Appendix B: Protocol Amendment Checklist

This checklist is designed to streamline the process of IRB review prior to study initiation. Based on the type of disaster, this checklist will provide specific details of study setting, target sample size, procedures and questionnaires that will be administered, as well as exposures and potential health effects of interest. This checklist also provides information about modified study documents (i.e., ICF revisions, additional questionnaires, etc.). Appendix D provides an example scenario where this checklist would be submitted for IRB approval prior to study initiation for a specific disaster.

I. Type of Disaster

Natural Disasters	***Man-made and Technological Disasters***
☐Earthquake/Tsunami	☐Chemical release/Oil spill
☐Flood	☐Biological emergency
☐Hurricane	☐Radiological/Nuclear
☐Tornado	☐Explosion
☐Wildfire	☐Civil unrest/ war
☐Extreme Temperature/Drought	☐Utility service disruption/blackout

☐Other: _____

II. Detailed description of disaster and justification for deployment:

_____
_____
_____
_____
_____

III. Research Setting:

_____

IV. Estimated Sample Size: _____

V. Accrual duration: _____

VI. Procedures:

☐ Core Biospecimen Set

- Urine Collection
- Oragene or buccal cell collection

☐ Basic Biospecimen Set

- Vital Signs
- Anthropometry
- Pulse Oximetry
- Venipuncture

- Urine Collection

☐ Enhanced Biospecimen Set

- Vital Signs
- Pulse Oximetry
- Urine Collection
- Nail Clipping Collection
- Hair Collection
- Anthropometry
- Venipuncture
- Spirometry
- Oral Swab Saliva Collection

☐Additional procedures: _____

☐Vital signs
☐Pulse Oximetry
☐Anthropometry
☐Venipuncture
☐Urine collection
☐Spirometry
☐Nail clipping collection
☐Oral swab saliva collection
☐Oragene or buccal cell 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
☐Digestive System
☐Endocrine System
☐Excretory System
☐Immune System
☐Integumentary System
☐Muscular System
☐Nervous System
☐Reproductive System
☐Respiratory System
☐Skeletal System
☐Other _____

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

X. List of attachments: