**Welcome to The NextGen Study**

Researchers at \_\_\_ and the National Cancer Institute (NCI) are doing this research study to understand the causes of cancer and other chronic diseases. We are working with your health care provider to enroll 200,000 healthy people in this study. We hope it will help improve the health of current and future generations.

The following pages will give you information about the study so that you can decide whether you would like to take part. In each section, you can click “Learn more” if you wish to get more detailed information. Your participation is completely voluntary. Your health care will remain the same whether or not you participate.

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1. *You can discuss participation with anyone you choose including family/friends.*
2. *Provide non-web-based contact information to contact for questions.*
3. *Do we need to develop FAQs or other support for providers since it would be natural for patients to ask their providers about participation?*
4. *What is the National Cancer Institute?*
5. *Why do you need 200,000 people to participate?*
6. *How may this study improve the health of current and future generations?*
7. *\*\*SEE ATTACHED DOCUMENT FOR DRAFT TEXT TO ADDRESS QUESTIONS*

**What will I be asked to do?**

To help us better understand certain health conditions, we need to learn more about you. In the study, we will ask you to:

1. Fill out surveys about some of your regular habits, your medical history, and where you have lived.
2. Provide blood and urine samples. These will be obtained either during your regular health care provider visits or through your local clinic.
3. Give us permission to assess your medical records and any lab samples, which will provide key details of your health.

Once you start the study, we hope you will remain a part of it for many years, even if you change your health care provider. We will periodically contact you to inform you about the study’s progress and ask you to complete more surveys, provide additional samples, renew your consent, and/or request your participation in additional study visits.

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1. *survey – plan to do it electronically on a simple web interface like this one, and can be filled out at their convenience*
   1. *how long will the survey take [give range and average]*
   2. *how do I access the survey? [give URL and tell them what they need (e.g., ID?). Tell them that they have to complete consent document first.]*
   3. *what types of questions will you ask me?*
   4. *Are there other ways to participate without doing this online? [At this time, the only way to participate in this study is to complete the questionnaire online. The questionnaire is accessible on any electronic device, including computers, laptops, tablets or mobile phones.]*
2. *future contact and the types of things we will ask*
3. *providing samples now & in the future (type, how much/many, when, how will it be collected, etc.; who will pay for blood/specimen collection) [There will be no cost to you to participate. All costs will be paid for by the NATIONAL CANCER INSTITUTE (others?)]*
4. *what will be done with samples/what kind of tests to be performed; what will you do if you find out something is wrong with me (and will you share it with my doctor – what if they are no longer in the same network?) [Something about a variety of tests that might be done, banking specimens for future use. Issue of clinical vs. non-clinical results.]*
5. *accessing existing medical records and samples – how will you get them, what will you do with them [we will work with your physicians and your healthcare system to access your medical records]*
6. *importance of long-term contact even if they change health care providers*
7. *future contact – how often, method of contact*

**Who will have access to my information?**

Your contact information will be kept confidential. Only the primary research team members at \_\_\_ and NCI will know that you are participating. Your survey responses, health information and samples will be coded by a number (not your name) and stored securely.

Data that we collect or generate in this study may be used for future medical research. We may share your data with other researchers in a manner consistent with all applicable federal and state laws and regulations. If your data are shared outside of the primary research team, we will remove identifying characteristics (name, address, identification numbers, etc) first, so that your data are not linked directly to you.

*LEARN MORE*

1. *Data and biospecimen repositories – how they are set up, who can access them, etc.*

Return of results (not just genetic) – hold for now

Return of results to family members – hold for now

**What are the risks and benefits of participating?**

The goal of this study is to learn about the causes of various diseases, with the hope of improving the health of current and future generations. Because this is a long-term study, it may not benefit you directly. There are no costs to you to take part in the study, and you will not be paid for taking part.

There is a small chance that participation in this study may involve a loss of privacy if someone who is not authorized gets access to the data we have stored about you. We will make every effort to prevent that from happening.

The most common physical risks are minimal and are related to drawing blood from your arm, including brief pain and/or bruising.

*LEARN MORE*

1. *What if I am injured or experience loss of privacy?*
2. *What safeguards do you have in place to protect my confidentiality?*
3. *Risks of data being stolen?*

*Draft text to address questions:*

*Benefits: Studies like this one provide an important opportunity to collect information on factors that may affect risk of disease. Our findings will help to inform future recommendations for healthy lifestyle to reduce risk of cancer.*

*Participating in this cohort study may not benefit you directly at this time. Many people who volunteer do so with the hope that health research may improve our understanding of diseases like cancer and ultimately advance science and improve medicine. Others people hope that there will be a benefit for their children.*

*Risks of blood draw: There may be some physical discomfort associated with blood drawing. The most common physical risks are minimal and are related to drawing blood from your arm, including brief pain, fainting and/or bruising. Because the skin is broken, an infection in the area can occur, although this is quite rare. If there is injury from drawing blood, the clinical staff at your health care facility will attend to you.*

*Other risks: Participation in the study may occasionally be inconvenient for you because of the time involved in participating. We will minimize this whenever possible, for example, by working with your healthcare providers to accomplish most of the tests during regular health visits.*

*There is a small chance that participation in this study may involve a loss of privacy if someone who is not authorized gets access to the data we have stored about you. We will make every effort to prevent that from happening, for example, having a certificate of confidentiality to prevent forced disclosure of your identity or any information about you. [not sure what this means]*

*We have safeguards in place to protect your confidentiality. See the “Who will have access to my information” part of the consent form*

**What if I want to stop participating?**

Participation is completely voluntary. If you decide to participate, you can stop at any time. If you want to leave the study, call \_\_\_ or email \_\_\_ to let us know.

*LEARN MORE*

1. *Who should I contact if I want to stop participating?*
2. *Will my healthcare be affected if I decide to stop participating?*
3. *Do I have to give a reason if I choose to stop participating?*
4. *What will happen to the information and specimens you have collected from me?*
5. *Draft text to address the questions above:*

*You can at any time, and without giving any reason, withdraw your consent to participate. Withdrawing from the study will have no effect on your healthcare or other benefits to which you are otherwise entitled.*

*If you withdraw from the study, we will make every effort to remove your information and any samples from future research, but in some cases this may be impossible. For example, if some research with your information or samples has already been completed, or if anonymized genetic data has already been entered into a large data repository.*

*You can also at any time request that any existing biological samples you provided be destroyed. We will make every effort to fulfill any such requests but it may not always be possible if research using your samples has already started.*

*Comment: There should be several levels of withdrawal (e.g. withdraw from continued active participation (i.e. can continue to use existing data and biospecimens but passive follow-up ok), withdraw from any continued follow-up (active or passive), withdraw from continued follow-up and request no further use of existing data and/or biospecimens)*

1. *Other suggested text: If you decide to leave the study, we may retain your lab samples as the costs and complexities of discarding such are very difficult in a study of this size. For example, your samples may be in multiple secure freezers and, in some cases, may have been combined with other participants’ samples (pooled blood, tissue microarrays, etc). Your retained samples will only be linked to your age and sex and will only be used for quality control analyses. All other survey data will be deleted from the master database. You will no longer be contacted about, or updated on, the study.*

**What if I have questions about the research study?**

If you have questions about this study, contact \_\_\_. If you have questions about your rights as a research participant, contact \_\_\_.

**Consent (final page with agree/do not agree)**