Informed Consent Form

Study: UTMB Rapid Acquisition of Pre- and Post-Incident Disaster Data Protocol (UT-RAPIDD)

Principal Investigator: Sharon Croisant, MS, PhD

Study Number: IRB Application #16-0118

Introduction:

You are being invited to take part in a research study conducted by the University of Texas Medical Branch (UTMB). Taking part in a research study is completely voluntary. You may choose not to take part, or you may withdraw from the study at any time. There will be no penalty for choosing not to participate. Before agreeing to take part in this research study, it is important that you read this consent form. Please ask the study staff to explain any sections you do not understand. Ask any questions you have, and make sure you understand the answers to your questions before signing. When you have finished reading and all of your questions have been fully answered, please sign and date the last page of this form if you agree to participate in the study. You will receive a copy of this form.

What is the purpose of this study?

The purpose of this study is to answer questions about the health effects of disaster exposures. The goal of the study is to create a registry of participants, collect biological samples and gather health data. The information collected will be made available in the future to researchers who will use this information to research potential short- and long-term health effects related to exposures to disasters such as *[DISASTER NAME]*.

Who can participate in this study?

You are eligible to participate in this study if you:

- Are at least 18 years of age
- Reside in or are deployed to a disaster area to conduct emergency response activities
- Do not have any conditions that, in the opinion of the Investigator, would pose an unacceptable risk to the participant or to the validity of the study results

What will I be asked to do in this study?

If you agree to be in the study, we will ask you to complete all of the items listed below. We hope that you will complete all of the items, but you may choose to opt out of any procedure(s).
[*WE WILL INSERT A LIST OF PROCEDURES IDENTIFIED IN APPENDIX B BASED ON THE SPECIFIC DISASTER. Example text provided below*]

Complete a questionnaire

- We will ask you for your contact information and ask questions about your health, lifestyle, emotions, medical history, activities related to disaster response, and things you are exposed to in the environment.

Provide samples from the list below

- Blood Draw – a trained medical examiner will collect about 7 tablespoons of blood from a vein in your arm.
- Urine
- Saliva
- Cheek cells
- Hair
- Nail clippings

Have a brief physical exam

- A medical examiner or trained research professional may measure your height, weight, heart rate, and blood pressure. We may also measure your hip and waist circumference over your clothes and the amount of oxygen in your blood by placing a sensor on your fingertip or earlobe.
- You may also be asked to complete a lung function test. This will require you to take a deep breath and exhale forcefully to measure the amount and/or speed of air that you inhale and exhale.

Agree to be contacted at a later date

- Occasionally, we may send you a form to update your contact information. We will ask you to complete and return the form, even if there are no changes.
- If there are more detailed health studies in the future, you will be given information about these studies at a later date. You can decide whether or not you want to take part at that time. Taking part in future follow-up studies is entirely voluntary.

How long will the study procedures take?

In total, the visit today will last approximately [##] minutes.

Will participating in this study impact my ability to serve as a responder to this disaster?

No, information collected in this study will not be used to determine your ability to serve in your intended role as a responder to this disaster. Information obtained from your questionnaires and physical examination will not be shared with your employer for any purpose unless you choose to share it.

Will I be given my study results?

The information we collect from this study and the registry examination is not a substitute for an exam conducted by a doctor. You may receive individual test results for blood pressure, heart rate, blood oxygen level, and lung function test measurements (if collected). You can share your results with a doctor or other healthcare provider. We will let you know if there are any urgent concerns that need immediate medical care from a doctor. If you do

not have a primary care provider or cannot afford to pay for care, you will be given a list of local clinics that provide care for services based on a sliding scale.

It may be years before your samples are tested. You will not receive any results from the future analysis of your samples unless we discover an abnormal finding.

Will my results be shared with my employer?

No, we will not collect information about your employer. We will not share your results with your employer or health insurance company.

How will my privacy be protected?

We will make every effort to protect your privacy and keep your data confidential. We will not use your name in any reports or presentations. A law called The Federal Privacy Act protects your information. Only members of the research study team will know your name. We will label your samples, questionnaires, forms, and other information with a special code number instead of your name. We will store your contact information separately. We will keep everything in locked rooms or cabinets or on secure, password-protected computer networks. Only authorized staff will see your private information. Your study information will not be released without your written permission except as necessary for the UTMB Research Services Human Research Protection Program and monitoring by representatives from UTMB who are bound by an agreement and the law to maintain your privacy and confidentiality.

How will my samples and questionnaire data be used?

We will freeze your samples and store them in secure freezers using a study ID number. At a later date, researchers may test your samples for a range of chemicals, hormones, or other biological changes. The exact number and specific types of tests that will be done on your samples is not yet known. Tests may include measurements of lipid levels, proteins, metals, dietary factors, chemical toxins, and measures of infection and inflammation. We will save DNA samples and store it securely for future studies. Analyses of samples and information you provide may be done at UTMB, the National Institutes of Health, or by other research collaborators, contractors or other institutions. Many of the research tests will not be done on everyone in the study. We will not test for illegal drugs.

What are the possible risks and discomforts?

This study involves minimal risk.

The questionnaires used in this study are widely used in research studies. The questions may cause discomfort by triggering emotions, stress, or other reactions about sensitive health topics or personal experiences. If you feel uncomfortable, you may skip any questions or end the questionnaire at any time.

The blood draw may involve a small risk of discomfort, bleeding or bruising, vein irritation, or infection, and a possibility of lightheadedness or fainting. If you experience any of these symptoms or any other symptoms at the site of a blood draw, please contact the study

coordinator at 409-772-9136.

The lung function test is a low-risk procedure with few side effects. You may experience coughing, lightheadedness, dizziness, fainting, or chest tightness. These symptoms usually resolve after the test is complete. You will complete this test in a seated position with a trained study examiner to minimize the risk of symptoms.

There is some risk of a breach of confidentiality as a result of unintentional disclosure of information collected. We will do everything we can to protect your privacy. All records will be kept confidential to prevent this from happening, and all research documents will be coded with a unique participant identification number and will not include any information that could be used to identify you personally. Steps taken to protect your privacy are described in more detail above.

What are the possible benefits?

You may help your community or others by participating in a research study that may add value to future public health disaster response. You may also benefit from receiving the results of your registry examination which you can share with your doctor or healthcare provider. However, you will not receive medical care or any direct benefit for participating in this research study.

Will it cost me anything to participate?

There are no costs to you other than your time for participation.

Will I be paid for participating?

For your time and effort, you will be reimbursed depending on the number and type of samples collected. Compensation will be $30 for survey completion, $30 for the blood draw, $10 for the urine sample, $10 for the sample of saliva, buccal cells, or hair, $10 for spirometry, and $10 for providing nail clippings. Payment will be provided by gift card upon completion of each visit.

How long will my participation last?

Since this study may be used to determine the long-term health effects associated with exposure(s) to disasters, the study could last longer than 10 years. Over time, we may contact you occasionally and ask you to update or confirm your contact information. Also during this time, you may be contacted by other researchers and asked to join a follow-up study. We hope that you will continue, but you may quit the study at any time.

Will I have to participate in future studies?

No. Future studies are separate from the UT-RAPIDD study. Participation is voluntary. If you are asked to participate in a follow-up study and voluntarily agree to do so, you will be asked at that time to review and sign a new consent form specific to that study.

What if I want to stop participating in this study?

You may withdraw from the study at any time. Your decision will not affect any medical care or benefits you might be entitled to. You may choose to have your samples destroyed or kept by UTMB for research purposes only. If you provide the study team with a written request, your samples will be destroyed. If you choose not to have your samples destroyed, researchers will have access to your samples, but not your name or contact information.

Do I have an alternative to participating?

The alternative to participating in this study is to not participate.

What will happen if I am injured in this study?

UTMB will provide short-term medical care for any injury resulting from your participation in this research study. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the University of Texas Medical Branch. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

What about conflict of interest?

The University of Texas Medical Branch reviews researchers at least yearly for conflicts of interest.

Who should I contact if I have problems or questions?

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Dr. Sharon Croisant, at (409) 772-9133, or Program Director Amber Anthony, at 409-772-9136.

If you have any complaints, concerns, input or questions regarding your rights as a subject participating in this research study or you would like more information, you may contact the Institutional Review Board, at (409) 266-9475

COMPLETE APPROPRIATE ITEM(S) BELOW:

A. Adult Patient's Consent

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions, and my questions have been answered. I have read this consent form and agree to be in this study. I understand that participating in this study is voluntary and I may withdraw at any time. I hereby consent to take part in this study.

_____ _____

Signature of Participant Date

_____

Print Name

_____ _____

Signature of Person Obtaining Consent Date

_____

Print Name

_____ _____

Signature of PI Sharon Croisant Date

THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM _____ to _____.