INSTITUTE/CENTER: **NIH/NCI**

PRINCIPAL INVESTIGATOR:

STUDY NUMBER:

STUDY TITLE:

Date Posted for Official Use:

IRB Approval Date:

Cohort:

Healthy adult volunteers without a history of cancer

Consent Version:

Draft 8/1/2019

WHO DO YOU CONTACT ABOUT THIS STUDY?

Connect Study Support Center	**Phone 1-800-xxx-xxxx** **Email: help@connectstudy.gov** **Website: connectstudy.gov**
NCI Senior Scientist TBD?	**Phone:** **Email:**
IHCS PI?	**Phone:** **Email:**

Contents

KEY INFORMATION ABOUT THIS RESEARCH

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at [IHCS] in partnership with the National Cancer Institute. This section provides the information we believe is most helpful and important to you to in making your decision about participating in this study. Additional information that may help you make a decision can be found in other sections of the document. Taking part in research is your choice.

Please read this information carefully and take all the time you need to make your choice. Be sure to ask us as many questions as you want. No matter what you decide, now or in the future, it will not affect your medical care.

[IHCS] and the National Cancer Institute invite you to participate in a study to help researchers understand what causes cancer and other diseases. We hope it will improve the health of current and future generations. To help us better understand certain health conditions, we need to learn more about you. If you decide to participate, we hope you will remain a part of the study for many years.

In this study, we will ask you to:

- Fill out surveys online about your medical history and lifestyle
- Allow access to your electronic health records
- Donate a saliva sample
- Allow us to receive a sample of tissue from past medical procedures such as biopsies if you have had any
- Allow us to receive a sample of tissue from future medical procedures, such as biopsy or surgery, if you should have any as part of your routine medical care
- Allow us to contact you in the future for additional surveys, health information, and biological samples.

We may also ask you to give other biological samples such as blood, urine, and stool.

While there will be no direct benefit to you, your participation can help improve the health of people in future generations as researchers use your data to learn more about how to prevent disease.

This study is expected to last 10 years or longer.

Additional information on the study can be found on the study's website, which can be accessed at [URL].

The remaining document will now describe more about the research study. This information should be considered before you make your choice. Members of the study team will talk with you about the information described in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). Take the time needed to ask any questions and discuss this study with [IHCS] staff, and with your family, friends, and personal health care providers.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to understand the causes of cancer and other diseases. In 2015, over 1.5 million people in the United States had a diagnosis of cancer and over 590,000 people died of cancer related causes. In the United States, cancer is the second leading cause of death. We hope this research study will help us improve the health of current and future generations and prevent future cancers.

We are asking you to participate in this research study because you are a healthy adult between the ages of 40-65 years old with no history of cancer.

The risk of developing cancer depends on many things such as lifestyle, environment, and genetics. Because these factors may change over a person's lifespan, we are hoping to study the effects of these factors over 10 years or longer.

WHAT WILL HAPPEN DURING THE STUDY?

HIPPA AUTHORIZATION FORM FOR THE USE OF PATIENT HEALTH INFORMATION FOR RESEARCH

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

What is an EMR?

What data is in my EMR?

Is there sensitive data in my EMR?

What exactly will you access in my EMR?

Why do you want access to my EMR?

Who will be sending you my EMR?

Who will be getting access to my EMR?

Is there anyone else who will see my EMR?

Canceling your permission

Expiration

Giving Permission [uncertain if we need a separate signature for the embedded HIPAA waiver]

HOW LONG WILL THE STUDY TAKE?

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

DISCUSSION OF FINDINGS

New information about the study

Return of research results

EARLY WITHDRAWAL FROM THE STUDY

WILL YOUR SPECIMENS OR DATA BE SAVED FOR USE IN OTHER RESEARCH STUDIES?

How Long Will Your Specimens and Data be Stored by the NIH?

Risks of Storage and Sharing of Specimens and Data

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

Will you receive reimbursement or direct payment by NIH as part of your participation?

Will taking part in this research study cost you anything?

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

Certificate of Confidentiality

Privacy Act

POLICY REGARDING RESEARCH-RELATED INJURIES