PRINCIPAL INVESTIGATOR:

National Cancer Institute Principal Investigator: Montserrat Garcia-Closas, M.D., Dr.P.H.

Kaiser Permanente Georgia Principal Investigator: Jennifer Gander, PhD

STUDY TITLE: Connect for Cancer Prevention Study

STUDY SITE: Kaiser Permanente Georgia

Cohort: People aged 40-65 who do not have a history of invasive cancer at enrollment (certain benign or precancers are acceptable)

Consent Version: 09/17/2021

WHO DO YOU CONTACT ABOUT THIS STUDY?

Connect Support Center	MyConnect.cancer.gov/support Email: ConnectSupport@norc.org Phone: 1-877-505-0253
Kaiser Permanente Georgia	Email: Jennifer.C.Gander@kp.org Phone: 404-809-6684

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. This study is taking place at more than one site.

You are being asked to take part in a research study at Kaiser Permanente. This section provides the information we believe is most helpful and important to you in making your decision about participating in this study. Additional information that may help you decide can be found in other sections of the document. Taking part in research at Kaiser Permanente is your choice.

- The Connect for Cancer Prevention Study (or Connect) is a research program to better understand the causes of cancer and how to prevent cancer. People who join Connect will answer survey questions, donate biological specimens (like samples of blood, urine, and saliva), and agree to share medical information over time to see who gets cancer and who does not.
- We will do everything we can to protect your privacy. Information that could identify you (like your name, date of birth, and address) will be kept separate from the information and specimens you provide. Your information and specimens will be linked only with a unique code. Despite our efforts, an unauthorized person could get access to your information and try to identify you even without your name. The chance of this happening is very small but not zero.

- Information that can identify you (like your name, date of birth, and address) will be used to collect other information that is specific to you. For example, information from health registries could be linked to the information you provide to Connect, or your address may be linked to information about air pollution where you live.
- Connect will store and share your information and specimens for use by researchers around the world. Before sharing your information with researchers, information that can identify you will be removed. Researchers will use your research information and specimens to better understand the causes of cancer, to help find new ways to prevent and treat cancer, and for other research purposes. Some research will look at your genetic code (DNA). We will ask you if you want to see your genetic ancestry information when it is available.
- It is your choice to join Connect. If you do join, we hope you will continue to take part in Connect for many years. You can change your mind and withdraw (quit) at any time by contacting the Connect Support Center (Cancer.gov/connectstudy/support).
- You will probably not benefit directly from joining Connect, but your information could help prevent cancer and other diseases in the future.
- More details can be found below or on the Connect website (Cancer.gov/connectstudy).

If you agree to join Connect, we will ask you to:

	**What:** Fill out surveys about your health, habits, and places you have lived. **When:** When you join and at least once a year in the future. **How:** You can complete surveys online with a computer, tablet, or mobile phone.
	**What:** Donate blood, urine, and saliva specimens. **When:** At the time you join and approximately every 2 to 3 years in the future. **How:** You can donate specimens at a health care clinic, laboratory, or in your home, depending on the type of specimen and where you live.
	**What:** Allow the Connect team to access your health information in your health and medical records. This may include data about your past or future health problems, test results, medical procedures (such as surgeries), images (such as X-rays), and medicines you take. **When**: At the time you join and later at regular intervals, unless you tell us to stop. **How**: Connect will collect this data directly from your health care provider or through the MyConnect participant application ("MyConnect app").
	**What:** Allow us to collect unused specimens, if any are collected at medical visits. For example: • Tissue from medical procedures, such as a biopsy or surgery • Specimens of stool (often used for colon cancer screening) or cells from a pap-smear (often used for cervical cancer screening) • Blood from blood tests (such as cholesterol checks)

	When: During the entire time of the study. These may include specimens taken and stored from your current, past, and future medical visits. **How:** Connect will collect these directly from your health care provider. You will not need to take any extra steps for this activity.
	**What**: Allow us to collect information about you from other sources (like linking to health registries, census data about your neighborhood, or environmental data). **When:** During the entire time of the study. This may include information from any time (including past, present, and future). **How:** Connect will collect this information directly from the sources. You will not need to take any extra steps for this activity.
 	**What:** Allow us to invite you to take part in new data collection activities in the future, such as: • Donate more specimens (like samples of toenails or hair) or samples from your home (like dust or dryer lint). • Have physical measures (like height, weight, and blood pressure) taken in the clinic or at home. • Share information from personal tech devices (either your own or those we provide to you). These are most often devices you wear or applications ("apps") on your phone. These could measure physical activity, diet, sleep, other habits, or things about your living environment, including your location. **When:** You may be asked anytime in the future. You can choose not to take part in these new activities and still participate in Connect. **How:** It will depend on the type of activity and where you live. Information will be given to you when we invite you to take part in future activities.

The remaining document will describe the research study in more detail. Please consider this information before deciding if you want to join the study. Members of the study team can talk with you about the information in this document. You can contact the Connect Support Center (Cancer.gov/connectstudy/support) if you have any questions. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research studies in which they would want to participate. Take the time you need to ask any questions and discuss this study with the Connect Support Center (Cancer.gov/connectstudy/support), and with your family, friends, and personal health care providers.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. Deciding not to participate in the study will not affect your routine medical care, your relationship with your current medical provider, or your health insurance. If you do choose to leave the study, please contact the Connect Support Center (Cancer.gov/connectstudy/support). You can choose

to stop getting study messages, stop doing study activities, or to withdraw from (quit)Connect altogether.

If after joining Connect you decide to withdraw (quit), we will not use or share your information and specimens with anyone else in the future. If you withdraw, you can also decide if you want your information or specimens destroyed. Your information will not be used for new studies. However, we cannot remove your information and specimens from research studies that have already started. We cannot get back information and specimens that have already been given out to researchers. Also, we will let researchers check the results of past studies. If they need your old data to do this work, we will give it to them.

Even if you withdraw, we will keep your name and contact information. We need this information so we can follow U.S. research laws and regulations.

WHY IS THIS STUDY BEING DONE?

The Connect for Cancer Prevention Study is a research program to better understand what causes cancer and to find new ways to prevent or treat cancer. If you join, we will gather information and specimens from you and from other people who join to answer these questions. Researchers will study the information and specimens. The information and specimens may also be used for general research (such as research on how to prevent or treat other health conditions).

You can join Connect if you are a patient or member of a partner health care system, between the ages of 40-65 at enrollment, and do not have a previous or current invasive cancer diagnosis. An important goal of Connect is to study conditions that increase the risk of developing cancer. Some of these conditions are very common and benign, while others are less common and may be referred to as cancer precursors, or precancers. We encourage you to join Connect if you have a previous or current diagnosis of benign conditions or cancer precursors, such as carcinoma *in situ* of the breast (also called LCIS or DCIS); cervical intraepithelial neoplasia (CIN) or cervical dysplasia; polyps, adenomas, or intramucosal carcinomas of the colon; endometrial hyperplasia, uterine fibroids; prostatic hyperplasia or prostatic intraepithelial neoplasia (PIN); lung nodules; or other conditions.

If you are unsure if you can join based on a diagnosis now or in the past, please contact the Connect Support Center (Cancer.gov/connectstudy/support).

WHAT WILL HAPPEN DURING THE STUDY?

If you decide to participate in Connect, you will be asked to create an account on the MyConnect participant application (or "MyConnect app") using your phone number or email address. In the MyConnect app, you will be asked to:

Provide personal identifying information. This will include information such as your name, date of birth, sex, social security number (if you choose to provide it), residential address, and other contact information. From time to time, we will ask if you have a new address, email, or phone number so we can keep in touch with you.

Fill out surveys online. When you join, we will ask you to complete an online survey about your health, habits, family, home, and work. The survey is broken into sections, so you can

pause and return to complete it at a later time. We expect the entire survey will take one to two hours to complete. We will contact you about other surveys at least once a year. These future surveys will ask you to update information you provided earlier and ask questions about new topics. Most future surveys will take 20 to 30 minutes to complete. We may also send you short surveys from time to time about your experience in Connect to help us improve how we conduct research.

Donate biological specimens. Biological specimens are samples of things like blood, urine, and saliva. When you join, we will ask you to donate at no cost to you:

- Blood: You will have blood drawn from a vein. This will require a needle stick in your arm or hand. The amount of blood we will draw is about 3 tablespoons. This blood draw will be set up with your health care system.
- Urine: We will ask you for a urine specimen ("pee in a cup").
- Saliva ("spit"): We will ask you to swish some mouthwash and spit it into a cup.

Information about the biological specimen collection will be provided in the MyConnect app. Depending on the type of specimen and where you live, you will donate the specimens at a local health care clinic, laboratory, or in your home. We may ask you to collect specimens (like saliva) at home and send them in the mail. If you are asked to send us specimens in the mail, Connect will give you the supplies, instructions, and postage. When you donate each specimen, we will ask you to fill out a short survey about your recent actions (like medicines you took or foods you ate).

From time to time we may ask you to donate these specimens again. Every time you donate these specimens, you will be asked to complete a short online survey about each specimen.

Allow your health care providers to disclose (release) your health and medical records, including information in your electronic health records. This includes information from your health care providers related to your health and health care, in the past, now, and in the future. It also includes test results, medical procedures (such as surgeries), images (like mammograms or X-rays), dental health records, and medicines. We will review your health and medical record at least once a year to get updated information. We may also ask for your medical records from health care providers outside of your current health care system. Health records can contain sensitive information. For example, they may tell us about medications used for depression, genetic conditions, sexual health, and/or sexually transmitted infections, including HIV status.

Allow us to collect unused specimens if any are available after clinical visits for your health care. These include specimens from clinical visits in the past, now, or in the future. Collecting these specimens does not affect your clinical care or involve any extra effort on your part. Examples of specimens collected for health care purposes are:

- Tissue specimens from biopsies or surgeries
- Specimens of stool (often used for colon cancer screening)
- Specimens from pap-smears (often used for cervical cancer screening)
- Blood from blood tests (such as cholesterol checks)
- Urine from urine tests

Allow us to get information from other data sources by linking your data: We will collect information from other data sources. Examples may include cancer or other health registries,

environmental databases (such as air quality reports from places where you live and work), and other databases (like information about your neighborhood from the census).

Allow us to invite you to donate extra specimens or information not already described. When invited to do these activities, you can say yes or no and still continue to participate in Connect. Here are examples of future activities we may invite you to do:

- Donate extra specimens (like toenails, hair, stool, or cheek swabs) or samples from your home (like dust, dryer lint, or vacuum bag/canister, air quality, drinking water)
- Have physical measures (like height, weight, waist and hip measurements, or blood pressure) taken by a healthcare provider in a clinic or by you at your home
- Share information from personal health technologies, such as wearable devices or apps. If you already have electronic apps on your phone or health trackers (like ones that measure your exercise, sleep, diet, or other health-related information), we may ask if you would share data with us. We may send you separate devices (like a fitness tracker or air pollution monitor) to collect information for Connect.

HOW WILL YOU CONTACT ME?

The Connect team will contact you a number of ways. These may include email, telephone, text message, postal mailing, health care system patient portal, or notifications on the MyConnect app. If we lose contact with you, we will try to reach you in other ways. For example, we may look in your medical record or reach out to backup contact(s) that you give us. We may also check public listings to help us find your up-to-date contact information.

WHAT WILL YOU DO WITH MY INFORMATION AND SPECIMENS?

We value the time, effort, and specimens that you choose to share with Connect. We want to make the most of your information and specimens, while protecting your identity and privacy. Your information and specimens will be used for future research and stored for an unlimited amount of time, unless you change your mind, withdraw (quit), and tell us you wish to have your information and specimens destroyed.

We are creating a public database on the Connect website. The information in the public database will be grouped across all participants. It will **not** include information about individual people. It will not include your name or other information that directly identifies you. Anyone will be able to use the public database to explore the group-level data.

We are creating a research database. The research database will have individual-level data and specimens. Access to this database will be controlled. Researchers will have to tell us what they plan to study using the Connect information and specimens. Their research must have valid scientific value. Researchers may be from anywhere in the world. They may work for your health care system, the National Cancer Institute, commercial companies (like drug companies), or other research institutions. When we share your information and specimens with researchers, we will leave out your personal identifying information.

Personal identifying information. A small number of staff on the Connect team will use information like your name, date of birth, social security number , or address to match

information from other sources to you. Providing your social security number is optional, and you can still participate in Connect if you choose not to provide it. These other sources could include cancer and other health registries, or demographic, environmental, census, and other exposure databases. We will use only the smallest amount of your personal identifying information necessary to confirm the information from other sources is yours.

Survey information. Your survey information is valuable. There are lots of important questions that can be answered with this information. Researchers will use it to compare things like lifestyle, diet, or medical problems among people who get cancer and those who do not. Your personal identifying information will not be linked to with your survey answers. Connect will not give your survey data to your doctor or put these data in your health record.

Donated specimens. Your blood, urine, saliva, and other specimens help researchers understand what is happening in your body. We may measure things that naturally occur, like cholesterol. We may also measure other things that affect health, like levels of vitamins or pollutants in the environment.

We may use your blood or saliva specimens to look at your entire genetic code in your DNA (like "whole genome sequencing"). Below we provide more information in a section called "Genomic Sequencing".

Researchers will use many methods to study your specimens. Because Connect will last for a long time, some of the methods may not even be invented yet.

We will store your blood, urine, saliva, and other specimens you provide (like hair and nails) in the Connect Central Repository. The Repository is a secure storage place for specimens. We will store your specimens at the Repository until they are used up.

What researchers learn from studying your specimens will be added to the Connect database.

Electronic health records and other medical records. Your health care system(s) has valuable health and medical information about you in electronic health records and medical records. For example, medical records can help with finding connections between your health patterns and the information in your medical records.

Leftover, unused clinical specimens. Your tissue, blood, or urine specimens, if collected, provide a picture of how your cells are working. With these specimens, researchers might find precancer or early signs of cancer to better understand how cancer develops and how to find cancers earlier. These and other specimens, like stool, allow researchers to look at changes over time.

GENOMIC SEQUENCING

We are requesting your permission to perform genomic sequencing of all or a portion of your genome in your blood, saliva, or tissue specimens (if you provide tissue) and link this to your medical and/or family history. Your specimens contain your genome, which is made up of DNA (deoxyribonucleic acid) which serves as the "instruction book" for the cells that make up our bodies. Genomic sequencing will determine the exact order of the base pairs (chemical letters) in your blood, saliva, and tissue. Your specimen(s) and medical information will help us study how differences in the genetic code affect the risk of cancer and other health outcomes.

However, you should know that the analyses that we perform in our laboratory are for research purposes only; they are not nearly as sensitive as the tests that are performed in a laboratory that is certified to perform genetic testing or testing for routine clinical care. For these reasons, we will not give you the results of the research tests done on your research specimens in most cases. There may be exceptions to what we share with you and this is described later in this consent form in the section for "Return of Research Results".

This study involves genetic and genomic testing on your specimens. Some genetic information can help predict future health problems in you and your family and this information might be of interest to your employers or insurers. The Genetic Information Nondiscrimination Act (GINA) is a federal law that prohibits plans and health insurers from requesting genetic information or using genetic information. It also prohibits employment discrimination based on your health information. However, GINA does not address discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed condition or disease that has a genetic component.

HOW LONG WILL THE STUDY TAKE?

If you join Connect, we hope you will be part of the study for your entire life. This is because our goal is to watch things that can change over a person's lifetime, such as habits like diet and exercise, and the environment. Some of these may affect the risk of cancer and other health problems. The information and specimens will be used for research for many years into the future.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

We plan to include 200,000 people in Connect.

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

Connect activities are considered low risk to participants. For each study activity, these are the risks and discomforts:

Personal identifying information. There is always a risk to your privacy whenever you use an online app. Using the MyConnect app is no riskier than any other app you might use. We will do everything we can to protect your privacy. Your personal identifying information will be securely stored with limited access and separate from your research information. Despite these precautions, there is a risk that an unauthorized person could get access to your stored data. The chance that this will happen is very small, but it is not zero.

Survey information. Some of the questions ask about sensitive information that could cause you distress. You are not required to answer these questions and you can skip these questions.

Donated Specimens. Blood draws may cause pain, redness, bruising or infection at the site of the needle stick. Rarely, some people faint. There are no known risks related to providing urine or saliva specimens.

Electronic health records and other medical records. Like your personal identifying information, there is a small risk to your privacy. Connect has put safeguards in place to keep your health and medical information private. These safeguards include controlling access to your health and medical information, removing your personal identifying information from your health and medical information, and maintaining current technology security standards.

Unused specimens. No risks or discomforts are expected from storing these specimens for Connect research purposes.

WHAT WILL HAPPEN IF I AM INJURED DURING THE STUDY?

This study only involves collection of information and specimens. It does not involve any treatment or the use of any drugs or devices. Therefore, we do not expect that you would experience any injury. If you are injured during your participation in this study, you should contact the Principal Investigator as soon as possible in person or at the telephone number listed in this consent form. Medical care may be obtained in the same way you would ordinarily obtain other medical treatment.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You will not directly benefit from being in this study.

Are there any potential benefits to others that might result from the study?

Connect will not provide medical treatments. It is a research program. You will not get direct medical benefit from giving your information and specimens. This kind of research usually takes many years and requires many participants like you to find medically useful results. However, your participation is very important and could contribute to our understanding of the prevention and treatment of cancer and other discoveries.

WHAT OTHER OPTIONS ARE THERE FOR YOU?

You can choose to not join Connect. There may be other studies looking at the causes of cancer and ways to prevent cancer in healthy individuals that you may choose to join.

DISCUSSION OF FINDINGS

New information about the study

If we find information that may affect your choice to be in Connect, we will contact you through the MyConnect participant app, mail, text messages, and/or email to tell you. This may be information we have learned while doing Connect research. It may also be from other researchers doing research through other studies.

Return of research results

Communications about return of results will occur primarily through the MyConnect participant app and could also include mail, email, or text messages.

Group findings from Connect. New research findings from Connect research will be shared in newsletters, through the MyConnect app, and on the study website (Cancer.gov/connectstudy). The findings that will be shared will be about groups of people in Connect. It will not include information about individual people. You can choose if you would like to receive these findings or not.

Your survey results. We will show you how your survey answers compare to the answers of other groups of people in Connect. We will also show you how your survey answers compare to national data, guidelines, or recommendations. For example, we will send you reports in the MyConnect app about how your diet compares to national recommendations. You can choose if you would like to receive survey results or not.

Your specimen results. We will share some information with you about things measured in your specimens. The things measured in your specimens might include antibodies to certain viruses, vitamin levels in your blood, or chemicals in your urine. When the results are available, we will contact you in the MyConnect app to ask if you want to receive them. If you choose to receive your results, Connect will have a plan to help you understand them. Connect will not share any results with your health care provider or add results from the study to your health records, but you can share any information you receive with your family or your doctor if you choose.

Your genetic and genomic test results. Using your specimens, we will look at your genetic code (DNA). Most of the results of the research tests done on your specimens will not be returned to you, but there are some exceptions. For example, we will offer you results of your genetic ancestry. When we have ancestry results, we will contact you to ask if you want to learn about the results . In the future, other genetic results could be available to you. When the results are available, we will contact you in the MyConnect app to ask if you want to receive them. If you choose to receive your results, Connect will have a plan to help you understand them. Connect will also help you understand the meaning of your results for your health and your family's health.

EARLY WITHDRAWAL FROM THE STUDY

If you agree to join Connect but you do not match the age, health care membership, and/or no history of cancer eligibility requirements to join the study, we will let you know that you cannot be a part of Connect. If we learn that you are no longer able to complete surveys, donate specimens, or otherwise participate in Connect, we may stop contacting you. We may still collect data from your health and medical records or other data sources even after we stop contacting you. No action will be needed on your part if this happens.

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR SPECIMENS AND DATA

Will your specimens or data be saved for use in other research studies?

As part of this study, we are collecting specimens and data from you. We will remove all information that can identify you , such as your name, social security number, date of birth, address, or medical record number and label your specimens and data with a unique code so

that you cannot easily be identified. However, the code will be linked through a key to information that can identify you. We plan to store and use these specimens and data for studies other than the ones described in this consent form that are going on right now, as well as studies that may be conducted in the future. These studies may provide additional information that will be helpful in understanding cancer or other diseases, and conditions. This could include studies to develop other research tests, treatments, drugs, devices, or that may lead to the development of a commercial product by the National Institutes of Health (NIH) and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

Will your specimens or data be shared for use in other research studies?

We may share your coded specimens and data with other researchers. If we do, while we will maintain the code key, we will not share it, so the other researchers will not be able to identify you. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at the NIH, other research centers and institutions, or commercial entities.

If you change your mind and do not want us to store and use your specimens and data for future research, you should contact the Connect Support Center (Cancer.gov/connectstudy/support). We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your specimens and data. For example, if some research with your specimens and data has already been completed, the information from that research may still be used. Also, for example, if the specimens and data have already been shared with other researchers, it might not be possible to withdraw them.

In addition to the planned use and sharing described above, we might remove all identifiers and codes from your specimens and data and use or share them with other researchers for future research. When we or the other researchers access your anonymized data, there will be no way to link the specimens or data back to you. We will not contact you to ask your permission or otherwise inform you before we do this. If we do this, we would not be able to remove your specimens or data to prevent their use in future research studies, even if you asked, because we will not be able to tell which are your specimens or data.

Will your genomic data be shared outside of this study?

As part of this research study, we will put your genomic data in a large database for broad sharing with the research community. These databases are commonly called data repositories. The information in this database will include but is not limited to genetic information, race and ethnicity, and sex. If your individual data are placed in one of these repositories, they will be labeled with a code and not with your name or other information that could be used to easily identify you, and only qualified researchers will be able to access them. These researchers must receive prior approval from individuals or committees with authority to determine whether these researchers can access the data.

Summary information about all of the participants included in this study (including you) will be placed in a database and will be available through open access. Examples of summary information could include the total number of participants diagnosed with cancer or the percent (%) of participants younger than 50 years old. That means that researchers and non-researchers

will be able to access summary information about all the participants included in the study, or summary information combined from multiple studies, without applying for permission. The risk of anyone identifying you with this information is very low.

NIH policies require that genomic data be placed in a repository for sharing. Therefore, we cannot offer you a choice of whether your data will be shared. If you do not wish to have your data placed in a repository, you should not enroll in this study.

How Long Will Your Specimens and Data be Stored by Connect?

There is no limit on the length of time we will store your information or specimens. Your information or specimens will be stored at the NCI and at partner health care systems.

Risks of Storage and Sharing of Specimens and Data

When we store your specimens and data, we take precautions to protect your information from others that should not have access to it. When we share your specimens and data, we will do everything we can to protect your identity. For example, when appropriate, we remove information that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known or someone may gain unauthorized access to your information. New methods may be created in the future that could make it possible to re-identify your specimens and data.

PAYMENT

Will you receive any type of payment for taking part in the study?

Yes, you will receive $25 (cash or gift card) when you finish the first set of activities:

- Fill out the first online survey
- Donate your first blood specimen

If you are unable to finish these study activities, you will not receive payment for the parts you completed. We expect most people to complete this first set of activities shortly after agreeing to join Connect. Payment is provided in the form of a gift card or cash depending on your health care system. Participants at most sites will receive a link to select an on-line gift card within 24 hours after completing the baseline survey and blood draw. At select sites, participants will receive cash at the clinic visit for the blood draw if the surveys have also been completed. If your health care system charges for parking when you come to donate your specimens, your parking ticket will be validated.

Over time, we will ask you to answer more surveys and donate more specimens. We may provide payment for some of these future activities. We will tell you the amount and form of payment when we invite you to do these activities. Plans for future payment may change over time and vary by location.

COSTS

Will taking part in this research study cost you anything?

No, Connect will cover all charges related to the research activities. This includes charges related to collecting specimens (like blood draw fees or postage for mailing). If you are contacted by text message, you will be charged standard rates. Connect will not cover medical care costs. Your doctor will continue to be responsible for your medical care.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You can also visit the study website (Cancer.gov/connectstudy) for further information about the study.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- Institutional Review Boards (a board that reviews the ethics and safety of the study) at the NIH and participating health care systems
- Staff who will help us link your personal identifying information to state or national registries.
- Researchers from your health care system
- Partnering researchers from other institutions. The other institutions may include universities, private companies, or non-profit organizations. We will remove as much personal identifying information as possible from your data before it is shared. We will do this to protect your privacy and confidentiality.

The researchers conducting this study and the NIH follow applicable laws and policies to keep your identifying information private to the extent possible. However, there is always a chance that, despite our best efforts, your identity and/or information about your participation in this research may be inadvertently released or improperly accessed by unauthorized persons.

In most cases, the NIH will not release any identifiable information collected about you without your written permission. However, your information may be shared as described in the section of this document on sharing of specimens and data, and as further outlined in the following sections.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this Certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH research information that we collect under the authority of the Public Health Service Act during your participation in this research study. This study's data will be stored under system 09-25-0200, Clinical, Basic and Population-based Research Studies of the NIH. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your record without your permission, such as if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to NIH staff (such as contractors and volunteers), to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to morbidity, mortality, disease, or tumor registries, when authorized by the Secretary of HHS, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act. If you do not want to share your information with us, then you cannot participate in this study.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Connect Support Center at Cancer.gov/connectstudy/support.

You may also contact the Principal Investigator, Montserrat Garcia-Closas, M.D., Dr.P.H. at ConnectPI@nih.gov or 240-276-7150.

For questions about your rights while in this study, call the NIH Institutional Review Board at 301-402-3713.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again. It can be viewed or downloaded from the MyConnect participant app after you sign up.

By clicking "Yes, I agree to join Connect" and typing your name, you confirm the following:

1. I have read these forms.
2. As stated in the consent and HIPAA Authorization, I will allow the use, storage, and disclosure (release) of my survey answers, samples, and health information for the research as described above.
3. If I have questions, I can contact the Connect Support Center at Cancer.gov/connectstudy/support
4. If I decide to leave the study, I can contact the Connect Support Center at Cancer.gov/connectstudy/support.

[X] Yes, I agree to join Connect

Please enter your legal name. If you are a member of Kaiser Permanente, please enter your first and last name exactly as it appears on your Kaiser Permanente ID card.

Name:

Date:

Signature: