to continue to follow all participants who enrolled in the Trial for at least five more years and we are asking your consent to participate in this follow-up.

We are constantly monitoring and analyzing the PLCO data to determine if screening for, and early detection of, PLCO cancers reduces the number of deaths from these diseases. To answer these important questions, more information is needed. To collect more data, the National Cancer Institute would like to continue the PLCO Trial. However, since the active screening part of the Trial has ended, the National Cancer Institute plans to centralize our data collection efforts. Although we (Screening Center) will still be involved in the study, a new National Cancer Institute Central Data Collection Center will send you annual questionnaires to obtain information about your health. We are contacting you to let you know about this change. **Please read the information provided with this letter and complete, sign and date the last page and return it in the pre-paid envelope.**

We very much hope you will decide to continue to participate since we are confident that the additional information you provide will substantially strengthen the scientific value of this study.

If you have any questions, please contact <NAME OF STAFF MEMBER AND TITLE> at <TELEPHONE NUMBER>. Again, thank you for continuing to be a part of the PLCO Cancer Screening Trial.

Sincerely,

<NAME OF PI>
Principal Investigator
<INSTITUTE>

Dr Christine D. Berg
Project Officer
National Cancer Institute

Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial

Continued Follow-up Consent Form

<Screening Center>

Description of Study

You are being asked to participate in centralized follow-up of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial. The purpose of this continued follow-up is to determine if the screening tests reduce deaths from prostate cancer, lung cancer, ovarian cancer, and cancers of the colon and rectum. The PLCO extended follow-up will also look for factors which may cause many types of cancer and other diseases. It is important to continue to collect more information because it will strengthen the scientific value of the PLCO Trial and the ability to answer the question if screening for cancer of the prostate, lung, ovary, colon or rectum reduces deaths from these diseases.

To collect more information from you, we plan to send your personal information (for example, date of birth and contact information including your name and address) to the National Cancer Institute Central Data Collection Center.

Your participation in PLCO so far

When you joined the PLCO Trial, you were randomized to receive either the cancer screening tests (intervention group) or your usual medical care (control group). If you were in the intervention group, you have undergone up to 6 years of annual screening as part of the PLCO Trial.

All PLCO participants have completed annual health questionnaires. <SCREENING CENTER> has, until now, sent these questionnaires and other mailings, such as the newsletters and cards, to you. If you had surgery for diagnosis or treatment of cancer or a related condition, <SCREENING CENTER> may have requested a copy of your medical records to document your diagnosis and treatment. <SCREENING CENTER> may also have asked your doctors and the hospitals where you were treated to provide a small sample of the tissue that was removed for your diagnosis or treatment. <SCREENING CENTER> has also searched state vital statistics databases to collect information on your health.

Your consent to participate in the PLCO Trial, collection of biologic specimens and linking your data to other health records for medical research has been provided in earlier documents. If you did not consent to these procedures they were not done.

What am I being asked to do?

As a participant in the PLCO Trial, **nothing you do will change**. The only difference is that the National Cancer Institute Central Data Collection Center will do what we <SCREENING CENTER> have been doing. This will involve sending your information to the National Cancer Institute Central Data Collection Center.

What do I have to do?

If you are willing to have your information sent to the National Cancer Institute Central Data Collection Center please **check Option A on the last page of this consent form, sign and return it in the pre-paid envelope.**

Right to Withdraw

1. If you decide that you do not want the National Cancer Institute Central Data Collection Center to get your information, but you are willing to have <SCREENING CENTRE> study staff search state health registries and vital statistics databases to continue to collect information on your health, **please check Option B on the last page of this consent form, sign and return it in the pre-paid envelope.**

___

2. Your participation in the PLCO study is completely voluntary and you may refuse to participate and/or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. If you wish to completely withdraw from the PLCO study, **please check Option C on the last page of this consent form, sign and return it in the pre-paid envelope.**

Risks

Your participation in the study is completely voluntary. This research project involves no more than minimal risk and does not affect your health care benefits or any other benefits you may receive.

Benefits

The study will not provide direct benefit to you other than the satisfaction of participating in this research for the possible benefit of future generations. However, your participation will help answer questions related to the health and longevity of persons in your age group and will help establish a scientific

understanding of the factors which influence the development, and progression of cancer and other diseases.

Information on New Findings

You will be informed about new information or changes in the study that may affect your health or your willingness to continue in the Trial.

Confidentiality

The personal information you provide (such as your name, address and date of birth) will be kept private under the Privacy Act, and will not be disclosed or used by anyone other than the PLCO staff and researchers without your consent. Your personal information can only be given out if required by law (for example, to Federal and regulatory agencies).

The results of research from the PLCO trial may be presented at meetings or in published articles. Your name or any other personal information will not be used.

Who Can Answer My Questions?

You are encouraged to ask questions any time during this research study. Questions can be addressed to the Project Manager at <<tel #>> or XXXX, Principal Investigator at <<tel #>>.

My Choice

I have read this document or it has been read to me. I understand the possible risks and benefits of this study. I know that being in this study is voluntary. I know I can stop being in this study and I will still get usual medical care.

*Please read each sentence below and think about your choice. After reading each sentence, please **check** (☒) **one** of the following **Options**:*

Option A

I agree to continue to participate in the follow-up of the PLCO Trial by having my information sent to the NCI Central Data Collection Center ☐

Option B

I do not want my personal information sent to the NCI Central Data Collection Center, but I agree to have <SCREENING CENTER> *study staff search state health registries and vital statistics databases to continue to collect information on my health* ☐

Option C

I do not want to continue to participate in the PLCO Trial ☐

Signature of Participant or Legally Authorized Representative **DATE**

Please sign, date and return this page to <SCREENING CENTER> in the pre-paid envelope. Thank you for your participation in PLCO.