Supplementary Materials 1: Documents sent to participants or spouses to obtain informed consent for participating in the Cancer Prevention Study-II Nutrition Cohort Colorectal Tissue Repository

**American Cancer Society**

**Consent to be a Research Subject**

**Title**: Cancer Prevention Study II Nutrition Cohort Colorectal Tissue Block Collection Study

**Principal Investigators:**  Peter Campbell, Ph.D., Eric Jacobs, Ph.D., Susan Gapstur, Ph.D.

## Introduction

You are being asked to be in a medical research study conducted by the American Cancer Society. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** Please carefully read this form or have it read to you and ask questions about anything that is not clear.

If you agree to join this research study, you will keep a copy of this consent. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. Nothing in this form can make you give up any legal rights. By signing this form you will not give up any legal rights.

## Purpose

You are being asked to volunteer because you have participated previously in the American Cancer Society Cancer Prevention Study II (CPS-II) by completing mailed questionnaires and reporting a cancer diagnosis. The American Cancer Society requests your permission to obtain the stored tissue that was removed during your surgery for cancer; these tissue specimens are often stored for decades in the pathology laboratory of the hospital where a cancer surgery was performed. We aim to examine the molecular characteristics of the tumor and nearby normal tissue.

## Procedures

Your participation in this study is related to your on-going involvement in CPS-II. In the current study, we request that you allow us to acquire the stored colorectal tissue sample that was removed during your surgery for colorectal cancer. These tissue specimens are stored in the hospital where your surgery was performed. Your current involvement in this study consists of reading, signing, and returning the forms enclosed in this mailing. This study is separate from your on-going involvement in CPS-II Nutrition Cohort, which involves the paper questionnaires you have received about every 2 years since 1992.

The colorectal tissue sample you allow us to acquire will be stored in a locked cabinet at the American Cancer Society’s Department of Epidemiology for future analyses of biologic markers of disease. No analysis will be done without appropriate scientific review of the research question. In order to protect your privacy, your tissue sample will be assigned an identification code that does not include any of your personal information. Your tissue sample will be stored for as long as it is useful, unless you ask us to destroy it sooner. By enrolling in this study, you are donating your specimens for research purposes, and you will not be informed of any of the results of the tests that may be performed on your specimens. Further research may be necessary before these results are meaningful. While some tests we perform may have known clinical importance, not all tests will be done for every person in the study, and it may be many years before your individual sample is analyzed. If you have specific concerns about your health, you should consult with your doctor to find out about tests available and appropriate for you. The researchers involved with this study and other individuals who may have access to your tissue sample are not authorized to, and are forever prohibited from, using this material for any attempt at cloning a human being.

## Risks and Discomforts

There are no known or expected risks to your participation. Although strict security measures are in place, it is possible that the confidentiality of your laboratory results may be breached. If this happens, people not connected with the study might be able to learn the results of any testing done on your tissue sample. It's possible, although highly unlikely, that the release of information that identifies you might cause problems with insurance or future employment.

## Benefits

This study is not designed to benefit you directly. This study is designed to learn more about what causes and prevents colorectal cancer. The study results may be used to help other patients in the future.

##### Alternative Procedures

This is not a treatment study. You are free to choose not to take part in it. However, you will continue to be enrolled in the Cancer Prevention Study II.

###### Confidentiality

There are safeguards in place to prevent the unintentional disclosure of information obtained for or produced by this study. You will be assigned a study identification number that will be attached to your tissue sample. A key to this code will be available only to the Principal Investigator and a select group of study managers at the American Cancer Society.

Research data will be kept in a password-protected database. Study documents will be kept in a locked, limited access research storage room. Study results that are published will be written so that individuals cannot be recognized or identified. Results of the tests will not be shared with your family, your doctor, your employer, any insurance company, or other third parties. However, we may share some research data, including tissue samples and results of laboratory analyses, with other scientists. These data will not be labeled with any demographic information that personally identifies you.

Agencies that make rules and policy about how research is done have the right to review research records. Those with the right to look at your study records include the Emory University Institutional Review Board. Records can also be opened by court order. We will keep your records private to the extent allowed by law. We will do this even if outside review occurs.

There is a Certificate of Confidentiality for this Study:

What the Certificate of Confidentiality protects: The National Institutes of Health has given the American Cancer Society a Certificate of Confidentiality for this study. The American Cancer Society would use it to block a legal request to give out study information. For example, if the American Cancer Society received a subpoena for study records, we would say no. The Certificate gives the American Cancer Society legal backup to say no. It covers information about you that could harm your image or finances. It also covers information about you that could harm your chances at a job or getting insurance.

What the Certificate of Confidentiality does not protect: The Certificate would not protect some information about you, including any information that you give out yourself or someone other than you or the American Cancer Society gives out.

**Compensation**

There will be no charge to you or your insurance company for acquiring your tissue sample. Any data, discoveries, materials or other products that come from the tissue samples will be the exclusive, permanent property of the American Cancer Society. You will not be entitled to compensation of any type for any products, data, or other items or information that are developed from the samples.

**Withdrawal from the Study**

You have the right to leave a study at any time without penalty. You may at any time request that the American Cancer Society destroy your tissue sample by contacting the investigator listed below.

## Questions

Contact Peter Campbell, PhD at \_\_\_\_\_\_\_\_\_\_\_\_:

* if you have any questions about this study or your part in it, or
* if you have questions, concerns or complaints about the research

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797.

## Consent

I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

By signing this consent form, I have not given up any of my legal rights.

Name of Subject

Signature of Subject Date

Signature of Legally Authorized Representative (when applicable) Date

Authority of Legally Authorized Representative or Relationship to Subject

(when applicable)

**Authorization to Use or Disclose Health Information that Identifies You for a Research Study**

Name of Study: Cancer Prevention Study II Nutrition Cohort Colorectal Tissue Block Collection Study

Name of Principal Investigators: Peter Campbell, PhD, Eric Jacobs, PhD, Susan Gapstur, PhD, MPH

Subject Name:

The privacy of your health information is important to us. In protecting your health information that identifies you, we will follow all requirements of the Health Insurance Portability and Accountability Act (“HIPAA” for short) that apply. This form will let you know how we will use any health information that you give us for this study that identifies you. Please read this form carefully and if you agree with it, sign it at the end.

**Research Study:** Cancer Prevention Study II Nutrition Cohort Colorectal Tissue Block Collection Study is a component of a long-term research study conducted by the American Cancer Society (ACS). The purpose of this research is to better understand the lifestyle, behavioral, environmental, and biologic factors that cause and prevent colorectal cancer in a large group of men and women in the United States.

**People That Will Use or Disclose Your Health Information that Identifies You and Purpose of Use/Disclosure:** The following people and groups will use and disclose your health information in connection with the study. In this form, all of these people and groups are called the “Information Users”:

The principal investigators, their research staff and people and organizations that they use to help them conduct the Research Study will use and disclose your health information to do this work.

There are a number of University persons/units, government agencies and other individuals and organizations that may use and disclose your health information to make sure that the Research Study is being conducted correctly and safely, and to monitor and regulate the research or public health issues. These people and organizations include the following: the Emory University Institutional Review Board.

By signing this document you agree to allow any of these Information Users to use or disclose your health information that identifies you in order to conduct the Research Study, or to monitor or regulate research. In addition, we will comply with any laws that require us to disclose your health information, such as laws that require us to report child abuse or elder abuse. We also will comply with legal requests, or orders that require us to disclose your health information, such as subpoenas or court orders. Finally, we may share your health information with a public health authority that the law authorizes to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and/or conducting public health surveillance, investigations or interventions.   
 **Description of Health Information that Identifies You that Will be Used or Disclosed**

The Information Users may use or disclose the following health information about you: Any information provided during the study as it pertains to the analysis of tissue specimens. The researchers agree to protect your health information by using it and disclosing it only as permitted in this Authorization and as directed by state and federal law. Once your health information has been disclosed to anyone outside this study, the information may no longer be protected under this Authorization.

**Revoking your Authorization:**  
You do not have to sign this Authorization. In addition, if you sign this Authorization, later, you may change your mind at any time and revoke (take back) this Authorization. If you want to revoke this Authorization you must write to: Peter Campbell, Ph.D., \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

If you revoke your Authorization, the Researchers will not collect any more health information that identifies you, but they may use or disclose identifiable information that you already gave them in order to notify any of the other Information Users that you have taken back your authorization; to maintain the integrity or reliability of the Research Study; and to comply with any law that they are required to obey.

**Other Items You Should Know:**

HIPAA only applies to people or organizations that are health care providers, health care payers or healthcare clearinghouses. HIPAA may not apply to all Information Users. If HIPAA doesn’t apply to an Information User, then that User doesn’t have to follow HIPAA requirements when it uses or discloses your health information.

You do not have to sign this authorization form, but if you do not, you may not participate in the Research Study. You may still receive non-research related treatment.

**Expiration Date:** This authorization will expire at the time in which the study is closed and the period for which any records relating to the study must be retained has ended.

As a study participant, if you have any questions regarding the study, you may call Dr. Peter Campbell the study's Principal Investigator at \_\_\_\_\_\_\_\_\_\_\_\_. If you have any questions regarding your rights as a study subject, you may call the Emory University Institutional Review Board at 404-712-0720 or 1-877-503-9797.

A copy of this authorization form will be given to you.

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Signature of Study Subject OR Subject's Legal Authorized Representative –

Date \_\_\_\_\_\_\_\_\_\_\_---Time\_\_\_\_\_\_\_\_\_\_

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Printed Name of Study Subject OR Subject's Legally Authorized Representative

If Representative, Relationship to Study Subject: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

May 14, 2014

Participant Name

Address

Dear Cancer Prevention Study Participant:

First, let me thank you for your participation in the Cancer Prevention Study. We really appreciate your cooperation in filling out the survey every two years and sending it back to us.

From that survey, our records indicate that you reported a diagnosis of colon or rectal (colorectal) cancer in (year). We verified this information after we received permission from you to see the medical record.

We are writing to you now to ask for your permission to obtain a specimen of the tissue that was removed during your surgery for colorectal cancer. These specimens are available from the pathology department of the facility where you had surgery for colorectal cancer. New scientific methods now make it possible to study the biology of these specimens in order to help understand causes of cancer. Your tissue specimen combined with the extensive questionnaire information you have provided over many years will make this research uniquely valuable. Therefore, we are attempting to obtain tissue specimens from all participants in the Cancer Prevention Study who reported colorectal cancer.

To allow us to obtain this tissue specimen, would you please sign, date, and return the blue colored consent **AND** HIPAA release forms that are attached? Please return the forms in the pre-stamped envelope provided. Keep the yellow pages for your records. If you **do not** wish to provide consent for us to obtain your tissue sample, please indicate below and return this letter:

|  |  |  |
| --- | --- | --- |
|  |  | I **do not** give consent to have the American Cancer Society obtain my tissue sample. |

As in the past, all information you provide is kept strictly confidential and is used only for medical statistical purposes. If you have any questions or concerns, please contact \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Thank you again for your help and continued participation in the Cancer Prevention Study. It is only through the help of generous people like you that we are able to conduct important research about the causes of cancer.

Sincerely,

Principal Investigator

Institution

Title: Cancer Prevention Study II Nutrition Cohort Colorectal Tissue Block Collection Study

Dear Principal Investigator,

I want to end my participation in the research study that is named above. In addition to ending my participation I would like to [choose one of the following options]:

REVOKE MY AUTHORIZATION FOR THE RESEARCHERS TO COLLECT AND USE MY INFORMATION:

\_\_\_\_\_\_ I will not participate in the research study, and I revoke my authorization to permit the researchers to collect and use any more information about me. I understand and agree that in certain circumstances the researchers may need to use my information even though I have revoked my authorization, for example, to let me know about any safety concerns, or to make any required reports to governmental regulatory agencies.

CONTINUE MY AUTHORIZATION FOR THE RESEARCHERS TO COLLECT AND USE MY INFORMATION:

\_\_\_\_\_\_ I will not actively participate in the research study any more, but the researchers may continue to collect and use information from my medical record as needed for the research study, but only for the reasons discussed in the consent form that I signed.

I understand that the researchers will respond to this letter by letting me know that they have received it.

Sincerely,

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Signature of Study Participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   
Printed name of Study Participant

**American Cancer Society**

**Spousal Consent to be a Research Subject**

**Title**: Cancer Prevention Study II Nutrition Cohort Colorectal Tissue Block Collection Study

**Principal Investigators:**  Peter Campbell, Ph.D., Eric Jacobs, Ph.D., Susan Gapstur, Ph.D.

## Introduction

You are being asked to be in a medical research study conducted by the American Cancer Society. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** Please carefully read this form or have it read to you and ask questions about anything that is not clear.

If you agree to join this research study, you will keep a copy of this consent form. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. Nothing in this form can make you give up any legal rights. By signing this form you will not give up any legal rights.

## Purpose

You are being asked to volunteer because you and your spouse have participated previously in the American Cancer Society Cancer Prevention Study II (CPS-II) by completing mailed questionnaires and because your spouse reported a cancer diagnosis. The American Cancer Society requests your permission to obtain the stored tissue that was removed during your spouse’s surgery for cancer; these tissue specimens are often stored for decades in the pathology laboratory of the hospital where a cancer surgery was performed. We aim to examine the molecular characteristics of the tumor and nearby normal tissue.

## Procedures

Your participation in this study is related to your on-going involvement in CPS-II. In the current study, we request that you allow us to acquire the stored colorectal tissue sample that was removed during your spouse’s surgery for colorectal cancer. These tissue specimens are stored in the hospital where your spouse’s surgery was performed. Your current involvement in this study consists of reading, signing, and returning the forms enclosed in this mailing. This study is separate from your on-going involvement in CPS-II Nutrition Cohort, which involves the paper questionnaires you have received about every 2 years since 1992.

The colorectal tissue sample you allow us to acquire will be stored in a locked cabinet at the American Cancer Society’s Department of Epidemiology for future analyses of biologic markers of disease. No analysis will be done without appropriate scientific review of the research question. In order to protect privacy, your spouse’s tissue sample will be assigned an identification code that does not include any personal information. Your spouse’s tissue sample will be stored for as long as it is useful, unless you ask us to destroy it sooner. By enrolling in this study, you are donating your spouse’s specimens for research purposes, and you will not be informed of any of the results of the tests that may be performed on your spouse’s specimens. Further research may be necessary before these results are meaningful. While some tests we perform may have known clinical importance, not all tests will be done for every person in the study and it may be many years before your spouse’s individual sample is analyzed. The researchers involved with this study and other individuals who may have access to your spouse’s tissue sample are not authorized to, and are forever prohibited from, using this material for any attempt at cloning a human being.

## Risks and Discomforts

There are no known or expected risks to you or your spouse's participation. Although strict security measures are in place, it is possible that the confidentiality of your spouse’s laboratory results may be breached. If this happens, people not connected with the study might be able to learn the results of any testing done on your spouse’s tissue sample.

## Benefits

This study is not designed to benefit you or your spouse directly. This study is designed to learn more about what causes and prevents colorectal cancer. The study results may be used to help other patients in the future.

##### Alternative Procedures

This is not a treatment study. You are free to choose not to take part in it. However, you will continue to be enrolled in the Cancer Prevention Study II.

###### Confidentiality

There are safeguards in place to prevent the unintentional disclosure of information obtained for or produced by this study. Your spouse will be assigned a study identification number that will be attached to the tissue sample. A key to this code will be available only to the Principal Investigator and a select group of study managers at the American Cancer Society.

Research data will be kept in a password-protected database. Study documents will be kept in a locked, limited access research storage room. Study results that are published will be written so that individuals cannot be recognized or identified. Results of the tests will not be shared. However, we may share some research data, including tissue samples and results of laboratory analyses, with other scientists. These data will not be labeled with any demographic information that personally identifies your spouse.

Agencies that make rules and policy about how research is done have the right to review research records. Those with the right to look at your spouse’s study records include the Emory University Institutional Review Board. Records can also be opened by court order. We will keep your spouse’s records private to the extent allowed by law. We will do this even if outside review occurs.

There is a Certificate of Confidentiality for this Study:

What the Certificate of Confidentiality protects: The National Institutes of Health has given the American Cancer Society a Certificate of Confidentiality for this study. The American Cancer Society would use it to block a legal request to give out study information. For example, if the American Cancer Society received a subpoena for study records, we would say no. The Certificate gives the American Cancer Society legal backup to say no. It covers information about you and your spouse that could harm your image or finances. It also covers information about you and your spouse that could harm your chances at a job or getting insurance.

What the Certificate of Confidentiality does not protect: The Certificate would not protect some information about you and your spouse, including any information that you give out yourself or someone other than you or the American Cancer Society gives out.

**Compensation**

There will be no charge to you or your insurance company for acquiring your spouse’s tissue sample. Any data, discoveries, materials or other products that come from the tissue samples will be the exclusive, permanent property of the American Cancer Society. You will not be entitled to compensation of any type for any products, data, or other items or information that are developed from the samples.

**Withdrawal from the Study**

You have the right to leave a study at any time without penalty. You may at any time request that the American Cancer Society destroy your spouse’s tissue sample by contacting the investigator listed below.

## Questions

Contact Peter Campbell, PhD at \_\_\_\_\_\_\_\_\_\_\_\_:

* if you have any questions about this study or you or your spouse's part in it, or
* if you have questions, concerns or complaints about the research

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797.

## Consent

I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

By signing this consent form, I have not given up any of my legal rights.

Name of Subject

Signature of Legally Authorized Representative (Spouse) Date

SPOUSE

Authority of Legally Authorized Representative or Relationship to Subject

**Authorization to Use or Disclose Health Information that Identifies Your Spouse for a Research Study**

Name of Study: Cancer Prevention Study II Nutrition Cohort Colorectal Tissue Block Collection Study

Name of Principal Investigators: Peter Campbell, PhD, Eric Jacobs, PhD, Susan Gapstur, PhD, MPH

Subject Name:

The privacy of your spouse’s health information is important to us. In protecting your spouse’s health information that identifies him/her, we will follow all requirements of the Health Insurance Portability and Accountability Act (“HIPAA” for short) that apply. This form will let you know how we will use any health information that you give us for this study that identifies your spouse. Please read this form carefully and if you agree with it, sign it at the end.

**Research Study:** Cancer Prevention Study II Nutrition Cohort Colorectal Tissue Block Collection Study is a component of a long-term research study conducted by the American Cancer Society (ACS). The purpose of this research is to better understand the lifestyle, behavioral, environmental, and biologic factors that cause and prevent colorectal cancer in a large group of men and women in the United States.

**People That Will Use or Disclose Your Spouse's Health Information that Identifies Your Spouse Purpose of Use/Disclosure:** The following people and groups will use and disclose your and spouse’s health information in connection with the study. In this form, all of these people and groups are called the “Information Users”:

The principal investigators, their research staff and people and organizations that they use to help them conduct the Research Study will use and disclose your spouse’s health information to do this work.

There are a number of University persons/units, government agencies and other individuals and organizations that may use and disclose your and your spouse’s health information to make sure that the Research Study is being conducted correctly and safely, and to monitor and regulate the research or public health issues. These people and organizations include the following: the Emory University Institutional Review Board.

By signing this document you agree to allow any of these Information Users to use or disclose your spouse’s health information that identifies your spouse in order to conduct the Research Study, or to monitor or regulate research. In addition, we will comply with any laws that require us to disclose your spouse’s health information, such as laws that require us to report child abuse or elder abuse. We also will comply with legal requests, or orders that require us to disclose your spouse’s health information, such as subpoenas or court orders. Finally, we may share your spouse’s health information with a public health authority that the law authorizes to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and/or conducting public health surveillance, investigations or interventions.

**Description of Health Information that Identifies Your Spouse that Will be Used or Disclosed**

The Information Users may use or disclose the following health information about your spouse: Any information provided during the study as it pertains to the analysis of tissue specimens. The researchers agree to protect your spouse’s health information by using it and disclosing it only as permitted in this Authorization and as directed by state and federal law. Once your spouse’s health information has been disclosed to anyone outside this study, the information may no longer be protected under this Authorization.

**Revoking your Authorization:**  
You do not have to sign this Authorization. In addition, if you sign this Authorization, later, you may change your mind at any time and revoke (take back) this Authorization. If you want to revoke this Authorization you must write to: Peter Campbell, Ph.D., \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

If you revoke your Authorization, the Researchers will not collect any more health information that identifies your spouse, but they may use or disclose identifiable information that you already gave them in order to notify any of the other Information Users that you have taken back your authorization; to maintain the integrity or reliability of the Research Study; and to comply with any law that they are required to obey.

**Other Items You Should Know:**

HIPAA only applies to people or organizations that are health care providers, health care payers or healthcare clearinghouses. HIPAA may not apply to all Information Users. If HIPAA doesn’t apply to an Information User, then that User doesn’t have to follow HIPAA requirements when it uses or discloses your health information.

You do not have to sign this authorization form, but if you do not, you may not participate in the Research Study. You may still receive non-research related treatment.

**Expiration Date:** This authorization will expire at the time in which the study is closed and the period for which any records relating to the study must be retained has ended.

As a study participant, if you have any questions regarding the study, you may call Dr. Peter Campbell the study's Principal Investigator at \_\_\_\_\_\_\_\_\_\_\_\_ . If you have any questions regarding your rights as a study subject, you may call the Emory University Institutional Review Board at 404-712-0720 or 1-877-503-9797.

A copy of this authorization form will be given to you.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Signature of Study Subject OR Subject's Legal Authorized Representative (SPOUSE) –

Date \_\_\_\_\_\_\_\_\_\_\_---Time\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Printed Name of Study Subject OR Subject's Legally Authorized Representative

If Representative, Relationship to Study Subject: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

May 14, 2014

Participant Name

Address

Dear Cancer Prevention Study Participant:

First, let me thank you for your participation in the Cancer Prevention Study. We really appreciate your cooperation in filling out the survey every two years and sending it back to us.

From that survey, our records indicate that your spouse reported a diagnosis of colon or rectal (colorectal) cancer in (year). We verified this information after we received permission to see the medical record.

We are writing to you now to ask for your permission to obtain a specimen of the tissue that was removed during your spouse’s surgery for colorectal cancer. These specimens are available from the pathology department of the facility where the surgery for colorectal cancer was performed. New scientific methods now make it possible to study the biology of these specimens in order to help understand causes of cancer. Your spouse’s tissue specimen, combined with the extensive questionnaire information your spouse provided to us over many years, will make this research uniquely valuable. Therefore, we are attempting to obtain tissue specimens from all participants in the Cancer Prevention Study who reported colorectal cancer.

To allow us to obtain this tissue specimen, would you please sign, date, and return the blue colored consent **AND** HIPAA release forms that are attached? Please return the forms in the pre-stamped envelope provided. Keep the yellow pages for your records. If you **do not** wish to provide consent for us to obtain your spouse’s tissue sample, please indicate below and return this letter:

|  |  |  |
| --- | --- | --- |
|  |  | I **do not** give consent to the American Cancer Society to obtain my spouse’s tissue sample. |

As in the past, all information you provide is kept strictly confidential and is used only for medical statistical purposes. If you have any questions or concerns, please contact \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Thank you again for your help and continued participation in the Cancer Prevention Study. It is only through the help of generous people like you that we are able to conduct important research about the causes of cancer.

Sincerely,

Principal Investigator

Institution

Title: Cancer Prevention Study II Nutrition Cohort Colorectal Tissue Block Collection Study

Dear Principal Investigator,

I want to end my spouse’s participation in the research study that is named above. In addition to ending my spouse’s participation I would like to [choose one of the following options]:

REVOKE MY AUTHORIZATION FOR THE RESEARCHERS TO COLLECT AND USE MY SPOUSE’S INFORMATION:

\_\_\_\_\_\_My spouse will not participate in the research study, and I revoke my authorization to permit the researchers to collect and use any more information about my spouse. I understand and agree that in certain circumstances the researchers may need to use my information even though I have revoked my authorization, for example, to let me know about any safety concerns, or to make any required reports to governmental regulatory agencies.

CONTINUE MY AUTHORIZATION FOR THE RESEARCHERS TO COLLECT AND USE MY SPOUSE’S INFORMATION:

\_\_\_\_\_\_ My spouse will not actively participate in the research study any more, but the researchers may continue to collect and use information from my spouse’s medical record as needed for the research study, but only for the reasons discussed in the consent form that I signed.

I understand that the researchers will respond to this letter by letting me know that they have received it.

Sincerely,

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Signature of Spouse of Study Participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   
Printed name of Study Participant