**Protocol Template**

Delete this box and all text in the form in ***blue italics* before submitting** to the IRB Office.

Mark sections that do not apply to your research as “NA.”

**PROTOCOL TITLE:**

**SECTION A: RESEARCH TEAM AND LOCATIONS**

**A1. RESEARCH TEAM**

|  |  |
| --- | --- |
| **Study Role** | **Institution/Company and Contact Information** |
| **Sponsor** | *Organization/Institution/Company:*      *Address:*      *Point of Contact:*       *Name and Degree:*       *Title:*      *Phone Number:*      *Email:*       |
| **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:*       |
| **Ombudsperson***(add additional space* *as needed)* | *Name, Rank, and Degree:*      *Title:*      *Institution/Company:*      *Address:*      *Phone Number:*      *Email:*       |

**A2. ROLES AND RESPONSIBILITIES**

 **A2.1 Principal Investigator**

 *Name:*

 *Study Responsibilities:* [*Required text for all protocols]*: Responsible for the conduct of the study in accordance with the protocol. *[Specify all other protocol responsibilities]*

*[Required text for protocols utilizing a delegation of authority log/mechanism]* Responsible for the conduct of the study in accordance with the protocol. Maintenance of a list of appropriately qualified persons to whom significant study-related responsibilities have been delegated. *[Specify all other protocol responsibilities]*

 **A2.2 Associate Investigator(s)**

 *Name(s):*

 *Study Responsibilities:*

 **A2.3 Ombudsperson**

 *Name(s):*

 *Study Responsibilities:*

**A3. RESEARCH LOCATIONS** *List all institutions, facilities, laboratories, other locations where research activities will occur. See the “Guide for Investigators” for examples. Add additional spaces as needed.*

**A4. MULTISITE RESEARCH** *If this institution will be the lead site and/or coordinating center for research that will be conducted at multiple institutions, provide the following information for the other performance sites:*

***Lead Site****:*

*Lead Site Investigator:*

*IRB that will review for the lead site:*

*Function/Role of Lead Site*:

***Performance******Site****:*

*Performance Site Investigator*:

*IRB that will review for the Performance Site*:

*Function/Role of Performance Site*:

*(add spaces for additional sites as needed)*

**SECTION B: RESEARCH METHODOLOGY**

**B1. ABSTRACT** *Summarize the proposed research in 500 words or less, to include the purpose, the subject population, the study’s design type, and procedures.*

**B2. BACKGROUND AND SIGNIFICANCE** *Include a literature review that describes in detail the rationale for conducting the study. Include descriptions of any preliminary studies and findings that led to the development of the protocol. The background section should clearly support the choice of study variables and explain the basis for the research questions and/or study hypotheses. This section establishes the relevance of the study and explains the applicability of its findings.*

**B3.** **MILITARY RELEVANCE** *Explain the military relevance of the proposed research* *as applicable.*

**B4. OBJECTIVES/SPECIFIC AIMS/RESEARCH QUESTIONS** *Describe the purpose and objective(s) of the research, specific aims, and/or research questions/hypotheses.*

**B5**. **RESEARCH PLAN**  *See the “Guide for Investigators” for examples.*

 **B5.1 Research Design** *State the type of research design in one to two sentences*

 **B5.2 Research Subjects/Population(s)**

 **B5.2.1**  **Subject Population(s)** *Describe the population being recruited for the research.*

**B5.2.2 Number of Subjects, Records, and/or Specimens** *State the total number of proposed research subjects, records, and/or specimens per group.*

 B5.2.3 Inclusion Criteria

 B5.2.4 Exclusion Criteria

 **B5.3 Research Procedures** *Describe step-by-step how the research will be implemented from beginning to end. Reference by* ***role*** *(not by name) who on the research team will be responsible for specific research and standard of care procedures.*

 B5.4 Data Collection *Describe all the data variables, information to be collected, the source of the data, and approvals needed for use of information from DOD databases OR alternatively use a table such as the one below. Refer to the “Guide for Investigators” for additional information.*

|  |  |  |
| --- | --- | --- |
| **Data Element/Variable** | **Source** | **Operational Specification** |
|  |  |  |
|  |  |  |

 B5.5 Managing Data and/or Human Biological Specimens for this Research *Include in this section the plan for acquisition, storage, shipment/transmission, access during the study, and the plan for storage and final disposition at the conclusion of the study. See the “Guide for Investigators” for additional information to include in this section.*

 **B5.6 Managing Data and/or Human Biological Specimens for Future Research** *If the research involves collecting, storing, or banking human specimens, data, or documents (either by the Investigator or through an established repository) for FUTURE research, see the “Guide for Investigators” and address relevant items in this section.*

**B5.7 Devices, Drugs, Dietary Supplements, Nutritional Supplements, And Biologics** *Refer to the “Guide for Investigators” for completing the following section(s), as applicable to this research.*

**B5.7.1 Devices**

 **5.7.1.1 FDA-approved device being used in this research according to the approved labeling**

 **5.7.1.2 FDA-approved device being used in this research in a manner other than its approved labeling**

 **5.7.1.3 Any device not approved by the FDA**

 **B5.7.2 Drugs**

 **B5.7.2.1 FDA-approved and used in accordance with the approved labeling**

 **B5.7.2.2 FDA-approved and used in a manner not in accordance with its approved labeling**

 **B5.7.2.3 Any drug not approved by the FDA**

**B8 Statistical Analysis**

 B5.8.1 Sample Size Estimation

**B5.8.2 Data analysis** *Outline the plan for analyzing the data.*

SECTION C: HUMAN RESEARCH PROTECTIONS

**C1. RECRUITMENT AND CONSENT** *See the “Guide for Investigators” for essential elements to include in this section as well as detailed information about waivers or alterations of consent; protected health information; and definition of research involving experimental subjects.*

 **C1.1 Identification and Selection of Subjects** *Explain how subjects will be identified and selected.*

 **C1.2 Recruitment Process** *Explain the recruitment process in detail.*

 **C1.3 Eligibility** *Explain in detail how eligibility will be determined.*

 **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

 C1.4.2 Research involving non-English speaking subjects

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

 **C1.4.4** **Research involving a** **waiver of the requirement for investigator to obtain a signed consent form**

 C1.4.5 Waivers of assent or parental permission when the research involves children

 **C1.4.6** **Research involving data collection for the** **USAMRDC Volunteer Registry Database**

**C2.COMPENSATION FOR PARTICIPATION** *See the “Guide for Investigators” for information about compensation for federal and non-federal employees.*

**C3.WITHDRAWAL FROM RESEARCH PARTICIPATION** *Explain the process for withdrawal and specify whether or not the subjects will be given the opportunity to withdraw their data their data/specimens in the event they wish to withdraw from the study.*

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

**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. See “Guide for Investigators” for specific information to include in this section.*

**C6. RISKS OF HARM, MEASURES TO REDUCE THE RISKS OF HARM, AND BENEFITS OF PARTICIPATION**

 **C6.1 Risks of Harm** *Identify all research risks of harm to which the subject will be exposed for each research procedure or intervention as a result of participation in this research.*

 *Research Procedure Name:*

 *Research Procedure Description:*

 *Research-related Risks:*

 *Measures to Minimize Risks of Harm: (Precautions, safeguards):*

 **C6.2 Incidental or Unexpected Findings** *Describe the plan to address incidental findings and unexpected findings about individuals identified during their participation in the research, as appropriate.*

**C6.3 Potential Benefits** *Describe any real and potential benefits of the research to the subject or society.**NOTE: PAYMENT FOR PARTICIPATION IS NOT A BENEFIT.*

**C7. DATA AND SAFETY MONITORING** *Describe the plan to monitor the data to ensure the safety of subjects. See the “Guide for Investigators” for details on the information to include in this section as relevant to this research.*

C8. REPORTABLE EVENTS *See the “Guide for Investigators” for information to include in this section.*

 C8.1 Expected adverse events

 C8.2 Unexpected adverse events and unanticipated problems

 C8.3 Adverse device effects

 C8.4 FDA-regulated research under IND and IDE

**SECTION D: REFERENCES**

*See the “Guide for Investigators”*

**SECTION E: ABBREVIATIONS AND ACRONYMS**

*See the “Guide for Investigators”*

**SECTION F: DoD PRIVACY RULE AND PROTECTED HEALTH INFORMATION (HIPAA)**

*Click in the appropriate box See the “Guide for Investigators” for definitions and further information.*

 NA – institution is not a covered entity

 NA – will not use or disclose protected health information

 HIPAA authorization will be obtained

 An application for waiver/alteration of HIPAA authorization will be submitted