**Site-Specific Protocol Addendum Template**

Complete only those sections where the core / master protocol does not detail the activities that will occur at this site. If a section is not applicable, mark “NA” next to the section.

Note: this addendum must accompany the core / master protocol each time the protocol is submitted for continuing review by the IRB.

**Delete this box** and all text in ***blue italics*** within the form **before submitting**

to the IRB Office.

**Site-Specific Protocol Addendum**

**PROTOCOL TITLE:**

**SECTION A: SITE RESEARCH TEAM AND LOCATIONS**

**A1. SITE RESEARCH TEAM**

|  |  |  |  |
| --- | --- | --- | --- |
| **Study Role** | **Institution/Company and Contact Information** | | |
| **Principal Investigator** | | *Name, Rank, and Degree:*  *Title:*  *Institution:*  *Address:*  *Phone Number:*  *Email:* | | |
| **Associate Investigator(s)**  *(add additional space*  *as needed)* | | | *Name, Rank, and Degree:*  *Title:*  *Institution/Company:*  *Address:*  *Phone Number:*  *Email:* | | |
| **Other Key Research**  **Personnel (as applicable)**  *(add additional spaces*  *as needed)* | | | *Name, Rank, and Degree:*  *Title:*  *Institution/Company:*  *Address:*  *Phone Number:*  *Email:* | | | |
| **Other Individuals Supporting**  **the Research (as applicable)**  *(add additional spaces*  *as needed)*  **Research Monitor** | | | *Name, Rank, and Degree:*  *Title:*  *Institution/Company:*  *Address:*  *Phone Number:*  *Email:*  *Name, Rank, and Degree:*  *Title:*  *Institution/Company:*  *Address:*  *Phone Number:*  *Email:* | | | |
| **Ombudsman** | | | *Name, Rank, and Degree:*  *Title:*  *Institution/Company:*  *Address:*  *Phone Number:*  *Email:* | | | |
| **Consultants** (Subject  Matter Experts, others) | | | *Name, Rank, and Degree:*  *Title:*  *Institution/Company:*  *Address:*  *Phone Number:*  *Email:* | | | |

**A2. ROLES AND RESPONSIBILITIES**

**A2.1 Key Research Personnel***Defined as persons who have direct contact with subjects or their identifiable data or specimens. Include degree, certifications, and military rank for military personnel.*

*Describe research responsibilities for each team member listed in section A1; grouping individuals with the same responsibilities together is acceptable.*

*Name(s):*

*Research Role:*

*Study Responsibilities:*

*Name(s):*

*Research Role:*

*Study Responsibilities:*

*Name(s):*

*Research Role:*

*Study Responsibilities:*

**A2.2. Others Involved in the Research at the Site, as applicable** *to include research monitor and ombudsman. Refer to DODI 3216.02, Encl 3 for additional information about studies that require a research monitor and/or an ombudsman. Note that the ombudsman may also be the research monitor. Describe the monitor’s role at this site and with whom the monitor will communicate; include other duties based on the specific risks or concerns about the research. Ensure the individual has expertise consonant with the nature of risk(s) identified within the protocol and is independent of the research team*

*Name(s):*

*Research Role:*

*Study Responsibilities:*

*Name(s):*

*Research Role:*

*Study Responsibilities:*

*Name(s):*

*Research Role:*

*Study Responsibilities:*

**SECTION B: Site-Specific Information**

**B1. RESEARCH SUBJECTS** *Describe the population being recruited for the research, differences in eligibility criteria and state the number of research subjects/records/specimens per group, the total number of subjects, and any differences in eligibility at this site. Estimate the number of individuals needed to consent and screen (but not necessarily enroll) to achieve the sample at this site.*

**B2. Research Procedures** *Describe any differences from the sponsor/core protocol in how the study procedures will implemented at this site, including the collection of data (e.g., site-specific databases).*

**B3. Managing Data and/or Human Biological Specimens for this Research** *Describe how data will be accessed during the study at this site; who will have access to the data/specimens and to the link between the subjects and their data/specimens; where data and/or specimens will be stored at the site; how they will be shipped/transmitted; and the security of the location where research data documents, files, reports will be stored. Describe where study records will be stored at this site when the study has been closed; confirm the record retention plan will be compliant with the institution’s record retention policies.*

**B4. Devices, Drugs, Dietary Supplements, Nutritional Supplements, And Biologics**

**B4.1 State the location at this site where the study drug(s) and/or devices will be stored.**

**B4.2 Describe accountability procedures at this site as they relate to drugs or devices.**

**B4.3 Identify who on the research team, in addition to the Principal Investigator, will be accountable for drugs/devices at this site.**

SECTION C: HUMAN RESEARCH PROTECTIONS

**C1. RECRUITMENT AND CONSENT**

**C1.1 Identification and Selection of Subjects** *Explain how and by whom subjects will be identified and selected at this site. Describe any site-specific eligibility criteria (e.g. military personnel, federal employees)*

**C1.2 Recruitment Process** *Explain the recruitment process in detail: identify by study role(s) who will approach subjects or their* *legally authorized representative about participation; when subjects or their legally authorized representative will be approached*

**C1.3 Eligibility** *Explain in detail how eligibility will be assessed and satisfied (e.g. medical record review, physical examination, laboratory evaluations). Identify who will determine eligibility.*

**C1.4 Consent Process** *Explain the consent process in detail. See the “Guide for Investigators” for essential elements of information to include when specific types of subjects are involved in the research or when a waiver from a requirement is involved.*

**C1.4.1 Research involving subjects with cognitive impairment or who lack capacity to provide informed consent** *Explain how the decision-making capacity of potential subjects will be assessed at this site, who will serve as the Legally Authorized Representative, how initial informed consent will be obtained from the LAR, and the plan for reassessing subjects’ decision-making ability over the course of the research and, if applicable, for obtaining consent from subjects who regain ability to consent after an LAR has given initial consent.*

**C1.4.2 Research involving non-English speaking subjects** *Explain whether the consent form and other study documents will be available in the subject’s primary language, whether someone able to discuss participation in the patient’s language will be present for the consent process, or whether a short-form will be used if the potential subject does not speak or read English, and how communicating with non-English speaking subjects will be maintained throughout their participation in the study.*

**C1.4.3 Research involving a waiver of the requirement to obtain informed consent OR alteration of the elements of informed consent** *Explain:*

* *why waiving the requirement to obtain informed consent or altering the elements of informed consent will not adversely affect subjects’ rights and welfare;*
* *why the research could not be conducted without the waiver or alteration; and*
* *whether or not subjects will be provided with information about their inclusion in this research. If information will be provided, explain how this will be done.*

**C1.4.4** **Research involving a** w**aiver of the requirement for investigator to obtain a signed consent form** *Explain EITHER:*

* *why the principal risk from signing an informed consent would be potential harm resulting from a breach of confidentiality (for example, research involving collecting detailed information about illegal drug use or other criminal behavior).*

*OR*

* *why the research involves no procedures for which written consent is normally required outside of the research context (for example, a study involving a blood draw, completion of questionnaires and interviews to obtain medical history would qualify for a waiver, since none of the procedures require written consent outside of the research).*

**C1.4.5** **Research involving data collection for the** **USAMRMC Volunteer Registry Database** *All research that* ***involves an Army Office of the Surgeon General (OTSG) regulated product****, requires the completion of Volunteer Registry data sheets (60-R Forms). Datasheets must be submitted to the MRDC at the conclusion of the study. Describe when and how the forms will be completed and submitted to the MRDC. If there is potential for attrition and loss to follow-up, consider completing Part A and B of the form at the time of enrollment, and completing Part C when the subject’s participation in the study ends. This will ensure subjects’ contact information is documented.*

*GTMR intramural research also requires the completion of Volunteer Registry data sheets; however in some cases this requirement may be waived. Contact the IRB Office Director prior to completing this section for guidance.*

**C2.COMPENSATION FOR PARTICIPATION** *Describe the plan to compensate federal and non-federal employees at this site. Include the schedule, amount, and method of payments; the total amount subjects can receive for completing the study; and the plan for pro-rating compensation should a subject withdraw prior to the completion of all study activities, as applicable.* *Refer to DODI 3216.02, Enclosure (3), paragraph 11 for additional guidance.*

**C3.WITHDRAWAL FROM RESEARCH PARTICIPATION** *Explain the process for withdrawal at this site when the subject wishes to end study participation. Include any additional circumstances not identified in the core/master protocol when the site PI might withdraw a subject.*

**C4. PRIVACY FOR SUBJECTS** *Describe the measures to protect subject’s privacy during recruitment, the consent process, and all research activities at this site.*

**C5. CONFIDENTIALITY PROCEDURES FOR RESEARCH RECORDS, DATA, HUMAN BIOLOGICAL SPECIMENS** *Describe all the measures to maintain confidentiality of research records, data, and specimens throughout the research and at its conclusion at this site. See “Guide for Investigators” for specific information to include in this section.*

**C6. INCIDENTAL OR UNEXPECTED FINDINGS** *Explain how incidental and/or unexpected findings about individuals identified during their participation in the research will be managed at this site.*

**C7. DATA MONITORING** *Describe the plan to monitor the data at this site to verify that data are collected and analyzed as specified in the research protocol.*

**SECTION D: ABBREVIATIONS AND ACRONYMS** *Include an alphabetical list of abbreviations and acronyms that were used in this site-specific document.*