**GenX Exposure Study Frequently Asked Questions**

**Section 1: Conduct and funding**

**Who is in charge of the study? Who is conducting this study?**

The principal investigator in charge of the GenX Exposure study is Dr. Jane Hoppin, the Deputy Director of the Center for Human Health and the Environment at North Carolina State University. There are also other co-investigators at NC State and East Carolina University. In addition, we have community partners in the New Hanover County, including Cape Fear River Watch and the New Hanover County Health Department. The local NAACP, researchers at UNC-Wilmington, and the Cape Fear Public Utility Authority are all helping with parts of the study, including getting results back to community members.

**Who is funding/paying for this study?**

This study is being funded by a federal grant from the National Institute of Environmental Health Sciences (NIEHS), which is a branch of the National Institutes of Health (NIH) under the federal Department of Health and Human Services.

**Is the county health department involved in this study?**

The New Hanover County Health Department is a community partner for this study. They are providing the location for blood collection, as well as helping to keep the community and health care providers updated on study activities.

**Section 2: Study activities and eligibility**

**Who is eligible, able, and allowed to participate in the study?**

All New Hanover County residents who have public utility water and have lived in the region for the past twelve months are eligible. We are recruiting 400 people ages 6 and older. Pregnant women, and those with HIV or hepatitis C are not eligible. All participants need to be willing to sign a consent form, provide both blood and urine samples, provide a drinking water sample, have their height and weight measured, and answer a short questionnaire.

**How many people will be in the study?**

We are interested in enrolling a total of 400 people, 100 women and 100 men of all ages, as well as 100 girls and 100 boys, aged 6-17.

**What do I need to do to enroll/participate?**

Interested people should contact the study either through our toll free number 1-855-

854-2641 or our study email address [genx-exposure-study@ncsu.edu](https://webregistry.ncsu.edu/webservice/details/webserviceId/genx-exposure-study%40ncsu.edu). Study staff will contact you to determine your eligibility and then schedule an appointment. We have a short set of questions to determine if you are eligible to participate.

**What will I have to do in the study? How much time will all this take?**

If you are eligible to participate, we will make an appointment for you to come to the clinic at a local health facility. We will also make an appointment to come to your home and collect a drinking water sample. If you complete this visit prior to the clinic visit, the clinic visit time will be shorter. Your total time commitment should be less than an hour.

* For the home visit, a team of two research staff members will come to your home to review the consent form that describes the study in detail. We will give you an opportunity to ask questions, and if you agree to participate, you will be asked to sign the consent form. You will be given a copy for your records. A drinking water sample will also be collected. This appointment will be made on a day and time that is convenient for you. This visit will take approximately 10-15 minutes, depending how many people in your home are participating.
* During the clinic appointment, you will provide blood and urine specimens, have your height and weight measured, and complete a brief questionnaire, This also is an opportunity to meet with some of the research team. This visit will take approximately 45 minutes.

**What will my child have to do to participate?**

Your child(ren) will be asked to do everything that adult participants complete. Your child(ren) will complete a short questionnaire with your help, and have their blood and urine collected. If multiple people in a household are participating, we will streamline the questionnaire, so that you do not have to repeat information.

Children aged 6-10 will be given information about the study by a research team member in your presence. If your child verbally agrees to participate, you will sign a parental permission document that provides, in detail, all of the specifics of the study.

For children aged 11-17, a research team member will review an assent document in your presence. If your child agrees to participate, he/she will be asked to sign the assent document, and you will be asked to sign the parental permission form. The research team member obtaining assent/parental permission will also sign the document. A copy of all signed documents will be given to you.

**What if I can’t complete a survey/have my blood drawn/collect my urine/have a water sample collected at my home?**

Only a small number of people will be able to enroll in this study from the community, so only people who are willing to complete all parts of the study’s activities can participate.

Any eligible participant can choose, at any time, not to participate or stop participating. In addition, if our staff is unable to draw your blood sample, you will still be eligible to participate in the study.be eligible to participate in the study.

**Can I go to the health facility anytime to enroll?**

We encourage you to call our study number or send us an email indicating your interest in the study. We will call you back, confirm your eligibility, and schedule an appointment. We want to make the process as quick as possible, so everyone needs to have an appointment.

**Can my family members also participate?**

Yes, we can enroll up to 4 family members per household to participate in the GenX Exposure Study.

**Can my whole family join the study?**

We would love for you and your family to participate. Right now, we can only enroll up to four family members from a household.

**My neighbor told me that he/she was interested. Can he/she participate?**

Yes, we would be happy to have your neighbor contact our office via telephone at 1-855-854-2641 or by emailing [genx-exposure-study@ncsu.edu](https://webregistry.ncsu.edu/webservice/details/webserviceId/genx-exposure-study%40ncsu.edu) if they are interested in participating.

**Can I tell my neighbors to join the study?**

We would be happy for you to share our study phone number and email with your friends and family who live in the Wilmington area.

**Section 3: Results, costs, and study findings**

**Will I get any results of the blood/urine/water samples collected/body measurement results?**

Yes, you will receive the results of the measurement of GenX and other chemicals detected in your blood, urine and water samples. In addition, you will receive results of clinical lab tests from your blood and urine and your body measurements. In blood samples, we are measuring thyroid and liver function and cholesterol levels. These may be related to GenX exposure, but we do not know. That is one of the goals of our research study. A written report will be mailed to your home once the tests are completed. You can share this information with your health care provider or anyone else, if you choose.

The overall study results will be shared with the community via a number of outlets, including news articles, public meetings, and websites.

**Will I be paid to participate?**

No, there is no compensation for participating.

**Will it cost me anything to participate?**

There is no cost to you, other than your time, to participate.

**What are you going to find out from this study?**

The GenX Exposure study is a research study, and we don’t know what we will find.

Questions we **will** be able to answer are: Will we find GenX in the body, in either blood and/or urine on the day of sample collection? And will we find GenX in the drinking water collected at your home on the day of sample collection?

Because GenX is no longer being released into the river, drinking water levels may be very low. If your blood, urine, and/or drinking water samples have no measurable GenX, this will only tell us you had no detectable measurements on the day that we collected the samples.

It is possible we might find that some demographic characteristics or drinking water history may be associated with GenX or other chemicals in the body. We will share these findings with the community

We are also measuring thyroid and liver function and cholesterol levels in the blood which may be related to GenX exposure, but we don’t know. That’s one of the goals of our research study. However, we will only have 400 people enrolled, so we will be limited in what we can report at this time.

**Section 4: Privacy/Confidentiality**

**How will my privacy/confidentiality be protected?**

Your answers to the screening questions and larger questionnaire will be stored securely in password protected files. We will not make reference to individuals when we report the results of the study. Each participant will be assigned a unique ID number used on the questionnaire and all samples collected. Datasets will contain only that ID number, not your name or other identifying information. To further protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health.

**What is a Certificate of Confidentiality?**

The researchers can use the Certificate of Confidentiality to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, or other proceedings, for example, if there is a court subpoena. The researchers will use the certificate to resist any demands for information that would identify you except in the following circumstances:

The certificate cannot be used to resist a demand for information from personnel of the US federal agency sponsoring the project and that will be used for auditing on program evaluation of agency funded projects or for information that must be disclosed to the federal Food and Drug Administration.

You should understand that this certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider or other person obtains your written consent to receive information, then the researchers will not use the certificate to withhold that information.

**Will anyone outside of this study use my information for additional research?**

The study samples are collected to focus on research questions related to GenX and other water contaminants and human health. In the future, outside investigators may request data collected in this study for other laboratory analyses to help further our understanding of these exposures. Outside investigators will not receive any information that could identify the samples or data as coming from you. If outside investigators need your address information for their project (for example, if they wanted to use something related to maps), we will require those investigators to protect this information in a similar manner to what we are doing. We will not provide your name to other investigators. All future projects will have to be approved by human subjects boards before consideration.

**Section 5: Sample and data collection use and measurements**

**How will my samples and questionnaire data be used?**

The samples collected for this study will be used to measure GenX and other chemicals detected in your blood, urine, and drinking water. We are also measuring thyroid and liver function and cholesterol levels in the blood. These may be related to GenX exposure, but we don’t know. That’s one of the goals of our research study. All questionnaire responses will be combined to create a dataset, which will be analyzed in addition to the other samples (blood, urine, water) collected from participants.

**What health measures are you assessing?**

We will measure height and weight during the study visit. We will analyze blood samples for cholesterol and other lipids, thyroid function, and a comprehensive metabolic panel to assess liver function. We will provide these results to study participants.

**What are the other chemicals you will be measuring in my (blood/urine/water) sample?**

The other chemicals being measured are called perfluoroalkyl substances, or PFAS, and are also used in the production of non-stick materials. We will also be measuring some other water contaminants identified in August 2017 called Nafion byproducts.

**Section 6: Future contact**

**Will I be contacted by the study to do anything else?**

We may recontact participants who have detectable levels of GenX or other chemicals in their blood or urine to provide additional blood or urine. It is also possible that they might be contacted about other follow-up studies. If we recontact you, you may agree or refuse to participate. Participation in any future study is voluntary.

**Will you collect my blood, urine, and water again?**

Our study currently does not allow us to follow you over time. If we find people who have detectable levels of GenX or other chemicals, it is possible that we might reach out to collect more samples. The GenX Exposure Study is potentially a jumping off point for another study.

**Are there laboratories that can measure GenX in my blood?**

Currently there are no commercial laboratories that measure GenX in biological or environmental samples.

**Section 7: GenX**

**What is GenX?**

GenX is a chemical used in the production of Teflon™ and other non-stick materials. It has been detected in the Cape Fear River, which is the drinking water source for Wilmington.

**Is GenX the only chemical that was released into the river?**

GenX is just one of several chemicals released into the Cape Fear River by the Chemours plant.

**What is already known about human exposure to GenX/toxicity of GenX?**

Little is known about human exposure to GenX or the toxicity of GenX. To date, there have been only a few published animal toxicology studies related to GenX exposure.

**How are my GenX measurements connected to my health issues?**

We understand you might be interested in how your measurements are connected to your health outcomes. However, this study will not relate GenX to a certain health condition. Our study is cross-sectional, meaning that we are measuring everything on the same day, so we can’t know for certain which came first, GenX exposure or the health outcome.

We are assessing only a few health measures: body mass index (BMI), liver function, cholesterol levels, and thyroid function. These do not capture the full range of human health concerns. They only provide a start to understanding potential health concerns.

Our study is small to evaluate most health outcomes. With only 400 people of all ages, the study is best suited to understand GenX exposure in the Wilmington area.

**What is a safe level of GenX?**

Currently there is little known about the human toxicity of GenX. The NC Department of Health and Human Services evaluated four published studies and set a ‘health goal’ of 140 ng/L (140 parts per trillion) for drinking water consumption in July 2017. There are no human data to assess safety.

**What will my GenX results mean?**

This is a scientific research project, so we are trying to learn a lot about GenX in this study. We will be able to tell you if we could measure GenX in your body on the day of sampling and how your level compares to others in the community. Before we share your individual results with you, we will discuss how to best share this information and its interpretation with our Community Science Advisory Panel. The Community Science Advisory Panel will help advise the study team about reporting back results to participants and provide guidance on ongoing or new community concerns about GenX and other perflourinated chemicals (PFAS). We will also provide information for the local health care community to help address your concerns, if they arise.

**Will you be able to tell me where the GenX in my blood came from?**

We will not be able to say where the GenX in your blood came from. The blood and urine samples will tell us if GenX is present, but we won’t be able to say where it came from. It is possible that there are other sources of GenX exposure that we do not know about.

**Section 8: Lawsuits**

**Does this study have anything to do with any lawsuits already filed?**

No, this study is not related to any lawsuit that has been filed.

**Can I use my results to file a lawsuit against the polluters?**

You will receive the results from your blood, urine and water sample analyses. You can do whatever you choose with this information.