

INFORMED CONSENT DOCUMENT

Project Title: Disaster Response Research Project

Principal Investigator: Peter Thorne, PhD

Research Team Contact: Nancy Wyland (319) 335-4756

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| <ul style="list-style-type: none">• If you are the parent/guardian of a child under 18 years old who is being invited to be in this study, the word “you” in this document refers to your child. You will be asked to read and sign this document to give permission for your child to participate. |
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This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You may discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because your home or business is located in the vicinity of a recent environmental or natural disaster.

The purpose of this research study is to learn more about hazardous exposures during and following an environmental or natural disaster and how they may affect the health and wellbeing of people living and working in the vicinity of direct or indirect exposure.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 300 people will take part in this study conducted by investigators at the University of Iowa.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for two years. Over the course of the year, a research team member will visit your home or business up to four times to take air, surface, or water samples. At these visits you will also be asked to complete a questionnaire. Each visit will take approximately 45 minutes.

WHAT WILL HAPPEN DURING THIS STUDY?

We will visit you in your home or business and take a look at the damaged areas. Investigators will take samples from surfaces in your home by wiping a pad over objects in your home, or samples of the air or water in your home or business, as well as samples in and around the location to test them for the presence of chemical or microbial toxins. Over the course of two years, a research team member will visit up to four times to take samples. You will be told the results of the sampling. You will be given a listing of resources that can provide disaster-specific remediation services to damaged buildings.

At some of these visits, you will be asked to complete a questionnaire. This questionnaire will ask about your birth date, where you live, how long you have lived there, what type of home or business it is, how long you are inside each day, and what indoor activities you take part in. In addition, you will be asked to provide information about your health before and after this disaster and whether you have noticed significant changes since the disaster occurred in your home, business or neighborhood. You may skip any question you prefer not to answer.

STUDY PROCEDURES

If you agree to be in the study, we will ask you to provide biological sample(s) and/or complete a lung function test, called spirometry. You may be asked to complete one, all, or just some of these study procedures, but you may choose to opt-out of any procedure(s) requested for this study. We believe analysis of your blood, urine, DNA and/or lung function may provide information on the types and levels of exposures to chemical or microbial toxins you may have experienced during the disaster.

List of Study Procedures

Procedure	Frequency
☐ Blood sample collection	3 times
☐ Buccal (cheek) cell collection	3 times
☐ Urine sample collection	3 times
☐ Spirometry	3 times

Blood sample collection (venipuncture)

You will be asked to provide a sample of blood. The blood will be taken with a needle and from your arm. This will take about 5 minutes. The blood will be analyzed for markers of inflammation, allergy or signs of environmental exposures.

Buccal (cheek) cell collection

Buccal cells are the cells from the inner lining of the mouth or cheek. These cells are routinely shed and replaced by new cells. As old cells die, they accumulate in the saliva in the mouth and are easily collected by a simple procedure at home. Buccal cells contain genetic material similar to what is found in blood, but is more easily collected by study participants at home. We are asking you to brush the inside of your cheek so that we can collect cells from the cheek lining. We will get DNA from these cells so that we can study genes. We will give you 3 special brushes. We ask that you use these to brush the inside of your cheeks. Instructions are included with the brushes. It will take about 10

minutes. These cells will be analyzed for expression of genes that are associated with inflammation or other signs of environmental exposure.

Urine sample collection

You may be asked to provide a urine sample in a sterile container. The urine sample can also provide us information about your environmental exposures

Spirometry

You may be asked to take a lung function test, called spirometry. A portable spirometer will be used. You will be seated during the test and asked to wear a disposable nose clip and to breathe out forcefully into a machine. The machine measures how much air you blow out and how fast it comes out. This test tells us how well your lungs are working. If you have asthma, your asthma must be within a certain range to qualify for this testing procedure. To the extent possible, you will be asked to not use your asthma inhaler on the day of the examination. If you take asthma medication(s), the timing and dosage will be recorded for several days preceding the test.

Cheek swab/Data Storage for Future Use

As part of this study, we are obtaining a cheek cell sample from you. We would like to study your cheek cell sample and data in the future, after this study is over.

The tests we might want to use to study your cheek cell sample and data may not even exist at this time. Therefore, we are asking for your permission to store your cheek cell sample and data so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding the effects of disasters, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your cheek cell sample and data might be used to develop products or tests that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.

If you agree now to future use of your cheek cell sample and data, but decide in the future that you would like to have it removed from future research, you should contact: Peter Thorne, PhD, (319) 335-4223. However, if some research with your cheek cell sample and data has already been completed, the information from that research may still be used.

Please place your initials in the blank next to Yes or No for the question below:

My cheek cell sample may be stored/shared for future gene studies in environmental health research.

_____ **Yes** _____ **No**

I would like to receive the results of my genetic test.

_____ **Yes** _____ **No**

In the event that you choose to receive your results and require additional genetic counseling, you will

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be referred to the medical genetics clinic at University of Iowa Hospitals and Clinics for further interpretation of your results. No compensation is available for genetic counseling from the University of Iowa and you would be responsible for the cost of this clinic visit.

Genetic Research

One purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for the body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

You are being asked to give a sample of cells from the inside of your cheek for genetic research. What we learn about you from this sample will not be put in your health record. Your test results will not be shared with your doctor. No one else (like a relative, boss, or insurance company) will be given your test results.

A single cheek swab sample will be obtained by having you brush the inside of your cheek so that we can collect cells from the cheek lining. This will take about 10 minutes of your time.

Genetic Information Nondiscrimination Act (GINA)

A new federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and employers of 15 or more persons to discriminate against you based on your genetic information. Based on this new law, health insurance companies and group health plans are prohibited from requesting your genetic information that we get from this research. This means that they may not use your genetic information when making decisions regarding your eligibility for insurance coverage or the amount of your insurance premiums. Be aware that this new federal law will not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. The law also does not prohibit discrimination if you already have a manifest genetic disease or disorder.

Photographs

One aspect of this study involves making a photograph of your home, business or neighborhood and any damage induced by the disaster. These photographs will be made for training and publication purposes and will not include your address or business name. Only the research team will have access to the original photographs; some prints may be used in study publications and those would then be accessible to the general public, we will have you sign a separate release for the use of your photos for this non-research use.

Photographs are optional; you may refuse to have your home or business photographed and still participate in the study.

☐ Yes ☐ No I give you permission to make photographs of my home or business during this study.

We will keep your name and contact information on file so that we may contact you in the future about

additional studies we may conduct. Agreeing to participate in this study in no way requires you to participate in future studies. If you are contacted for future studies you will be asked to sign a separate Informed Consent Document specific to that study. All biological samples and data collected for this study will be kept indefinitely; however, information identifying research participants will be destroyed fifteen years after the end of the study.

WHAT ARE THE RISKS OF THIS STUDY?

You will be asked to complete four questionnaires. Some of the questions ask personal information. You may be uncomfortable discussing this with the researchers. The questionnaires ask about smoking and the use of tobacco. You may choose to skip any questions you would prefer not to answer. The questionnaires also ask about the extent of damage to your home or business, and you may disclose information that could affect its perceived or actual value. There are no physical risks to you from participating in this study. The information collected for this research study will be kept confidential to the full extent permitted by law.

Blood sample collection

The risks of taking blood include pain, bleeding, a bruise at the point where the blood is taken, redness and swelling of the vein and infection, and a rare risk of fainting.

Buccal (cheek) cell collection

The risks of taking buccal cells from inside the cheek are very low with few side effects. You may experience mild local trauma at the collection site.

Although no specific genetics research is planned under this protocol, if DNA is isolated from these samples by future researchers for genetic analyses, the risks associated with genetics research may apply. This includes breach of confidentiality of test results that could result in impacts on employability, insurability, discrimination, or psychosocial risks to the participant or participant's family.

Urine sample collection

There are no risks for the process of urine sample collection.

Spirometry

Spirometry is a very low-risk procedure with few side effects. Participants may experience transient coughing, lightheadedness, dizziness, fainting, and chest tightness. These symptoms usually resolve after the test is complete.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may not benefit from being in this study. A benefit means that something good happens to you. We think that a potential benefit might be learning whether the disaster that occurred in your neighborhood might make you sick. We also hope to learn more about the impact of environmental disasters and how to best address them through this study.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for participating in this study. You will receive a gift card valued at \$25 upon completion of all testing and the final questionnaire.

WHO IS FUNDING THIS STUDY?

The National Institute for Environmental Health Sciences (NIEHS) is funding this research study. This means that the University of Iowa is receiving payments from the NIEHS to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- No compensation for treatment of research-related illness or injury is available from the University of Iowa unless it is proven to be the direct result of negligence by a University employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that institutional authorities such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. These authorities include: Federal government regulatory agencies, Auditing departments of the University of Iowa, and The University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will keep all information that we acquire from you strictly confidential. All data collected from you will be labeled with an identification code and not your name. The list linking your name and your unique identification code will be stored in a secure location that is accessible only to the researchers on this project. All data will be kept in locked file cabinets and storage areas, and all electronic data will be kept on a secure, password and firewall protected computer system at the University of Iowa. Access to study files will be limited only to research team members.

If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be identified.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to participate. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

WHAT WILL HAPPEN TO MY BIOLOGICAL SAMPLES AND DATA LONG-TERM

All samples and data will be retained indefinitely. However, information identifying research participants will be destroyed fifteen years after the end of the study. Samples or data will only be destroyed before then at your written request. You may decide at any point up until the time we remove your identity from the data and samples to not have your specimens or data stored. In this case, you must provide a written request to do so, including a description of which samples or data should be destroyed. Once the written request is received, the PI will have the requested samples/data destroyed and report what was done to both you and to the IRB. This decision will not affect your participation in this protocol or any other future research protocols through the University of Iowa.

What if I Decide to Drop Out of the Study?

If you decide to leave the study early, we will ask you to contact Peter S. Thorne, PhD, (319) 335-4216, peter-thorne@uiowa.edu

Will I Receive New Information About the Study while Participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can Someone Else End my Participation in this Study?

Under certain circumstances, the researchers might decide to end your participation in this research study earlier than planned. This might happen if your home or business is determined to be unsafe for the research team; you have chosen to not allow sampling in and/or outside your home or business or tamper with the sampling process, or because funding for the research study has ended.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Peter Thorne, PhD, (319) 335-4223, peter-thorne@uiowa.edu. If you experience a research-related injury, please contact: Peter Thorne, PhD, (319) 335-4223, peter-thorne@uiowa.edu

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 240 College of Medicine Administration

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Building, The University of Iowa, Iowa City, Iowa, 52242 (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, <http://research.uiowa.edu/hso>. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

Do not sign this form if today's date is on or after \$STAMP_EXP_DT.

(Signature of Subject)

(Date)

Parent/Guardian's Name and Relationship to Subject:

(Name - printed)

(Relationship to Subject - printed)

Do not sign this form if today's date is on or after \$STAMP_EXP_DT.

(Signature of Parent/Guardian)

(Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally

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authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

(Signature of Person who Obtained Consent)

(Date)