

Department of
Homeland Security
**United States
Coast Guard**



COAST GUARD HUMAN RESEARCH PROTECTION PROGRAM

COMDTINST M6500.1
May 2011

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COMMANDANT INSTRUCTION M6500.1

Subj: COAST GUARD HUMAN RESEARCH PROTECTION PROGRAM

- Ref: (a) Title 32, Code of Federal Regulations, Part 219
 (b) DHS Management Directive 026-04, Protection of Human Subjects, 25 May 2007
 (c) Title 45, Code of Federal Regulations, Part 46, Subparts A-E
 (d) The Belmont Report, 44 Federal Register 23192 (April 18, 1979)
 (e) Information and Life Cycle Management Manual, COMDTINST M5212.12 (series)
 (f) Title 21, Code of Federal Regulations, Part 312
 (g) Title 21, Code of Federal Regulations, Part 812

1. PURPOSE. This Manual establishes policy, assigns responsibilities, and provides guidelines to ensure the protection of human subjects in research conducted by, within or for the Coast Guard (CG).
2. ACTION. All Coast Guard unit commanders, commanding officers, officers-in-charge, deputy/assistant commandants, and chiefs of headquarters staff elements shall comply with the provisions of this Manual. Internet release is authorized.
3. DIRECTIVES AFFECTED. None.
4. ENVIRONMENTAL ASPECT AND IMPACT CONSIDERATIONS. Environmental considerations were examined in the development of this Manual and have been determined not to be applicable.

DISTRIBUTION – SDL No. 158

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NON-STANDARD DISTRIBUTION:

5. No paper distribution will be made of this instruction. Official distribution will be via the Coast Guard Directive (CGDS) DVD. An electronic version will be located on the following Information and Technology CG-612 web sites. Intranet:

<http://cgweb.comdt.uscg.mil/CGDirectives/Welcome.htm>, Internet:
<http://www.uscg.mil/directives/>, and CGPortal:
<https://cgportal.uscg.mil/delivery/Satellite/CG612>.

6. BACKGROUND.

- a. Human subject research is essential to protect the health, safety, well being, and performance of CG personnel. Research involving human subjects receives considerable national and international attention. Support from all echelons is required to maintain the highest standards of research conduct and to ensure the ethical treatment and well-being of human research subjects.
- b. Research as defined in reference (a) is a “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.” Detailed definitions are contained in Chapter 1.

7. SCOPE.

- a. This Manual applies to:
- (1) All biomedical and social-behavioral research involving human subjects conducted by CG activities or personnel, involving CG personnel and CG employees as research subjects or supported by CG activities through any agreement (e.g. contract, grant, cooperative agreement, or other arrangement) regardless of the source of funding, funding appropriation, nature of support, performance site, or security classification. It also applies to human subject research using CG property, facilities, or assets.
 - (2) Human subject research (as defined in paragraph 6.b) conducted in the development, testing or evaluation of any item, system, vehicle, aircraft, piece of equipment, or other materiel, even if a person is not the direct object of the research (e.g., training exercises associated with the testing of personal protective equipment when worn by a person).
 - (3) Human subject research that meets criteria for exemption as defined in reference (a) and as determined by the CG Institutional Review Board (IRB) Chair. Investigators shall not make this determination.
- b. All CG research activities involving human subjects shall meet DHS requirements as set forth in references (b) and (c).
- c. The CG will have two authorized IRBs, the COMDT (CG-11) IRB and the Research and Development Center (RDC) IRB. This instruction refers to both as the CG IRB.
- d. The requirements in this Manual shall not be suspended or waived due to operational contingency or during times of national emergency, except by explicit action of the Commandant of the CG.

- e. Nothing in this Manual is intended to supersede either the requirements for health or safety reviews required by other authority, or to limit the authority of health care practitioners to provide emergency medical care to the extent individuals are permitted to do so under applicable federal, state, or local law.
8. DEFINITIONS. Definitions are described in detail in Chapter 1 of this Manual.
9. POLICY.
- a. Guiding Principles. The CG uses the ethical principles outlined in reference (d), the Belmont Report, “Ethical Principles and Guidelines for the Protection of Human Subjects of Research,” as the foundation for its human research protection program. All research involving human subjects conducted or supported by the CG shall comply with the requirements of the Common Rule per reference (c) (Subpart A). All research conducted or supported by the CG involving vulnerable classes of subjects including pregnant woman, fetus, neonates, prisoners and children will comply with the provisions of reference (c) (Subparts B, C, and D). The following key principals are:
 - (1) Respect for Persons. The rights, welfare, interests, privacy, confidentiality, and safety of human subjects shall be held paramount at all times and all research projects shall be conducted in a manner that avoids all unnecessary physical or psychological discomfort, and economic, social, or cultural harm.
 - (2) Beneficence. Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: do not harm and maximize possible benefits and minimize possible harms.
 - (3) Justice. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are to each person an equal share, to each person according to individual need, to each person according to individual effort, to each person according to societal contribution, and to each person according to merit.
 - b. Education and Training. All personnel involved in reviewing, approving, supporting, conducting, managing, or overseeing research involving human subjects must complete initial and ongoing research training on ethics and human subject protections commensurate with each individual’s level of involvement, duties, and responsibilities. The COMDT (CG-11) IRB Chair shall determine the appropriate training for all personnel.

- c. Informed Consent. Voluntary informed consent is fundamental to ethical research with humans. Informed consent is not simply a document. It is a process that begins with subject recruitment, and includes a thorough discussion with prospective participants and/or their legally authorized representatives and continues for at least the duration of the research. Depending on the research, ongoing discussion with and education of participants may continue long after the original informed consent is obtained. For additional requirements on informed consent refer to Enclosure (1). Member must sign an informed consent document which is witnessed and dated.

- d. Classification of Studies.
 - (1) Minimal Risk. The CG IRB shall evaluate all minimal risk research studies.

 - (2) Greater Than Minimal Risk (GTMR). The CG IRB shall evaluate all research involving greater than minimal risk and may confer with a consulting IRB as appropriate.

 - (3) Exempted Research. The CG IRB will determine and document whether research protocols meet one or more categories of exemption as defined in reference (a). Investigators may not make this determination and may not start any research activities until the CG IRB provides official exemption documentation.

 - (4) Expedited Review. The CG IRB Chair (or designee) will review and determine whether research protocols meet the expedited review criteria as defined in reference (a). If the IRB Chair (or designee) determines that the research meets the criteria for exempt review, the CG IRB Chair (or designee) and at least one other IRB member will review the proposal. Enclosure (2) contains a copy of the sample exemption request.

 - (5) Survey Research. All survey research protocols require IRB review. Surveys conducted entirely within the command that protect participants' identity may attain exempt status, but initial CG IRB review is required for all research.

 - (6) Classified Research. Classified research with human subjects is held to the same ethical principles and human subject protections as unclassified research. Classified research is not eligible for review under expedited review procedures.

- e. Assurance Compliance. All human subjects research (not otherwise exempt) conducted or supported by the CG will be accomplished under an Assurance of Compliance approved for federal wide use by the Office for Human Research Protection.

10. RESPONSIBILITIES.

- a. CG Director, Health, Safety, and Work-Life, Commandant (CG-11). COMDT (CG-11) is the single authority for policy development, oversight, compliance and

ongoing monitoring concerning human research protection in the CG. COMDT (CG-11) shall:

- (1) Serve as approving authority for all human research protocols conducted by, within, or for the CG.
 - (2) Ensure compliance with DHS and Code of Federal Regulations concerning protection of human subjects (references a-g).
 - (3) Designate authority for CG IRB members.
 - (4) Ensure that IRB members receive initial and continuing training on ethics and human subjects' protection.
 - (5) Ensure all records that document human research protection in the CG are maintained in accordance with reference (e).
 - (6) Maintain records of all Assurances.
- b. CG Institutional Review Board (IRB). The primary role of the CG IRB is to ensure the safety and welfare of human research subjects. The CG will have two authorized IRBs, the COMDT (CG-11) IRB and the Research and Development Center (RDC) IRB. This instruction refers to both as the CG IRB. The CG-11 IRB makes recommendations to COMDT (CG-11) as the approving authority for research protocols and will serve as the liaison for CG compliance with reference (b). The CG RDC IRB makes recommendations to the RDC Commanding Officer as the approving authority for RDC research protocols. The CG IRB must:
- (1) Review all human research protocols conducted by, within, or for the COMDT (CG-11) or RDC.
 - (2) Recommend approval/disapproval or necessary modifications to human research protocols for COMDT (CG-11) or Commanding Officer RDC.
 - (3) Determine the need for medical monitoring in human research protocols.
 - (4) Ensure that medical monitor reports are forwarded to COMDT (CG-11) or to the Commanding Officer RDC.
 - (5) Review and, if appropriate, take action on allegations of research misconduct or non-compliance with human subject protections.
 - (6) Ensure all records that document human research protection in the CG are maintained properly, then destroyed when 5 years old or when usefulness has been served, whichever is later, in accordance with reference (e).

- (7) The RDC IRB will maintain detailed records of all review activities and provide reports as necessary. All records of IRB activity, research protocols, approval letters, informed consent forms, unexpected events and volunteer registry forms will be available and auditable. COMDT (CG-11) IRB will audit RDC IRB records at appropriate intervals as determined by COMDT (CG-11) IRB Chair.
 - (8) The RDC IRB will comprise personnel with qualifications listed in 32 CFR 219. The RDC IRB will seek COMDT (CG-11) IRB consultation on any proposed projects that involve research beyond the expertise of the RDC IRB.
 - (9) For DHS conducted or sponsored research, in lieu of requiring submission of an Assurance to DHS, DHS will accept the existence of an Assurance approved for federal wide use by the Office of Human Research Protections (OHRP). All human subjects research (not otherwise exempt) conducted or supported by the CG will be accomplished under an Assurance of compliance approved for federal wide use by OHRP.
- c. Command Responsibility. Commanders, commanding officers, officers in charge, and all personnel involved in the study, shall maintain concern for the safety and welfare of volunteer subjects. In addition, they shall:
- (1) Ensure that subjects' decisions to participate are voluntary and are protected from undue influence.
 - (2) Ensure that all human subject research as defined in 7.a has been approved by the CG IRB.
 - (3) Prior to implementing any studies involving bargaining unit employees, all labor obligations must be met. CG IRB shall contact servicing Command Staff Advisor or HR specialist for advice and guidance on proper labor obligations.
 - (4) For research involving more than minimal risk and also involving military personnel, officers and enlisted members shall not influence the decisions of their subordinates to participate or not to participate as research subjects.
- d. Principal Investigator (PI). PIs have primary responsibility for compliance with all human subject protection regulations, directives, and instructions. PIs shall:
- (1) Assume responsibility for the quality of the research and for the safety and welfare of human subjects.
 - (2) Complete and document initial and continuing training on research ethics and human subject protections. Ensure all personnel involved in the research study have completed appropriate human subject protection training as specified by CG IRB.

- (3) Obtain written determination from the CG IRB indicating that the proposed activity is classified as research with human subjects or that the activity meets criteria for exemption per reference (a).
 - (4) Ensure that the research project staff is credentialed in the area of research under study. The name and curriculum vita (CV) of the PI and associate researchers must be provided with the protocol.
 - (5) Obtain CG IRB approval per Chapter 2 of this Manual prior to conducting or continuing research.
 - (6) Obtain CG IRB approval prior to implementing proposed amendments to approved research.
 - (7) Notify the CG IRB in writing of unanticipated problems involving risks to subjects or others; serious adverse events; serious or continuing noncompliance with the human subject protection regulations and CG IRB requirements; and protocol deviations.
 - (8) Obtain informed consent from research subjects or their legally authorized representatives and provide them a copy of the completed informed consent document prior to the start of research, unless a waiver of the documentation is approved by the institution.
- e. Associate Investigator (AI). An AI is generally a researcher with limited experience and/or training who works under the mentorship of a PI to fully develop or demonstrate research skills. The AI shall:
- (1) Plan and conduct studies (e.g., formulate research, prepare protocols, develop methodology, handle subjects, collect and analyze data, prepare reports, etc.) with guidance and monitoring from a PI. An AI will not implement a protocol without substantive involvement of a PI.
- f. Study Physician (SP). A SP will be assigned to any research study when the CG IRB determines that the expertise of a medical doctor is required. The name and CV of the study physician must be provided. The CG IRB may determine that an alternate medical professional (e.g., physician assistant, nurse practitioner, nurse, or corpsman) may carry out the duties of the study physician. The study physician shall:
- (1) Participate in all experimental procedures requiring medical proficiency or oversight.
 - (2) Record and report all serious and unexpected adverse events to the CG and local IRBs within 3 days of occurrence.
 - (3) Place a signed and dated description of the adverse event in the subject study file sufficiently detailed that the IRB Chair has a clear picture of the occurrence.

g. Medical Monitor. The CG IRB shall determine the need for medical monitoring for all research projects. A medical monitor must be assigned to all GTMR studies. The name and CV of the medical monitor must be provided with the protocol. This individual should be a qualified physician, other than the Principal Investigator, not associated with this particular protocol. The CG IRB may determine that an alternate medical professional (e.g., physician assistant, nurse practitioner, nurse, or corpsman) may serve as a medical monitor. Depending on the nature of the study, the medical monitor may be assigned to assess one or more of the following phases of a research project: subject recruitment, subject enrollment, data collection, or data storage and analysis. The medical monitor shall:

- (1) Review and monitor all experimental procedures for health and safety risks and report to the CG and local IRBs.
- (2) Suspend the execution of the research protocol, if necessary, to prevent undue harm to subjects.
- (3) Review all serious and unexpected adverse events associated with the protocol and provide an unbiased written report of the event within 10 calendar days of the initial report to the local and to the CG IRBs.
- (4) Comment on the outcomes of the Adverse Event (AE) and relationship of the AE to the test article(s) or experimental procedure(s).
- (5) Review and concur with the details of the AE report provided by the principal investigator and/or study physician.

11. FORMS/REPORTS. The forms referenced in this Manual are available in CG Electronic Forms on the Standard Workstation or on the Internet: <http://www.uscg.mil/forms/>, CG Portal at <https://cgportal.uscg.mil> and Intranet at <http://cgweb.comdt.uscg.mil/CGForms>.

Mark J. Tedesco /s/
Director of Health, Safety, and Work-Life

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CHAPTER 1. DEFINITIONS

- A. Adverse Event. Any unfavorable and unintended occurrence associated with the conduct of a research project.
- B. Approval Authority for Research Protocols. Individuals with delegated approval authority that permit research to begin. Such individuals also have authority to certify a research protocol.
- C. Assurances. A written document provided by an institution engaged in research involving human subjects that is conducted or supported by a federal department or agency that has adopted the Common Rule. Through this document, an institution assures the relevant department or agency head that it will comply with the requirements set forth in the Common Rule.
- D. Assurance Approval Authority. Entity authorized to approve and renew institutional assurances to CG activities and extramural performers conducting human subject research, and the authority to accept other CG or federal assurances.
- E. Certification. The official written notification by the performing institution that a research project or activity involving human subjects has been reviewed and approved by an IRB per an approved assurance. [32 CFR 219.102(j)]
- F. Engaged in Research. An activity becomes engaged in research when its personnel or agents either intervene or interact with living individuals for research purposes; or obtain individually identifiable private information for research purposes.
- G. Extramural Performer. Any individual or organization that is a party to a contract, grant, interagency transfer, or other agreement with any CG activity. An organization includes any federal, state, municipal, or other government activity, or any corporation, institution, foundation, agency, or other legal entity, whether foreign or domestic.
- H. Human Subject.
 - 1. Means a living individual about whom an investigator (whether professional or student) conducting research obtains either data through intervention or interaction with the individual, or identifiable private information. Intervention includes all procedures (e.g., questionnaire/survey, venipuncture, etc.) where data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (e.g., the identity of the subject is or may readily be ascertained or

associated with the information) in order for obtaining the information to constitute research involving human subjects. [32 CFR 219.102(f)]

2. Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. [21 CFR 50.3(g) and 21 CFR 56.102(e)]
- I. Institutional Review Board (IRB). The IRB is a committee established in accordance with 32 CFR 219 to review research to ensure the protection of the rights and welfare of human research subjects.
 - J. Institutional Review Board (IRB) Member – CG IRBs. A CG IRB member must be a current federal employee, an individual appointed under the Intergovernmental Personnel Act (IPA), or a consultant consistent with the requirements established by 5 USC 3109. Status as a contractor or federal retiree alone is not sufficient to qualify as a federal employee for the purpose of IRB membership.
 - K. Minimal Risk. The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (32 CFR 219.102(i)).
 - L. Non-compliance. Deliberate or inadvertent departure from or failure to comply with federal regulations, DHS directives, CG instructions, or IRB requirements for the protection of human research subjects.
 - M. Principal Investigator (PI). In CG-supported human subject research, an individual who possesses the required education, knowledge, skills, experience (credentials) to initiate, conduct and oversee human subject research, and has completed the required research ethics training including human subject protections. In addition:
 1. For CG Supported Intramural Research. A PI must be a current federal employee (uniformed or civilian, staff, or trainee), covered under the Intergovernmental Personnel Act (IPA), or a consultant consistent with the requirements established by 5 USC 3109, and must be assigned to or employed by a specific command. Status as a contractor or federal retiree alone is not sufficient to qualify individuals as PI for such research.
 2. For CG Supported Extramural Research. A PI must meet the criteria established by the institution that receives the award.
 - N. Protocol. The detailed written research plan.
 - O. Research. Any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

1. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities (32 CFR 219.102(d)).
 2. Research includes, but is not limited to, any project, task, test, pilot study, experiment, investigation, study, clinical study, clinical investigation, clinical trial, evaluation, developmental effort or similar undertaking, whether or not conducted or supported under a program that is officially considered research. Any effort, even if not considered research for other purposes, is considered research for purposes of this Manual.
- P. Research Misconduct. Means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
1. Fabrication is making up data or results and recording or reporting them.
 2. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
 3. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
 4. Research misconduct does not include honest error or differences of opinion (42 CFR 93.103).
- Q. Risk. Any possibility of harm, discomfort, or injury (physical, psychological, sociological, or other) as a consequence of participation in the research protocol.

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CHAPTER 2. INSTITUTIONAL REVIEW BOARD (IRB) SUBMISSION REQUIREMENTS

- A. Protocol Preparation. Protocols will be formulated within the mission areas of Coast Guard (CG) or the Department of Homeland Security (DHS). The problem or objective to be addressed will be stated in clear, concise language. The required elements of a protocol are as follows:
1. Protocol Title. The protocol title must be the same as the project/proposal title unless multiple protocols are being submitted within one proposal.
 2. Principal Investigator (PI). Provide the complete name, address, phone number, and email address of the principal investigator. Include a copy of the primary investigator's (PI) curriculum vitae (CV) and certificate of completion of human subject protection training with the protocol. If the protocol involves the use of non-OTC pharmaceuticals, a copy of Good Clinical Practice (GCP) training certificate must also accompany the submitted protocol. To be considered current, training is required within 12 months of submitting any protocol involving drugs/devices. The training may be taken by correspondence or internet-based training, but an on-site course must have occurred no more than 3 years prior to protocol submission. List the names of all personnel who will have significant involvement in the research study; include their practice license (e.g., MD or RN), highest degree(s), job title, and employing institution. In addition, if a Medical Monitor has been assigned to the study, which is required for Greater Than Minimal Risk (GTMR) studies, include his/her name and provide a copy of the current CV.
 3. Location of Study. List location(s) where the data is to be collected. If applicable, include the name, degree(s), title, employing institution, and complete address of the investigator(s) for each site.
 4. Time Line of Project. State the month and year the project is expected to start, when data collection will be complete, and when final report is expected.
 5. Military/Security Relevance. Clearly state the problem to be investigated. Describe how this issue currently impacts the DHS or the CG and what information is to be gained by this research. Include gap analysis, Program Manager or stakeholder endorsement, and/or other research drivers as appropriate. If possible, link products of the proposed research to CG or Homeland Security programs/needs.
 6. Introduction/Literature Review. Provide a comprehensive description of previous research relevant to this project. Ensure that an adequate foundation has been laid which shows what knowledge already exists and what information is lacking in this field of study.
 7. Objectives. Provide a detailed description of the objectives of the study (what information or technology will be obtained from this project).

8. Study Population. Describe the target population (e.g., all CG personnel, aviators, or those operating on a specific platform or within a specific rate), approximate number, and pertinent demographic characteristics (e.g., age, number of years in service, number of career hours exposed to a particular hazard). Describe the methods that will be used to obtain a sample of subjects from the accessible population (e.g., convenience, simple random, stratified random) together with the inclusion and exclusion criteria (include age, gender, and ethnicity). All study populations will be covered per reference (c).
 - a. If pregnant subjects will be excluded from participation in the study, the method used to determine pregnancy status in women of childbearing potential must be specified. It is the CG's current policy that women volunteers must consent to a serum pregnancy test within 48 hours from the start of all GTMR protocols. Additionally, if the research involves within subjects repeated measures designs (e.g., multiple condition drug tests), subjects will be tested 48 hours prior to administration/conduct of each condition. This procedure may also be required for certain minimal risk protocols if imposed as a condition of subject safety by the medical monitor, or the IRB.
 - b. Also, state the time that will elapse between the pregnancy test and exposure to research procedures or medical products and how long the non-pregnant subject should use effective contraceptive practices after participating in the study. Please note that contraceptive practices may be necessary for male subjects participating in certain types of studies.
9. Protocol Design and Methodology. Outline the proposed methodology in sufficient detail to show a clear course of action. Minimum guidance for the plan should include:
 - a. Description of the recruitment process, to include copies of all recruitment and advertisement materials for review.
 - b. Description of the Informed Consent process. State who will perform the informed consent interview and when the interview will take place relative to the participant beginning study participation. Address how privacy and time for decision-making will be provided and whether or not the potential subject will be allowed to discuss the study with anyone before making a decision. When using a verbal consent procedure, indicate who will serve as the witness to the informed consent interview. Two copies of the consent form should be completed--the subject gets the original copy and a copy is kept for the PI's study records. Enclosures (1) and (3) contain copies of the informed consent and interview witness forms. Electronic copies of these forms can be obtained from the COMDT (CG-113) website (<http://www.uscg.mil/hq/cg1/cg113/cg1133/IRB.asp>).
 - c. Sample size and subject assignment. Describe the process used to calculate sample size to ensure that adequate sample size has been chosen. Describe the method that will be used to assign subjects to various conditions when using between groups designs or the process used to select the order of conditions when using within

subject designs (e.g., randomization, matched pairs). Describe the system that will be used to code individual subject data files.

- d. Study evaluations. List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility for study participation. Describe any evaluations to be made during the conduct of the study (e.g., laboratory, psychological, etc.). Also, describe data handling requirements (e.g., specimens to be collected; schedule and amounts; storage, to include where and whether special conditions are required; labeling; and disposition).
- e. Assessments. Provide a copy of data collection forms, questionnaires, rating scales, and/or interview guides that will be used in the study (e.g., cognitive, reaction time, simulated or actual task performance, and mood assessments). Include a copy of the scenario if the protocol involves data collection under simulated conditions.
- f. Describe the research intervention or activity that the subject will experience. Provide sufficient detail in chronological order for a person uninvolved in the research to understand what the subject will experience. If the protocol involves repeated measures, include a test schedule that clearly conveys the time required by each volunteer to complete the study.
- g. Describe the statistical analysis plan. Include any analyses which might be conducted prior to collection of full data set (for example, to ensure sample size will be adequate to draw conclusions). Describe the statistical design and corresponding rationale in detail.
- h. References. Provide a current and fully annotated bibliography/reference section based upon a detailed literature review in the introduction.
- i. Budget. Include an estimate of man hours, salary requirements, equipment, travel costs and other expenses which might be incurred during the conduct of the research.

10. Risks/Benefits Assessment.

- a. Describe risks (e.g., physical, psychological, social, economic, legal, and privacy/confidentiality risks) associated with the research, measures to be taken to minimize and/or eliminate risks or to manage unpreventable risks and special medical or nursing care that will be needed prior to, during, or following participation.
- b. Describe benefits of the research to the subject. If there will be no benefits to the subjects (other than knowing he/she has contributed to science), state this in the protocol and consent form.

- c. Payment or compensation for participation is not considered to be a benefit and must be addressed in a separate section.

11. Reporting of Serious or Unexpected Adverse Events.

- a. Adverse Events (AEs) and Serious or Unexpected Adverse Events (SAEs) can occur in the conduct of any research project. Include a definition of what constitutes an AE or SAE in the study. See Chapter 3 for definitions and Enclosure (4) for example reporting forms. Electronic copies of the sample definitions and reporting forms can be found on the COMDT (CG-113) website <http://www.uscg.mil/hq/cg1/cg113/cg1133/IRB.asp>.

- b. All research protocols must address the following requirements:

An AE temporally related to participation in the study should be documented whether or not considered related to the test article or procedure. This definition includes current illnesses and injuries and exacerbations of preexisting conditions including changes to psychological state. Include the following in all Investigation New Drug (IND) and Investigational Device (ID) safety reports: subject identification number and initials; principal investigator's name and name of CG clinic or DoD Military Treatment Facility (MTF); subject's age, gender, and ethnicity; test article/procedure and dates of administration; signs/symptoms and severity; date of onset; date of resolution or death; relationship to the study drug, event or procedure; action taken; concomitant medication(s) including dose, route and duration of treatment; and date of last dose, if applicable.

- c. Describe agencies or offices to be notified with point of contact information in the event of a serious and unexpected adverse event. For all protocols involving human subjects, including investigational new drug or device studies, the following information about reporting serious and SAE, must be included in the protocol:

(1) Unanticipated problems involving risk to subjects or others, serious or life-threatening adverse events related to participation in a research study, and all subject deaths, should be promptly reported the CG IRB Chairs.

(2) A complete written report will follow the initial notification. The written report will be sent thru the IRB Chairs to the COMDT (CG-11) for review.

- d. Adverse events that are not deemed to be serious by the medical monitor will be recorded and placed in the individual subject study files and reported to the CG IRB Chair within 10 days. These events may be recorded on an AE form (see Enclosure (4) for a sample form) or on an IRB pre-approved check sheet which covers these types of events (e.g., slight headache, complaints of tired eyes, slight upset stomach following simulator flight). Electronic copies of the sample reporting forms can be found on the COMDT (CG-113) website. This information will be tallied at the

conclusion of testing and submitted as part of the final report necessary for protocol completion and closure.

12. Description of Protocol Drugs or Devices. If the protocol uses an investigational drug or device, provide the following information:
 - a. IND/IDE number and name of sponsor.
 - b. Complete names and composition of all medication(s), device(s), or placebo(s).
 - c. Source of medications, devices, or placebos.
 - d. Location of storage for study medications.
 - e. Dose range, schedule, and administration of test articles.
 - f. Washout period, if used, should be described in detail.
 - g. Duration of drug or device treatment.
 - h. Concomitant medications allowed.
 - i. Antidotes and treatments available.
 - j. Disposition of unused drug.
 - k. The procedure by which the IND sponsor will monitor the protocol in accordance with reference (e).
- l. In addition to the above list of requirements to address in the protocol, include the following with the protocol submission:
 - (1) A copy of the Investigator's Brochure and/or device manual and associated case report/data collection forms.
 - (2) A signed Form FDA 1572 for IND Applications that have been approved by the FDA, including the following information (for non-FDA new drug protocols, the following information should be included in the protocol):
 - (a) Name, address, and a statement of the qualifications for each investigator and the name of each sub-investigator working under the PI.
 - (b) Names and addresses of facilities to be used.
 - (c) Name and address of each IRB reviewing the protocol.

- (3) For Investigational Devices, include CG's IRB assessment of the risk, such as minimal or GTMR of the investigational device you plan to use in your study. If the device poses significant risk to research subjects, specify the IDE number obtained from the FDA, the name of the sponsor, and the procedure by which the IDE sponsor will monitor the protocol in accordance with reference (f).
13. Disposition of Data. Describe where data will be stored, who will keep the data, how the data will be stored, and the length of time data will be stored. Note that records of IND studies must be kept until 2 years after a New Drug Application is approved/issued, or for 2 years after the IND is withdrawn (ICH Harmonized Tripartite Guideline for Good Clinical Practice). Records required for IDE studies should be retained for 2 years after the latter of the following dates: the date that the investigation is terminated or completed and the date that the records are no longer required for support of the pre-market approval application.
14. Amendment of the Protocol. Describe the procedures to be followed if the protocol is to be modified, amended or terminated before completion. Note that any modification to the protocol, consent form and/or questionnaires must be submitted to the CG IRB for review and approval.
15. Departure from the Protocol. Describe procedures and notifications to be made in the event of deviations from the approved protocol requirements.
16. Roles and Responsibilities of Study Personnel. Briefly describe the duties of all study personnel, which should include each of the persons listed as investigators, research staff, consultants, and the medical monitor. Describe their roles in the research effort (e.g., Research Coordinator, 80%, recruit and consent subjects, maintain study records, administer study drug, take and record vital signs, enter data into computer data base). A CG PI will be required on every CG protocol.
17. Investigators conducting GTMR research must include the following description of requirements of the Volunteer Registry Database (VRDB) in the protocol and consent form:
- a. It is the policy of the CG that data sheets are to be completed on all volunteers participating in research for entry into the USCG VRDB. The information to be entered into this confidential database includes name, address, employee identification number, study name, and dates. The intent of the database is two-fold: first, to readily answer questions concerning an individual's participation in research sponsored by CG, and second, to ensure that the CG can exercise its obligation to ensure research volunteers are adequately warned (duty to warn) of risks and to provide new information as it becomes available. The CG IRB will maintain VRDB records for a minimum of 5 years.
 - b. Include in the protocol language to indicate that the VRDB sheets must be completed. In addition, include the completion of the VRDB sheets in the study

procedure timelines. A copy of the VRDB form can be found on the COMDT (CG-113) Website under Human Research Guidelines and Check Sheets/VRDB form. The data sheets must be sent to the respective CG IRB Chairs.

- c. VRDB sheets shall be submitted annually and upon completion of the study. Use of the VRDB sheets is not required for Exempt or Minimal Risk studies, unless otherwise indicated.
18. If subjects will be recruited through an advertisement, newspaper article, or similar process, a copy of the approved advertisement must be provided.
 19. For studies involving investigational drugs or devices the FDA has established guidelines on advertisements for subjects. General guidance includes name and address of PI, summary of research purpose, brief eligibility criteria, truthful list of benefits, and the person to contact for further information.
 20. If the research involves surveys, questionnaires, or other instruments, include a copy of the most recent IRB-approved version of each of these documents with the protocol submission. For either of these instruments that are used, the following information at a minimum should be addressed:
 - a. The instrument should be labeled with the complete title of the study and instructions for completing and returning the instrument.
 - b. The instructions should state that the subject can refuse to answer specific items without repercussions.
 - c. Address the process used for validation.
 - d. The instructions should be comprehensible and unambiguous.
 21. Describe the procedure for confidentiality of hardcopy or electronic data in the protocol and consent form.

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CHAPTER 3. ADVERSE EVENT**A. Definitions pertaining to Serious and Unexpected Adverse Events (SAE) resulting from research with investigational drugs:**

1. Adverse Event (AE). An AE is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.
2. Serious Adverse Drug Experience. Any adverse drug experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of an existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse (21 CFR 312.32).
3. Unexpected Adverse Drug Experience. Any adverse drug experience, the specificity or severity of which is not consistent with the current investigator brochure; or, if an investigator brochure is not required or available, the specificity or severity of which is not consistent with the risk information described in the general investigational plan or elsewhere in the current application, as amended. For example, under this definition, hepatic necrosis would be unexpected (by virtue of greater severity) if the investigator brochure only referred to elevated hepatic enzymes or hepatitis. Similarly, cerebral thromboembolism and cerebral vasculitis would be unexpected (by virtue of greater specificity) if the investigator brochure only listed cerebral vascular accidents. "Unexpected," as used in this definition, refers to an adverse drug experience that has not been previously observed (e.g., included in the investigator brochure) rather than from the perspective of such experience not being anticipated from the pharmacological properties of the pharmaceutical product (21 CFR 312.32).
4. Serious and Unexpected. Any event that occurs during a subject's participation in the study that meets the criteria established in the 21 CFR 312 definitions for both serious and unexpected. Note that events not associated with participation in the study, e.g., those that occur after screening, but before administration of a test article, would not be considered serious and unexpected (21 CFR 312.60).

5. Investigational New Drug (IND) Safety Report. As required by 21 CFR 312.55, sponsors of IND research are required to “keep each participating investigator informed of new observations discovered by or reported to the sponsor on the new drug, particularly with respect to adverse effects and safe use.”
 6. Unanticipated Adverse Device Effect. An unanticipated adverse device effect means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects (21 CFR 812.3).
- B. Definitions pertaining to Serious and unexpected adverse events resulting from research not regulated by the Food and Drug Administration.
1. In accordance with 32 CFR 219, as a condition of receiving an assurance of compliance, Institutional Review Boards (IRBs) will have “written procedures for ensuring prompt reporting to the IRB, and appropriate CG officials, of any unanticipated problems involving risks to subjects or others.” AEs that are serious or unexpected as identified within the context of the FDA definitions qualify as unanticipated problems. Therefore, any event that results in death, a life-threatening experience, inpatient hospitalization or prolongation of an existing hospitalization, a persistent or significant disability /incapacity, or a congenital anomaly/birth defect qualify as an SAE. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a SAE when, based upon appropriate medical judgment, they may jeopardize the research participant and may require medical or surgical intervention. Examples of unanticipated problems that qualify as SAEs follow:
 - (a) In research involving an exercise intervention, events resulting in lost time from work or a limitation in the ability of the participant to perform normal daily activities (e.g., a muscle strain in the back).
 - (b) In research involving active duty military personnel, events that result in a temporary or permanent profile.
 - (c) In research involving personal or telephonic interviews, a suicidal ideation expressed during an interview.
 - (d) In outcomes research in disease management in which there is no direct intervention, events that have not been previously observed in participants taking part in this or similar research qualify as SAEs. Hospitalization for sequelae of the disease under observation, if identified as an outcome variable in the study design and coordinated in advance with the IRB and HSRRB with regard to the regular

reporting of events, would not be an SAE. Deaths from the disease under investigation, however, are reportable as SAEs.

- (e) For drug or device research involving FDA approved products not subject to regulation under 21CFR 312 or 21 CFR 812, SAEs refer to adverse events not described in the approved product labeling or events occurring at a greater frequency than the approved product labeling (21 CFR 314.80).

NOTE: The CG requires reporting of serious and unexpected adverse events. In addition, the continuing review report submitted to the IRB of record will contain a compilation of all adverse events and the respective outcomes associated with the product during the course of the year.

Enclosure (4) is a form that may be used for reporting of serious and unexpected adverse events. Other forms may be used, but similar data elements should be collected.

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SAMPLE INFORMED CONSENT FORM

CONSENT TO PARTICIPATE IN RESEARCH

[Insert title of the study.] [If the study involves using different consent forms for different populations, identify the population group as the subtitle of the study.]

Suggested text:

You are asked to participate in a research study conducted at the *[Insert the study site]* by *[name(s) of investigator(s)]*. Your participation in this study is voluntary. You should read the information below and ask questions about anything you do not understand before deciding whether or not to participate.

Guidelines:

- *Use simple language.*
- *Be concise.*
- *Use the pronoun “you” consistently throughout*

(except for the signature of the subject on the last page).

PURPOSE OF THE STUDY

[State what the study is designed to discover or establish.]

PROCEDURES

Suggested text:

If you volunteer to participate in this study, we would ask you to do the following things:

Guidelines:

- *Describe the procedures chronologically using lay language, short sentences and short paragraphs. The use of tables or flow diagrams will help to organize this section and increase readability. Distinguish which procedures are experimental and which are standard clinical treatments. Include screening evaluations and a listing of inclusion/exclusion criteria. Define and explain medical and scientific terms in ordinary language (for example, describing the amount of blood to be drawn in terms of teaspoons or tablespoons).*
- *Specify the subject's assignment to study groups, the number of subjects expected to be enrolled, length of time for participation in each procedure, the total length of time for participation, frequency of procedures, location of the procedures to be done, etc.*

- *For research involving randomization of subjects into different arms of studies, specify the randomization procedures.*
- *For research involving the use of placebo, describe “placebo” in lay terms*

POTENTIAL RISKS AND DISCOMFORTS

Guidelines:

- *Identify each procedure and then describe any reasonably foreseeable risks, discomforts, inconveniences, and how these will be minimized. Quantify risks using understandable comparisons.*
- *In addition to physiological risks/discomforts, describe any psychological, social, or legal, risks that might result from participating in the research. If screening involves drug screening, serologic HIV or hepatitis C testing, explain the extent to which data will be kept confidential. Address local or federal reporting requirements, if any. Inform the subjects about availability of follow up or referral for treatment.*

ANTICIPATED BENEFITS TO SUBJECTS

Suggested text:

[Describe the anticipated direct benefits to subjects resulting from their participation in the research. If consent will be obtained from a legal representative of the subject, the direct benefit to the subject must be elaborated in the consent form.]

Guidelines:

- *If there is no likelihood that participants will benefit directly from their participation in the research, state as much in clear terms. For example: “You should not expect your condition to improve as a result of participating in this research” or “This study is not being done to improve your condition or health. You have the right to refuse to participate in this study.”*
- *Do not include payment for participating in this section.*

ALTERNATIVES TO PARTICIPATION

Guidelines:

- *Describe any appropriate alternative therapeutic, diagnostic, or preventive procedures that should be considered before the subjects decide whether or not to participate in the study. If there are no efficacious alternatives, state that an alternative is not to anticipate in the study. If the prospective subjects are suffering from a terminal illness, and there are no alternative treatments available, you should say so; but add that treatment of symptoms and pain control are available through supportive care. In*

other words, avoid suggesting that participation in the research is the only way to obtain medical care and attention.

- *If prospective subjects have a chronic, progressive disorder, for which no treatment had been demonstrated to be safe and effective, say that, as well. But also describe opportunities for managing symptoms, improving ability to function, etc. so that it does not appear that the patient will be abandoned if he/she does not agree to participate.*

PAYMENT FOR PARTICIPATION

Guidelines:

- *Federal law, 24 USC 30, permits compensation for blood draws, not to exceed \$50 per blood draw, to be paid to “On-Duty” service members. A service member who is participating while “On-Duty” may only be compensated for blood draws, and may be otherwise compensated for research participation.*
- *Federal law, 24 USC 30, provides an exception to the Dual Compensation Act, which prohibits service members from being paid by any source other than regular military salaries while “On-Duty”. “Off-Duty” service members may be compensated in the same manner as non-military research subjects. “Off-Duty” service members therefore may be paid more than \$50 per blood draw, and may be compensated for research participation generally (not only for blood draws). *Note: Payment to “Off-Duty” service members for research participation other than blood draws must **not** be directly from a federal source (payment from a contractor or other non-federal source is permissible).*
- *Service members need to have Command permission to participate in research while “Off-Duty”. “Off-Duty” research participation may affect a service member’s ability to perform his/her military duties. Principal Investigators should confirm that a service member’s Commander supports the service member’s research participation.*
- *State whether the subject will be paid or offered other benefits (e.g., free care). If not, state so.*
- *If the subject will receive payment, describe remuneration amount, when payment is scheduled, and prorated payment schedule should the subject decide to withdraw or be withdrawn by the investigator.*
- *If the subject will be reimbursed for expenses such as parking, bus/taxi, etc., state so*

MEDICAL CARE FOR RESEARCH RELATED INJURY

Note: The following is a required element of informed consent for research involving greater than minimal risk.

Suggested text:

For greater than minimal risk research involving private citizens, include the following statement: Other than medical care that may be provided, there is no compensation available for your participation in this research study; however, you understand this is not a waiver or release of your legal rights.

CONFIDENTIALITY

Suggested text:

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs, videos, or audiotape recordings of you will be used for educational purposes, your identity will be protected or disguised. [*Describe how personal identities will be shielded, disguised, etc.*]
[When the research records may be subject to inspection by FDA, a funding agency, or an industrial sponsor, you must add:]

Authorized representatives of the CG, FDA, and the manufacturer of the drug [*or device*] being tested [*insert name of company*] may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others.

Guidelines:

- *Give a brief description of how personal information, research data, and related records will be coded, stored, etc., to prevent access by unauthorized personnel.*
- *Explain how specific consent will be solicited, if any other uses are contemplated.*
- *If applicable, state if and when individual responses to survey questionnaires will be destroyed, following analyses of the data.*

PARTICIPATION AND WITHDRAWAL

Suggested text:

Your participation in this research is voluntary. If you choose not to participate, that will not effect your relationship with (enter study site) or your right to health care or other services to which you are otherwise entitled. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice.

CONSEQUENCES OF WITHDRAWAL

(Note: If this does not apply to your research, please omit this entry and delete the heading.) [*Explain the consequences of a subject's decision to withdraw from the research and any follow up the subject may be asked to complete, for reasons of safety.*]

WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR

Suggested text:

The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. If you experience any of the following side effects [*list and describe*] or if you become ill during the research, you may have to drop out, even if you would like to

continue. The investigator will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

NEW FINDINGS

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.

IDENTIFICATION OF INVESTIGATORS

In the event of a research related injury or if you experience an adverse reaction, please immediately contact one of the investigators listed below. If you have any questions about the research, please feel free to contact [*Identify the point of contact. Include the daytime telephone numbers and addresses. For greater than minimal risk studies, include night/emergency telephone numbers.*]

VOLUNTEER REGISTRY DATA BASE REQUIREMENTS

For all studies involving greater than minimal risk to subjects, the Volunteer Registry Data Base must be included in the consent form (see COMDT (CG-113) website – <http://www.uscg.mil/hq/cg1/cg113/default.asp>).

RIGHTS OF RESEARCH SUBJECTS

You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research subject, you may contact the [*Insert name, address, and telephone number of the point of contact.*]

SIGNATURE OF RESEARCH SUBJECT

I have read the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form.

Name of Subject

Signature of Subject

Date

Address

SIGNATURE OF WITNESS

My signature as witness certifies that the subject signed this consent form in my presence as his/her voluntary act and deed.

Name of Witness

Signature of Witness

Date

SAMPLE EXEMPTION REQUEST

ABSTRACT

Summary of the proposed research including purpose of study and proposed methodology.

BRIEF RATIONALE OF OBJECTIVES

Provide an introduction section that outlines the rationale for the study. Include the research framework, supporting literature, and research question(s) as well as relevant hypotheses.

DESCRIPTION OF POPULATION

Provide number of participants, recruitment process, selection criteria, and rationale for exclusion.

DESCRIPTION OF METHODOLOGY AND PROCEDURES

Include project's procedures and the methods of obtaining informed consent, where will the project be conducted, how assent be secured (if minors), content of informed consent, data collection instruments (e.g., questionnaires, surveys, observations, archived data, etc.)

USE OF DATA/ANALYSIS

Explain how information from human subjects will be analyzed, presented, and used. Also, describe confidentiality assurance process.

BENEFITS, COST, RISKS, COMPENSATION

Describe potential risks to participants (including emotional, physical, social, financial consequences, etc.) and steps to mitigate and minimize risks. Explain what may be revealed from the results of this project. Also indicate potential benefits to participants as well any planned compensation.

INFORMED CONSENT FORMS

Include all informed consent forms to be used during the project.

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SAMPLE WITNESS TO INFORMED CONSENT FORM

Witness to Consent Interview

On the date given next to my signature, I witnessed the "Consent Interview" for the Research Study named above in this document. I attest that the information in this consent form was explained to, and apparently understood by, the subject or the subject's legally acceptable representative.

Name of Witness _____

Signature of Witness _____ Date _____

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REPORT OF SERIOUS AND UNEXPECTED ADVERSE EVENT FORM

For any section in which additional space is needed, complete on plain bond paper.

Report Type: ___Initial ___Follow-up ___Medical Monitor

IRB Log No: A-

Study Title:

Principal Investigator Name:

Study Drug/Device:

Reporting Individual (printed name, title/position, and phone number):

Total study enrollment to date: _____ participants _____ withdrawals _____ deaths

Subject Data: Subject ID _____ Age _____ Gender _____

Study Group/Arm _____ Enrollment Site _____

Event description (include admission/discharge dates, event resolution if known, subject status) and attach supporting documents (discharge summaries, lab reports, etc.):

Seriousness –check all that apply	Relationship to drug/device
<input type="checkbox"/> Fatal	<input type="checkbox"/> Not Related <input type="checkbox"/> Not Applicable
<input type="checkbox"/> Life Threatening	<input type="checkbox"/> Possibly <input type="checkbox"/> Probably
<input type="checkbox"/> Disability	<input type="checkbox"/> Definitely Related
<input type="checkbox"/> Hospitalization (initial or prolonged)	<input type="checkbox"/> Unclassifiable
Other (specify)	

Pertinent Medical History (to include medication use):

Actions Taken or Anticipated Actions in Response to this Event (Changes to consent form/protocol, blind broken, subject dropped from study):

Event reported to IRB of record: yes no n/a (circle one)

Date reported to IRB of record:

Other Serious and Unexpected Adverse Events Reported for this Study:

Enclosure (4) to COMDTINST M6500.1

For Medical Monitor Reports Only - Assessment of Report from the PI (comments on concurrence/non-concurrence with diagnosis, treatment and relationship of event to participation in study):

Reporter printed name

Reported signature

Date