

U.S. Army Medical Research and Materiel Command
Office of Research Protections

Site-Specific Protocol Addendum

The use of this United States Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP) Site-Specific Protocol Addendum is recommended for a multi-site study **only** if the Institutional Review Board (IRB) application is unavailable for a site.

Please complete each section below. If information included in the Master Study Protocol adequately describes the local activity at the study site, please indicate the information is described in the Study Master Protocol.

Please assign a version number and/or date for the completed addendum document.

1. **Protocol Title:**

2. **Study-site Information:**

Name of Institution/Company:

Address:

3. **Study-site Information for the Site-Investigator:**

Name of Site-Investigator:

Title:

Institution/Affiliation:

Address:

Telephone number:

Cell /Other number:

Email Address:

Fax number:

4. **Study-site Number:**

5. **Assurance Information:**

DHHS OHRP Assurance FWA number:

Expiration Date:

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6. IRB/Ethic Committee Information:

Name of Human Subjects Protection oversight office for study-site:

Name & Number of reviewing IRB/EC:

Telephone Number at Office:

Fax number at Office:

If available, Point of Contact at IRB/EC:

Name:

Telephone Number:

Email Address:

7. Local Site-Specific Information:

- a. Identify key study personnel (include name, title, address, point of contact information).

- b. Description of key study personnel roles and responsibilities.

- c. Describe the local recruiting procedures and strategies. Identification of personnel responsible for completing tasks.

- d. Describe the local consenting process. Provide a copy of the site-specific consent form(s). If an Ombudsman is named for the study site, provide name, title, and point of contact information.

- e. Identify local study collaborations at the site such as pharmacy, laboratories, and other institutional departments.

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- f. Describe the local specimen/sampling procedures in place. Include acquisition, disposition, storage, unique coding. If samples will be kept for future use, describe procedures and the security measures for short-term and long-term management. Provide name of repository.

- g. Describe the plan for on-site management of study records and data, and subject study records. Explain procedures and security measures in place for short-term and long-term management. Declare who will have access to data.

- h. Describe the local measures in place to promote privacy and confidentiality.

- i. Describe any unique site-specific study procedures that are not referenced in the Core/Master Protocol.

- j. Declare any unique study population/cultural influences, socioeconomic conditions, etc.

- k. Declare any other site-specific reporting obligations and procedures. Name any additional oversight boards or committees.

Version Number / Date: