PROTOCOL TITLE:

Texas A&M University Rapid Acquisition of Pre- and Post-Incident Disaster Data Protocol

SHORT TITLE:

TAMU-RAPIDD Protocol

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Based upon the RAPIDD Protocol Adopted by the National Institute of Environmental Health Sciences (NIEHS) and the University of Texas Medical Brach Rapid Acquisition of Pre- and Post-Incident Disaster Data Protocol

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1.0 Purpose of the Study

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 through either direct or indirect exposure. The survey is designed to gather information about the mental and physical health of community members affected by the disaster, to identify ongoing needs resulting from the disaster, and to understand how response and recovery activities can be improved for future disasters.

1.1 Primary Objective

1. To establish a human subjects research protocol as the basis for future research response during or in the immediate aftermath of a natural or manmade disaster

1.2 Secondary Objectives

1. In the event of a disaster, procedures and methods outlined in this parent protocol will be used to:
    a. Gather resident's sociodemographic, health status, exposure, and lifestyle information before or immediately after exposure to a disaster;
    b. Establish baseline data that can be used to identify potential associations between disaster exposures and health outcomes.

2.0 Background Information and Scientific Rationale

Barriers to conducting disaster research during an active event must be addressed to accomplish the goals of preventing and reducing injury, illness, disability, death, and damage, while also bolstering the effectiveness and efficiency of recovery efforts and improving our understanding of the health effects associated with different types of disasters. Delays in the conduct of research after disasters can be 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. An important issue commonly encountered in optimizing disaster planning and response is how to collect credible baseline information in a consistent and timely manner. Scientific investigations during a disaster response can either seek to provide shorter-term findings to guide decision making during the response phase or to provide the foundation for studying longer-term exposures and potential health effects (National Science Board, 2011).

Although advances have been made in the area of disaster research over time, there is still a need for better designed and more effectively executed research strategies that can address the challenges of conducting disaster-related research (Lurie et al., 2013), particularly during the early stages of an event. Several key areas have been identified by the National Institute of Environmetnal Health Sciences (NIEHS) as part of the Disaster Research Reponse (DR2) Program that can be addressed in order to achieve more timely research responses to natural and man-made disasters (Instutute of Medicine, 2014). These include access to funding, an expedited institutional review board (IRB) process, scientific review and Office of Management and Budget (OMB) approval processes, methodology standardization, development of pre-approved protocols that can be implemented

immediately, and having operations and supplies in place to initiate the rapid collection of baseline information. The TAMU-RAPIDD Protocol has been developed using these DR2 guidelines to address many of these issues and to demonstrate the feasibility of reliable and valid rapid collection of time-critical samples and data during a disaster scenario.

3.0 Inclusion and Exclusion Criteria

The sample size will depend on the prevalence of exposures and outcomes of interest for the disaster under study. We will use sample size estimates for a range of exposure and disease prevalence scenarios to guide our enrollment target. While this parent protocol will enroll no subjects, future study populations (for which an IRB sub-study will be filed) will include community members who are or are likely to be exposed to a disaster area as a result of residence. The following inclusion and exclusion criteria will be used to establish eligibility, and will be reviewed with participants prior to enrollment to verify eligibility. There are no enrollment restrictions with regard to gender, race, or ethnic background. Consenting adult pregnant women are eligible to participate because this research does not include activities that may affect the pregnancy or the fetus.

Study candidates must meet **all** of the following inclusion criteria to be enrolled:

1. At least 18 years of age

Study candidates who meet **any** of the following exclusion criterion cannot be enrolled:

1. Adults unable to consent
2. Minors under the age of 18: infants, children, teenagers
3. Prisoners
4. 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

4.0 Procedures Involved

In their 2011 report, the National Biodefense Science Board (NBSB offered a list of recommendations for improved mobilization of scientific resources in the investigative response to disasters that threaten public health, which includes developing "the concepts, doctrine, infrastructure, and personnel needed to begin scientific investigation and data collection rapidly in various types of incidents" (NBSB, 2011). Implicit in this NBSB recommendation are two key principles: First, responses should be rapid. Second, variation in the responses should be addressed during the planning process. The TAMU-RAPIDD protocol was structured with those two key principles in mind.

A number of elements of the study are expected to remain the same, regardless of the type or location of the disaster in which the protocol is implemented. Study elements that are expected to remain unchanged (e.g., descriptions of the procedures performed, risks of procedures, and human subjects protection measures), have been placed in the main body of the protocol. In contrast, some aspects of the protocol cannot be specified in advance, such as the disaster setting and target sample size.

We are seeking approval for a protocol that allows for a range of data collection activities early in the response phase of a future disaster. **In the event of an actual disaster, we intend to submit an expedited sub-study to clarify the disaster setting, target sample size, exposures and potential**

health effects of interest, as well as the specific questionnaires and procedures that will be implemented. This approach will reduce the time to study initiation by enabling IRB review of the umbrella protocol prior to the disaster event.

4.1 Questionnaire Administration

The study duration will depend on the nature of the disaster that becomes the focus of this research project. We estimate that the informed consent process, detailed in section 8.0, will require approximately 10 minutes of participant time. Questionnaire administration is estimated to last 15 minutes if consent for all study procedures is received and completed. It is important to note that the composition of these procedure sets are only recommendations and may be revised at the time of the disaster to assure that the most appropriate set of study procedures for the situation are conducted.

The TAMU-RAPIDD protocol is designed to allow for the investigation of a wide range of outcomes of interest for a given disaster scenario. Study staff will administer questionnaires aimed at collecting demographic variables, information about general/overall health (including mental health), environmental exposures, lifestyle, and/or sociological parameters. Age is the only demographic variable that determines eligibility. Data on gender, race, and ethnicity [required for National Institutes of Health (NIH) human participants reporting] are only used to characterize the study population.

The questionnaire instrument will incorporate questions from both the epidemiologic 12-item Short-Form Health Survey (Ware et al. 1996) and the Agency for Toxic Substances and Disease Registry's (ATSDR) Exposure Survey (ATSDR, 2010). Instruments from the database of the NIH DR2, developed by NIEHS in collaboration with the National Library of Medicine (NLM), may also serve as a source of tools and resources. If no suitable questions to generate disaster-specific information are identified from these sources, the study team will convene the necessary experts who are able to help modify existing questionnaires or recommend alternate options for collecting information.

5.0 Multiple Sites

N/A

6.0 Incomplete Disclosure or Deception

N/A

7.0 Recruitment

If feasible, the study may be advertised in advance through community-based organizations and stakeholders as part of an overall study recruitment strategy. Recruitment strategies will be sensitive to the fact that disaster responders and community members affected by a disaster may be engaged in

critical emergency operations or in an evacuation situation that must be prioritized over research considerations.

The TAMU-RAPIDD team will develop an information sheet that can quickly inform prospective participants of study aims. Study documents and recruitment materials are currently developed in English, but speakers of other languages may be included depending on the community involved. Translated materials will be developed for these populations and submitted as a sub-study to the IRB for approval. Effective strategies for the development of culturally appropriate recruitment materials for the study will be determined by soliciting participation and input from community organizations and partners. Bilingual study staff will work with non-English speaking individuals to the extent possible for anticipated languages (e.g., Spanish or Vietnamese).

Due to the variability inherent in disaster responses, the PI, under advisement of community-based orgnaizaitons and stakeholders, will determine and implement the most appropriate recruitment strategy based on the context of the situation. Only recruitment materials that have first received IRB approval will be used in the field.

8.0 Consent Process

The PI is responsible for ensuring informed consent is obtained from all participants and properly documented in compliance with 45 CFR 46.

A written information sheet and a modified Simple Survey Consent Script will be used to guide the informed consent process. The information sheet will contain contact information for PI Dr. Garett Sansom and the TAMU IRB in the event that questions or concerns emerge after the visit. To help potential participants make an informed decision about enrollment, the designated study staff, trained in informed consent administration, will discuss the study's purpose, duration of participation, procedures, risks, benefits, record confidentiality, how to contact study personnel, and the rights of participants. Potential participants will be given ample time to ask questions and obtain clarifications regarding the study prior to agreeing to enroll. Study staff will follow the modified Simple Survey Consent Script to obtain verbal consent prior to the initiation of any study procedures. Bilingual study staff will be available to work with non-English speaking participants for common foreign languages (e.g., Spanish) likely to be encountered.

9.0 Process to Document Consent

Consent will be obtained verbally using the adapted Simple Survey Consent Script. No written record of consent will be retained.

10.0 Risks to Participants

The proposed study presents minimal risk to participants. The questionnaires used for this study are based on instruments that are widely used in epidemiological studies and disaster research and have been evaluated for their reliability, validity, ease of use and overall low participant burden. The main

risk in questionnaire administration involves discomfort around personal experiences that may be traumatic; in some cases such questions could trigger emotions, stress, or other reactions that are difficult or painful for the participant to experience (e.g., post-traumatic stress disorder). To help minimize this risk, participants will be told that they may skip any or all questions or end the interview at any time. Also, to the extent possible at the study site, a private setting for completing sensitive surveys or interviews will be provided. Further, field staff will receive training in handing emotionally difficult situations and have a list of mental health referral sources available to participants in distress.

11.0 Potential Benefits to Participants

Participation in this study is not anticipated to provide any direct benefit to a participant's overall health or any existing disaster impacts. Study participants may benefit from the positive feelings associated with participating in a study that explores the effects of a disaster that may add value to their community. The knowledge gained from this study may have a significant impact on future public health responses to disasters.

12.0 Financial Compensation

Participants will not receive financial compensation for survey completion, nor will they be responsible for any costs because of participation in the research.

13.0 Provisions to Protect the Privacy Interests of Participants

All investigators and staff involved in this project are required to have had training in epidemiologic methods and competencies in field data collection. Personnel involved in human subjects research design, data management, and/or reporting are required to have completed the HIPAA Privacy and Security for Human Research training offered by the Texas A&M University Office of Research Compliance and Biosafety and Human Subject Protection Training provided through Collaborative Institutional Training Initiative (CITI). The Principal Investigator (PI) will:

- Submit the protocol, modified Simple Survey Consent Script, written information sheet, proposed recruitment materials, and any other materials for participants to the TAMU IRB for review and approval
- Obtain IRB approval of the annual Continuing Review for the duration of the study
- Obtain IRB approval for all sub-studies to the protocol, written information sheet, and other study documentation referenced above
- Monitor and evaluate study progress, including periodic assessments of accrual, administration of informed consent, data quality, timeliness of data collection, participant risk versus benefit, and other factors that can affect study outcomes

14.0 Confidentiality and Data Management

All records will be kept confidential to the extent provided by federal, state, and local law. The project team will be responsible for overseeing the collection of data into an in-house, secure electronic data management system and ensuring data accuracy, completeness, consistency, and timeliness. All data

management staff will receive data management system training as well as other relevant training. The investigator is ultimately responsible for assuring that data are complete, accurate, and recorded in a timely manner. Source documentation (the point of initial recording of information) should support the data collected and will be maintained to allow for the reconstruction and evaluation of the study. Source documents for this study will include original records and data, completed questionnaires, and paper tracking logs utilized by study staff. The Principal Investigator and study staff will ensure that all records, including source documents and regulatory documents pertaining to the conduct of this study, are made available to the TAMU IRB and its representatives and auditors from regulatory authorities to facilitate monitoring visits and/or study audits.

All study records will be retained for a minimum of 6 years after study completion. Study records that will be retained include IRB approvals and correspondence, tracking logs, completed questionnaire instruments, and other study documentation that may be developed during the course of the study. To protect against unauthorized access and accidental or premature destruction of these documents, hard copies of any paper data collection tools will be maintained in a secure, locked storage cabinet that is only accessible to study staff. Electronic records collected as part of the study procedures will be stored in an encrypted, password-protected TAMU database. Appropriate security controls will be implemented to ensure that all data access is defined by roles, which restrict access to the bare minimum necessary for individuals to complete their project duties. The results of the study may be presented in reports, published in scientific journals, or presented at medical meetings. However, participants will not be identified in any study reports.

15.0 Data Monitoring Plan to Ensure the Safety of Participants

The PI will be responsible for ensuring the safety of research subjects and the integrity of research data, consistent with regulatory and NIH requirements.There is minimal risk associated with the study, and the main objective of this study is to create a repository of data. Thus, the nature of this study does not warrant the use of a Data and Safety Monitoring Board.

16.0 Data Banking

N/A

17.0 Qualifications to Conduct Research and Resources Available

Research study staff have the necessary education, qualifications, and experience to conduct all research study activities. As is true of existing staff, new hires will be required to undergo pre-employment screening and produce credentials commensurate with the anticipated level of complexity. After hire, they will receive training in human subjects' protection, ethics, and study specific training modules including disaster-specific health and safety training, informed consent administrations, procedural conduct, and questionnaire administration. Corrective actions for unsatisfactory performance will include coaching, retraining, or termination.

18.0 Community-Based Participatory Research

Close and ongoing community engagement is expected to enhance the scientific validity of the study, make it more broadly relevant from a public health perspective, and expand its benefits to the affected communities. The community will play an integral role in all phases, from priority setting to knowledge dissemination, and the activities will take into account the unique social, physical, cultural, and environmental vulnerability of these neighborhoods. Community engagement activities will not be limited to the pre-implementation phase but will continue during implementation and through results dissemination to assure that the study is reflective of the needs of the local community. Community partners will likely engage in the following activities:

1. Facilitate dialogue between affected community members and the study team
2. Identify effective communication strategies and vehicles tailored to the communities' needs
3. Assist in the dissemination of study-related information locally and regionally
4. Proactively identify issues of concern with study implementation and options for resolutions

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