

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, East Carolina University, University of North Carolina-Chapel Hill, and Duke University. In addition, we have community partners, including New Hanover County Health Department, Cape Fear River Watch, New Hanover County NAACP, Cumberland County Health Department, Sustainable Sandhills, and Haw River Assembly.

Who is funding/paying for this study?

The study is funded by grants from the National Institute of Environmental Health Sciences (NIEHS). NIEHS 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 and Cumberland County Health Department are community partners for this study. They are providing the location for the clinic visit, 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?

We previously enrolled individuals from Wilmington and Fayetteville. These people will be invited to continue.

New participants will be recruited in New Hanover and Brunswick Counties and Pittsboro based on their water source. Anyone living in the service area who used municipal water for at least one year is eligible.

In communities with impacted groundwater (e.g., Fayetteville), residents must have had their well tested for PFAS by NC Department of Environmental Quality (NCDEQ) or Chemours to be eligible.

We are recruiting up to 1400 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 blood and urine samples, have their height and weight measured, and answer an annual questionnaire.

Why are you recruiting differently in Fayetteville area?

In Fayetteville, unlike the other communities, PFAS levels differs by location. For example, some wells have higher levels of PFAS than others. To be able to best test for health effects related to PFAS, we need to include people who have both high and low PFAS levels.

Because of the sampling done by Chemours and DEQ, we have a list of levels of GenX in all wells tested to date. From this list we are able to identify people with potentially high exposure and those with potentially lower exposures. From each group, we are recruiting a random sample. This means that everyone with a tested well is potentially eligible.

We are mailing postcards to eligible households. Unfortunately, we cannot enroll all people with PFAS exposure.

How many people will be in the study?

We are interested in enrolling a total of 1400 people ages six and older.

What do I need to do to enroll/participate?

Interested people in New Hanover County and Brunswick County should contact the study through our toll free number 855-854-2641.

For interested people in the Fayetteville area, study staff will be contacting residents whose wells were previously sampled by Chemours or NCDEQ. Study staff will contact you to determine your eligibility and then schedule a consenting and clinic appointment. We have a short set of questions to determine if you are eligible to participate. Study staff will ask these questions over the phone or may ask them through an internet survey.

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. Your total time commitment should be about one hour.

- During the clinic appointment, you will provide blood and urine specimens, and have your height and weight measured. This also is an opportunity to meet with some of the research team. This visit will take approximately 30 minutes. We will do this at least once and may ask you to participate in future blood collections.
- There will be a questionnaire conducted on an annual basis.
- There will be short surveys over the phone or internet to answer questions about COVID-19 symptoms and disease.
- You will be recontacted over time so that we can learn about the potential long-term health impacts of PFAS.

- We may also ask you to provide a saliva sample (about 1 Tablespoon).

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, urine and saliva 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?

Only a limited 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.

Can I go to the health facility anytime to enroll?

No, we must schedule all appointments in advance. We ask that you call our study number 855-854-2641 indicating your interest in the study. We will call you back, confirm your eligibility, and schedule an appointment. We may send out internet surveys for eligibility screening and scheduling that you can complete yourself.

People in the Fayetteville area will be sent an online form to see if they are eligible. People in the Wilmington area and Pittsboro area will also be able to complete a form online to see if they are eligible on [our website](#).

We want to make the process as efficient and as safe as possible, so everyone needs to have an appointment scheduled before coming to the health facility.

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 4 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 855-854-2641 if they are interested in participating. Study staff will contact them to determine their eligibility.

Can I tell my neighbors to join the study?

Yes, 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, Fayetteville area, or Pittsboro area. When they contact us, study staff will determine their eligibility.

Section 3: Results, costs, and study findings

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

Yes, you will receive the results of the measurement of PFAS detected in your blood 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 PFAS 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.

Why might you collect saliva samples?

Saliva samples may allow you to collect your own sample in the future. Saliva is being used for many purposes in biology and human health. Because we are planning to continue the study for a long time, we want to be sure we have these options in the future.

We did collect saliva samples in Wilmington in November 2020. We are investigating how useful saliva is for antibodies, particularly to SARS-CoV-2. If useful here, we may try to use saliva samples in the future to better understand how PFAS chemicals influence biological responses that we can measure in saliva.

Will I be paid to participate?

For your participation in this study, you will receive \$20.00 cash for each completed clinic visit. If you cannot provide a urine sample, or have your height and weight measured, or if we fail to collect a blood sample it will not affect your compensation. You will also be eligible to win a random drawing prize of \$50.00 cash. There are five \$50.00 cash prizes in the random drawing for all members of the GenX Exposure Study.

If you withdraw from the study prior to completing the clinic visit, you will not receive compensation. The odds of winning one of the \$50.00 cash prizes is 1/280.

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 PFAS in the body, in either blood and/or urine from 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 PFAS 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 PFAS exposure, but we don't know. That's one of the goals of our research study.

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 PFAS 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 PFAS detected in your blood and urine. We are also measuring thyroid and liver function and cholesterol levels in the blood. All questionnaire responses will be combined to create a dataset, which will be analyzed in addition to the other samples (blood, urine) 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 chemicals you will be measuring in my blood sample?

The chemicals being measured are called perfluoroalkyl substances, or PFAS, and are used in the production of non-stick materials.

Section 6: Future contact

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

The blood, urine, and body measurements will be taken twice over the first five years of this study. We will recontact you annually to participate in the questionnaire. We hope to continue this study for 20 years so that we can learn more about the health effects of PFAS. Participation in any future study is voluntary.

Will you collect my blood and urine again?

Our study currently allows us to follow you over time. We will ask you to participate in an annual questionnaire and we may ask to collect your blood, urine, and body measurements again.

Are there laboratories that can measure PFAS in my blood?

The NC Department of Health and Human Services maintains a list of clinical laboratories that can test for PFAS. Not all these labs are willing to take individual samples. Additionally, analysis for GenX and some of the newer chemicals (e.g., Nafion byproduct 2) are not included in these panels. We maintain [a list on our website](#) with the current laboratories offering this service.

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 PFAS 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?

This is a prospective study; we plan to follow you over time, at least 5 years and up to 20 years, to learn more about health outcomes potentially related to PFAS exposure. 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.

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.

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 perfluorinated 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 or other PFAS 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.