CALIFORNIA EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in an experimental procedure. Before you decide whether you want to participate in the experimental procedure, you have a right to:

1. Be informed of the nature and purpose of the experiment;
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
3. Be given a description of any discomforts and risks reasonably to be expected from your participation in the experiment;
4. Be given an explanation of any benefits reasonably to be expected from your participation in the experiment;
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to you, and their relative risks and benefits;
6. Be informed of the avenues of medical treatment, if any, available to you after the experimental procedure if complications arise;
7. Be given an opportunity to ask any questions concerning the medical experiment or the procedures involved;
8. Be instructed that consent to participate in the experimental procedure may be withdrawn at any time and that you may discontinue participation in the medical experiment without prejudice;
9. Be given a copy of this form and the signed and dated written consent form; and
10. Be given the opportunity to decide to consent or not to consent to the medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on your decision.

I have carefully read the information contained above and I understand fully my rights as a potential subject in a medical experiment involving people as subjects.

_____		
SIGNATURE OF PARENT OR LEGALLY AUTHORIZED REPRESENTATIVE	**PRINTED NAME (CHILD)**	**DATE**
_____		
SIGNATURE OF MOTHER OR LEGALLY AUTHORIZED REPRESENTATIVE	**PRINTED NAME (MOTHER)**	**DATE**

INFORMED CONSENT

Study Title
Perfluorinated Alkylate Substances in Human Breastmilk

IRB #
2012809

Principal Investigator
Jason Sauberan, PharmD
Neonatal Research Institute
SHARP Mary Birch Hospital for Women and Newborns
3003 Health Center Drive, San Diego, CA 92123
Emergency Number (24 hours): 858-939-4298

Sponsor
3M Company EpiTox Research Department
3M Center, 220-6W-08
St. Paul, MN 55144

If you are serving as a legally authorized representative, a guardian or are providing parental permission for a child in this study, the terms "you" and "your" refer to the person for whom you are providing consent or parental permission.

PARTICIPATION IN A RESEARCH STUDY

Research is not the same as treatment or medical care. The purpose of a research study is to answer scientific questions.

Your participation is voluntary. You are free to say yes or no, or to drop out after joining. There is no penalty or loss of benefits if you say no. Whatever you decide, you and your family's regular medical care will not change.

It is important that you read this consent form and ask the study doctor any questions you may have. Please take your time to make your choice. Discuss it with your friends and family.

WHY ARE YOU BEING ASKED TO TAKE PART IN THIS STUDY?

Since you are pregnant and expected to deliver your baby at term, we would like to ask your permission for you, and your baby after they are born, to join this research study.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 60 mother-infant pairs will be enrolled in this study at Sharp HealthCare.

HOW LONG WILL YOU BE IN THE STUDY?

You will be in this study from your third trimester until your infant is 12 months of age, approximately 15 months. All study participation events will take place at your routine obstetrician visit, in the hospital when you give birth, and at your infant's routine pediatrician office visits. You will not have to make any extra visits with research staff or with the health care system outside of your routine pregnancy and child-health related encounters to participate in this study.

WHAT IS INVOLVED IN THIS STUDY?

We are asking for your permission to have you and your infant be in a research study so that we can learn new information that may help others.

Chemicals called perfluoroalkyl and polyfluoroalkyl substances (PFAS) are used in many household and industrial products. Some of them can take a long time to breakdown in the environment. People can get exposed to trace levels of PFAS chemicals from the environment. These chemicals can reach the fetus during pregnancy, and can reach the breastmilk after pregnancy.

We are conducting this study to determining what the PFAS levels are that infants are exposed to in our San Diego community.
To do this study, we are asking your permission to provide the researchers with three things:

- Samples of your infant's food source – breastmilk or formula.
- Sample of your home water supply
- Blood samples: one from you during your third trimester, one from the umbilical cord, one from you after birth, and at least two but no more than three from your infant.

Breastmilk samples can be collected in the privacy of your home using hand expression, or a breastmilk pump if you have one, and stored in a milk bottle in your refrigerator. If you need milk bottles, they will be provided to you at no cost. The amount of milk we are asking for is 5 to 10 mL (1 to 2 teaspoons). We are asking for you to collect one milk sample 0 to 2 days prior to each of your infant's routine pediatrician visits. These visits typically start at the first week of age, then again at 1, 2, 4, 6, 9 and 12 months of age. We are asking that you bring your collected milk sample to the pediatrician's office where a researcher will accept it from you.

If at any time you are formula feeding, you will be asked to bring 5 to 10 mL sample of pre-mixed liquid formula. If you are using powder formula, you will be asked to bring a 10 mL water sample from the source used to mix the formula at each routine pediatrician visit.

The volume of blood to be collected is 1 mL from you ($1/5^{th}$ of a teaspoon) and 0.5 mL from your infant ($1/10^{th}$ of a teaspoon). Every attempt will be made to collect blood samples when you or your infant are already having routine blood work ordered by your doctors.

WHAT ARE THE RISKS OF THE STUDY?

Donating breastmilk for this study risks not having enough milk for your infant to feed. If you or your infant's pediatrician believes you are not producing enough milk at any given visit to have enough extra to give to the study, then milk will not be collected at that study visit.

Temporary discomfort or mild pain are risks from blood collection. Pain can be increased if puncturing previously traumatized skin. Rare complications include swelling and infection.

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

This study is not being done to determine if your child has a health risk from PFAS exposure. There will be no direct benefits to your child. We hope the information we learn will help doctors determine if the amount of PFAS in infants in our community is a health concern or not.

WHAT OTHER OPTIONS ARE THERE?

You do not have to join this study. You are free to say yes or no. Your regular medical care will not change if you say no.

WILL YOU OR YOUR CHILD BE PAID TO BE IN THIS STUDY?

You will be paid a one-time $50 USD in cash upon study enrollment to be in this study, and $20 USD cash for each visit where blood (yours or your infant's) is sampled outside of routine bloodwork ordered by your or your infant's doctor. These payments are meant to compensate you for your time.

It is possible that you could lose wages during the time if you or your child is hospitalized for some unforeseen complication from blood collection. No additional compensation is available in these cases.

WHAT ARE THE COSTS?

There are no extra costs for being in this study.

You and/or your health plan/insurance company will need to pay for all of the other costs of treating your pregnancy and your infant's care while in this study. You will be responsible for co-pays and deductibles in the same way as outside of a study.

RESEARCH-RELATED INJURY

There are no funds to pay you for loss of work or other costs, lost time or pain to you or your family. If your child gets sick or hurt in this study, please tell your study doctor. Your child will be treated or referred for medical treatment. In the event that you suffer a research-related injury, your medical expenses will be your responsibility or that of your insurance provider.

Sharp HealthCare will not provide any compensation for treatment of research related injury or illness. You or your insurer will be billed for any additional costs. The study staff can provide more information.

PAYMENT TO STUDY SITE

The sponsor will reimburse the study site for time, effort, and oversight by the study doctors and staff to perform procedures and tasks, and to accurately collect and submit study data.

NEW INFORMATION

During the study, we may learn new information you need to know. For example, some information may affect your child's health or well-being. If we learn these kinds of information, we will tell you.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Organizations or individuals that may inspect and/or copy your medical and/or research records for quality assurance and data analysis include groups such as:

- Study Doctor and Research Staff
- Sharp HealthCare Institutional Review Board (IRB, a group of people who review the research to protect your rights)
- The sponsor of this study and its staff, representatives, and business collaborators

If the results of this study are published or presented at meetings, your identity will remain confidential.

Your information will be coded and stored anonymously in a database with information about other people in this study. Access to this database will be very limited.

As part of this research study you will be asked to sign an additional document, Authorization to use Protected Health Information (PHI). This authorization will explain in further detail how your Protected Health Information (PHI) will be used and shared in the study, who will have access to it, what information will be obtained, and how long Sharp HealthCare will use your information. It will also explain what to do if you decide you no longer want to share your PHI, and your rights regarding your ability to see and copy your research information.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

Participating in this study is entirely voluntary. There is no penalty for not participating or leaving the study after your child has decided to participate. Your child may stop at any time (even before he/she starts). There is no penalty for stopping or loss of benefits to which you are otherwise entitled. Your and your infant's regular medical care will not change.

If your infant gets sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.

If you decide to remove your infant from the study, it is important that you notify the study investigator. They will tell you if there are any potential risks of leaving.

WHAT WILL HAPPEN TO THE SAMPLES YOU AND YOUR CHILD GIVE?

Milk and blood samples collected during this study will be kept for up to 6 months before they are subjected to testing. Any leftover milk or blood will be kept for up to 10 years.

Milk and blood samples collected for this study will be de-identified and stored in a secure location. They will be used for research only. This research may be done by for profit companies. All the testing done on milk and blood samples for this study will be performed for PFAS related research purposes only. Samples will not be subjected to genetic testing. It is possible that the Sponsoring Company may work with third parties including other companies and with other research institutions to conduct the testing and research.

Researchers will not report their results to your obstetrician or to your child's pediatrician. The research results will not appear in your or your child's medical record. The research results will not be used to make decisions about your child's present or future medical care.

You may withdraw your consent to the use of your or your infant's donated sample(s) at any time by contacting the Study Investigator in writing. If you withdraw your consent to the use of the samples and the samples can be identified and have not been analysed yet, the study doctor or the Sponsoring Company will arrange to have them destroyed. If the samples have already been tested and have been used, the test results cannot be withdrawn.

WHOM DO YOU CALL IF YOU HAVE ANY PROBLEMS, COMPLAINTS, CONCERNS, OR QUESTIONS?

If you have problems, complaints, concerns, or questions about this study, you may talk to your study doctors anytime.

If you have questions about:	**Call:**
This study (including complaints and requests for information)	858-939-7424 Jason Sauberan, PharmD 858-939-6307 Neonatal Research Institute
If you get sick or hurt in this study	858-939-4170 Dr. Anup Katheria
Your rights as a research participant and: • Discuss problems, concerns, and questions • Obtain information	Sharp HealthCare Institutional Review Board 7930 Frost Street, Suite 300 San Diego, CA 92123 (858) 939-7161

Emergency number (24 hours):
858-939-4298 (Sharp Mary Birch Neonatal ICU. Have Dr. Katheria paged)

OPTIONAL: WE WOULD LIKE YOU TO DONATE LEFTOVER MILK OR BLOOD SAMPLES FOR FUTURE RESEARCH

After we do tests on your milk and on you and your child's blood in this study, some may be left over. We would like you to donate this leftover milk or blood for PFAS-related research at the Sponsor Company. This will *not* include genetic research. Leftover milk or blood will remain de-identified and will not be shared with other scientists for research outside the Sponsor Company.

You do not have to donate your left-over milk or you and your child's leftover blood for research. You are free to say yes or no. Your participation in the main study will not change if you say no. Your regular medical care will not change if you say no.

If in the future we want to use your milk or you and your child's leftover blood for research other than PFAS-related research, an ethics review committee or institutional review board (IRB) will review the request. The IRB will decide if we need to ask for your consent to do the research.

All collected milk and blood will be stored in a secure location. It will be used for research only. This research may be done by for profit companies. Researchers will not report their results to you or your study doctor or to your child's personal doctor. The research results will not appear in you or your child's medical record. The research results will not be used to make decisions about you or your child's present or future medical care.

If you donate your milk and you and your child's blood for future PFAS-related research, you can change your mind anytime. Just call the Study Investigators and tell us you do not want us to use you and your child's leftover blood for research. There is no penalty for changing your mind. Your child's regular medical care will not change. Your child's participation in the main study will not change. However, we cannot return any leftover blood. It will be destroyed by the Sponsoring Company.

Read each question and think about your choice. Please circle **YES** or **NO**.

Do you agree to donate your leftover milk and you and your child's leftover blood sample to the Sponsor to perform future PFAS-related research related research? (circle one) **YES** **NO** Initials: Date:

SIGNATURE

Your signature below indicates that you have read the above information. You agree to take part in the study until you decide otherwise.

You are not waiving your legal rights by signing this consent form.

You will receive a signed copy of this consent form and your study doctor will retain a copy in his or her files.

_____

SIGNATURE OF PRINCIPAL INVESTIGATOR/DESIGNEE **PRINTED NAME** **DATE**

CHILD PARTICIPANT:

_____

SIGNATURE OF PARENT OR LEGALLY AUTHORIZED REPRESENTATIVE **PRINTED NAME (CHILD)** **DATE**

_____

AUTHORITY OF PARTICIPANT'S LEGALLY AUTHORIZED REPRESENTATIVE OR RELATIONSHIP TO PARTICIPANT

MOTHER PARTICIPANT:

_____

SIGNATURE OF MOTHER OR LEGALLY AUTHORIZED REPRESENTATIVE **PRINTED NAME (MOTHER)** **DATE**

_____

AUTHORITY OF PARTICIPANT'S LEGALLY AUTHORIZED REPRESENTATIVE OR RELATIONSHIP TO PARTICIPANT

---------- **USE THE FOLLOWING ONLY IF APPLICABLE** ----------

If this consent form is read to the participant because the participant is unable to read the form, an impartial witness not affiliated with the research or study doctor must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the participant. The participant freely consented to be in the research study.

_____
PRINTED NAME OF IMPARTIAL WITNESS

_____ _____
SIGNATURE OF IMPARTIAL WITNESS **DATE** **TIME**

NOTE: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling participants who do not speak English.

Authorization to Use your Protected Health Information (PHI)

Study Title: Perfluorinated Alkylate Substances in Human Breastmilk

Investigator: Jason Sauberan, PharmD
Neonatal Research Institute
Sharp Mary Birch Hospital for Women and Newborns

Sponsor: 3M Company
3M Center, 220-6W-08
St. Paul, MN 55144

Protected Health Information, or PHI, is any personal health information through which you can be identified. We are asking for your permission to use your and your child's PHI in this research study. The specific information that will be used will be your and your child's name and date of birth, your medical record number, and your child's hospitalization account number.

The following people will access and use your and your child's PHI for the purpose of this research:

- Jason Sauberan, Primary Investigator
- Dr. Anup Katheria, Sub-Investigator, SHARP Neonatal Research Institute
- Dr. Yousuke Horikawa, Sub-Investigator, SHARP Rees Stealy Pediatrics
- SHARP Neonatal Research Institute research associates

Who else may see your and your child's PHI?

- the Sharp HealthCare Institutional Review Board
- the Sponsor, 3M Company

How long will the Neonatal Research Institute use your information, and what will it be used for?

- Your and your child's date of birth, your medical record number, and your infant's hospitalization account number will be used on a Master Log that will list who is enrolled in the study. You and your infant will be assigned a unique study number on the Master Log. Your study numbers will then be used on all study data collection forms and sample containers so that only your delivery date can be identified from the date of cord blood sampling by anyone reviewing the data collection forms or containers. No other data that identifies you or your infant will be collected on the forms.
- Your information will be used to collect data to conduct this research.
- This permission to access your and your child's PHI expires 21 years from the date of your signature. Research reports can be used forever.
- The Master Log containing your and your infant's PHI will be kept in a secure location in the research office with restricted access, or in a secure medical records storage facility on Sharp property, for 21 years from the date of the last participants enrolled. It will not be disclosed to anyone other than those people previously mentioned who will access and use your and your child's PHI for the purpose of this research.
- After disclosure by the research staff, your and your child's information leaves the control of Sharp HealthCare. That means that your and your child's Protected Health Information may be shared with other entities and may no longer be protected by the privacy laws and regulations that protect such information normally.

What if you change your mind and want to withdraw your authorization for the use and disclosure of your and your child's PHI for this study?

You must write to the study investigator and tell him that you no longer want to share your information at: Jason Sauberan, PharmD. Neonatal Research Institute, SHARP Mary Birch Hospital for Women and Newborns, 3003 Health Center Drive, San Diego, CA 92123.

- You and your infant will no longer be a part of the research study.

- The research team can continue to use any of the PHI that they already have already collected.
- You will still get the same medical care that you have always had from the SHARP Mary Birch Hospital for Women and Newborns and Sharp Rees Stealy Medical Group.

Do you have the right to see and receive a copy of your and your child's research information? Yes, after the study is completed.

Authorization:
If you agree to share your and your child's PHI, you must sign this form below. If you do not sign this form, you will not be able to participate in the research study. You will be given a copy of this form.

CHILD PARTICIPANT:

_____

SIGNATURE OF PARENT OR LEGALLY AUTHORIZED REPRESENTATIVE **PRINTED NAME (CHILD)** **DATE**

_____

AUTHORITY OF PARTICIPANT'S LEGALLY AUTHORIZED REPRESENTATIVE OR RELATIONSHIP TO PARTICIPANT

MOTHER PARTICIPANT:

_____

SIGNATURE OF MOTHER OR LEGALLY AUTHORIZED REPRESENTATIVE **PRINTED NAME (MOTHER)** **DATE**

_____

AUTHORITY OF PARTICIPANT'S LEGALLY AUTHORIZED REPRESENTATIVE OR RELATIONSHIP TO PARTICIPANT

Expiration Date: 21 years from date of signature