

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



COAST GUARD HUMAN RESEARCH PROTECTION PROGRAM

COMDTINST M6500.1A
10 MARCH 2018



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10 MARCH 2018

COMMANDANT INSTRUCTION M6500.1A

Subj: COAST GUARD HUMAN RESEARCH PROTECTION PROGRAM

- Ref:
- (a) Title 45, Code of Federal Regulations, Part 46, Subparts A-E
 - (b) DHS Management Directive 026-04, Protection of Human Subjects, 25 May 2007
 - (c) Title 32, Code of Federal Regulations, Part 219
 - (d) Safety and Environmental Health Manual, COMDTINST M5100.47 (series)
 - (e) The Belmont Report, 44 Federal Register 23192 (April 18, 1979)
 - (f) Information and Life Cycle Management Manual, COMDTINST M5212.12 (series)
 - (g) Employment of Experts and Consultants: Temporary or Intermittent, 5 USC 3109
 - (h) Title 21, Code of Federal Regulations, Part 312
 - (i) 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 participants in research and test and evaluation activities conducted by, within, or for the Coast Guard (CG).
2. ACTION. All CG unit commanders, commanding officers, officers-in-charge, deputy/assistant commandants, and chiefs of headquarters staff elements must comply with the provisions of this Manual. Internet release is authorized.
3. DIRECTIVES AFFECTED. Coast Guard Human Research Protection Program, COMDTINST M6500.1 is hereby cancelled.
4. BACKGROUND.
 - a. Research activities are essential to protect the health, safety, well-being, and performance of CG personnel, including active duty, reservists, auxiliarists, and civilians. Reference (a) requires government agencies and private organizations engaging in research activities to guarantee fundamental protections to participants,

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ensuring their ethical treatment, health, and well-being. Support from CG leadership is required to ensure compliance with Reference (a).

- 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.
5. DISCLAIMER. This guidance is not a substitute for applicable legal requirements, nor is it itself a rule. It is intended to provide operational guidance for CG personnel and is not intended to nor does it impose legally-binding requirements on any party outside the CG.
 6. MAJOR CHANGES. Major changes to the previous version of this Manual are summarized below:
 - a. Clarifies the roles and responsibilities of the Coast Guard Academy (CGA), Research and Development Center (RDC), and Commandant (CG-11) Institutional Review Boards (IRBs).
 - b. Updates responsibilities of Commandant (CG-11), to establish access to Clinical Trials for CG members.
 - c. Updates the review of System Test and Evaluations (ST&E) plans, including applicable roles and responsibilities of the Safety Review Board (SRB).
 - d. Clarifies roles and responsibilities of Test Directors (TDs) in ushering ST&E plans through the review process.
 - e. Adds responsibilities to Principal Investigators (PIs) and TDs in the preparation and implementation of Data Usage Agreements (DUAs) in projects requiring data sharing with external organizations.
 - f. Adds responsibilities to PIs and TDs in the preparation and use of official memoranda, describing agreements with external organizations when partnerships are required for the execution of research and ST&E activities.
 7. ENVIRONMENTAL ASPECT AND IMPACT CONSIDERATIONS.
 - a. The development of this Manual and the general policies contained within it have been thoroughly reviewed by the originating office in conjunction with the Office of Environmental Management, Commandant (CG-47). This Manual is categorically excluded under current Department of Homeland Security (DHS) categorical exclusion (CATEX) A3 from further environmental analysis in accordance with "Implementation of the National Environmental Policy Act (NEPA), DHS Instruction Manual 023-01-001-01 (series).

- b. This Manual will not have any of the following: significant cumulative impacts on the human environment; substantial controversy or substantial change to existing environmental conditions; or inconsistencies with any Federal, State, or local laws or administrative determinations relating to the environment. All future specific actions resulting from the general policy in this Manual must be individually evaluated for compliance with the National Environmental Policy Act (NEPA), Department of Homeland Security (DHS) and Coast Guard NEPA policy, and compliance with all other applicable environmental mandates.
8. DISTRIBUTION. No paper distribution will be made of this Manual. An electronic version will be located on the following Commandant (CG-612) web sites. Internet: <http://www.dcms.uscg.mil/directives/>, and CGPortal: <https://cg.portal.uscg.mil/library/directives/SitePages/Home.aspx>.
9. RECORDS MANAGEMENT CONSIDERATIONS. This Manual has been evaluated for potential records management impacts. The development of this Manual has been thoroughly reviewed during the directives clearance process, and it has been determined there are no further records scheduling requirements, in accordance with Federal Records Act, 44 U.S.C. 3101 et seq., National Archives and Records Administration (NARA) requirements, and the Information and Life Cycle Management Manual, COMDTINST M5212.12 (series). This Policy does not have any significant or substantial change to existing records management requirements.
10. SCOPE.
 - a. This Manual applies to:
 - (1) Research activities as defined in Paragraph 6(b) per Reference (a), including ST&Es, involving CG personnel, personnel from other government agencies, and/or civilians as research participants, conducted by CG personnel, 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 any research using CG property, facilities, or assets.
 - (2) Research activities as defined in Paragraph 6(b) per Reference (a), including ST&Es, 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).
 - b. All CG research activities as defined in Paragraph 6(b) per Reference (a) shall meet DHS requirements as set forth in References (a), (b), (c), and (d).
 - c. The CG will have three authorized IRBs: the Commandant (CG-11) IRB, the Research and Development Center (RDC) IRB, and the Coast Guard Academy (CGA) IRB. This Manual refers to all three 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.

11. DEFINITIONS. Definitions are described, in detail, in Chapter 1 of this Manual.

12. POLICY.

- a. Guiding Principles. The CG uses the ethical principles outlined in Reference (e), 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 and ST&E activities, involving human participation, conducted or supported by the CG shall comply with the requirements of the Common Rule per Reference (a) (Subpart A). All research conducted or supported by the CG involving vulnerable classes of subjects including pregnant women, fetuses, neonates, prisoners and children will comply with the provisions of Reference (a) (Subparts B, C, and D). The following key principles are:
 - (1) Respect for Persons. The rights, welfare, interests, privacy, confidentiality, and safety of participants 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 activities involving human participants must complete initial and ongoing research training on ethics and participants'

protections commensurate with each individual's level of involvement, duties, and responsibilities. The CG IRB Chair determines the appropriate training for all personnel engaged in research and test and evaluation activities.

- c. Informed Consent. Voluntary informed consent is fundamental to ethical research involving human participants. Informed consent is not simply a document. It is a process that begins with recruitment of prospective participants and includes a thorough discussion with each and every person, or their legally authorized representatives, and continues for at least the duration of the research. Depending on the research, ongoing discussions and education of participants may continue long after the original informed consent is obtained. For additional requirements on informed consent refer to: https://cg.portal.uscg.mil/units/cg113/HRPP/COMDTINST6500.1A/Enclosures/HRPP_Informed Consent Form.pdf.
- d. Participants. Participants must sign an informed consent document, which is witnessed and dated, when indicated by the CG IRB.
- e. Research Classification.
 - (1) Minimal Risk. The CG IRB shall evaluate all minimal risk (for definition see Chapter 1) research studies.
 - (2) Greater Than Minimal Risk (GTMR). The CG IRB shall evaluate all research involving greater than minimal risk (for definition see Chapter 1) and may confer with a consulting IRB as appropriate.
 - (3) Exempted Research. The CG IRB will determine and document whether research proposal meet one or more categories of exemption as defined in Reference (a).
 - (4) Expedited Review. The CG IRB Chair will review and determine whether research protocols and ST&E plans meet the expedited review criteria as defined in Reference (a). If the IRB Chair determines that the submitted materials meet the criteria for expedited review, then the IRB Chair and at least one other IRB or Safety Review Board (SRB) member will review the research proposal or ST&E plan.
 - (5) Survey Research. All survey research protocols require IRB review. Survey projects conducted entirely within the unit or command may attain exempt status as long as procedures clearly protect participants' personal identifiable information. However, CG IRB review is required to arrive at the determination of exemption.
 - (6) Advanced Education Research. All advanced education research, whether pursued privately or through an established CG advanced education program, and that involve the use of or interface with CG personnel, records, data, or assets require CG IRB review.

- (7) ST&E. All ST&E plans and procedures require submission to CG IRB for review and approval. The CG IRB will coordinate with the SRB per Reference (d) to conduct the review and produce the approval memorandum.
- (8) Classified Research. Classified research involving human participants is held to the same ethical principles and protections as unclassified research. Classified research is not eligible for review under expedited review procedures.
- (9) Assurance of Compliance. As required in Reference (b), all research activities (not otherwise exempt) conducted or supported by the CG will be accomplished under a written assurance of compliance showing agency adoption of the Federal Policy for the protection of human subjects. The CG relies on the U.S. Department of Health and Human Services, Office of Human Research Protection (OHRP), approved Federal Wide Assurance (FWA) as its assurance of compliance.

13. RESPONSIBILITIES.

a. Director, Health, Safety, and Work-Life, Commandant (CG-11) shall:

- (1) Serve as the single authority for policy development, oversight, compliance, and ongoing monitoring concerning protection of all persons participating in research and ST&E activities in the CG.
- (2) Serve as approving authority for the establishment of IRBs in the CG.
- (3) Ensure compliance with DHS and Code of Federal Regulations concerning protection of human subjects (References (a)-(i)).
- (4) Designate authority for CG IRB members.
- (5) Ensure all records that document human research protection in the CG are maintained in accordance with References (a) and (f).
- (6) Maintain records of all Assurances per Reference (a).
- (7) Provide blanket authorization for CG participation in the National Cancer Institute's (NCI) Clinical Trials Cooperative Group Program.

b. CG (IRB): The CG IRB shall:

- (1) Make recommendations to the approving authority for research and ST&E protocols.
 - (a) Commandant (CG-11) IRB makes recommendations to Commandant (CG-11) as the approving authority for CG research and ST&E protocols,

- (b) CG RDC IRB makes recommendations to the RDC Commanding Officer as the approving authority for RDC research protocols,
 - (c) CGA IRB makes recommendations to the CGA Superintendent as the approving authority for CGA research protocols, and
 - (d) CG RDC or CG CGA IRBs shall consult with Commandant (CG-11) IRB on any research and ST&E protocols that involve activities beyond the expertise of the IRB membership.
- (2) Serve as the liaison for CG compliance with Reference (b), and assure the safety, welfare, and privacy protections of all participants in research and ST&E conducted or supported by the CG.
 - (3) Ensure IRB membership is in compliance with qualifications listed in Reference (a).
 - (4) Ensure IRB members are current federal employees (uniformed, civilian, staff, or trainee), are appointed under the Intergovernmental Personnel Act (IPA), or are consultants consistent with the requirements established by 5 USC 3109 (Reference (g)). Status as a contractor or federal retiree alone is not sufficient to qualify as a federal employee for the purpose of IRB membership.
 - (5) Ensure that IRB members receive initial and annual training on ethics and human subjects' protection as required by the CG IRB Chair.
 - (6) Review all research protocols and ST&E plans conducted by, within, or for the CG.
 - (7) Ensure Principal Investigators (PIs) or TDs are current federal employees (uniformed, civilian, staff, or trainee), covered under the Intergovernmental Personnel Act (IPA), or are consultants consistent with the requirements established by Reference (g). Status as a contractor or federal retiree alone is not sufficient to qualify individuals as PIs or TDs in CG supported research activities, including ST&Es.
 - (8) Ensure PIs or TDs possess the required education, knowledge, skills, and experience (credentials) to initiate, conduct, and oversee research activities, including ST&E, and have completed required ethics training, including human subject protections.
 - (9) Recommend approval, disapproval, exemption, or necessary modifications to research and ST&E protocols.
 - (10) Determine the need for Study Physician (SP) and/or Medical Monitor (MM) in research activities, including ST&Es. 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 either the SP or MM.

- (11) Ensure that MM reports are forwarded to the approving authority.
 - (12) Review and, if appropriate, take action on allegations of research misconduct or non-compliance with human subject protections.
 - (13) Coordinate with SRB for the review and approval of ST&E plans.
 - (14) Ensure that all records that document research participants' protections in the CG are maintained properly, then destroyed when five years old or when usefulness has been served, whichever is later, in accordance with Reference (f).
 - (15) 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.
 - (16) Ensure all labor agreement obligations are met when using bargaining unit employees in research and ST&E activities. Coordinate with Command Staff Advisor or Human Resource (HR) specialists for advice and guidance on proper labor obligations.
 - (17) Ensure that all IRBs monitoring research conducted by, supported by, or executed for the CG maintain an up-to-date Assurance of Compliance document, approved for federal wide assurance by OHRP.
- c. Command Responsibility. Commanders, commanding officers, officers in charge, civilian directors, Chiefs of Headquarters staff elements, and all personnel involved in the study, shall:
- (1) Ensure the safety and welfare of participants in research and ST&E activities.
 - (2) Ensure that participants' decisions to participate are protected from any undue influence or coercion. For all research involving CG personnel, supervisors shall not influence the decisions of their subordinates to participate.
 - (3) Ensure that all research and ST&E protocols are reviewed and approved by the CG IRB or SRB prior to initiating any activity.
 - (4) Ensure all labor agreement obligations are met prior to involving bargaining unit employees in research and ST&E activities. Coordinate with Command Staff Advisor or HR specialist for advice and guidance on proper labor obligations.
 - (5) Ensure that all research protocols reviewed by a non-CG IRB, including any IRB determinations, are reviewed and approved by the CG IRB prior to awarding federal funding.

- d. Principal Investigator (PI) and Test Director (TD) shall:
- (1) Obtain review and approval of research protocols or test plans through the CG IRB per References (a) and (d). Additional information on research proposal and test and evaluation plan are available at:
<https://cg.portal.uscg.mil/units/cg113/HRPP/COMDTINST6500.1A/Enclosures/HRP P Research Protocol.pdf> and
<https://cg.portal.uscg.mil/units/cg113/HRPP/COMDTINST6500.1A/Enclosures/HRP P Test and Evaluation.docx>.
 - (2) Ensure compliance with all Regulations, Directives, and Instructions that ensure protections (safety, health, and privacy) to research participants.
 - (3) Assume responsibility for the quality of the research (as defined in Paragraph 6 (b) per Reference (a)) and for the safety and welfare of research participants.
 - (4) Complete and document initial and continuing training on research ethics and participant protections as applicable to the research activity. Ensure all personnel involved in research activities have completed appropriate training as specified by the CG IRB.
 - (5) Ensure that research Associate Investigators (AIs) or ST&E Team Members (TMs) are current federal employees (uniformed, civilian, staff, or trainee), covered under the Intergovernmental Personnel Act (IPA), or are consultants consistent with the requirements established under Reference (g). Status as a contractor or federal retiree alone is not sufficient to qualify individuals as AIs or TMs for CG supported research activities, including ST&Es.
 - (6) Ensure that the research project staff is credentialed in the area of research under study. The name and appropriate proof of credentials (e.g., Curriculum Vita (CV); evidence of professional training) of the PI, TD, SP, MM, AIs, and/or TMs must be provided with the research protocol and/or test plan.
 - (7) Obtain written determination from the CG IRB indicating that the proposed activity is classified as research or that the activity meets criteria for exemption per Reference (a).
 - (8) Obtain CG IRB and/or SRB approval, as indicated in Chapter 2 of this Manual and Chapter 5 of Reference (d), prior to initiating any research activities, including ST&Es.
 - (9) Obtain CG IRB and/or SRB approval prior to implementing any proposed amendments to approved research.

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- (10) Immediately notify the CG IRB or SRB, in writing, of any unanticipated risks to participants or others, serious adverse events, serious or continuing noncompliance with the human subject protection regulations and CG IRB/SRB requirements, and any protocol or research plan procedural deviations.
 - (11) When indicated by the CG IRB, obtain informed consent from research participants, or their legally authorized representatives. Provide participants, or their legal representatives, a copy of the completed informed consent document prior to the start of research, unless a waiver of the documentation is approved by the CG IRB. More information on informed consent is available at:
https://cg.portal.uscg.mil/units/cg113/HRPP/COMDTINST6500.1A/Enclosures/HRP_P_Informed Consent Form.pdf.
 - (12) Develop a Memorandum of Agreement (MOA) with external organizations when required by the CG IRB, obtain approval of the MOA through the cognizant CG legal office, and submit approved documents to the CG IRB along with the research proposal or ST&E plan.
 - (13) Develop a Data Usage Agreement (DUA) when research requires sharing data with external organizations, governmental and non-governmental, obtain approval of the DUA through the cognizant CG legal office, and submit documents to the CG IRB along with the research proposal and/or ST&E plan. A sample DUA is available at:
https://cg.portal.uscg.mil/units/cg113/HRPP/COMDTINST6500.1A/Enclosures/HRP_P_Data Use Agreement.pdf.
 - (14) When required by the CG IRB, administer Non-Disclosure Agreement (NDA) to research team members, partners, or contractors, and submit signed NDAs to the CG IRB. A sample NDA is available at:
https://cg.portal.uscg.mil/units/cg113/HRPP/COMDTINST6500.1A/Enclosures/HRP_P_Non Disclosure Agreement.pdf.
- e. Associate Investigator (AI) shall: Plan and conduct studies (e.g., formulate research, prepare protocols, develop methodology, manage research participants, 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) shall:
- (1) Participate in all experimental procedures requiring medical proficiency or oversight.
 - (2) Record and report all serious and unexpected AEs to the CG IRB and responsible IRB within 3 days of occurrence.
 - (3) Place a signed, dated, and sufficiently detailed description of the adverse event in the subject study file to provide a clear picture of the occurrence.

- g. Medical Monitor (MM). A MM must be assigned to all GTMR studies. The CG IRB may determine that an alternate medical professional (e.g., physician assistant, nurse practitioner, nurse, or corpsman) may serve as a MM. The MM shall:
- (1) Review and monitor all experimental procedures for health and safety risks and report to the CG IRB and responsible IRB.
 - (2) Suspend the execution of the research protocol, if necessary, to prevent undue harm to subjects.
 - (3) Review all serious and unexpected AEs associated with the protocol and provide an unbiased written report of the event within 10 calendar days of the initial report to the CG IRB and responsible IRB.
 - (4) Comment on the outcomes of the 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 PI, TD, and/or SP.
- h. ST&E Team Member (TM) shall: Conduct test procedures as prescribed in the test plan without deviations, unless modifications are reviewed and approved by the SRB.
15. FORMS/REPORTS. The forms referenced in this Manual are available in CG Electronic Forms on the Standard Workstation or on the Internet at: <http://www.dcms.uscg.mil/Our-Organization/Assistant-Commandant-for-C4IT-CG-6-/The-Office-of-Information-Management-CG-61/Forms-Management/> or CGPortal at: <https://cg.portal.uscg.mil/library/forms/SitePages/Home.aspx>.
16. REQUEST FOR CHANGES: Units and individuals may recommend changes by sending an email via the chain of command to: HQS-DG-lst-cg-113@uscg.mil.

ERICA G. SCHWARTZ /s/
Rear Admiral, U.S. Public Health Service
Director, Health, Safety, and Work-Life

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CHAPTER 1: DEFINITIONS

Advanced Education Research. Research conducted as part of requirements of a graduate or undergraduate degree program conducted under auspices and oversight of an accredited University or College.

Adverse Event. See Chapter 3.

Approval. The official written notification by the performing institution that a research project or activity involving human participants has been reviewed and approved by an Institutional Review Board (IRB) or Safety Review Board (SRB) as required by an approved assurance or indicated by CG policy.

Approval Authority for Research Protocols. Individual with delegated approval authority that permits research to begin. Such individuals also have authority to certify a research protocol.

Associate Investigator. A fully accredited researcher who collaborates with the PI, providing specific technical assistance; or a researcher with limited experience and/or training who works under the mentorship of a PI to gain research experience and/or develop research skills.

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.

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.

Engaged in Research. An activity becomes “engaged in research” when research personnel or agents either intervene or interact with living individuals for research purposes; or obtain individually identifiable private information, medical records, or professional information for research purposes.

Exempted Research. Research exempt from direct IRB oversight under 45 CFR 46.

Expedited Research Review. IRB review process requiring a minimum of two IRB members, one of which must be the Chair of the IRB.

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.

Human Participant or Subject. Refers to a living individual participating in research and/or test and evaluation activities, with whom an investigator or test team member interacts in the course of conducting research, obtaining either data through interventions, or interaction with the individual, or recording identifiable private information. Intervention includes all procedures (e.g., questionnaires/surveys, observations of behavior, recordings of voice responses, video recordings of activities during research activities, venipuncture, etc.) where data are gathered and manipulations of the participant or the participant's environment (including systems or equipment participants use or interact with) that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator or test team member, and participants. 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).

Informed Consent (IC). Official document describing research objectives and procedures, risks associated with research procedures, and assurances protecting the privacy, health and well-being of participants. The IC document also includes responsible points of contact (e.g., Research PI, responsible IRB Chair, etc.) for participants to clarify questions, lodge complaints, and express concerns associated with the research before, during, and after participation.

Institutional Review Board (IRB). The IRB is a committee established in accordance with References (a) and (c) to ensure the protection of participants' rights and welfare.

Institutional Review Board (IRB) Member. A CG IRB member must be a current federal employee (uniformed, civilian, staff, or trainee), an individual appointed under the Intergovernmental Personnel Act (IPA), or a consultant consistent with the requirements established by 5 USC 3109 (Reference (g)). Status as a contractor or federal retiree alone is not sufficient to qualify as a federal employee for the purpose of IRB membership.

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 (References (a) and (c)).

Greater than Minimal Risk (GTMR). The probability and magnitude of harm or discomfort anticipated in the research may exceed those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (References, (a) and (c)).

Medical Monitor (MM). This individual should be a qualified physician, other than the PI or SP, not associated with the research protocol. Depending on the nature of the study, the MM 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 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 MM.

Non-compliance. Deliberate or inadvertent departure from or failure to comply with federal regulations, DHS directives, CG policies, or IRB requirements for the protection of participants in research activities as defined in Reference (a), and Paragraph 6(b) of this Manual.

Principal Investigator (PI). In CG-supported research activities (Reference (a), and Paragraph 6(b) of this Manual), the PI is an individual who possesses the required education, knowledge, skills, and experience (credentials) to initiate, conduct, and oversee research activities, and has completed the required ethics training, including human subject protections. In addition, for CG supported extramural research, a PI must meet the criteria established by the institution that receives the award. The criteria must comply with References (a) or (c).

Protocol. The detailed written research plan.

Research. Any systematic investigation, including research development, and testing and evaluation, designed to develop or contribute to generalizable knowledge. 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 (References (a) and (c)). Research includes, but is not limited to, any project, task, ST&E, 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 systematic investigation, even if not considered research for other purposes, is considered research for purposes of this Manual.

Research Misconduct. Means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Fabrication includes making up data or results and recording or reporting them. Also, falsification includes 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. Plagiarism includes appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Research misconduct does not include honest error or differences of opinion.

Responsible IRB. The responsible IRB assumes primary responsibility to ensure that activities conducted under an approved research project comply with Reference (a).

Risk. Any possibility of harm, discomfort, or injury (physical, psychological, sociological or other) as a consequence of participation in the research protocol or ST&E activities.

Safety Review Board (SRB). The SRB is composed of subject matter experts capable of identifying hazards resulting from the execution of procedures described in ST&E plans. The SRB reviews, requests modifications, and approves ST&E plans to ensure that hazard mitigation procedures, included in the test plan, minimize risk and safeguard participants.

Study Physician. A medical doctor or alternate medical professional assigned to a research study when the CG IRB determines that the expertise is required.

ST&E Activities. Procedures conducted to assess the functioning, reliability, and efficacy of any process, procedure, operational tactics, system, subsystem, operational platform, software, hardware, equipment, or tool.

Survey Research. In survey research, the researcher selects a sample of respondents from a population and administers a standardized questionnaire to them. The questionnaire, or survey, can be a written document that is completed by the person being surveyed, an online questionnaire, a face-to-face interview, or a telephone interview.

System Test and Evaluation Team Member (TM). A member of the test and evaluation team, conducts procedures as prescribed in the ST&E plan, collects data, analyzes data, interacts with participants, and works under the direction and supervision of the TD.

System Test and Evaluation (ST&E) Plan. A description of procedures to be executed by ST&E participants, whether operating or evaluating the system, and a corresponding list of potential hazards mapped to each T&E task, consequences of such actions, and feasible hazard mitigation procedures, to be submitted to the SRB for review and approval prior to execution of ST&E procedures. All ST&E procedures requiring participants to either evaluate or operate the system in protected environments (e.g., laboratory, hanger, flight line, dock, in-port, maintenance shop, etc.) or in operational environments, must be described in a test plan. TDs have primary responsibility to submit the test plan to the SRB describing all system test and evaluation procedures and a corresponding list of potential hazards, consequences, and feasible mitigation procedures.

Test Director (TD). In CG-supported ST&E activities, the TD is an individual who possesses the required education, knowledge, skills, and/or experience (credentials) to initiate, conduct, and oversee ST&E activities, and has completed the required training, including human subject protections training, to perform CG supported intramural and extramural ST&E activities. In addition, for CG supported extramural research, a TD must meet the criteria established by the institution that receives the contract award and said criteria must be approved by the CG IRB.

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 and 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 PI. Include a copy of the PI's CV and certificate of completion of human subject protection training with the protocol. If the protocol involves the use of non-over the counter 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. 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 MM has been assigned to the study, which is required for 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 completed, and when the 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 a 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 MM 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.
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 IC process. State who will perform the IC 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 IC interview. Two copies of the IC form should be completed, the subject gets the original copy and a copy is kept for the PI's study records.
 - 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 analysis which might be conducted prior to collection of full data set (e.g., sample size determination). 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 links to reporting forms.

- 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; PI'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 participants, including IND or ID studies, the following information about reporting AE 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 to the CG IRB Chair.

- (2) A complete written report will follow the initial notification. The written report will be sent thru the CG IRB Chair to the signatory authorities signing the OHRP Assurance document for review.

- d. AEs that are not deemed to be serious by the MM will be recorded and placed in the individual subject study files and reported to the CG IRB Chair within three days. These events may be recorded on an AE reporting form available at: https://cg.portal.uscg.mil/units/cg113/HRPP/COMDTINST6500.1A/Enclosures/HRPP_Adverse_Event.pdf 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). 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 IND or ID, provide the following information:

- a. IND/IDE (Investigational Device Exemption) 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 (h).
- 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 Food and Drug Administration (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 IDs, include CG's IRB assessment of the risk, such as minimal or GTMR of the ID 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 (i).

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 two years after a New Drug Application is approved/issued, or for two years after the IND is withdrawn (ICH Harmonized Tripartite Guideline for Good Clinical Practice). Records required for IDE studies should be retained for two 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 MMs. Describe their roles in the research effort (e.g., recruit and consent subjects, maintain study records, administer study drug, take and record vital signs, enter data into computer database). A CG PI will be required on every CG protocol.
17. Investigators. Conducting GTMR research must include the following text describing the use of the Volunteer Registry Form (VRF) in the protocol and consent form:
 - a. It is the policy of the CG that VRFs are to be completed on all volunteers participating in GTMR. A copy of the VRF is available by contacting the CG IRB. The information to be collected 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 this information for a minimum of five years.
 - b. Include in the protocol language to indicate that the VRF information must be collected. In addition, include the collection of the VRF information in the study procedure timelines. The VRFs must be sent to the respective CG IRB Chairs.
 - c. VRFs shall be submitted annually and upon completion of the study. Use of the VRF is not required for Exempt or Minimal Risk studies, unless otherwise indicated.

18. Study Advertisements. If subjects will be recruited through an advertisement, newspaper article, or similar process, a copy of the approved advertisement must be provided. For studies involving INDs or IDs, the FDA has established guidelines on advertisements for participant recruitment. 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.
19. Data Collection Instruments. 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.
20. Data Protections. Describe the procedure for confidentiality of hardcopy or electronic data in the protocol and consent form.

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 FDA.
1. In accordance with 32 CFR 219, as a condition of receiving an assurance of compliance, 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 qualifies 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 restricted duty status.
 - c. In research involving personal, telephonic, or video interviews, a suicidal ideation or other indication of self-harm, expressed during an interview.
 - d. In research involving personal, telephonic, or video interviews, an expressed desire to harm others.
 - e. 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 with regard to the regular reporting of events, would not be an SAE. Deaths from the disease under investigation, however, are reportable as SAEs.

- f. For drug or device research involving FDA approved products not subject to regulation under 21 CFR 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.

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. Report serious and unexpected adverse events within three days of occurrence to Commandant (CG-11) using the form available at:

https://cg.portal.uscg.mil/units/cg113/HRPP/COMDTINST6500.1A/Enclosures/HRPP_Adverse Event.pdf. Other forms may be used, but similar data elements should be collected.