



Joint Task Force National Capital Region Medical INSTRUCTION

NUMBER 3216.02
SEP 19 2011

J-7

SUBJECT: Protection of Human Subjects and Adherence to Ethical Standards in Joint Task Force-Supported Research

References: See Enclosure 1

1. PURPOSE. This Instruction, in accordance with the authority in Reference (a):

a. Establishes policy and assigns responsibility for the protection of human subjects in research conducted by, within, or for Joint Task Force National Capital Region Medical (JTF CapMed) in alignment with DoD Directive 3216.02 (Reference (b)).

b. Implements part 219 of title 32, Code of Federal Regulations (CFR), also known as and hereafter referred to as “the Common Rule” (Reference (c)).

2. APPLICABILITY

a. This Instruction applies to:

(1) JTF CapMed and all Joint Medical Treatment Facilities (MTFs) and Centers in the National Capital Region (i.e., Fort Belvoir Community Hospital, Walter Reed National Military Medical Center, and the Joint Pathology Center).

(2) All research conducted or supported by the JTF CapMed involving human subjects as defined in the Glossary. All such activities include both a systematic investigation designed to develop or contribute to general scientific knowledge AND a living individual about whom an investigator obtains data through intervention or interaction. All activities meeting both of these conditions will hereafter be referred to as “research” in this Instruction.

(3) Any part of a project that is described as research, development, testing, and evaluation (RDT&E), a clinical investigation, or a medical activity would be considered regulated research as defined in parts 50, 56, 312, 600, and 812 of title 21, CFR (Reference (d)), unless the project qualifies as an exception as defined in section 4 of this policy or the Glossary.

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b. This Instruction does NOT apply to human subject research that meets criteria for exemption as defined in Reference (c). However, only personnel identified in the Human Research Protection Plan (HRPP) may make this determination. Investigators must submit their projects to be evaluated for exemption.

c. Applicability of this Instruction is NOT dependent upon the budget activities funding the research, the mission of the organization conducting or supporting the research, the security classification of the research, the location of the research in the United States or a foreign country, or whether the research is conducted or supported under a program that is not considered research for other purposes.

3. DEFINITIONS. See Glossary

4. POLICY. It is JTF CapMed policy that:

a. All human subjects research conducted or supported by JTF CapMed adheres to the ethical principles described in the Common Rule, which incorporates the principles of The Belmont Report that are documented in pages 23192-7 of Volume 44, Number 76, Federal Register (Reference (e)).

b. Certain categories of human subjects in research are recognized as vulnerable populations, groups, or individuals and are afforded additional protections as specified in section 6 of Enclosure 2.

c. Research involving human subjects for testing of chemical or biological warfare agents is generally prohibited by section 1520a of title 50, United States Code (U.S.C.) (Reference (f)), subject to possible exceptions for research for prophylactic, protective, or other peaceful purposes.

d. Appropriated funds shall not be used to support research involving a human being as an experimental subject, as defined in this Instruction, without the prior informed consent of the experimental subject or in accordance with section 980 of title 10, U.S.C. (Reference (g)) and this Instruction (see section 9 of Enclosure 2 for details).

e. Research involving human subjects covered under this Instruction shall also comply with applicable Federal and State laws and regulations. When the research is conducted outside of the United States, it must also comply with applicable requirements of the foreign country and its national laws and requirements. In the event of conflict between this Instruction, including its references, and other applicable laws and requirements such that compliance with both is impossible, the requirements most protective of the human subjects shall be followed. In the application of this paragraph, JTF CapMed shall consult with legal counsel and seek guidance from the Commander JTF (CJTF).

5. RESPONSIBILITIES. See Enclosure 2.
6. PROCEDURES. See Enclosure 3.
7. RELEASABILITY. UNLIMITED. This Instruction is approved for public release and is available on the Internet from the JTF CapMed Web Site at: www.capmed.mil.
8. EFFECTIVE DATE. This Instruction is effective immediately.



STEPHEN L. JONES
Major General, U.S. Army
Deputy Commander

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ENCLOSURE 1

REFERENCES

- (a) JTF CAPMED-D 5107.05, "Education, Training and Research (Research) Work Group Charter," March 29, 2010
- (b) DoD Directive 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," March 25, 2002
- (c) Parts 108 and 219 of title 32¹, Code of Federal Regulations
- (d) Parts 50, 56, 312, 600, and 812 of title 21, Code of Federal Regulations
- (e) Pages 23192-7 of Volume 44, Number 76, Federal Register, April 18, 1979 (also known as "The Belmont Report")²
- (f) Section 1520a of title 50, United States Code
- (g) Sections 139a (1) (A), 980, 1074f, and 1102 of title 10, United States Code
- (h) DoD Instruction 3210.7 "Research Integrity and Misconduct," May 14, 2004
- (i) Sections 2105, 3109, 3371-3376,³ and 5536 of title 5, United States Code
- (j) Sections 241(d) and 289g-289g-2 of title 42, United States Code
- (k) Section 252 of Public Law 103-160, "National Defense Authorization Act for Fiscal Year 1994," November 30, 1993
- (l) Subparts A-D of part 46 of title 45, Code of Federal Regulations
- (m) Section 30 of title 24, United States Code
- (n) Executive Order 13526, "Classified National Security Information," December 29, 2009
- (o) Section 501-513 and 523-525 of Public Law 107-347, "Confidential Information Protection and Statistical Efficiency act of 2002 (CIPSEA)," December 17, 2002
- (p) DoD Instruction 6200.02, "Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs," February 27, 2008
- (q) DoD Directive 6025.13, "Medical Quality Assurance (MQA) in Military Health System," May 4, 2004
- (r) DoD Directive 5240.01 "DoD Intelligence Activities," August 27, 2007

¹Also known as "the Common Rule"

² Available on the Internet at <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>. The Belmont Report's 2-volume appendix is available from the Government Printing Office as DHEW Publication Nos. (OS) 78-0013 and (OS) 78-0014

³ Also known as "The Intergovernmental Personnel Act of 1970, as amended"

ENCLOSURE 2

RESPONSIBILITIES

1. CJTF. The CJTF shall:

a. In accordance with Reference (b), be the single authority for policy development, oversight, compliance, and ongoing monitoring concerning human research protections in the JTF CapMed Joint MTFs and Centers. The CJTF is responsible for the JTF CapMed Joint MTFs and Centers HRPP, except for those authorities and responsibilities retained by the Director of Defense Research and Engineering (DDR&E) or at higher DoD levels.

b. Develop, issue, and monitor a JTF CapMed Joint MTFs and Centers HRPP management plan.

c. Establish and oversee policies and procedures that ensure compliance with Reference (b), this Instruction, and any other supplementing or implementing issuances.

d. Hold Command authority and oversee Joint MTF Commanders, Center Directors, Officers in Charge, and Institutional Official(s) (IO) in the implementation of their HRPP.

e. Submit DoD Assurances from Joint MTF and Center institutions for review by the Army Assistant Surgeon General for Force Projection (ASGFP) under the terms of an interservice support agreement and follow ASGFP guidance to meet DoD standards for their approval.

f. Provide reports as required by Reference (b) to DDR&E or higher authorities via the Army Assistant Surgeon General for Force Projection (ASGFP).

g. Provide representatives to DoD human subject research review committees as requested by DDR&E in compliance with Reference (b) (see Enclosure 3).

h. Maintain pertinent records as required by this Instruction or a reference cited herein.

i. Report to AHRPO or other DoD Assuring Authority and DDR&E in a timely manner the following:

(1) Any serious or continuing noncompliance related to research involving human subjects that has been substantiated by inquiry or investigation and any subsequent actions taken based on the findings consistent with section 16 of Enclosure 3. JTF CapMed may send an initial notification of potential serious or continuing non-compliance based on the gravity or magnitude of the initial allegation.

(2) Any notifications to JTF CapMed by another Federal agency that a Joint MTF or Center institution is under investigation for cause or for noncompliance with the Common Rule.

2. JOINT COMMANDERS, COMMANDING OFFICERS, CENTER DIRECTORS, OFFICERS IN CHARGE, AND IOs. Joint Commanders, Commanding Officers, Center Directors, Officers in Charge, or IOs shall:

- a. Establish and maintain an HRPP to ensure the institution's compliance with this Instruction.
- b. Provide the institutional resources needed to ensure compliance with this Instruction.
- c. Establish and maintain a DoD assurance and other appropriate Federal assurances before engaging in research involving human subjects. In some approved situations, institutions may be covered by another institution's Assurance.
- d. Review and, if appropriate, take action on any allegations of non-compliance with human subject protections.
- e. Establish and maintain a procedure for research misconduct that complies with DoD Instruction 3210.7 (Reference (h)). Review and, if appropriate, take action on any allegations of research misconduct according to that procedure.
- f. Report the following to their higher level research review authority, the sources of the appropriate Assurances, and appropriate sponsor(s):
 - (1) Unanticipated problems involving risks to subjects or others.
 - (2) Any serious or continuing noncompliance related to research involving human subjects that has been substantiated by inquiry or investigation and any subsequent actions taken based on the findings. The IO or Commander may send an initial notification of potential serious or continuing non-compliance based on the gravity or magnitude of the initial allegation.
 - (3) All suspensions or terminations of previously approved research protocols.
 - (4) Substantiated findings of research misconduct including fabrication, falsification, or plagiarism that involves research covered under this Instruction.
 - (5) All audits, investigations, or inspections of a JTF-supported research protocol other than routine local audits without substantial adverse findings.
 - (6) All audits, investigations, or inspections of the institution's HRPP conducted by an outside entity (e.g., the FDA or the OHRP).
 - (7) Significant communication between the institutions conducting research and other Federal departments and agencies regarding compliance and oversight.

g. Ensure that sponsors for INDs and IDEs are designated in compliance with DoD and JTF CapMed policy.

ENCLOSURE 3

PROCEDURES

1. JTF CAPMED HRPP MANAGEMENT PLAN. The JTF CapMed will develop, maintain, and enforce an HRPP management plan that complies with the policy established by section 219 of Reference (c) and Reference (b).

2. REQUIREMENTS FOR A FEDERAL ASSURANCE

a. Activities for Which a JTF CapMed Institution is Required to Have a Federal Assurance. Any Joint MTF or Center institution engaged in non-exempt research involving human subjects that is conducted or supported by the Department of Defense shall have a Federal assurance consistent with section 219.103 of Reference (c) and acceptable to the funding agency.

(1) A Joint MTF or Center institution engaged in non-exempt research involving human subjects shall have:

(a) A DoD assurance of compliance.

(b) A Health and Human Services (HHS) assurance when funded by HHS (unless HHS will accept a DoD assurance). When conducting HHS-funded research, the DoD institution must follow this Instruction and any additional HHS requirements.

(2) A Joint MTF or Center institution submitting a DoD assurance via CJTF shall include the items identified in section 219.103 of Reference (c).

(a) The Joint MTF or Center institution shall identify on their DoD assurance at least one Institutional Review Board (IRB). The institution shall identify IRBs that are part of the institution, or if the DoD institution does not have an IRB within the institution, it shall identify the IRBs that will review the majority of the non-exempt research involving human subjects conducted by the institution's investigators on its DoD assurance.

(b) When an IRB is not part of the institution, there must be a written agreement defining the responsibilities and authorities of each organization in complying with the terms of the institution's Assurance and this Instruction (e.g., an Institutional Agreement for IRB Review). The existence of a DoD Institutional Agreement for IRB Review or a similar agreement will satisfy the Federal assurance requirements at sections 219.103(b)(2)-(5) of Reference (c).

b. Activities for Which a Joint MTF or Center Institution is Not Required to Have an Assurance

(1) An institution is not required to have an Assurance if its personnel only conduct research that does not involve human subjects or the research involving human subjects meets the exemption criteria in section 219.101(b) of Reference (c).

(2) An institution that is only providing resources to support research involving human subjects (see Glossary definition of “DoD-supported research”) is not required to have an Assurance unless they are engaged in non-exempt research involving human subjects (e.g., providing investigators, recruiting human subjects, or otherwise conducting research involving human subjects).

(3) An institution is not required to have an Assurance if it is collaborating in a research protocol that is non-exempt research involving human subjects and the institution’s role in the collaborative research is limited to any of the following:

(a) Specific tasks that do not involve interaction or intervention with a human subject;

(b) Research activities that meet the exemption criteria in section 219.101(b)(2)-(4) of Reference (c), even if the entire research study does not; or

(c) Specific tasks that do not include the collection or handling of identifiable data. Research in which the data are coded and the institution is prevented from having access to the code are considered non-identifiable for the purpose of this subparagraph.

(4) An institution that does not need an Assurance but conducts or supports exempt research involving human subjects must have an approved HRPP that includes policies and procedures to ensure proper application of the exemption criteria in section 219.101(b) of Reference (c).

3. RESEARCH IN JOINT MTF OR CENTER INSTITUTIONS INVOLVING HUMAN SUBJECTS

a. Joint MTF or Center Institutional Approval and Oversight

(1) Joint MTF or Center institutions conducting research involving human subjects shall have procedures to ensure appropriate determinations for activities that do not constitute research involving human subjects, activities that qualify as research involving human subjects, or activities that are research involving human subjects that meet the exemption criteria in section 219.101(b) of Reference (c). Such procedures shall include the appointment, oversight, and appropriate training of JTF CapMed personnel.

(2) The Joint institution shall have policies and procedures to require scientific review of non-exempt research involving human subjects and to ensure this review is considered during the IRB review process.

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(3) IRBs may review non-exempt research involving human subjects using materials (data, documents, records, or specimens) that have previously been collected for non-exempt research involving human subjects, provided the materials were not collected for the currently proposed research, by using expedited review procedures under section 219.110(a) of Reference (c).

(4) When the research involving human subjects is being conducted in a foreign country and not on a U.S. installation, the institution shall confirm that all applicable national laws and requirements of the foreign country have been met in addition to the requirements in this Instruction. The IRB shall also consider the cultural sensitivities in the setting where the research will take place.

(5) The Joint institution shall have policies and procedures to ensure the research involving human subjects has been approved by all required organizations before human subjects are recruited or any other research activities with human subjects begin. The IRB may approve a research protocol contingent upon its approval by other organizations (e.g., required reviews can be conducted in parallel).

(6) An IRB, in accordance with part 219 of Reference (c), shall approve all non-exempt research involving human subjects before any activities that involve human subjects can begin. The IRB must provide oversight of the ongoing research and review such research at least annually.

(7) Joint MTF or Center institutions shall rely on an IRB whose membership meets the requirements in this subparagraph. In special circumstances, the institution may rely on an extramural IRB if the conditions in subparagraph 3.a.(8) of this section are met.

(a) The IRBs shall consist of members who are Federal employees; Service members; individuals covered by sections 3371-3376 of title 5, U.S.C. (also known as "The Intergovernmental Personnel Act of 1970, as amended") (Reference (i)); or individuals appointed as experts or consultants in accordance with section 3109 of Reference (i). Status as a contractor or Federal retiree alone is not sufficient to qualify as a Federal employee for the purpose of IRB membership.

(b) The requirement to have a non-affiliated member (section 219.107(d) of Reference (c)) can be fulfilled by a Federal employee from an organization that is not part of the institution as defined on the institution's Federal assurance. At least one alternate for the non-affiliated member shall be designated to increase the likelihood that a non-affiliated member is present at the meetings.

(c) The Joint institution shall consider including community member(s) on the IRB who are familiar with the perspectives of the human subjects (i.e., the community being recruited) commonly recruited and vulnerable subjects recruited by the institution. The community member(s) may or may not be affiliated with the institution or have a scientific background. The appointment of the community members must comply with subparagraph 3.a.(7)(a) of this section.

(d) The IRBs may consult with subject matter experts (e.g., in science, statistics, ethics, subject population) who are not Federal employees or committee members, but these consultants may not vote.

(8) When the Joint institution is engaged in non-exempt research involving human subjects and is collaborating with a non-DoD institution, the JTF CapMed institution may rely on the non-DoD institution's IRB if these minimum conditions are met:

(a) The institution determines the collaborating non-DoD institution has an appropriate Federal assurance.

(b) The involvement of DoD personnel in the conduct of the research involving human subjects is secondary to that of the non-DoD institution.

(c) The Joint MTF or Center institution, the non-DoD institution, and the non-DoD institution's IRB have a written agreement defining the responsibilities and authorities of each organization in complying with the terms of the Federal assurances and this Instruction (i.e., have an Institutional Agreement for IRB Review or similar agreement). The CJTF shall approve the terms of the agreement prior to the JTF CapMed institution's engagement in the research.

(d) The CJTF or a CJTF-designated authority must conduct an appropriate administrative review of the research to ensure it is in compliance with DoD policies and procedures prior to the DoD institution's engagement in the research.

b. JTF CapMed Review and Oversight of Joint MTF or Center Institution Approved Research Protocols

(1) CJTF or a CJTF-designated authority will conduct an administrative review and approve all research involving all non-exempt human subjects approved by an institution when any of these conditions occur:

(a) The research will be conducted in a foreign country with the exceptions of research conducted by an established DoD overseas medical research institution or on a U.S. installation overseas and enrolling only DoD personnel or U.S. citizens.

(b) The research involves a collaboration with a non-DoD institution and the DoD institution is relying on the extramural institution's IRB, which is not composed of Federal employees (i.e., approved using the criteria described in subparagraph 3.a.(7)).

(c) The research permits a waiver of informed consent under paragraph (b) of section 980 of Reference (g).

(d) The research involves any fetal research covered under sections 289g–289g-2 of title 42, United States Code (Reference (j)).

(e) The research is required to be approved by either the DDR&E or the Head of the Office of the Secretary of Defense (OSD) or DoD Component as delegated by the DDR&E (see sections of this enclosure) “Additional Protections,” “Unique DoD limitations,” and “Classified research”).

(2) The CJTF or CJTF-designated authority administrative review must be conducted before the research involving human subjects can begin to ensure compliance with all applicable regulations and policies, including any applicable laws and requirements and cultural sensitivities of a foreign country if conducted in a foreign country. This Component-level review is not intended to be an additional IRB review.

4. EDUCATION AND TRAINING. Personnel involved in the conduct, review, or approval of Joint MTF or Center research involving human subjects, including the non-affiliated IRB members, will receive initial and continuing education and training in compliance with the standards set forth in Reference (b).

a. Both initial and continuing education and training shall be commensurate with the duties and responsibilities of the personnel.

b. Training and education of personnel shall be documented.

c. Professional certification in the field of human research protection is encouraged for all DoD personnel involved in review and oversight of research involving human subjects.

5. SELECTION OF HUMAN SUBJECTS AND EVALUATING RISK

a. Selection of Human Subjects. The selection of human subjects reflecting gender and minority participation in DoD-conducted or -supported clinical research involving human subjects shall comply with section 252 of Public Law 103-160 (Reference (k)). The Head of the OSD or Assuring Component may exercise the waiver authority under this law. This waiver authority may be delegated, as described in the Assuring Component’s HRPP management plan, but not to an individual at the level of the institutional HRPP.

b. Evaluating Risk. The phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests” in the definition of minimal risk (section 219.102(i) of Reference (c)) shall not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. For example, the risks imposed in research focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

6. ADDITIONAL PROTECTIONS FOR HUMAN SUBJECTS. In addition to the requirements of part 219 of Reference (c), additional safeguards described in this section shall be provided for

human subjects in all DoD-conducted and -supported research who may be considered vulnerable due to their association with groups or populations specifically defined by Federal regulations in subparts B-D of part 46 of title 45, Code of Federal Regulations (Reference (I)) and this Instruction. For purposes of this Instruction, actions authorizing or requiring any action by an official of the Department of HHS about any requirements of subparts B-D of Reference (I) shall be under the authority of the DDR&E. Investigators, IRBs, IOs, and DoD Component personnel reviewing research protocols shall consider the need for appropriate similar safeguards for other vulnerable populations, such as: research involving human subjects and investigators in supervisor-subordinate relationships, human subjects with decisional or mental impairments, human subjects with a physical handicap, or any other kind of human subject in unique circumstances that may warrant provision of additional protections. As appropriate, qualified individuals (e.g., research monitors, ombudsmen, advocates) may be appointed to perform oversight functions or help the human subjects.

a. Pregnant Women, Fetuses, and Neonates as Subjects

(1) Non-exempt research involving human subjects that involves pregnant women, fetuses, or neonates as human subjects must meet the additional relevant protections of subpart B of Reference (I), unless modified by DoD or JTF policy. Research involving pregnant women as subjects may be exempt from the requirements of part 219 of Reference (c) and Reference (I) if the research meets the exemption criteria at section 219.101(b) of Reference (c). If the pregnant woman is a prisoner, then paragraph 6.b. of this section also applies. If the pregnant woman is a minor, paragraph 6.d. of this section also applies. For the purposes of applying paragraph 6.a., the phrase “biomedical knowledge” in subpart B of Reference (I) shall be replaced with “generalizable knowledge” throughout the subpart.

(2) The applicability of subpart B of Reference (I) is limited to research involving:

(a) Pregnant women as human subjects involved in research that is more than minimal risk and includes interventions or invasive procedures to the woman or the fetus; or

(b) Fetus or neonate as human subjects.

(3) Research involving human subjects using fetal tissue shall comply with sections 289g–289g-2 of Reference (j).

b. Prisoners as Subjects

(1) Research Intending to Enroll Prisoners as Subjects

(a) Research involving human subjects that enrolls prisoners must meet the additional relevant protections of subpart C of Reference (I), unless modified by DoD policy or instruction.

(b) Research intending to enroll prisoners as subjects cannot be reviewed by the IRB through an expedited review procedure.

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(2) Categories of Allowable Research Involving a Prisoner. In addition to the four categories of permissible research involving human subjects identified in subpart C of Reference (l), two additional categories are allowable.

(a) Epidemiological research that meets the following criteria can also be approved in accordance with the requirements of subpart C of Reference (l) and the requirements of this Instruction:

1. The research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor associations for a disease.
2. The research presents no more than minimal risk.
3. The research presents no more than an inconvenience to the human subject.
4. Prisoners are not a particular focus of the research.

(b) Research involving human subjects that meets the criteria described at section 219.101(b) of Reference (c) can be approved by a convened IRB in accordance with the requirements of subpart C of Reference (l) and this Instruction.

(3) When a Subject Becomes a Prisoner

(a) When a previously enrolled human subject becomes a prisoner, the principal investigator shall promptly notify the IRB.

(b) If the principal investigator asserts to the IRB that it is in the best interests of the prisoner-subject to continue to participate in the research while a prisoner, the IRB Chair may determine that the prisoner-subject may continue to participate until the convened IRB can review this request to approve a change in the research protocol and until the IO and DoD Component office review the IRB's approval to change the research protocol. Otherwise, the IRB Chair shall require that all research interactions and interventions with the prisoner-subject (including obtaining identifiable private information) cease until the convened IRB can review this request to approve a change in the research protocol.

(c) The convened IRB, upon receipt of notification that a previously enrolled human subject has become a prisoner, shall promptly re-review the research protocol to ensure that the rights and wellbeing of the human subject, now a prisoner, are not in jeopardy. The IRB should consult with a subject matter expert having the expertise of a prisoner representative if the IRB reviewing the research protocol does not have a prisoner representative. If the prisoner-subject can continue to consent to participate and is capable of meeting the research protocol requirements, the terms of the prisoner-subject's confinement does not inhibit the ethical conduct of the research, and there are no other significant issues preventing the research from continuing as approved, the convened IRB may approve a change in the study to allow this prisoner-subject

to continue to participate in the research. This approval is limited to the individual prisoner-subject and does not allow recruitment of prisoners as subjects.

(d) This type of request for change in the research protocol cannot be reviewed and approved by the IRB using expedited review procedures. The research does not have to meet one of the six allowable categories of research as described in subparagraph 6.b.(2).

c. Research Involving Detainees as Subjects

(1) Research involving a detainee (see Glossary) as a human subject is prohibited, except for:

(a) Activities covered by investigational new drug or investigational device provisions of Reference (c) when for the purpose of diagnosis or treatment of a medical condition in a patient. Such research may be offered to detainees (with the detainees' informed consent) when the medical products are subject to Reference (c) as investigational new drugs or investigational medical devices and only when the same product would be offered to Service members in the same location for the same medical condition.

(b) Research for improving conditions of detention, provided that the research involves no more than minimal risk and that the requirements of this Instruction, including paragraph 6.b. of this section regarding prisoners as subjects, are met.

(2) Permitted research involving detainees as subjects shall comply with all sections of this Instruction, including paragraph 6.b. of this section and paragraphs 6.a. and 6.d., as applicable.

d. Children as Subjects

(1) Research conducted or supported by the Department of Defense that recruits children to be subjects must meet the additional relevant protections of subpart D of Reference (I), unless modified by DoD policy or this Instruction. If the minor is a pregnant woman, then paragraph 6.a. of this section also applies. If the minor is a prisoner, paragraph 6.b. of this section also applies.

(2) The footnote in section 219.101(i) of Reference (c), prohibiting specific exemptions described in section 219.101(b) from applying to children, is also applicable to DoD-conducted or -supported research involving human subjects unless otherwise clarified by DoD policy or this Instruction.

e. DoD Personnel as Subjects

(1) Superiors (e.g., military and civilian supervisors, unit officers, and noncommissioned officers (NCOs)) are prohibited from influencing the decisions of their subordinates (e.g., junior enlisted personnel and equivalent civilians) regarding participation as subjects in research involving human subjects covered by this Instruction.

(2) Supervisors (unit officers, senior NCOs, and equivalent civilians) in the chain of command shall not be present at any human subject recruitment sessions or during the consent process in which members of units under their command are afforded the opportunity to participate as human subjects. When applicable, supervisors so excluded shall be afforded the opportunity to participate as human subjects in a separate recruitment session.

(3) The IRB shall discuss appointing an ombudsman to monitor the recruitment process to ensure the voluntary nature of individual participants is adequately stressed and confirm the information provided about the research is adequate and accurate. The determination to appoint an ombudsman should be based in part on the human subject population, the consent process, and the recruitment strategy. The ombudsman should not be connected with the conduct of the research. The ombudsman may also be the research monitor.

(4) IRBs reviewing research intending to enroll DoD personnel as subjects shall consider the unique risks and requirements for this population. If the IRB is not composed of at least one member with working knowledge of the unique risks and requirements imposed on DoD personnel, the IRB shall consult with appropriate experts before approving the research.

(5) Service members shall get command permission to participate in research involving human subjects while on-duty. A Service member's ability to perform his or her military duties may be affected by participating during off-duty time (i.e., on leave or during non-duty hours). Therefore, Service members shall follow their command's policy for approving off-duty employment or activities. The IRBs of DoD institutions or Human Research Protection Official (HRPOs) may require Principal Investigators to confirm that a Service member's commander supports the member's participation in DoD-supported research involving human subjects.

7. RESEARCH MONITOR

a. For research involving human subjects determined by the IRB to involve more than minimal risk to human subjects (as defined in section 219.102(i) of Reference (c)), the IRB shall approve an independent research monitor by name. Additionally, the research monitor may be identified by an investigator or appointed by an IRB or IO for research involving human subjects determined to involve minimal risk. There may be more than one research monitor, e.g., if different skills or experiences are necessary. The monitor may be an ombudsman or a data safety monitoring board.

(1) The duties of the research monitor shall be determined on the basis of specific risks or concerns about the research. The research monitor may perform oversight functions (e.g., observe recruitment, enrollment procedures, and the consent process for individuals, groups, or units; oversee study interventions and interactions; review monitoring plans and unanticipated problems involving risks to subjects' or others' reports; and oversee data matching, data collection, and analysis) and report their observations and findings to the IRB or a designated official.

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(2) The research monitor may discuss the research protocol with the investigators, interview human subjects, and consult with others outside of the study about the research. The research monitor shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report. Research monitors shall have the responsibility to promptly report their observations and findings to the IRB or other designated official.

(3) The IRB must approve a written summary of the monitors' duties, authorities, and responsibilities. The IRB or HRPP official shall communicate directly with research monitors to ensure they understand and accept their duties, authorities, and responsibilities.

(4) The research monitors shall be professionals with expertise consonant with the nature of risk(s) identified within the research protocol, and they shall be independent of the team conducting the research involving human subjects.

b. The DoD-assuring authority may waive the requirement to have a research monitor on a case-by-case basis when the inclusion of a research monitor is not necessary to provide additional protections for human subjects. This waiver authority may be delegated to a DoD official, as described in the Component's HRPP management plan, but not at or below the position of the institution's IO.

8. UNIQUE DoD LIMITATIONS ON WAIVER OF INFORMED CONSENT

a. Sections 219.116(c) and (d) of Reference (c) identify conditions where an IRB may waive informed consent for DoD-conducted and DoD-supported research involving human subjects. Section 980 of Reference (g) imposes limitations on waiving informed consent when using DoD appropriated funds. Section 980 of Reference (g) is applicable ONLY to DoD-funded research involving a human being as an experimental subject as defined in the Glossary. Section 980 of Reference (g) is not applicable to exempt research involving human subjects.

b. When the research meets the Glossary definition of research involving a human being as an experimental subject, informed consent must be obtained in advance from the experimental subject or the subject's legal representative consistent with part 219 of Reference (c) if the subject cannot consent. If consent is to be obtained from the experimental subject's legal representative, the research must intend to benefit the individual subject. The determination that research is intended to be beneficial to the individual experimental subject must be made by an IRB consistent with part 219 of Reference (c).

c. The requirement of paragraph 8.b. of this section may be waived by the DDR&E if all the following conditions are met:

(1) The research is necessary to advance the development of a medical product for the Military Services.

- (2) The research may directly benefit the individual experimental subject.
- (3) The research is in compliance with all other applicable laws and regulations.

9. PROTECTING HUMAN SUBJECTS FROM MEDICAL EXPENSES IF INJURED

a. DoD-Supported Research Involving Human Subjects. All non-exempt research involving human subjects shall, at a minimum, meet the requirement of section 219.116(a)(6) of Reference (c). The Common Rule does not require payment or reimbursement of medical expenses, provision of medical care, or compensation for research-related injuries.

b. DoD-Conducted Research Involving Human Subjects. The DoD Components shall establish procedures to protect human subjects from medical expenses (not otherwise provided or reimbursed) that are the direct result of participation in DoD-conducted non-exempt research involving human subjects that involves more than minimal risk. Such procedures may consist of utilizing the Secretarial Designee program as described by section 108.4(i) of Reference (c) during the pendency of the human subject's involvement in the research, which may be extended further upon the approval of the Under Secretary of Defense for Personnel and Readiness.

c. Joint MTF or Center Institution Collaborative Research Involving Human Subjects

(1) When collaborating with a non-DoD institution, the Joint MTF or Center institution shall establish procedures comparable to those required by paragraph 9.b. of this section to protect human subjects from medical expenses (not otherwise provided or reimbursed) that are the direct result of participation in non-exempt research involving human subjects and that are a direct result of research activities performed by DoD personnel. This does not apply to expenses resulting from the injury due to actions performed by the non-DoD institution(s).

(2) When DoD personnel are conducting the research at the collaborating institution and the Department of Defense does not have the primary involvement, the JTF CapMed institutions are not required to have procedures to protect human subjects from medical expenses. For this purpose the determination of primary involvement shall be based on consideration of the type and portion of the JTF CapMed institutions involvement in the collaborative research (e.g., research staff, human subjects, facilities, equipment, IRB, and all other assets).

(3) When the collaboration is such that it is difficult to separate DoD involvement from that of the extramural institution, the Head of the OSD or DoD Assuring Component may waive this requirement to have procedures to protect human subjects from medical expenses. This waiver authority may be delegated, as described in the Component's HRPP management plan, but not at or below the position of the institution's DoD IO.

10. COMPENSATION TO HUMAN SUBJECTS FOR PARTICIPATION IN RESEARCH

a. Compensating Human Subjects for Blood Draws

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(1) Joint MTF or Center Institution-Conducted Research Involving Human Subjects. All human subjects (Federal employee or not) in DoD-conducted research may be compensated up to \$50 for each blood draw if the research meets the purpose of section 30 of title 24, U.S.C. (Reference (m)). Payment for blood draws may come from a Federal or a non-Federal source. IRBs may approve additional reasonable compensation for any other aspect of all human subjects' participation in research unless it is prohibited by this Instruction or DoD policy.

(2) Non-DoD-Conducted Research Involving Human Subjects. All human subjects that are Federal employees in DoD-supported non-exempt research conducted by a non-DoD institution may be compensated up to \$50 for each blood draw when the research subject is on duty (i.e., not on leave and participating during their duty hours) if the research meets the purpose of Reference (m). Human subjects involved in research that meets the purpose of Reference (m) who are not Federal employees or are Federal employees in an off-duty status may be compensated for blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research. IRBs may approve additional reasonable compensation for any other aspect of all human subjects' participation in research unless it is prohibited by this Instruction or DoD policy.

b. Compensating On-duty DoD Personnel. DoD personnel who are human subjects in DoD-conducted or -supported research while on duty (i.e., not on leave and participating during their duty hours) may only be compensated for blood draws as described in this section and may not be otherwise compensated for general research participation. By permitting compensation for blood draws, Reference (m) provides an exception to section 5536 of Reference (i), which prohibits personnel from being paid by any source other than their regular Federal salaries while they are on duty.

c. Compensating Off-duty DoD Personnel. In addition to payments for blood draws as described in paragraph 10.a. of this section, DoD personnel who are human subjects in DoD-conducted or -supported research while off duty also may be compensated for general research participation in the same way as human subjects who are not DoD personnel. However, payment to off-duty DoD personnel for research participation other than blood draws must not be directly from a Federal source (payment from a Federal contractor or other non-Federal source is permissible).

11. SERVICE MEMBERS AND THEIR STATUS AS ADULTS. For purposes of legal capacity to participate in DoD-conducted or -supported research involving human subjects, all active duty Service members and all Reserve Component members in a Federal duty status are considered for purposes of this Instruction to be adults. When Service members are under 18 years of age, students at Service Academies, or trainees, the IRB shall carefully consider the recruitment process and the necessity to include such members as human subjects.

12. CLASSIFIED RESEARCH INVOLVING HUMAN SUBJECTS. For all DoD-conducted and -supported non-exempt research involving human subjects that involves classified

information as defined in Executive Order 13526 (Reference (n)), the additional requirements in this section apply. The involvement of classified information may be limited to information needed for IRB approval and oversight of the research; information needed to inform the human subjects during the consent process; and information provided by the human subjects during the course of the research. This section does not apply if the information required to be contained in the research protocol or needed by either the IRB or the human subjects is not classified but the research is part of a classified activity.

a. Secretary of Defense approval is required. Submission for approval shall be from the Head of the OSD or Assuring Component. The request shall be coordinated with the DDR&E and General Counsel of the Department of Defense.

b. Waivers of informed consent are prohibited.

c. Informed consent procedures shall include:

(1) Identification of the Department of Defense as the supporting institution of the research, unless the research involves no more than minimal risk. The Secretary of Defense may grant an exception to this requirement on the grounds that providing this information could compromise intelligence sources or methods.

(2) A statement that the research is classified and an explanation of the impact of the classification.

d. IRB approval process shall meet the following requirements:

(1) IRB review shall be conducted using a full board review. Use of an expedited review procedure is prohibited.

(2) At least one non-affiliated member shall be a non-Federal employee (other than as a special government employee for purposes of service on the IRB).

(3) Any IRB member who disagrees with a majority decision approving a project may appeal the decision to the Secretary of Defense. The appeal shall be included in the DoD Component's submission to the Secretary of Defense.

(4) The IRB shall determine whether potential human subjects need access to classified information to make a valid, informed consent decision.

13. ADDITIONAL PROTECTIONS FOR CONFIDENTIALITY. This section outlines certain authorities that Joint MTF and Center institutions may consider, subject to applicable requirements, for particular sensitive research activities when additional protections for confidentiality would improve participation and results.

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a. Confidential Information Protection and Statistical Efficiency Act (CIPSEA) for Non-Statistical Agencies. Any DoD Component may use the authority pursuant to sections 501-513 of Section 501-513 of Public Law 107-347 (Reference (o)) to assure that data or information acquired by the DoD Component under a pledge of confidentiality for exclusively statistical purposes shall be used exclusively for statistical purposes and may not be disclosed in identifiable form for any other purpose, except with the informed consent of the respondent. Use of this authority is subject to the requirements of sections 512 and 523-525 of Reference (o), including that the research involving human subjects is conducted by a DoD Component or other Federal agency and not by a contractor, grantee, or other non-Federal entity, and that use of the authority is reported annually to OMB by the DoD Component.

b. Certificate of Confidentiality. A Joint MTF or Center institution or activity conducting DoD-supported research involving human subjects may request a Certificate of Confidentiality from the National Institutes of Health (NIH) of the Department of HHS pursuant to section 241(d) of Reference (j). Such a Certificate of Confidentiality authorizes persons engaged in biomedical, behavioral, clinical, or other research related to mission areas of the NIH to protect the privacy of human subjects of sensitive research against compulsory disclosure in any Federal, State, or local judicial, administrative, or legislative proceeding to identify human subjects. Issuance of any Certificate of Confidentiality is at NIH's discretion and is subject to the requirement of section 241(d) of Reference (j) and any other NIH guidelines.

14. RECORD KEEPING

a. Part 219 of Reference (c) requires all institutions engaged in DoD-conducted and -supported research involving human subjects to retain records for at least 3 years after the completion of the research. Research involving human subjects may be covered by other Federal regulations that impose longer record-keeping requirements. JTF CapMed institutions may rely on collaborating extramural institutions to keep the required records that were generated by the extramural institution, or the JTF CapMed institutions may make arrangements to transfer the records.

b. The JTF CapMed shall also retain records regarding the oversight of Joint MTF or Center-supported research involving human subjects for at least 3 years after the completion of the research, HRPP education or training program, or other action relevant to the HRPP. Additionally, JTF CapMed shall keep all records regarding CJTF waivers, exemptions, and extensions, and all CJTF requests for exceptions, waivers, exemptions, and extensions submitted to the DDR&E for action.

c. Joint MTF or Center institutions may be required under certain circumstances to retain records for periods longer than specified in this section. For further recordkeeping guidance and instruction, the Joint MTF or Center institution shall consult their relevant records disposition schedules.

d. Records maintained by extramural institutions that document compliance or noncompliance with this Instruction shall be made accessible for inspection and copying by

authorized representatives of the Department of Defense at reasonable times and in a reasonable manner as determined by JTF CapMed.

15. NONCOMPLIANCE WITH THIS INSTRUCTION. All Joint MTF and Center institutions shall respond to allegations of noncompliance with this Instruction. For allegations that involve more than one DoD Component or an extramural institution, the involved institutions should jointly determine and assign executive responsibility for responding to the allegation(s). For allegations involving an extramural institution, the DoD Component supporting the research shall ensure the allegation is properly investigated and reported to the DoD Component. All findings of serious or continuing noncompliance with this Instruction that have been substantiated by inquiry or investigation shall be reported to the DDR&E in a timely manner.

16. APPLICABILITY TO OTHER REQUIREMENTS. Compliance with this Instruction does not imply that all other applicable requirements have been met for DoD-conducted and -supported research involving human subjects. Additionally, research involving human subjects using surveys, materials under the purview of the FDA, or individually identifiable health information may be subject to additional DoD requirements. States may have differing definitions and protections for vulnerable populations. Research involving human subjects conducted in foreign countries may be subject to additional national and local regulations.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

CCHRPP	Coordinating Committee for Human Research Protection Programs
CIPSEA	Confidential Information Protection and Statistical Efficiency Act of 2002
DDR&E	Director of Defense Research and Engineering
FDA	Food and Drug Administration
HHS	Health and Human Services
HRPO	Human Research Protection Official
HRPP	Human Research Protection Program
IO	Institutional Official
IRB	Institutional Review Board
NIH	National Institutes of Health
NCO	Noncommissioned Officer
OSD	Office of the Secretary of Defense
OT&E	Operational Test and Evaluation
RDT&E	Research, Development, Test and Evaluation

PART II. DEFINITIONS

Unless otherwise noted, these terms and their definitions are for the purpose of this Instruction.

administrative review. A review of research protocol documents related to DoD-supported research involving human subjects which ensures the institution engaged in the research involving human subjects meets the requirements in all applicable regulations and policies. This review is NOT an IRB review.

assurance. See “institutional assurance.”

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 (Reference (c)).

classified research. Research for which the protocol or other information required by the IRB for review and oversight or required or provided by the research subjects includes classified information, as defined in Reference (n).

continuing noncompliance. A pattern that suggests the likelihood that, without intervention, instances of non-compliance will recur. A repeated unwillingness to comply with this Instruction or a persistent lack of knowledge of how to comply with this Instruction.

Common Rule. The regulation adopted by multiple Federal departments and agencies for the protection of human subjects in research. The Department of Defense's implementation of the Common Rule is part 219 of Reference (c); the Department of HHS's implementation of the Common Rule is subpart A of Reference (l).

detainee. Defined in Reference (l).

DoD-conducted research involving human subjects. DoD-conducted research involving human subjects or intramural research is one type of DoD-supported research involving human subjects (see "research involving human subjects" and DoD-supported research involving human subjects). When DoD personnel are conducting research involving human subjects, their institution is engaged in research involving human subjects (see "engaged in research involving human subjects").

DoD personnel. DoD civilian employees and members of the Military Services.

DoD civilian employee. An individual meeting the definition of "employee" consistent with section 2105 of Reference (i). It includes employees of DoD Non-Appropriated Fund Instrumentalities; DoD civilian employees filling full-time, part-time, intermittent, or on-call positions; and individuals serving under personal services contracts consistent with section 2.101 of Reference (n). It excludes employees of contractors (other than personal services contractors) and foreign nationals of host countries.

Service members. Individuals appointed, enlisted, or inducted for military service under the authority of the Department of Defense. The Military Services are the Army, the Navy, the Air Force, the Marine Corps, the Coast Guard, and the Reserve Components, which includes the Army and the Air National Guards of the United States. Members of the Reserve Components are included when in a duty status.

DoD-supported research involving human subjects. Research involving human subjects for which the Department of Defense is providing at least some of the resources (see "research involving human subjects"). Resources may include but are not limited to funding, facilities, equipment, personnel (investigators or other personnel performing tasks identified in the research protocol), access to or information about DoD personnel for recruitment, or identifiable data or

specimens from living individuals. It includes both DoD-conducted research (intramural research) and extramural research.

exempt research involving human subjects. Research involving human subjects that meets at least one criteria of section 219.101(b) of Reference (c).

experimental subject. See “research involving a human being as an experimental subject.”

extramural organization. An entity that is not part of the Department of Defense.

Federal assurance. A written document submitted by an institution (not an IRB) engaged in non-exempt research involving human subjects conducted or supported by the Department of Defense or other Federal departments and agencies that have codified the Common Rule in their CFR. Through the Federal assurance, an institution commits to the Federal department or agency that the institution shall comply with the requirements set forth in the Federal regulations for the protection of human subjects as described in the Common Rule. The elements of a Federal assurance are outlined in section 219.103(b) of Reference (c).

fetus. The product of conception from implantation until delivery as defined in subpart B of Reference (l).

human subject. A living individual about whom an investigator conducting research obtains identifiable private information or data through intervention or interaction with the individual.

identifiable private information. Defined in section 219.102(f) of Reference (c).

institution. JTF CapMed commands, units, activities, and detachments.

IRB. A committee established in accordance with Reference (b) to review research to ensure the protection of the rights and welfare of human research subjects.

minimal risk. 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 (Reference (c)).

neonate. Newborns as defined in subpart B of Reference (l).

non-affiliated IRB member. Defined in section 219.107(d) of Reference (c). This member is not connected with the institution(s), as defined in the institution’s Federal assurance that is creating or relying on the IRB, or a member of the immediate family of a person who is associated with the institution creating or relying on the IRB.

non-compliance. Deliberate or inadvertent departure from or failure to comply with Federal regulations, DoD issuances, JTF issuances, or IRB requirements for the protection of human research subjects.

Principal Investigator. In JTF-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:

For JTF-supported intramural research, a Principal Investigator must be a current Federal employee (uniformed or civilian, staff, or trainee), covered under the Intergovernmental Personnel Act, or a consultant consistent with the requirement established by Reference (i), 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 principal investigators for such research.

For JTF-supported extramural research, a Principal Investigator must meet the criteria established by the institution that receives the award.

non-exempt research involving human subjects. An activity that meets the definitions of research and human subject but does not meet at least one of the criteria at section 219.101(b) of Reference (c).

ombudsman. A person who acts as an impartial and objective advocate for human subjects participating in research.

prisoner. Any individual (other than captured or detained personnel) involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal, civil, or military stature, individuals detained in other facilities by virtue of statues or commitment procedures, which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing (Reference (g)).

prisoner representative. An individual member on the IRB who shall have working knowledge of the human subject population to be recruited and a reasonable familiarity with the operations of the prison or other confinement facility involved in the research.

private information. Defined in section 219.102(f) of Reference (c).

protocol. The detailed, written research plan.

research. Any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general 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 (Reference (d)).

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 Instruction.

The terms “research,” “clinical research,” “clinical study,” “study,” and “clinical investigation” are deemed synonymous. Clinical investigation means any experiment that involves a test article and one or more human subjects, and meets the appropriate requirements for prior submissions to the Food and Drug Administration. (Excerpted from sections 56.101 (c) and 50.3 (c) of Reference (d).)

research involving human subjects. Activities covered by section 219.101(a) of Reference (c) (including exempt research involving human subjects) and this Instruction.

Investigators or other personnel performing tasks identified in the research protocol conduct research involving human subjects when they do any of the following tasks:

Intervene for research purposes with any human subjects of research by performing invasive or noninvasive procedures;

Intervene for research purposes with any human subject of the research by manipulating the environment of the subject;

Interact for research purposes with any human subject of the research;

Obtain the informed consent of any human subjects for the research; or

Obtain for research purposes identifiable private information or identifiable biological specimens from any source (e.g., human being or repository) for research.

The following activities conducted or supported by the Department of Defense are NOT research involving human subjects:

Activities carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease in Service members and other mission-essential personnel under force health protection programs of the Department of Defense, including health surveillance pursuant to section 1074f of Reference (g) and the use of medical products consistent with DoD Instruction 6200.02 (Reference (p)).

Authorized health and medical activities as part of the reasonable practice of medicine or other health professions undertaken for the sole purpose of patient treatment.

Activities performed for the sole purpose of medical quality assurance consistent with section 1102 of Reference (g) and DoD Directive 6025.13 (Reference (q)).

Activities performed solely for an operational test and evaluation (OT&E) project where the activities and project meet the definition of OT&E as defined in section 139(a)(2)(A) of Reference (g).

Survey, interview, or surveillance activities and related analysis performed solely for authorized foreign intelligence collection purposes, as authorized by DoD Directive 5240.01 (Reference (r)), in direct support of military operations.

Monitoring activities performed solely for assessing compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units, including such activities as occupational drug testing, occupational health and safety reviews, and security classification monitoring.

Program evaluation activities, including customer satisfaction surveys, user surveys, outcome reviews, and other methods, designed solely to assess the performance of DoD programs where the results of the evaluation are only for the use of Government officials responsible for the operation or oversight of the program being evaluated and are not intended for generalized use beyond such program.

research involving a human being as an experimental subject. An activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving a human being as an experimental subject is a subset of research involving human subjects. This definition relates only to the application of section 980 of Reference (g); it does not affect the application of part 219 of Reference (c). This definition does not include activities that are not considered research involving human subjects, activities that meet the exemption criteria at section 219.101(b) of Reference (c), and research involving the collection or study of existing data, documents, records, or specimens from living individuals.

research monitor. Professionals with expertise consonant with the nature of risk(s) identified within the research protocol, whose role is to protect the safety and well-being of human subjects.

risk. Any possibility of harm, discomfort, or injury (physical, psychological, sociological, or other) as a consequence of any act or omission. (See “minimal risk.”)

secretarial designee program. Defined in section 108.3 of Reference (c).