Research Protocol

Instructions for completing form fields (shaded areas): Type or copy and paste text directly into the shaded areas.

Title of Research:

Principal Investigator:

Name:
Company:
Address:
Phone Number:
Email Address:

Associate Investigator(s):

Name:
Company:
Address:
Phone Number:
Email Address:

Government Project Manager:

Name:
Company:
Address:
Phone Number:
Email Address:
Is this research study being conducted pursuant to a contract:
☐ **Yes** ☐ **No**

Location of Study:

1.0 Project Background:

- ❖ Literature Review
- ❖ Rationale for conducting the study

If your response exceeds the space available, please attach additional pages and reference "Research Protocol, Section 1.0, Project Background."

2.0 Research Purpose and Objective(s):

- ❖ Why is the study being conducted?
- ❖ What is/are the proposed outcome(s)?
- ❖ Might the outcomes inform policy?

If your response exceeds the space available, please attach additional pages and reference "Research Protocol, Section 2.0, Research Purpose and Objective(s)."

3.0 Selection and Recruitment of Subjects:

- Who will be your subjects?
- How many will be in the study?
- Where will you get your subjects?
- How will they be contacted/recruited for the study?
- When recruiting subjects for the research study the following must be addressed in the letter or flyer (Note: Please attach a copy of the recruitment letter or flyer):

Describe the basic study design

1. What is the purpose of the project?
2. What makes the subject a good candidate for the project? Explain why he/she was picked (random selection, *etc*.)
3. What will the subject need to do (explain the time commitment requirement) (*This does not have to be a long explanation; however, enough information must be provided so that each individual has a basic understanding. For example, simply ask them to call for more information*.)
4. Will the subject be paid? If so, then what are the criteria for payment?

Explain that participating in research is voluntary. It will not affect TRICARE benefits for which the subject is eligible

If your response exceeds the space available, please attach additional pages and reference "Research Protocol, Section 3.0, Selection and Recruitment of Subjects."

4.0 Procedure and Methodology:

- ❖ Description of exactly what you are going to do
- ❖ Provide a synopsis of the day-in-the-life of a subject

If your response exceeds the space available, please attach additional pages and reference "Research Protocol, Section 4.0, Procedure and Methodology."

5.0 Involvement of Other Institutions/Agencies: (*There are times when several Institutions/Agencies are involved in a project. In this section, please indicate the following*)

- ❖ Provide the name and contact information (e.g., address, phone number) for each subject that is participating in the project
- ❖ Provide a detailed description of each Institution's/Agency's role in the project (e.g., One Institution/Agency may be the one that conducts a survey; another may conduct analysis.)
- ❖ If no other Institutions/Agencies are involved, then check "Not Applicable"

If your response exceeds the space available, please attach additional pages and reference "Research Protocol, Section 5.0, Involvement of Other Institutions or Agencies."

☐ **Not Applicable** (there will not be any other Institutions/Agencies involved)
Otherwise, please provide requested information on other Institutions/Agencies:

6.0 Experimental Design and Data Analysis:

If your response exceeds the space available, please attach additional pages and reference "Research Protocol, Section 6.0, Experimental Design and Data Analysis."

7.0 Risks: (Each of these items must be addressed.)

7.1.1 What are the potential risks of the research (non-subject related)?

If your response exceeds the space available, please attach additional pages and reference "Research Protocol, Section 7.1.1, Potential Risks of the Research."

7.1.2 What are the risks to the subjects?

If your response exceeds the space available, please attach additional pages and reference "Research Protocol, Section 7.1.2, Risks to the Subjects."

7.1.3 What procedures are in place to minimize risks?

If your response exceeds the space available, please attach additional pages and reference "Research Protocol, Section 7.1.3, Procedures to Minimize Risk."

7.1.4 How will you protect the confidentiality of research data?

If your response exceeds the space available, please attach additional pages and reference "Research Protocol, Section 7.1.4, Protecting Confidentiality of Research Data."

7.1.5 If the project requires access to a TMA database (Military Health System Data Repository (MDR) or M2), how will you get access to the data: e.g., will the Government Project Manager facilitate getting the data?

If your response exceeds the space available, please attach additional pages and reference "Research Protocol, Section 7.1.5, Getting the Data."

7.1.6 How will data be transmitted from and/or to the data source?

If your response exceeds the space available, please attach additional pages and reference "Research Protocol, Section 7.1.6, Transmitting Data."

7.2 If using sensitive personal information such as health information or social security numbers, complete all questions in this section (Please note that removing name and social security number does not mean that the dataset is "de-identified.")

☐ **Not Applicable** (Check here if you will not be using sensitive personal information.)

7.2.1 How will you protect the information? (Will the data be password protected? Will the data be stored in a secured filing cabinet/office? Who will have access to the data?)

If your response exceeds the space available, please attach additional pages and reference "Research Protocol, Section 7.2.1, Protecting the Information."

7.2.2 How will the data be displayed/reported? (Will the data be presented only in aggregate form? What is the procedure for dealing with a small sample size?)
If your response exceeds the space available, please attach additional pages and reference "Research Protocol, Section 7.2.2, Displaying/Reporting Data."

7.2.3 How will the privacy and confidentiality of subjects be protected?
If your response exceeds the space available, please attach additional pages and reference "Research Protocol, Section 7.2.3, Protecting Privacy and Confidentiality."

8.0 Bibliography:

If your response exceeds the space available, please attach additional pages and reference "Research Protocol, Section 8.0, Bibliography."

9.0 Informed Consent: Attach a copy of any written consent form used for the protocol and ensure that it includes the information in this section.

9.1.1 Consent to Participate in a Research Study

- A statement that the study involves research
- All medical terms and complex sentences presented in simple terms for the average layperson to understand (*i.e.*, typically considered the 8th grade level of comprehension)

9.1.2 Purpose of the Research Study

- An explanation of the purposes of the research study in layman's terms

9.1.3 Procedures

- The expected duration of the subject's participation
- A description of any procedures that are experimental
- A description of any unforeseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others that may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject

9.1.4 Risks

- Risks associated with this study are minimal. Discuss each risk and efforts to mitigate the risks

9.1.5 Benefits

- Will the subject be paid? If so, then when and how much? If not being paid, then provide statements to that effect

9.1.6 Confidentiality

- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained, and that notes the possibility that the U.S. Food and Drug Administration (FDA) may inspect the records

9.1.6 Contacts for Additional Assistance

- An explanation of whom to contact for answers to pertinent questions about the research subjects' rights, and whom to contact in the event of a research-related injury to the subject

If you (the research subject) have questions concerning your rights as a research subject, or if you have any complaints about your treatment while participating in this study, then you can contact:

Contact Information for the Principal Investigator	Office of the Assistant Secretary of Defense (Health Affairs) (OASD (HA))/TMA Contact Information
	OASD (HA) TRICARE Management Activity Human Subjects Research Protections 7700 Arlington Boulevard, Suite 5101 Falls Church, VA 22042 703-681-1135

9.1.7 Voluntary Participation

- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

Entering a research study is voluntary. Anyone who is asked to be in a research study may say no. No one has to become a research subject. If you start a research study, you may stop at any time. You do not have to give a reason. No one can discriminate against you or treat you differently if you choose not to be in a research study or later decide to stop your participation.

9.1.8 Signature and Date Requirements
❖ Research subject and the person explaining consent must sign, print full names and date the consent document ❖ Include above the signature block a statement such as the following:
I have read this form and its contents were explained. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records.

Signature

All information provided in this Research Protocol and the accompanying attachments are complete and accurate. I understand that this document is binding upon and will inure to the benefit of the Principal Investigator of the above-referenced research project and his/her respective successors and/or assigns.

In accordance with DoD 8520.02, only Principal Investigators with a Common Access Card (CAC) may provide an electronic signature as permitted on this template. For Principal Investigators who do not have a CAC, please print the completed application, provide a handwritten signature, and scan the document so that it may be attached to an email for submission.

Signature of the Principal Investigator	Date
Printed Name of the Principal Investigator	Title/Rank