PFAS Clinical Guidance

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NASEM PFAS Medical Guidance on PFAS Testing and Health Outcomes Committee August 12, 2021

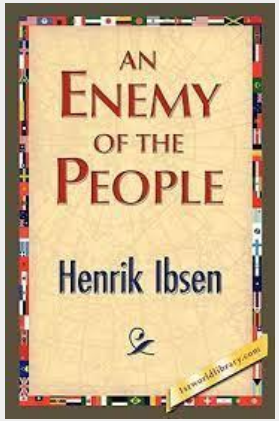
PFAS Project Lab

Social Science Environmental Health Research Institute

Northeastern University & Whitman College

Funding: NIEHS (1R01ES017514-01A1, P42ES027706, 1 R25 GM109447-01, 1 T32 ES023769-01, 1R13 ES028097-01, 1R13ES030609-01), NSF (SES-0924241, SES-1456897)

Medical Guidance Around Both Infectious Diseases and Toxics Has Always Been a Community Concern and Often Fraught with Conflict



bcpp Breast Cancer Prevention Partners
Exposing The Cause Is The Cure

BREAST CANCER ACTION 30 years
RADICAL DISRUPTION.
COMPASSIONATE RESISTANCE.

When you fill out the inclusion table on a grant application, remember it was a result of political struggle

Program Director/Principal Investigator (Last, First, Middle):

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

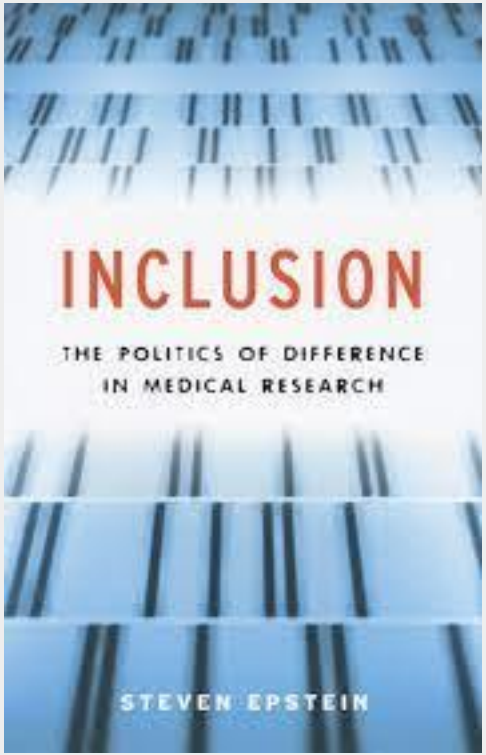
Study Title:
Total Enrollment: **Protocol Number:**
Grant Number:

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race					
Ethnic Category	**Females**	**Males**	**Sex/Gender Unknown or Not Reported**	**Total**	
Hispanic or Latino					**
Not Hispanic or Latino					
Unknown (individuals not reporting ethnicity)					
Ethnic Category: Total of All Subjects*					*
Racial Categories					
American Indian/Alaska Native					
Asian					
Native Hawaiian or Other Pacific Islander					
Black or African American					
White					
More Than One Race					
Unknown or Not Reported					
Racial Categories: Total of All Subjects*					*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)					
Racial Categories	**Females**	**Males**	**Sex/Gender Unknown or Not Reported**	**Total**	
American Indian or Alaska Native					
Asian					
Native Hawaiian or Other Pacific Islander					
Black or African American					
White					
More Than One Race					
Unknown or Not Reported					
Racial Categories: Total of Hispanics or Latinos**					**

*. These totals must agree.
**. These totals must agree.

0925-0001/0002 (Rev. 08/12) Page Inclusion Enrollment Report Format Page



This Committee has Consistently Heard from Speakers and Community Liaisons that Affected Communities Want…

- Blood testing
- Medical monitoring/screening

So that is what our team is doing…

PFAS-REACH

PFAS Research, Education, and Action for Community Health

- Core scientific partners
  - Laurel Schaider, PI, Silent Spring Institute
  - Phil Brown, PI, Northeastern University
  - Courtney Carignan, co-I, Michigan State University
- Core community partners
  - Testing for Pease
  - Community Action Works
  - Massachusetts Breast Cancer Coalition
- Other affiliated researchers
  - Martha Powers, Farzad Noubary, Northeastern University
  - Maia Fitzstevens, Vincent Bessonneau, Ruthann Rudel, Julia Brody, Silent Spring Institute

Science Advisory Board for PFAS-REACH

Name	Affiliation	Expertise
Richard Clapp	Univ. of Massachusetts	Epidemiology
Alissa Cordner	Whitman College	Sociology
Jamie DeWitt	East Carolina University	Toxicology
Alan Ducatman	Formerly West Virginia University	Occupational medicine, Clinician
Edward Emmett	University of Pennsylvania	Occupational medicine, Clinician
Tony Fletcher	London School of Hygiene & Tropical Medicine	Epidemiology
Philippe Grandjean	Harvard University	Environ. medicine

Medical Guidance Documents – Our Team

- Andrea Amico – Testing for Pease
- Phil Brown – Northeastern Univ.
- Alissa Cordner – Whitman College
- Courtney Carignan – Michigan State Univ.
- Jamie DeWitt – East Carolina University
- Alan Ducatman – West Virginia University (retired)
- Edward Emmett – University of Pennsylvania
- Maia Fitzstevens – Silent Spring Institute
- Tony Fletcher – London School of Hygiene & Tropical Medicine
- Elizabeth Friedman – Children's Mercy Hospital, Kansas City
- Alex Goho– Silent Spring Institute
- Philipp Grandjean- Harvard University
- Shaina Kasper – Community Action Works
- Cheryl Osimo – Massachusetts Breast Cancer Coalition
- Martha Powers – Northeastern University
- Laurel Schaider– Silent Spring Institute

Our goal and process

- One year in the making
- Goal: provide community members and clinicians information about the types of tests that would be appropriate to consider for people who've had high PFAS exposures, not necessarily to say that everyone who thinks they've been exposed to PFAS should get all of these tests
- Guidance was inspired by the C8 Medical Monitoring Program and relied heavily on comprehensive documents from federal and international agencies as well as individual peer-reviewed studies
- Input from community partners in PFAS-REACH
- Learning from affected communities around the US and abroad
- Discussions with physicians and scientists on our Science Advisory Board
- Analysis of weaknesses in existing ATSDR medical guidance
- Iterative feedback
- Input from health communication professionals
- Posted to website on July 21, 2021
- Blood testing document in progress - we're working with National PFAS Contamination Coalition members for feedback and their knowledge on the issue

Guidance Documents available at https://pfas-exchange.org/

PFAS-REACH
PFAS Research, Education, and Action for Community Health

PFAS Exposure: Information for patients and guidance for clinicians to inform patient and clinician decision making

For people in PFAS-impacted communities

Purpose

This guidance document is intended for people living in communities with contaminated water or who have had some other source of substantial exposure to PFAS. This guidance document is not targeted to those at average risk from PFAS.

What is medical screening?

Medical screening is the testing for early signs of disease. Screening for certain conditions or subclinical changes may be advised for those who have or have had known elevated exposure to PFAS. Medical screening may identify early indicators of disease and allow you to work with your clinician to determine next steps.

What are PFAS?

Per- and polyfluoroalkyl substances (PFAS) are a large group of over 9,000 human-made chemicals, exposure to which has been associated with several serious health effects. They are extremely resistant to breakdown, highly mobile in the environment, and have contaminated hundreds of drinking water supplies. PFAS have been found in the blood of over 99% of Americans and some PFAS can remain in the body for years.

How can I be exposed to PFAS?

At home

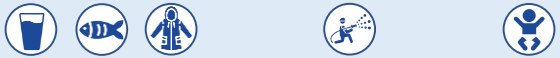
- Drinking contaminated water
- Eating food contaminated from environmental sources or from processing and packaging
- Using stain- and water-resistant products, grease-proof food packaging, nonstick cookware, and many other consumer products

At work

Some people, such as firefighters and those in chemical production and application industries, may be exposed to products containing PFAS at work.

Early in life

PFAS can cross the placenta and accumulate in breast milk, so children can be exposed in the womb and during early life through breastfeeding.



How are PFAS regulated in drinking water?

- PFAS are not regulated under the U.S. Environmental Protection Agency's Safe Drinking Water Act. This means there are no federally enforceable standards and public water suppliers are not required to routinely test or treat for PFAS under federal law.
- In 2016, the U.S. Environmental Protection Agency established a non-enforceable Lifetime Health Advisory of 70 parts per trillion (ppt) for PFOA and PFOS (two of the most common PFAS chemicals) individually or combined, for municipal drinking water. Some scientists and regulators think this advisory is not sufficiently protective of human health.
- As of April 2021, 12 states have adopted more stringent, and in some cases enforceable, drinking water guidelines. The PFAS Exchange provides more information about national and state drinking water guidelines. Some states have established guidelines for additional PFAS chemicals, down to 10–20 ppt.
- The Northeastern University Contamination Site Tracker has documented hundreds of contaminated sites in the U.S., with more sites being added as testing continues.

This fact sheet is a product of the PFAS-REACH (Research, Education, and Action for Community Health) study. PFAS-REACH is funded by the National Institute of Environmental Health Sciences (Grant No. R01ES028311).

July 2021

What are the health effects of PFAS?

Many studies have evaluated harmful health effects of PFOA, PFOS, and a handful of other PFAS chemicals. Several national and international health agencies have reviewed the results of peer-reviewed epidemiological (human populations) and toxicological (laboratory animals) research and written scientific assessments based on these studies, including:

- Agency for Toxic Substances and Disease Registry (2021)
- Centers for Disease Control and Prevention (2019)
- C8 Science and Medical Panels (2005–2013)
- European Environment Agency (2019)
- International Agency for Research on Cancer (2017)
- National Toxicology Program (2016)

A note about these studies

Current strength of evidence ranges from very strong and near certain for lipid, liver, and immune outcomes, to "more likely than not" for others.

At least one of these assessments concluded that PFAS exposure is associated with:

- Increase in total cholesterol and LDL cholesterol
- Decreased antibody response to vaccines
- Longer time to pregnancy
- Kidney and testicular cancer
- Thyroid disease
- Liver damage
- Increased risk of pregnancy-induced hypertension and/or pre-eclampsia
- Chronic kidney disease, elevated uric acid, hyperuricemia, and gout
- Immune system disruption
- Adverse developmental outcomes, including small decrease in infant birth weight and altered mammary gland development

What about COVID-19?

It is currently unknown whether PFAS has any effect on the COVID-19 vaccination. There is no evidence that anyone should not be vaccinated against COVID-19 on the basis of prior PFAS exposure. All groups are strongly advised to follow updated advice from the Centers for Disease Control and Prevention on the COVID-19 vaccination, which is based on the latest research findings.

As the scientific community continues to study the health impacts of PFAS, preliminary and/or suggestive epidemiologic and animal evidence is regularly emerging. Some studies have found associations with:

- Non-alcoholic fatty liver disease
- Autoimmune disease, such as ulcerative colitis and Type 1 diabetes
- Shortened duration of lactation in mothers
- Decreased male fertility

How can I reduce the amount of PFAS in my body?

For people with known elevated PFAS levels in their body, the most important way to reduce the amount of PFAS in the body is to avoid new exposures. Some PFAS chemicals, like PFOS and PFOA, can remain in the body for years. Currently, there are **no medically approved treatments** to speed up removal of PFAS from the body.

- **X** Agents or processes known to remove PFAS from the body, such as cholestyramine, phlebotomy, hemodialysis, or apheresis, are not medically approved treatments for PFAS specifically.
- **X** Chelation and "alternative" medicine programs, such as detoxes and cleanses, are not known to remove PFAS from the body. Many of these can also pose their own health risks.

How can I avoid PFAS exposure?

PFAS exposures are widespread, so it is difficult to avoid PFAS entirely. However, you can take steps to reduce your personal exposure going forward:

- If you know or suspect PFAS to be in your drinking water, you can use a filter to lower the levels. Visit the PFAS Exchange's drinking water fact sheet to learn more about where to find a lab to test your water for PFAS, and resources to find filters for removing PFOA and PFOS in your drinking water.
- Avoid stain-resistant carpets, treatments, and waterproofing sprays. Green Science Policy Institute's PFAS Central maintains a current list of PFAS-free products.
- Avoid take-out containers and other food packaging that may contain PFAS by eating more fresh foods and home-cooked meals.

For more suggestions, visit the PFAS Exchange's exposure reduction tips and download Silent Spring Institute's Detox Me smartphone app.

PFAS-REACH
PFAS Research, Education, and Action for Community Health

PFAS Exposure: Information for patients and guidance for clinicians to inform patient and clinician decision making

For clinicians

About this guidance document

The guidance summarized here is to help inform discussion and decision making for physicians and their patients. Many of the tests and screenings noted are part of basic primary care annual appointments. In 2019, the American Medical Association (AMA) resolved to support research and policy to address the effects of PFAS exposure.

We based the following suggestions for medical screening tests on those previously developed and implemented for a PFAS-impacted community as well as peer-reviewed research and scientific assessments using weight of evidence approaches from:

- Agency for Toxic Substances and Disease Registry (2021)
- Centers for Disease Control and Prevention (2019)
- C8 Science and Medical Panels (2005-2013)
- European Environment Agency (2019)
- International Agency for Research on Cancer (2017)
- National Toxicology Program (2016)

These recommendations are for those living in communities with contaminated water or who are exposed to other sources of PFAS that substantially increases their internal burden of PFAS. These recommendations are not targeted to those with average levels of PFAS exposure.

Guidance for adult patients

Laboratory tests

- **Lipid panel (cholesterol, LDL, HDL, triglycerides).** PFAS exposure has been associated with higher total and LDL cholesterol and fatty liver.
- **Liver function tests**, such as ALT, AST, and GGT. PFAS exposure has been associated with higher-than-normal liver function tests, as well as hepatoxicity, including hepatocyte and liver architecture damage.
- **Serum creatinine and urine protein and urine albumin**. PFAS exposure is associated with chronic kidney disease and kidney cancer. An important note for researchers is that there is enhanced excretion of PFAS in moderate-to severe kidney disease, especially if there is albuminuria. Reduced serum PFAS concentrations for those individuals introduces a bias towards the null if not controlled for in epidemiologic studies.
- **Thyroid tests**, such as TSH with or without FT4. PFAS exposure has been associated with thyroid disease.

Clinical examinations

- **Regular testicular examinations**. Exposure to high levels of PFAS has been associated with increased risk of testicular cancer.

Counseling topics

- **Vaccine response**. PFAS exposure has been associated with decreased antibody response to vaccines. There is currently no consensus on revaccinating patients with low vaccine titer when tested a month following vaccination (i.e., Tdap, MMR); more research is needed.
- **Home blood pressure monitoring during pregnancy**. PFAS are associated with elevated blood pressure during pregnancy and with preeclampsia.
- **Breastfeeding**. Babies can be exposed to PFAS during pregnancy since PFAS can cross the placenta. PFAS chemicals also accumulate in breast milk. However, the benefits of breastfeeding are clear, and include benefits to maternal as well as child health. There is insufficient evidence to recommend against breastfeeding based on maternal PFAS exposure.

Guidance for pediatric patients

Laboratory tests

- **Lipid panel (cholesterol, LDL, HDL, triglycerides)**. PFAS exposure has been associated with higher total and LDL cholesterol and fatty liver.
- **Liver function tests**, such as ALT, AST, and GGT. PFAS exposure has been associated with higher-than-normal liver function tests, as well as other evidence of hepatoxicity, including hepatocyte and liver architecture damage.
- **Thyroid test**, such as TSH with or without FT4. PFAS exposure has been associated with thyroid disease.

Clinical examinations

- **Regular testicular examinations**. Children have a longer duration of exposure and therefore may have greater risk for development of the presumed long-term effects of PFAS exposure, such as testicular cancer.

Counseling topics

- **Vaccine response**. PFAS exposure has been associated with decreased antibody response to vaccines. There is currently no consensus on revaccinating pediatric patients with low vaccine titer when tested a month following vaccination (i.e., DTaP, MMR); more research is needed.
- **Endocrine disruption**. PFAS have been associated with lower levels of sex hormones in young children.

References

Agency for Toxic Substances and Disease Registry (ATSDR). Toxicological Profile for Perfluoroalkyls. U.S. Department of Health and Human Services. 2021. https://www.atsdr.cdc.gov/ToxProfiles/tp200.pdf.

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Acknowledging stress & addressing uncertainty

Uncertainty about long-term health effects can cause stress among patients who have been exposed to PFAS contamination.

Previous studies have shown that providing results of chemical exposure tests, along with contextual information and steps for action, can make people feel empowered.[1]

ATSDR has developed resources for medical professionals to address concerns of residents in communities impacted by contamination: www.atsdr.cdc.gov/stress/resources/clinicians-tip-sheet.html

[1] JG Brody et al. (2006). https://doi.org/10.2105/AJPH.2006.094813

Contributors

PFAS-REACH partners

Silent Spring Institute — Researching the Environment and Women's Health
Michigan State University
Northeastern University — Social Science Environmental Health Research Institute
Testing for PEASE
Community Action Works

Medical partner organization

Children's Mercy Kansas City

Thank you to the researchers, medical professionals, and community members who reviewed this document.

This fact sheet is a product of the PFAS-REACH (Research, Education, and Action for Community Health) study. PFAS-REACH is funded by the National Institute of Environmental Health Sciences (Grant No. R01ES028311).

July 2021

In progress: PFAS Blood Testing

Purpose of this document

If an individual has learned that they have been exposed to high levels of PFAS, they often seek out a PFAS blood test to learn more about their own exposures. This document is intended to provide information about what PFAS blood testing can and can't provide.

What can I learn from a PFAS blood test?

A blood test measures how much of certain PFAS are in a person's blood at the time of the test. This can provide an indication of how much PFAS has entered their body over time (years) and allow comparisons to determine whether levels are elevated. Personal blood test results can also help an individual make more informed decisions with their doctor about reducing their exposures and monitoring their health [Learn more from our resource *PFAS Exposure: Information for patients and guidance for clinicians to inform patient and clinician decision making*].

Residents of communities with known PFAS-contaminated drinking water and/or those with occupational exposures may seek PFAS blood testing; with this information they can document a baseline of exposure, feel empowered to reduce exposure, and compel local and/or state and/or federal action.

PFAS Blood Testing

- What won't a PFAS blood test tell me?
  - Test results cannot provide definitive information about specific health problems that might be related to PFAS exposure.
- How to interpret your PFAS blood test
  - Our tool, *What's My Exposure*, can help you interpret your test results: https://www-pfas.pfas-exchange.org/report/graphtool/
- How do I get a PFAS blood test?
- Limitations

Here's a list of North American labs that offer PFAS blood testing

List in progress

Common PFAS Blood Testing Questions – *in progress*

In progress:

Vaccine Response and PFAS Exposure in Children

- How do I know if my child's vaccinations are still effective given their exposure to PFAS?
- Where do I get an antibody titer test for my child?
- Are antibody titer tests covered by health insurance?
- Is there evidence that PFAS exposure will affect the efficacy of the COVID-19 vaccine?

Will the results tell me if my child should be revaccinated?

Revaccination is a personal discussion you can have with your child's clinician. It's not clear that low levels of antibodies would mean that your child is likely to get sick and it's not clear whether a second vaccination would raise antibody levels. The current standard of care does not call for revaccination based on low titer results.

In addition to monitoring antibody levels, you can talk to your doctor about other medical monitoring options to check for other early markers of disease that could be linked to PFAS exposure

Disseminating the Documents

- PEHSUs
- Activist groups
- Health professional organizations
- PFAS research centers
- State and federal agencies
- National organizations such as AAAS EPI-Center, ECOS, ASTHO, National Governors Association, ITRC
- Presentation at International Society for Exposure Science: "Translating Research to Action with Improved Medical Screening Guidance for PFAS" (August 2021)
- Article in Environmental Health News (next slide)
- We hope this committee will help and that all of you listening today will help as well

- *And doing lots of educational work with health professionals*

Jun 29, 2021

Improved medical screening in PFAS-impacted communities to identify early disease

People highly exposed to PFAS often face significant hurdles in getting screened for potential health effects from the exposure. That needs to change.

Isabella Raponi , Phil Brown and Alissa Cordner

How are our guidance documents being used?

Ayesha Khan and Jaime Honkawa from Nantucket PFAS Action Group set up a presentation to Nantucket Health Dept. and Nantucket Cottage Hospital for September 2021

Letter to PFAS Committee from Community Liaisons

A letter to the ad hoc National Academies Committee on Guidance on PFAS Testing and Health Outcomes from the Community Liaisons

The National Academies of Science, Engineering, and Medicine (the National Academies) appointed the ad hoc committee on Guidance on PFAS Testing and Health Outcomes (the "Committee") as a way for the National Academies to provide an authoritative and objective review of current evidence for human health effects of per- and polyfluoroalkyl substances (PFAS). The review will concern only those PFAS being monitored by the Centers for Disease Control and Prevention (CDC) in their National Report on Human Exposure to Environmental Chemicals and guidance will be provided to the CDC, the Agency for Toxic Substances and Disease Registry (ATSDR), and the National Institute of Environmental Health Sciences (NIEHS). The Committee also will provide recommendations regarding potential changes to CDC/ATSDR PFAS clinical guidance.

As Community Liaisons to this Committee, we represent communities impacted by PFAS contamination, advocate for management, remediation, and/or restriction of PFAS into the environment, study PFAS from a scientific perspective, or have been personally and/or professionally impacted by PFAS exposures. Our goal in writing this letter is to demonstrate our support for this Committee and its charge; as well as, highlight what we believe are critical actions needed for impacted communities which include, but are not limited to, PFAS blood testing and medical monitoring, improved education for healthcare providers, increased focus on environmental justice, extra attention to occupational exposures and vulnerable populations.

We appreciate the time the Committee took to hear our voices. The Town Hall meetings provided an opportunity for Community Liaisons and others to share their PFAS experiences with the Committee--which were often stories of deep trauma and stress, typically exacerbated by lack of access to quality health communications. We thank the Committee for their work and hope this letter affirms what the Committee heard and will use it to inform their review and recommendations. Multiple common themes emerged from these sessions. We see value in elevating them for further consideration.

Letter from others supporting the liaison letter

(Will be submitted shortly)

Dear members of the National Academies of Science, Engineering, and Medicine's PFAS Medical Guidance on PFAS Testing and Health Outcomes Committee:

As members of the larger environmental health and justice community, we are grateful that NASEM has convened this Committee and has had many public sessions featuring leaders from the world of PFAS science and activism. We are pleased to support the letter sent by 40 of the 41 Community Liaisons that you appointed to help shape the Committee's work. The letter points to important concerns that the Committee should address in preparing its final report. In our varied work in environmental health and justice, we understand how important it is that these concerns be highlighted in order to help deal with one of our nation's most significant threats to environmental health.

Funding

NIEHS (1R01ES017514-01A1, P42ES027706, 1 R25 GM109447-01, 1 T32 ES023769-01, 1R13 ES028097-01, 1R13ES030609-01)

NSF (SES-0924241, SES-1456897)

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