

Disaster Response

PI: Peter Thorne

IRB ID #: 201602753

Form Content

I. Project Introduction

- I.1** ***Project to be reviewed by:***
IRB-01
- I.2** ***Project Title:***
Disaster Response Research Protocol
- I.3** ***Short Title (optional):***
Disaster Response
- I.4** ***Provide a short summary of the purpose and procedures of the study proposed in this IRB application.***
- ***DO NOT include information on studies not proposed in this application.***
 - ***Use LAY terminology only. This must be easily understandable by IRB community members and nonscientists.***
 - ***DO NOT cut and paste technical abstracts from funding applications that may not be understood by a general audience.***

Following recent natural and man-made disasters, the importance of incorporating health-related scientific investigations into disaster responses has become widely recognized. The far reaching environmental health impacts of Hurricane Katrina in 2005, the Deepwater Horizon (DWH) oil spill in 2010 and the 2011 Tohoku earthquake in Japan, with its subsequent tsunami and nuclear reactor incident, all underscore the need for research to illuminate the short and long-term impacts of disaster. In a call to action published in the New England Journal of Medicine in 2013, the Assistant Secretary of Preparedness and Response (ASPR) and the heads of NIH and CDC wrote that "the knowledge that is generated through well-designed, effectively executed research in anticipation of, in the midst of, and after an emergency is critical to our future capacity to better achieve the overarching goals of preparedness and response." Yet, barriers to conducting timely research remain. The difficulty of obtaining IRB approvals in a timely manner can be insurmountable, resulting in missed scientific opportunities. These delays in research are harmful not only because they hold up the discovery of new findings but because they result in the loss of perishable data that is difficult to reconstruct months or years after the event.

This application is designed to establish an umbrella approval for rapid response research in the event of an environmental disaster, such as a flood, fire, or chemical spill. Such events generate exposures within communities that can be detrimental to human health, and as a consequence, provide unique, time-sensitive opportunities for learning about how these exposures might affect the people living in their vicinity. The Environmental Health Sciences Research Center at the University of Iowa has identified disaster response as one of its goals. This center is primarily focused on air and water quality and environmental exposures affecting human health. Because of this focus, we have tailored an IRB approval, questionnaires and consent documents in a generic fashion to address environmental exposure research. In the event of an environmental disaster, such as the Iowa Flood of 2008 or the Iowa City Landfill fire of 2013 or a train derailment like that of 2014, we would submit a modification to this umbrella approval in the form of an abstract detailing the environmental event, the toxins to be studied, and a specific research plan.

This application proposes, that in the event of an environmental disaster, we would collect health and home survey information and biological samples (urine, blood, buccal cells and/or spirometry tests) from residents, workers, or business owners located in the vicinity of the disaster.

- I.5** *Specify your research question(s), study aims or hypotheses (do not indicate "see protocol")*
The purpose of this study is to learn more about hazardous exposures during an environmental or natural disaster and how they may affect people living in the vicinity of direct or indirect exposure.
- I.6** *Background and significance and/or Preliminary studies related to this project. (do not indicate "see protocol")*
The Environmental Health Sciences Research Center conducted a research project following the Iowa Flood of 2008. The documents and protocols in this umbrella application are modeled after that research study. The study sought to determine the types of environmental contaminants present in a flood-damaged area of Cedar Rapids, and whether they produced adverse health effects in its population over time.
- I.7** *Literature cited / references (if attaching a grant or protocol enter N/A).*
Hoppe KA, Metwali N, Perry SS, Hart T, Kostle PA, Thorne PS. Assessment of airborne exposures and health in flooded homes undergoing renovation. Indoor Air 22(6):446-56, 2012.

Lurie N, Manolio T, Patterson AP, Collins F, Frieden T. Research as a part of public health emergency response. N Engl J Med 28:368(13):1251-5, 2013.

II. Research Team

II.2 Team Members UI Team Members

Name	E-mail	College	Contact	Key Prsn	UI COI	VAMC COI	Consent Process Involvement	Deactivated
Peter Thorne, MS, PHD	peter-thorne@uiowa.edu	College of Public Health	Yes	Yes	No		Yes	No
Andrea Dodd, PHD	andrea-a-dodd@uiowa.edu	College of Public Health	No	No	No		No	No
Hans-Joachim Lehmler, PHD	hans-joachim-lehmler@uiowa.edu	College of Public Health	No	Yes	No		No	No
Nervana Metwali, PHD	nervana-metwali@uiowa.edu	College of Public Health	No	No	No		No	No
Edith Parker, PHD	edith-parker@uiowa.edu	College of Public Health	No	Yes	No		Yes	No
Nancy Wyland, BA, MFA	nancy-wyland@uiowa.edu	College of Public Health	Yes	Yes	No		Yes	No

Non-UI Team Members

Name	Institution	Location	FWA	Role	DHHS	Contact	Key Prsn	UI COI	VAMC COI	Consent Process Involvement	Email
Nothing found to display.											

II.3 ***The Principal Investigator of this study is:***
Faculty

II.6 ***Identify the key personnel. The system will automatically designate the PI and all faculty members on the project as “key personnel.” For information about other team members who should be designated as “key personnel” please click on the help information.***

Name	Is Key Personnel
Peter Thorne, MS, PHD	Yes
Andrea Dodd, PHD	No
Hans-Joachim Lehmler, PHD	Yes
Nervana Metwali, PHD	No
Edith Parker, PHD	Yes
Nancy Wyland, BA, MFA	Yes

III. Funding/Other Support

III.1 ***Funding Sources***

Type	Source	Grant Title	Name of PI on Grant	Status	Status Description
	US Department of Health & Federal Agency Human Services, National Institutes of Health	Environmental Health Sciences Research Center	Thorne, Peter	Awarded	

* new source name

III.2 ***Which office will process the agreement for this project***
Sponsored Programs - Federal/State/Local Agency Funded

III.3 ***Does any member of the research team have a financial conflict of interest related to this project according to the [Conflict of Interest in Research](#) policy? If yes, please indicate which members below.***

Name	Has Conflict of Interest
Peter Thorne, MS, PHD	No
Andrea Dodd, PHD	No
Hans-Joachim Lehmler, PHD	No
Nervana Metwali, PHD	No
Edith Parker, PHD	No
Nancy Wyland, BA, MFA	No

III.5 ***What is the current status of this funding source?***

Source	Status	Other Status Description
US Department of Health & Human Services, National Institutes of Health	Awarded	

IV. Project Type

IV.1 ***Do you want the IRB to give this project***
Regular (expedited or full board) review

IV.2 ***Enter the date you will be ready to begin screening subjects/collecting data for this project.***
12/01/2015

- IV.3 Are you requesting a [waiver of informed consent/authorization](#) (subjects will not be given any oral or written information about the study)?
No

V. Other Committee Review

- V.1 Does this project involve any substance ingested, injected, or applied to the body?
• Do not answer yes, if the involvement includes a device, wire, or instrument
No
- V.2 Are any contrast agents used for any purpose in this study?
No
- V.9 Will any subject be asked to undergo a diagnostic radiation procedure (including radiographic, nuclear medicine, DEXA)?
No
- V.14 Will any subject be asked to undergo a radiation therapy procedure (including external beam therapy, brachytherapy, or nuclear medicine therapy)?
No
- V.20 Does this project involve the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participant?
No
- V.21 Will any portion of this project be conducted in the CRU, or does it use any CRU resources?
No
- V.22 Will this project use any resource/patients of the HCCC?
No
- V.23 Will any part of this project be conducted on VAMC premises?
No
- V.24 Does this project involve VAMC patients or records?
No
- V.25.a Will the study involve any of the following activity at UI Health Care, even if subjects or their insurance will not be billed for the item or service, and regardless of the study funding source (including studies with departmental or no funding)?
• Procedures, tests, examinations, hospitalizations, use of Pathology services, use of clinic facilities or clinical equipment, or any patient care services, including services conducted in the Clinical Research Unit; or
• Physician services or services provided by non-physicians who are credentialed to bill (ARNPs, Physician Assistants, etc.)
No
- V.26 The study involves nursing, nursing resources or evaluates nursing practices.
No

VI. Subjects

- VI.1** *How many adult subjects do you expect to consent or enroll for this project?*
200
- VI.2** *What is the age of the youngest adult subject?*
18.0
- VI.3** *What is the age of the oldest adult subject?*
100.0
- VI.4** *What is the percentage of adult male subjects?*
50
- VI.5** *What is the percentage of adult female subjects?*
50
- VI.6** *How many minor subjects do you expect to consent or enroll for this project?*
100
- VI.7** *What is the age of the youngest minor subject?*
0.0
- VI.8** *What is the age of the oldest minor subject?*
17.0
- VI.9** *What is the percentage of minor male subjects?*
50
- VI.10** *What is the percentage of minor female subjects?*
50
- VI.11** *Will any of the minors enrolled be in foster care or Wards of the court?*
No
- VI.13** *Describe EACH of your subject populations*
- *Include description of any control group(s)*
 - *Specify the Inclusion/Exclusion criteria for EACH group*
 - *Studies under IRB-03 enrolling non veterans as part of the subject population must present a compelling argument to the IRB for the inclusion of non-Veterans (e.g., insufficient number of Veterans; survey of VA employees; study of active duty military; study involving Veterans' family members), and the research is relevant to the care of Veterans or active duty military personnel.*
- Human subjects for study will be family members who have lived in a home in the vicinity of the environmental or natural disaster prior to, during, and following the occurrence of the disaster.
- VI.14** *Provide an estimate of the total number of subjects that would be eligible for inclusion in each of your study populations (include your control population if applicable)*
Depending on the nature of the disaster, as well as the size and breadth of affected community(ies) the number of people eligible for inclusion could be in the thousands. The extent of our ability to launch a research project at the advent of a disaster situation will depend on our available capacity at that time, in terms of human and financial resources, as well as the timeliness of our capacity to respond.
- VI.15** *Describe how you will have access to each of your study populations in sufficient number to meet your recruitment goals.*

With assistance from the county health department, we will be able to identify homes in the vicinity of the disaster and recruit a sufficient number of study homes by conducting pre-screenings and in-home assessments.

VI.16 ***Do you plan to recruit/enroll non-English speaking people?***

No

VI.18 ***Do you propose to enroll any of the following in this study as subjects?***

- *Employee of the PI or employee of a research team member*
- *Individual supervised by PI or supervised by member of research team*
- *Individual subordinate to the PI or subordinate to any member of the research team*
- *Student or trainee under the direction of the PI or under the direction of a member of the research team*

No

VI.20 ***Will subjects provide any information about their relatives?***

Yes

VI.21 ***Describe in detail how this information will be obtained. NOTE: The collection of identified data about family members makes the family member a subject in the study. This would require a consent process with the family member or a request for waiver of consent to collect these data. See the Research Guide for more information.***

Yes. Parents will be asked to provide information about their young children.

VI.22 ***List the data to be collected about subject relatives including the names of any surveys, questionnaires etc. to be used. Attach data collection tools under the Relative/Proxy Data Collection Instruments category.***

Information will be collected on people living in the home. This will include the following surveys/questionnaires:

- 1) Disaster Response Home Inspection Checklist
- 2) Disaster Response Research Project Questionnaire Part 1
- 3) Disaster Response Research Project Questionnaire Part 2

VI.23 ***Will anyone (other than the subject) provide you with information about the subject (e.g. proxy interviews)?***

Yes

VI.24 ***Describe in detail how this information will be obtained.***

Yes, parents for very young children will complete the Disaster Response Research Project Questionnaire, Parts 1 and 2 on behalf of their children.

VI.25 ***List the data to be collected from proxy individuals including the names of any surveys, questionnaires etc. to be used. Attach data collection tools under the Relative/Proxy Data Collection Instruments category.***

Disaster Response Research Project Questionnaire Part 1
Disaster Response Research Project Questionnaire Part 2

VI.26 ***Is this project about pregnant women?***

No

VI.27 ***Will this project involve fetuses?***

No

VI.28 ***Does this project involve adult subjects who may be incompetent or have limited decision-making capacity on initial enrollment into the study?***

No

VI.32 *Does this project involve subjects whose capacity to consent may change over the course of the study?*
No

VI.37 *Does this project involve prisoners as subjects?*
No

VII.A. Project Description (A)

VII.A.1 *Where will project procedures take place (check all that apply)?*

- Other UI campus site - 176 IREH
- U.S. off-campus - Off-campus locations will be identified through an IRB modification at the time the disaster occurs.

VII.A.2 *Is this project also being conducted by other researchers at their own sites (e.g. a multi-site collaborative project)?*
No

VII.B. Project Description (B)

- VII.B.1 *Does this project involve any of the following (Check all that apply):*
- ☐ **Registry** – The collection and maintenance of data (not including biologic samples) in which: (1) the individuals in the registry have a common or related condition(s), and/or (2) the individuals in the registry are interested in being contacted for future studies by investigators other than those listed in Section II of this project. ([UI Guide](#))
 - ☒ **Repository** – The collection, storage, and distribution of human biologic samples and/or data materials for research purposes. Repository activities involve three components: (i) the collection of data and/or specimens such as blood, tissue, saliva, etc.; (ii) the storage of data or specimens, and data management function; and (iii) the sharing of data/specimens with recipient investigators other than the original investigators. (paraphrased from [OHRP](#))
 - ☐ **Expanded Access** – A process regulated by the Food and Drug Administration (FDA) that allows manufacturers to provide investigational new drugs to patients with serious diseases or conditions who cannot participate in a clinical trial. Examples of expanded access include non-protocol access to experimental treatments, including protocol exception, single-patient IND, treatment IND, compassionate use, emergency use, continued access to investigational drug, and parallel track ([ClinicalTrials.gov](#) & [FDA](#)).
 - ☐ **Clinical (or Treatment) trial** – A prospective biomedical or behavioral research study of new treatments, new drug or combinations of drugs, new devices, or new approaches to surgery or radiation therapy. (NIH and [ClinicalTrials.gov](#) & [FDA](#))
 - ☐ **Physiology intervention/study** – A pharmacologic or measurement study aimed at understanding basic mechanisms of disease and/or of normal human physiology, often without any therapeutic intent (though a clinical trial could include such components, often labeled as “translational” or “basic science” aims.) Measurements in such studies could include, but are not limited to, a blood draw, EKG, EEG, MRI, auditory or sensory testing, checking vital signs, DEXA scans, eye tracking, specimen collection, exercise, fasting, special diets, etc.
 - ☒ **Behavioral intervention/study** – May be used to refer to studies of individual or group behavior. This option does not include drugs, biologics, or devices but could include psychotherapy, lifestyle counseling, behavior modification, etc.
 - ☐ **Diagnostic trial** – Protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition ([ClinicalTrials.gov](#) & [FDA](#))
 - ☐ **Other**

VII.B.2 *Does this project involve a [drug washout](#) (asking subject to stop taking any drugs s/he is currently taking)?*

No

VII.B.11 *Is there a separate, written protocol that will be submitted in addition to this IRB New Project form? (Note: a grant application is not considered to be a protocol)*

No

VII.B.18 *Does this project involve testing the safety and/or efficacy of a medical device?*

No

VII.C. Project Description (C)

VII.C.1 *Does this project involve any [research on genes or genetic testing/research](#)?*

Yes

VII.C.2 *What information will be obtained from the DNA samples?*

If we observe differential responses to environmental exposures associated with the disaster we may identify gene-environment interactions predisposing to these adverse effects.

VII.C.3 *What data will be stored with the DNA samples? (e.g., identifiers, code numbers linked to identifiers, diagnoses, other clinical information, etc.)*

The samples will bear a code that will allow the IRB-named investigators to link genetic data to exposures and health outcomes.

VII.C.4 *Will subjects be able to request at a later time that samples be destroyed?*

Yes

VII.C.5 *Where will the DNA and any associated information be stored?*

The DNA samples will be stored in a locked cabinet in a locked laboratory storage room in Dr. Thorne's laboratory. The data will be stored electronically on the secure side of the College of Public Health server.

VII.C.6 *Describe the mechanisms for maintaining confidentiality at the storage location.*

DNA samples will have a code number and the document linking that code to subject data will only be available to the IRB-named investigators.

VII.C.7 *Could the DNA and/or associated information be shared in the future with other researchers?*

Yes

VII.C.8 *Describe the procedure for sharing:*

If shared, the code linking these samples to subject data would not be shared.

VII.C.9 *Will the subjects have the option of receiving any DNA testing results?*

Yes

VII.C.10 *Describe the availability of genetic counseling if necessary:*

The research team will offer translation of DNA testing results to participants. In the event that a participant requires additional genetic counseling, they will be referred to the medical genetics clinic at University of Iowa Hospitals and Clinics for further interpretation. No compensation is available for genetic counseling from the University of Iowa.

VII.C.11 *Is the laboratory that will be performing the DNA testing CLIA certified?*

Yes

VII.C.12 Will the DNA samples be destroyed at the conclusion of the study?

Yes

VII.D. Project Description (D)**VII.D.1 Check all materials/methods that will be used in recruiting subjects (you will need to attach copies of all materials at the end of the application):**

- Other - Recruitment/enrollment of research participants during and immediately following a disaster is particularly challenging. Depending on the nature of the disaster, there are multiple approaches to recruitment/enrollment. Initially, we will work with the county health department(s) to identify individuals living in the affected area(s). We will contact individuals by telephone, by going door to door to homes in the affected area, or by visiting shelters established for displaced persons

VII.D.8 Will a member of the research team discuss the study with the subject in person prior to the subject agreeing to participate?

Yes

VII.D.9 Describe the physical location where the consent process will take place:

In the subject's home if intact, or in a shelter providing services.

VII.D.10 Will a member of the research team discuss the study with the subject by phone prior to the subject agreeing to participate?

Yes

VII.D.11 Describe:

The subject will be contacted by phone if the subject can be reached by phone; otherwise, subjects will be contacted in person. Because of the time-sensitive nature of this research, individuals living within the vicinity of the disaster will be asked at that time about their interest in participating. If they are not interested, there will be no further contact. If they indicate interest, the purposes of the study and what would be required of them will be explained over the telephone, and an in-person meeting in the individual's home will be scheduled.

VII.D.12 Who will be involved in the [consent process](#) (including review of consent document, answering subjects' questions)?

Name	Consent Process Involvement
Peter Thorne, MS, PHD	Yes
Andrea Dodd, PHD	No
Hans-Joachim Lehmler, PHD	No
Nervana Metwali, PHD	No
Edith Parker, PHD	Yes
Nancy Wyland, BA, MFA	Yes

VII.D.15 Check all materials that will be used to obtain/document informed consent:

- Consent Document
- Assent Document

VII.D.16 Are you requesting a [waiver of documentation](#) of consent (either no subject signature or no written document)?

No

VII.D.19 Before the subject gives consent to participate are there any screening questions that you need to directly ask the potential subject to determine eligibility for the study?

No

VII.D.25 ***After the subject agrees to participate (signs consent), are there any screening procedures, tests, or studies that need to be done to determine if the subject is eligible to continue participating?***

Yes

VII.D.26 ***List and describe screening***

Subjects will be asked, "Have you or your family experienced loss of property, health, or life by this disaster?" We will enroll both those who answer "yes" and some who answer "no."

VII.D.27 ***Discuss how much time a potential subject will have to agree to consider participation and whether or not they will be able to discuss the study with family/friends before deciding on participation.***

The potential participant will have as long as he/she needs to determine whether he/she wishes to participate. The participant may choose to sign the consent form at first contact or choose to think about or discuss participation with friends/family. If he/she would prefer to think about participation, we will ask if we may call them back at a later time to determine if he/she wishes to participate.

VII.D.28 ***How long after the subject agrees to participate do study procedures begin?***

Immediately or shortly after agreeing to participate.

VII.D.29 ***Provide a description of the enrollment and consent process for adult subjects***

- *Describe each study population separately including control population*
- *Include when recruitment and consent materials are used*
- *Use 3rd person active voice "The Principal Investigator will identify subjects. For example, the principal investigator will identify potential subjects, the study coordinator will discuss the study with subjects over the telephone and schedule the first study visit, etc..."*
- *Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process*

There are two mechanisms envisioned for recruitment. First, households will be randomly selected from county health department records for residents living in the vicinity of the environmental disaster and will be contacted by phone or in person by research team members. If the disaster has displaced residents from their homes, recruitment will occur at disaster relief centers by inviting all comers to participate.

Research team members will meet in person with potential participants to further describe the project, go through the Informed Consent and/or Assent documents and ask if the participant has any questions about the project. Adult participants will provide informed consent for themselves. Once all questions are answered, the research team member will have the participant sign and date the consent document. A copy of the consent and assent materials will be provided to all participants.

Participants will be offered a list of resources that can provide disaster-specific remediation services to damaged buildings.

Potential subjects who elect not to participate will not be contacted further.

VII.D.30 ***Describe how you will obtain the consent of the parents or legal guardians for child/minor subjects in this study***

- *Describe each study population separately including control population*
- *Include when recruitment and consent materials are used*
- *Use FIRST person, and provide detail as to order of events*
- *Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process*

Households will be randomly selected from county health department records for residents living in the vicinity of the environmental disaster and will be contacted by phone or in person by research team members. If the disaster has displaced residents from their homes, recruitment will occur at disaster relief centers by inviting all comers to participate.

Research team members will meet in person with potential participants to further describe the project, go through

the Informed Consent and/or Assent documents and ask if the participant has any questions about the project. Adult participants will provide informed consent for themselves. Parents will also consent for all children aged 0-17. Children aged 7-12 will be asked to sign an assent document. Teenagers over the age of 17 will be asked to read the consent document and sign it along with their parents. Once all questions are answered, the research team member will have the participant sign and date the consent document. A copy of the consent and assent materials will be provided to all participants.

Potential subjects who elect not to participate will not be contacted further.

- VII.D.31** *What are the plans for the assent process for children/minors in this study? (You may choose more than one procedure if you have different child populations in your study)*
- Children/minors will sign an assent or consent document -

- VII.D.36** *Provide a detailed description and rationale for each of the procedures chosen above and describe the child/minor populations to which they apply in your study.*
- Because there is the possibility that children/minors will be asked to provide biological samples, children aged 7-12 will be asked to sign an assent document indicating their willingness to do so. Children under the age of 7 will be enrolled if their parents sign a consent form on their behalf, as they are unlikely to understand research concepts. Teenagers over the age of 17 are generally expected to have the ability to consent of their own volition.

- VII.D.37** *Does the study include any form of deception (e.g., providing participants with false information, misleading information, or withholding information about certain study procedures)?*

Examples:

- *Procedure includes a cover story that provides a plausible but inaccurate account of the purposes of the research.*
- *Participants will be provided with false information regarding the particular behaviors of interest in the research.*
- *Procedures include a confederate pretending to be another participant in the study.*
- *Participants will be told that the research includes completion of a particular task, when in fact, that task will not be administered.*
- *Study is designed to introduce a new procedure (or task) that participants are not initially told about.*
- *If yes, a waiver of informed consent must be requested under question IV.3.*

No

VII.E. Project Description (E)

- VII.E.1** *Will subjects be randomized?*

No

- VII.E.3** *Will any questionnaires, surveys, or written assessments be used to obtain data directly from subjects in this study?*

Yes

- VII.E.4** *List all questionnaires, surveys, written assessments and ATTACH each one to the application. (NOTE: You are NOT prohibited from attaching copyrighted materials to this application)*

Disaster Response Home Inspection Checklist

Disaster Response Research Project Questionnaire Part 1

Disaster Response Research Project Questionnaire Part 2

- VII.E.5** *Does this project involve creating any audiotapes, videotapes, or photographs?*

Yes

VII.E.6 *Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.*

Describe study populations separately if they will be participating in different procedures - include CONTROL population if applicable.

DESCRIBE:

- *What subjects will be asked to do/what happens in the study (in sequential order)*
- *The time period over which procedures will occur*
- *The time commitment for the subject for individual visits/procedures*
- *Long-term followup and how it occurs*

Study investigators will visit the resident's home or business and review the damaged areas. Investigators will take surface samples or samples of the air or water in the 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 additional samples. Participants will be told the results of the sampling.

At these visits, participants will be asked to complete a questionnaire. This questionnaire will ask about the participant's birth date, residence, how long they have lived there, what type of residence or business it is, how long they are inside each day, and what indoor activities they take part in. In addition, participants will be asked to provide information about their health status before and after the environmental disaster and whether they have noticed significant changes since the environmental disaster occurred in the home, business or neighborhood. They will also be asked about their occupancy of emergency shelters or disaster housing. They may skip any question they prefer not to answer. Administration of the questionnaire(s) will take approximately 45 minutes.

At the first visit, participants will be asked to complete a home inspection checklist. The checklist will gather information about various rooms in the home, including the type of flooring, heating, cooking facilities, exhaust, etc.

Participants will be asked to provide biological sample(s) and/or complete a lung function test, called spirometry.

They may be asked to complete one, all, or a subset of these study procedures, and may choose to opt-out of any procedure(s) requested for this study. Biological sampling procedures (blood draw, buccal cell collection, urine specimen collection) will take approximately 2 minutes each. Spirometry will require 15 minutes. Biological sampling will occur up to 3 times.

Participants will be told the results of the air, water, and biological procedures via a detailed letter sent via email or mailed (if preferred).

VII.E.7 *Will you attempt to recontact subjects who are lost to follow-up?*

No - those lost to followup will not be recontacted

VII.E.9 *Will subjects be provided any compensation for participating in this study?*

Yes

VII.E.10 *Cash*
No

VII.E.11 *Gift Card*
Yes

VII.E.12 *Check*
No

VII.E.16 *Other*
No

VII.E.18 *If you plan to compensate subjects using cash, checks or cash equivalent does your unit have a [Cash Handling Procedure](#) in place that has been approved by Accounting Services?*
Yes

VII.E.19 *Describe the compensation plan including*

- *Compensation amount and type per visit*
- *Total compensation*
- *Pro-rating for early withdrawal from study*

Subjects will receive a gift card valued at \$25.00 upon completion of study testing and final questionnaire(s).

VIII. Risks

VIII.1 *What are the risks to subjects including*
- *emotional or psychological*
- *financial*
- *legal or social*
- *physical?*

Participants will be asked to complete a questionnaire and a home inspection checklist. Some of the questions ask personal information and participants may be uncomfortable discussing this with the researchers. For example, the questionnaire asks about smoking and the use of tobacco. The checklist also asks about the extent of damage to the participant's home or business, and information disclosed for the study could affect its perceived or actual value.

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.

The risks of taking buccal cells from inside the cheek are very low with few side effects. Participants may experience mild local trauma or infection 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 or epigenetic 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.

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

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.

VIII.2 *What have you done to minimize the risks?*

- *If applicable to this study ALSO include:*
 - *How you (members of your research team at Iowa) will monitor the safety of individual subjects.*
 - *Include a description of the availability of medical or psychological resources that subjects might require as a consequence of participating in this research and how referral will occur if necessary (e.g. availability of emergency medical care, psychological counseling, etc.)*

All data collected will be labeled with a participant ID code rather than names. The list connecting the participant ID code/bar code to participant information will be kept in a secure location separate from data.

Data will be stored on a secure, password and firewall protected computer system; hard-copy materials will be stored in locked file cabinets in a locked office. Access to study files will be limited only to research team members. Participants will always be referred to using ID numbers rather than names when research team

members communicate with each other.

All biological sampling and testing will be conducted by research personnel trained in the procedure(s).

In the event that a participant is injured or becomes ill from taking part in this study, medical treatment at the University of Iowa Hospitals and Clinics will be offered. However, no compensation for treatment of research-related illness or injury will be made available from the University of Iowa unless it is proven to be the direct result of negligence by a University employee.

VIII.3 *Does this study have a plan to have an individual or committee review combined data from all subjects on a periodic basis (such as summary or aggregate safety and/or efficacy data)?*

No

IX. Benefits

IX.1 *What are the direct benefits to the subject (do not include compensation or hypothesized results)?*

Participants will not directly benefit from being in this study beyond learning the type(s) and levels of chemical and microbial exposures they may have experienced during the disaster and their potential health impacts.

IX.2 *What are the potential benefits to society in terms of knowledge to be gained as a result of this project?*

In the future, other people might benefit from this study because this study may lead to improvements and safeguards in responses to disasters where there is the potential for exposure to microbial and chemical toxins.

X. Privacy & Confidentiality

X.1 *What are you doing to protect the [privacy](#) interests of the subjects?*

The minimum information required to accomplish the goals of this research project will be requested from study participants. If a participant declines to share information required for the purposes of the study, that person and his/her family will be necessarily disqualified from the study. Interviews will be conducted in the homes of research subjects or at sites offering disaster relief services.

X.2 *Are you collecting the Social Security Number of any subjects for any purpose?*

No

X.4 *How will information/data be collected and stored for this study (check all that apply):*

- Paper/hard copy records (hard copy surveys, questionnaires, case report forms, pictures, etc.) - Paper/hard copy records (hard copy surveys, pictures, report forms) will be transported by latched briefcase by interviewer, into a locked file cabinet in a locked office, where they will be stored.
- Electronic records (computer files, electronic databases, etc.) - Electronic files will be stored in a computer and are password protected and backed up on the University of Iowa, College of Public Health's main server. The computer is password protected and remains in a locked office. The data are located on a secure file server located in a dedicated locked server room. The data are backed up every business night and protected through access controls, IP security policies, and hardware firewall.
 - Name - Tim Marek
 - Title - IT Support Specialist
 - University Job Classification - Faculty/Staff
- Biologic samples (blood draws, cheek swabs, saliva samples, tissue samples, etc.) - Biological samples will be stored in a secured laboratory. Most samples will be stored in -80 degree Celsius freezers in a locked biorepository. Samples will have bar code labels with sample ID numbers only.
 - Name - Peter Thorne
 - Title - Professor
 - University Job Classification - Faculty/Staff

- X.5 ***Do the confidentiality protections indicated above allow only members of the research team to access the data/specimens?***
Yes
- X.7 ***Are you seeking a [Certificate of Confidentiality](#) from NIH for this study?***
No

XI. Data Analysis

- XI.1 ***Describe the analysis methods you will use, including, if applicable, the variables you will analyze***
The study includes descriptive data (regarding characteristics of the disaster, disaster information dissemination and availability of relief services. Quantitative data on exposures and health outcomes will be analyzed using appropriate statistical methods, including primarily summary statistics, bivariate comparisons, linear regression models, and logistic regression models.
- XI.2 ***Provide the rationale or power analysis to support the number of subjects proposed to complete this study.***
The number of subjects are based on our prior disaster research and feasibility.

XII. Future Research

- XII.1 ***Do you wish to keep any information about subjects involved with this research project so that members of the current research team may contact them in the future for your own research projects?***
Yes
- XII.2 ***Do you wish to keep any information about subjects involved with this research project so that [other researchers](#) may contact them for future research?***
No
- XII.3 ***List the data or information you will keep:***
We will keep all surveys, analyzed data and biological samples collected from the study.
- XII.4 ***Does this project involve storing any data, tissues or specimens for future research?***
Yes – contribution for future use is optional
- XII.5 ***Describe how you will keep track of those who consent to future use and those who do not and how you will prevent future use for those who do not consent.***
Participants may be contacted in the future about additional studies. Participation in this study does not obligate them to participate in future studies. If we contact participants in this study for future studies a separate Informed Consent Document process specific to that study will be conducted. 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.

New Project Form Attachments

Attachment Name	Category	Ver	Size	Attached
Informed consent Disaster Response-2-1.rtf	Informed Consent	5	190 k E	03/30/16
Child assent document Disaster Response.rtf	Assent	1	53 k E	03/14/16
EHSRC FINAL SUBMISSION.pdf	Funding Source Grant	1	8 M E	12/18/15
Disaster Response Health Questionnaire Part1.rtf	Subject Data Collection	1	276 k E	12/18/15

	Instruments		
Disaster_Response_Health_Questionnaire_Part2.rtf	Subject Data Collection Instruments	1 644 k E	12/18/15
Disaster_Response_Home_Inspection.rtf	Subject Data Collection Instruments	1 299 k E	12/18/15
Disaster_Response_Protocol_Amendment_Checklist.rtf	Miscellaneous	1 62 k E	03/14/16
Assurance_Document.pdf	Assurance Document	1 89 k E	12/18/15
Cash_Handling_approval.pdf	Cash Handling Approval	1 187 k E	01/29/16