Effects of exposure to per- and polyfluoroalkyl substances (PFAS) on innate and adaptive immune responses to tetanus-diphtheria (Td) vaccination among adults in a community-based panel study

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RUTGERS
School of Public Health

CONSENT TO TAKE PART IN RESEARCH

Title of Research: Effects of exposure to per- and polyfluoroalkyl substances (PFAS) on innate and adaptive immune responses to tetanus-diphtheria (Td) vaccination among adults in a community-based panel study
Principal Investigator: Robert Laumbach, MD, MPH, CIH, DABT

RESEARCH SUMMARY: This consent form is part of an informed consent process for research study, and it will provide information that will help you decide whether you want to take part in this research. It is your choice whether to take part or not.

PURPOSE: The purpose of this study is to understand how exposure to a chemical called Perfluorononanoic acid (PFNA) affects the body's response to vaccination to the standard tetanus and diphtheria vaccine. If you take part in the research, you will be asked to receive a tetanus-diphtheria (Td) booster, and have your blood and saliva collected at 7 study visits over a 30-day period. Your time in the research will take 45 minutes for the first study visit and each visit thereafter will be less than 15 minutes in length (2.25 hours total) over the course of 30 days.

RISKS/BENEFITS: Possible harms or burdens of taking part in the study may be pain, redness, or swelling where the vaccine was given, mild fever, headache, feeling tired, and nausea, vomiting, diarrhea, or stomachache sometimes happen after Td vaccination. People sometimes faint after medical procedures, including vaccination. As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death. When your blood is drawn, there may be a bruise, or bleeding, or infection, at the place where your blood is drawn. However, infection is rare. When swabbing the gumline, there may be minor bleeding if done too roughly. Possible benefits of taking part may be that you will be vaccinated against tetanus and diphtheria.

ALTERNATIVES: Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research and what will be asked of you if you choose to take part in it. If you have any questions now or during the research, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this research?
Dr. Robert Laumbach is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team. Dr. Laumbach may be reached at 848-445-6084 or Rutgers-Environmental and Occupational Health Sciences Institute (EOHSI), 170 Frelinghuysen Road, Piscataway, New Jersey 08854.

The Principal Investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Sponsor of the Study: Centers for Disease Control and Prevention (CDC)

Why is this research being done?
The purpose of this study is to understand how exposure to a chemical called Perfluorononanoic acid (PFNA) affects the body's response to vaccination to the standard tetanus and diphtheria vaccine.

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Who may take part in this research and who may not?

- **Inclusion Criteria**
  Adults (18 years of age and older), weigh at least 110 pounds, and who participated in the main study may be eligible to participate in this supplemental study.
- **Exclusion Criteria**
  - Pregnancy
  - Having had a tetanus-diphtheria booster within the past 10 years
  - Having experienced difficult blood draws
  - Prior severe adverse reaction to a vaccination
  - Currently taking medications that suppress the immune system
  - Recent dental surgery or procedure 4 weeks before starting the study and within the 4-week study period.

Why have I been asked to take part in this research?
You are asked to take part in this additional study because you have participated in the PFAS health study. That study was formally known as the "human health effects of drinking water exposures to per- and poly-fluoroalkyl substances (PFAS): A multi-site cross-sectional study."

How long will the research take and how many participants will take part?
The study will take seven study visits over a period of 30 days. The first visit will be 45 minutes and each visit thereafter will be less than 15 minutes in length (2.25 hours total) over the course of 30 days. Additional visits will occur 1, 2, 3, 7, 14, and 30 days after the initial study visit. Up to 20 subjects will participate, and the study will take 1 year to complete.

Visit	Day	Visit	Visit time
1	1	Consent, blood draw, saliva sample, Td booster	45 minutes
2	2	Blood draw, saliva sample	15 minutes
3	3	Blood draw, saliva sample	15 minutes
4	4	Blood draw, saliva sample	15 minutes
5	7	Blood draw, saliva sample	15 minutes
6	14	Blood draw, saliva sample	15 minutes
7	30	Blood draw, saliva sample	15 minutes

What will I be asked to do if I take part in this research?
You will participate in 7 study visits. You will be asked to refrain from eating, drinking (water is okay), and brushing your teeth within one hour before each study visit.

At each study visit:

- You will have a tablespoon (15 mL) of your blood drawn by needle stick.
- You will collect your saliva swabbing your gumline with a small sponge for 1-2 minutes.

In addition, at the first study visit:

- Your height, weight, and temperature will be measured.
- If you are female with the possibility of being pregnant, you will be given a pregnancy test. If the pregnancy test is positive, you cannot participate in the study.
- You will be given a Tetanus-Diphtheria (Td) booster vaccine.
- You will be asked to answer questions about reactions to the vaccine.

What are the risks of harm or discomforts I might experience if I take part in this research?

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- TENIVAC (Tetanus-Diphtheria) Vaccination: Pain, redness, or swelling where the shot was given, mild fever, headache, feeling tired, and nausea, vomiting, diarrhea, or stomachache sometimes happen after Td vaccination. People sometimes faint after medical procedures, including vaccination. As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

- Blood Draw: When your blood is drawn, there may be a bruise, or bleeding, or infection, at the place where your blood is drawn. However, infection is rare.

- Oral Swab: When swabbing the gumline, there may be minor bleeding if done too roughly.

Are there any benefits to me if I choose to take part in this research?
The benefits of taking part in this research are that you will be boosted against Tetanus and Diphtheria, which is a recommended booster for adults every 10 years. However, it is possible that you may not receive any direct benefit from taking part in this research.

What are my alternatives if I do not want to take part in this research?
You have the option to obtain your Tetanus-Diphtheria booster from a provider not associated with the study. You also have the right to not take part in this research.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the research, you will be updated about any new information that may affect whether you are willing to continue taking part in the research. If new information is learned that may affect you after the research or your follow-up is completed, you will be contacted.

Will I receive the results of the research?
No, individual results will not be provided to participants as the research does not involve studying anything of clinical relevance. However, aggregated findings may be disseminated through publications or presentations.

Will there be any cost to me to take part in this study?
There are no costs to you for participating in this research.

Will I be paid to take part in this study?
You will receive $50 at each study visit for a total of up to $350 for completing all 7 study visits.

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. All information about you will be stored in our secure electronic database. Only study investigators will have access to these data. All samples will be coded by a study identification number (study ID). All staff associated with the project will be trained in procedures for maintaining confidentiality. Results of the research may be presented at meetings or in publications, but your name and identity will never be disclosed. Sometimes, however, researchers need to share information that may identify you with people that work for the University, government regulators, or study sponsor.

The research team may use or share your information collected or created for this research with the following people and institutions:
- The Rutgers University Institutional Review Board and Compliance Boards

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- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The Food and Drug Administration

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

What will happen to my information—questionnaire data and test results, and any blood or saliva remaining after the research is over?

After information that could identify you has been removed, de-identified biospecimens collected for this research may be used for other research we conduct without obtaining additional informed consent from you.

What will happen if I am injured during this research?
Participants in this research will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which include those mentioned under risks of harms. In addition, it is possible that during the course of this research, new adverse effects of TENIVAC that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for participants who sustain personal injuries or illnesses as a direct consequence of participation in the research. The participant's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid, or TRICARE/CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University. However, by signing this form, you are not giving up any legal rights to seek further compensation.

What will happen if I do not wish to take part in the research or if I later decide not to stay in the research?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the research at any time. If you do not want to enter the research or decide to stop taking part, your relationship with the research staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. Laumbach, Rutgers-EOHSI, 170 Frelinghuysen Road, Piscataway, NJ 08854. After the study is closed, your data cannot be withdrawn because there may not be any identifiers to link the data with you. We are required by the Food and Drug Administration to continue to report anything that is related to the safety of the drugs used in the research.

Who can I contact if I have questions?
If you have questions, concerns, or complaints about the research, want more information or if you feel you may have suffered a research related injury, you can contact the Principal Investigator

Robert Laumbach, MD, MPH, CIH, DABT
Rutgers – EOHSI
848-445-6084

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research participant, you can contact the Rutgers IRB/Human Research Protection Program via phone at (973) 972-3608 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

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AGREEMENT TO TAKE PART IN RESEARCH

Participant Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this research have been answered. I agree to take part in this research.

Participant Name (Print):_____

Participate Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the research including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____

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