

Appendix D: Example of Protocol Implementation During a Disaster Scenario

Hurricane Scenario

A Category 5 Hurricane (highest category on the Saffir-Simpson Hurricane Scale) has made landfall in Wilmington, North Carolina resulting in catastrophic damage to the Cape Fear region. Maximum sustained winds were greater than 160 mph and the storm surge exceeded 20 feet. Many structures in the region have been destroyed and there is a large amount of debris on the streets. Floodwaters in low-lying areas have not receded and it is suspected that they are tainted with raw sewage, pesticides, animal, agricultural waste and other environmental contaminants. Though massive evacuations saved many lives, residents who failed to evacuate in a timely fashion were left stranded resulting in a significant search and rescue operation. A FEMA urban search and rescue task force and incident support team based in Washington, D.C. has been activated to respond to the region. Additional groups of local/state disaster workers and volunteers are deploying to the region to assist in rapid needs assessment and cleanup operations.

The needs of the local community have exceeded the resources available to local/regional authorities and there has been an official request from the City of Wilmington for state and federal assistance. The concern about exposure to hazardous materials in the post-hurricane environment has led NIEHS to consider implementation of the RAPIDD protocol. A large cadre of local disaster workers who have received Hazardous Waste Worker Training under the NIEHS Worker Training Program (WTP) are preparing to deploy to the region. NIEHS has identified this disaster worker group as a cohort of interest to determine the health impact of the hurricane on responders. Since the RAPIDD protocol has already received IRB pre-approval to study a disaster responder cohort, the implementation of the study can be expedited to permit the collection of baseline data from the WTP trained disaster worker group prior to exposure to possible hazardous materials in the post-hurricane environment. The RAPIDD study team submits the Protocol Amendment Checklist (Appendix B) and requests an expedited review of the RAPIDD protocol. Since the NIEHS IRB has already pre-approved the body of the RAPIDD protocol, the IRB can solely review the new material which should reduce the time needed for an approved protocol to be initiated in the field. Once approval is attained, a pre-designated and trained corps of “research responders” is activated by NIEHS to implement the RAPIDD Study and is deployed to the pre-deployment staging area in Wilmington. A sample completed Appendix B checklist for this disaster scenario is provided below.

Sample Completed Protocol Amendment Checklist

I. Type of Disaster

Natural Disasters

- ☐ Earthquake/Tsunami
- ☐ Flood
- ☒ Hurricane
- ☐ Tornado
- ☐ Wildfire
- ☐ Extreme Temperature/Drought
- ☐ Other: _____

Man-made and Technological Disasters

- ☐ Chemical release/Oil spill
- ☐ Biological emergency
- ☐ Radiological/Nuclear
- ☐ Explosion
- ☐ Civil unrest/ war
- ☐ Utility service disruption/blackout

II. Detailed description of disaster and justification for deployment:

The City of Wilmington has requested support from state and federal resources and the NIEHS Worker Training Program (WTP) responders have been deployed to the Cape Fear region to respond to Hurricane X. There is concern over the environmental contaminants in the floodwaters (e.g., raw sewage, pesticides, animal, agricultural waste) and the effects of exposure to these hazardous substances. Rapid collection of baseline data from WTP disaster responders will be valuable in investigating the potential short- and long-term health effects of exposure to the debris and flood waters following this hurricane.

III. Research Setting: WTP Staging Area in Wilmington, NC

IV. Estimated Sample Size: 100

V. Accrual duration: 2 months

VI. Procedures:

☐ Core Biospecimen Set

- Urine Collection
- Oragene or buccal cell collection

☒ Basic Biospecimen Set

- Vital Signs
- Pulse Oximetry
- Urine Collection
- Anthropometry
- Venipuncture

☐ Enhanced Biospecimen Set

- Vital Signs
- Pulse Oximetry
- Anthropometry
- Venipuncture

- Urine Collection
- Nail Clipping Collection
- Hair Collection
- Spirometry
- Oral Swab Saliva Collection

☐ Additional procedures: _____

- | | |
|---|--|
| ☐ Vital signs | ☐ Spirometry |
| ☐ Pulse Oximetry | ☐ Nail clipping collection |
| ☐ Anthropometry | ☐ Oral swab saliva collection |
| ☐ Venipuncture | ☐ Oragene or buccal cell collection |
| ☐ Urine collection | ☐ Hair collection |

(Provide description of procedure and list document changes and section numbers in section X of this sheet.)

VII. Questionnaires (check all that will be completed during the visit):

- ☐ Core Registry Form
☒ Basic Health Registry Form
☐ Enhanced Health Registry Form
☐ Other: _____

(A detailed list of the actual questionnaires to be used can be found in attachment [##] in section X of this sheet.)

VIII. Outcomes of interest:

- | | |
|---|--|
| ☒ Cardiovascular System | ☐ Muscular System |
| ☒ Digestive System | ☐ Nervous System |
| ☐ Endocrine System | ☐ Reproductive System |
| ☐ Excretory System | ☒ Respiratory System |
| ☐ Immune System | ☐ Skeletal System |
| ☐ Integumentary System | ☐ Other |
- _____

IX. Provide a description of protocol, consent, and/or other document changes with section numbers.

Protocol – No changes have been made to the protocol

ICF –

1. Inserted disaster name – pg. 1 “What is the purpose of this study?”
2. Listed study procedures – pg. 2 “What will I be asked to do in this study?”
3. Inserted estimated time of enrollment and study exam – pg. 3 “How long will the study procedures take?”
4. Revised remuneration amounts based on procedures specific to this disaster – pg. 4 “Will I be paid for participating?”

ICF quick reference guide –

1. Listed study procedures – “During the registry visit”
2. Revised remuneration amounts – “Payment to Participants”

FAQs –

1. Listed study procedures – “What will I be asked to do”
2. Revised remuneration amounts – “Will I receive compensation for participating in this study?”

Basic Health Registry Questionnaire –

1. Inserted disaster name – pg. 1 script
2. Inserted estimated time for completion – pg. 1 script

X. List of attachments:

Existing or revised documents

- ICF
- ICF quick reference guide
- FAQs
- Basic Health Registry Questionnaire
- Medical results handouts

New documents

- Recruitment script
- Informational study handout
- Medical referral handout
- Certificate of Confidentiality