

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

- 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:

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 | • Anthropometry |
| • Pulse Oximetry | • Venipuncture |
| • Urine Collection | • Spirometry |
| • Nail Clipping Collection | • Oral Swab Saliva Collection |
| • Hair Collection | |

Additional procedures: _____

- | | |
|---|--|
| <input type="checkbox"/> Vital signs | <input type="checkbox"/> Spirometry |
| <input type="checkbox"/> Pulse Oximetry | <input type="checkbox"/> Nail clipping collection |
| <input type="checkbox"/> Anthropometry | <input type="checkbox"/> Oral swab saliva collection |
| <input type="checkbox"/> Venipuncture | <input type="checkbox"/> Oragene or buccal cell collection |
| <input type="checkbox"/> Urine collection | <input type="checkbox"/> 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:

- | | |
|--|--|
| <input type="checkbox"/> Cardiovascular System | <input type="checkbox"/> Muscular System |
| <input type="checkbox"/> Digestive System | <input type="checkbox"/> Nervous System |
| <input type="checkbox"/> Endocrine System | <input type="checkbox"/> Reproductive System |
| <input type="checkbox"/> Excretory System | <input type="checkbox"/> Respiratory System |
| <input type="checkbox"/> Immune System | <input type="checkbox"/> Skeletal System |
| <input type="checkbox"/> Integumentary System | <input type="checkbox"/> Other |
-

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

X. List of attachments: