BY ORDER OF THE COMMANDER

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HEADQUARTERS UNITED STATES CENTRAL COMMAND
OFFICE OF THE CHIEF OF STAFF
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Medical Services

THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH ACTIVITIES

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1. PURPOSE

This regulation acknowledges all Federal laws, Department of Defense (DoD) and Defense Health Agency (DHA) regulations, directives and instructions for the protection of human subjects in DoD research activities conducted or supported within the USCENTCOM area of responsibility (AOR). Most importantly, theater based human subjects research in combat casualty care is intended to contribute to a better understanding of health, medical, and operational issues of military personnel related to combat operations. Furthermore, this research is established with the objective to capture, validate, and disseminate new medical knowledge gained through a scientific process, where outcomes not only facilitate new standards of care for casualties with traumatic injuries, but also for injury prevention, and rehabilitation all of which support the warfighter.

2. APPLICABILITY

This regulation applies to all USCENTCOM Service Components, Combined and other Joint Task Forces (CJTFs), all other U.S. military forces operating under Title 10 within the geographic AOR assigned or allocated to Commander, USCENTCOM by approved global force management (GFM) processes (e.g., command plan), DoD civilian employees and DoD contractor/sub-contractor personnel deploying with U.S. forces (hereafter referred to as "DoD personnel") consistent with DoD and Service-specific guidance.

a. Any non-DoD personnel who under a bi/multi-lateral agreement have been assigned and/or allocated to work in a U.S. commanded military treatment facility (ashore or afloat).

b. DoD personnel assigned and/or allocated to work within a Department of State (DoS) led healthcare facility.

c. All DoD (conducted or supported) research involving human subjects as defined in Appendix B. All such activities must include both systematic investigation designed to develop or contribute to generalizable knowledge and involve a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or about whom identifiable private information will be obtained. All activities meeting both of these conditions will hereinafter be referred to as "research involving human subjects" within this USCENTCOM regulation (CCR).

d. Activities such as research, development, testing and evaluation (RDT&E) that meet the definition of research involving human subjects (as defined in Appendix B), as well as clinical investigations or medical activities regulated by the Food and Drug Administration (FDA) in accordance with (IAW) DoDI 3216.02 (Reference (1)).

e. USCENTCOM Command Surgeon (CCSG) elected not to seek renewal of DoD assurance, a requirement to authorize original research under a USCENTCOM Human Research Protection Program (HRPP), which expired on 1 August 2016 but endorses research under other assurance programs.

f. As a general rule, USCENTCOM does not conduct research involving the FDA oversight requirements, but if such research were conducted in theater DoDD 6200.02 (Reference (9)) will apply.

g. Applicability is not dependent upon the budget activities funding the research, the mission of the DoD organization conducting or supporting the research, the security classification of the research, the location of the research, or whether the research is conducted or supported under a program that is not considered research for other purposes.

h. This CCR does not apply to the U.S. Naval Medical Research Unit No. 3 (NAMRU-3), Cairo, Egypt.

3. REFERENCES

References used in this regulation are listed in Appendix A.

4. TERMS AND DEFINITIONS

Terms used in this regulation are defined in Appendix B.

5. POLICY

USCENTCOM supports all U.S. federal laws and DoD directives, instructions, and policies intended to establish and monitor protection of human subjects, and the application of ethical standards to ensure theater compliance with research activities. Further, USCENTCOM accepts its responsibilities for protecting the rights and welfare of all human research subjects in the operational environment and does not permit, under any circumstances, the use of captured or detained personnel as human subjects in any theater research protocol.

6. USCENTCOM CHIEF OF STAFF

a. Supports the protection of human subjects in DoD research activities conducted or supported within the USCENTCOM AOR.

b. Holds the authority and responsibility for the implementation of a USCENTCOM HRPP management plan IAW DoDI 3216.02 (Reference (1)).

c. When an HRPP is established, one must do the following;

(1) Appoint in writing an institutional official (IO) for the overall administration of USCENTCOM's assurance for the protection of human research subjects.

(2) Submit reports to the Assistant Secretary of Defense (ASD) for Research and Engineering ASD (R&E) and ASD for Nuclear, Chemical and Biological Defense Programs for research involving human subjects for testing of chemical or biological warfare agents.

(3) Submit reports to the ASD (RT&E) for any misconduct or noncompliance issues related to the protection of human subjects in research.

7. USCENTCOM SECURITY COOPERATION DIVISION (CCJ5)

When applicable, the Security Cooperation Office (SCO) serves as the USCENTCOM point of contact for obtaining host nation (HN) approval/disapproval for DoD research on human subjects involving HN military personnel.

8. USCENTCOM STAFF JUDGE ADVOCATE (CCJA)

Assists the USCENTCOM Chief of Staff (CoS) and CCSG when allegations of serious or continuing noncompliance are substantiated by inquiry or investigation related to the protection of human subjects within USCENTCOM's AOR.

9. USCENTCOM COMMAND SURGEON (CCSG)

a. When directed, establishes and maintains a HRPP management plan IAW DoDI 3216.02 (Reference (1)) to ensure USCENTCOM's compliance with all Federal and DoD regulations, directives and instructions.

b. When directed, establishes a DoD Institutional Agreement (IA) between USCENTCOM and the DoD institution for supplying Institutional Review Board (IRB) review services to USCENTCOM. This Agreement becomes part of USCENTCOMs Assurance for the Protection of Human Research Subjects and includes the scientific peer review of studies conducted in the AOR.

c. When appointed, serves as an IO of USCENTCOM's Assurance for the Protection of Human Research Subjects under this Regulation and IAW DoDI 3216.02 (Reference (1)).

(1) Accepts full responsibility for the conduct of research performed in theater with respect to compliance with applicable Federal and DoD relevant laws, regulations, and guidelines.

(2) Ensures proposed research activities are evaluated to determine if they are, or are not human subjects research, as defined in DoDI 3216.02 and 32 Code of Federal Regulations (CFR) 219.102, and whether they meet exemption criteria in 32 CFR 219.101(b).

(3) Ensures the USCENTCOM HRPP is reviewed and re-approved at least annually or more frequently when major changes in the HRPP are identified.

(4) Defines the geographical locations within the AOR where research may be conducted.

(5) Enforces compliance with the terms of the USCENTCOM Assurance and HRPP. The IO serves as the compliance officer, ensuring that IRB recommendations for the termination or suspension of a non-compliant research activity are enforced as appropriate.

(6) Suspends research within a defined location when an effective HRPP cannot be ensured.

(7) When required, appoints an Area Approving Official (AAO) and delegates the responsibility for oversight of research involving human subjects within a defined location (e.g., Afghanistan, Iraq and Kuwait).

(8) Appoints a USCENTCOM Human Protections Administrator (HPA) and, when necessary a Theater HPA, both with the responsibility for the regulatory oversight of research that is conducted or supported within the AOR.

(9) Ensures research is conducted under the highest ethical standards and establishes a formal review process for allegations of research misconduct IAW with DoDI 3210.7 (Reference (6)).

(10) Provides the AOR with the resources needed to ensure compliance with the protection of human research subjects.

(11) Ensures education and training is completed IAW DoDI 3216.02 for all personnel assigned to conduct or support research involving human subjects in theater.

10. USCENTCOM SERVICE COMPONENT AND CJTF COMMAND SURGEONS

a. Enforces compliance with this CCR.

b. Ensures all personnel conducting or supporting research that involves human subjects is in compliance with DoD education and training requirements.

c. Ensures personnel conducting or supporting research involving human subjects are in compliance with their training for Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA), as appropriate.

d. When directed, implements and monitors the USCENTCOM HRPP management plan.

11. GENERAL

To conduct human subjects research in USCENTCOM's Theater, the following areas will be addressed: (1) research studies/protocols are operated under an approved DoD Assurance; (2) human subjects research, not exempt from Federal or DoD human subjects protection, is reviewed and approved by a duly constituted IRB; (3) investigators are trained in the basic tenets of human subjects protection requirements; and (4) mechanisms exist for ongoing compliance oversight. USCENTCOM ensures research and non-research performed in theater is focused toward relevant issues significant to the combatant command and will not hinder ongoing combat operations or health service support to these operations.

12. THEATER BASED RESEARCH

a. Research may be conducted by medical personnel at Role 1, Role 2 (both Light Maneuver and Enhanced), Role 3 (ashore or afloat), and with medical personnel performing en route care during patient evacuation/movement IAW DoD 3216.02.

b. Categories of research that may be conducted are, but not necessarily limited to, observational (descriptive) biomedical, social and behavioral research. This may involve retrospective record or database reviews, and prospective studies that either require advance informed consent (e.g., survey research) or are eligible for waivers of informed consent (e.g., certain types of descriptive studies).

c. The feasibility of conducting controlled clinical trials of medical interventions under established Good Clinical Practice standards is significantly impacted by the high operational tempo (OPTEMPO), and short duration of contact that characterizes military medicine in the deployed environment of a combat zone.

13. THEATER BASED NON-RESEARCH

a. Performance Improvement Program (PIP) is the systematic process aimed at improving the effectiveness and efficiency of healthcare operations and is considered a non-research venue. Refer to CCR 40-1, Quality Management for Healthcare Operations (Reference (7)) for PIP procedures.

b. The IRB reviews non-research use of investigational products that will support the DoD Force Health Protection (FHP) program, and DoD Military Training Facilities who may require emergency use of investigational drugs and devices (e.g., U.S. Army Institute of Surgical Research's Burn Intensive Care Unit, Landstuhl Regional Medical Center, and operational healthcare units within USCENTCOM's AOR).

c. Reviews must never delay or preclude activities essential to military strategic or operational missions, patient care or FHP. This includes investigations required by DoD-specific regulations such as Epidemiological Consultations (EPICONs) or directed by emergent FHP issues.

d. EPICONS are required investigations using research methodologies in response to disease outbreaks. For example, preventive medicine requires investigation of health outcomes in service members with toxic exposures and as such, interpreting and reporting illness and injury data in this context is not considered human subjects research.

e. U.S. Army Medical Materiel Development Activity (USAMMDA) FHP Division manages a portfolio of treatment protocols IAW DoDI 6200.02, addressing preventive or therapeutic treatments designed to meet the anticipated or potential needs of service members and works closely with the IRB to ensure appropriate review, approval, and oversight of the portfolio of FHP treatment investigational drugs (INDs) for use in theater.

14. RESEARCH UNDER A DOD ASSURANCE OTHER THAN USCENTCOM (NON-CENTCOM HRPP)

a. The principle investigator (PI) will contact USCENTCOM to obtain endorsement of their proposal when identifying USCENTCOM or the "operational/deployed environment" as the site for their research activities. The following questions at a minimum, must be addressed by the PI for the consideration of endorsement by the CCSG:

(1) Is there a requirement to send research member(s) into an area of operation (e.g., Iraq, Kuwait or Afghanistan) as part of the protocol; and/or

(2) Will the subjects be required to perform or be subjected to interventions (e.g., taking of blood, body fluid or tissue specimens while in theater); and/or

(3) Is the PI requesting interaction (i.e., physical or virtual) to DoD Forces or non-U.S. military personnel operating within USCENTCOMs Theater to participate in a research protocol.

b. The PI will provide a brief description of their protocol to the USCENTCOM Chief, CLINOPS at: centcom.macdill.centcom-hq.mbx.ccsg-clinops@mail.mil. Information will be sent to the appropriate Service Component and/or CJTF Command Surgeon for their review and adjudication with final endorsement from the CCSG.

c. No projects or proposals are authorized in medical facilities without CCSG endorsement.

15. RESEARCH UNDER A USCENTCOM DOD ASSURANCE (USCENTCOM HRPP)

a. To meet Federal, and DoD regulations, policies and guidance for the implementation of a theater research program for combat casualty care, USCENTCOM must formally develop and establish at a minimum the following:

(1) DoD Assurance. USCENTCOM will comply with the assurance protocols contained within HA Policy 05-003.

(2) DoD IA. This document is used when an institution will be engaged in human subject research and will use an IRB that is not organizationally or legally part of the institution. This agreement ensures that the engaged institution, with the Federal Assurance and the IRB

providing the review and approval of the research know the responsibilities of each party to this agreement.

(3) Institutional Agreement for Institutional Review (IAIR). This agreement, when signed, becomes part of the USCENTCOM DoD Assurance for the Protection of Human Research Subjects and applies to all research performed under the USCENTCOM HRPP.

(4) Continental U.S. (CONUS) Regulatory Activities Office. Primary role for this office is to provide USCENTCOM with the ethical review and regulatory oversight for the protection of human subjects in research.

(5) HRPP. The HRPP describes how USCENTCOM will fulfill the responsibilities described in the DoDI 3216.02 and implement procedures for DoD-conducted or –supported research involving human subjects which apply to this Institutional Organization. The goal for the HRPP is to assure research activities involving human subjects are guided by ethical principles set forth in The Belmont Report (Reference (2)).

b. USCENTCOM required positions include, but may not be limited to the following:

(1) Headquarters (HQ) HPA formally appointed by the USCENTCOM IO and has operational oversight for the compliance of the USCENTCOM Assurance and HRPP for theater.

(2) Theater Human Protections Administrator (THPA) is formally appointed by the USCENTCOM IO to support the HQ HPA with the monitoring and compliance of the Assurance and HRPP in theater.

16. SUSPENSION OR TERMINATION OF RESEARCH

Both the USCENTCOM CCSG and the approving IRB have the authority to suspend or terminate approval of research that is found to be non-compliant with applicable requirements, regulations, or the research protocol. Any suspension or termination of approval shall include a statement for the action, and shall be reported promptly to the appropriate Human Research Protections Office and to department or agency head(s).

17. PRISONERS OF WAR, CAPTURED OR DETAINED PERSONNEL

IAW DoDI 3216.02, detainees and prisoners of war may not participate in human subjects research. USCENTCOM mandates that suspected insurgents and detainees are also prohibited from participating in research. The only exception is for the purpose of diagnosis or treatment of a medical condition in a patient by investigational new drug or device under the provisions as outlined in DoDI 3216.02 paragraph 7,C,(2).

18. NON-U.S. PERSONNEL

Data obtained from HN civilians or military personnel may only be collected as part of a research protocol that has been determined by the IRB to meet one of the following conditions:

a. The activity proposed does not meet the definition of human subjects research.

b. The study meets a criterion that exempts it from human subjects protection regulatory requirements.

c. The proposed study is determined by the IRB to present minimal risk to participants and is eligible for a waiver of informed consent IAW criteria set forth in 32 CFR 219.116(d).

19. CLASSIFIED RESEARCH INVOLVING HUMAN SUBJECTS

Secretary of Defense approval is required for all classified non-exempt research involving human subjects. Submission for approval shall be IAW DoDI 3216.02 from the Head of the OSD or DoD Component conducting or supporting the non-exempt research involving human subjects. The request will be coordinated with the ASD (R&E) and General Counsel of the DoD after IRB approval.

20. DOCUMENTATION OF HUMAN RESEARCH PROTECTION ACTIVITIES

a. IAW U.S. federal regulations, records associated with USCENTCOM human research regulatory files will be kept at least three years after the IRB has accepted the closure report.

b. While Federal regulations and normal DoD practice is to have records remain on-site at the research location, combat zones and operational environments pose unique challenges.

c. Security of research documents in the AOR will be the responsibility of the on-site PI. On-site PIs will:

(1) Keep documents associated with the research project in a locked and secure environment (minimizing hard copy storage and maximizing electronic systems and files).

(2) Ensure study records are inventoried and shipped to the PI at the institution of record when a study is closed.

21. DISSEMINATION OF RESEARCH FINDINGS

a. IAW DoDD 5230.09, Clearance of DoD Information for Public Release, "any official DoD information intended for public release that pertains to military matters, national security issues, or subjects of significant concern to the DoD, shall be reviewed for clearance prior to release."

b. Clearance is granted when actionable intelligence and/or classified information are not disclosed, DoD interests are not jeopardized, and the author accurately portrays official policy, even if the author takes issue with that policy.

c. Medical information derived from USCENTCOM's theater may be presented when reporting research findings in professional material such as abstracts, manuscripts, presentations (speeches and/or any other open venues where professional medical activities, analyses, and/or research are reported), charts/graphs, data sources, websites, photographs, interviews, videos, or audio recordings and other forms of electronic media.

(1) Open venues include professional journals, conferences, symposiums, magazines, newspapers, web site postings, weblog (blog) postings, internet information forums, television, and radio. Note the release of medical information considered actionable medical information (AMI) may be used by enemy forces to enhance their tactics or techniques to inflict harm.

(2) Professional material or work presented in these forums listed here are subject to review for operational security (OPSEC), public affairs office (PAO) and AMI.

d. USCENTCOM research findings (presentations/publications/manuscripts) will be reviewed for clearance by either JTS or the IRBs OPSEC and PAO prior to public release with a copy sent to USCENTCOM at: centcom.macdill.centcom-hq.mbx.ccsg-clinops@mail.mil.

(1) Presentations/publications/manuscripts of DoD conducted/sponsored research must contain DoD-specific disclaimers and must not contain any of the following:

(a) Classified or For Official Use Only (FOUO) information.

(b) Essential elements of friendly forces information.

(c) Weapon systems or equipment vulnerabilities.

(d) Specific links between defined wounding methods and the resulting wound patterns.

(e) Specific links between injuries sustained while wearing defined personal protective equipment and the resulting wound patterns.

(f) Specific links between injuries sustained while in defined vehicles and the resulting wound patterns.

(g) Discussion of specific ballistic agents and the resulting failure of personal protective equipment or vehicles.

(h) Linking casualties with or injuries that occurred from specific attacks, located in a specific location, or on a specific date.

(i) Units and their locations.

(j) Casualty rates in relation to deployed troop strength or compared over time.

(k) Troop rotation or movement patterns or schedules.

(l) Photographs or videos of wounded or deceased service members unless photographs do not revel vulnerabilities of personal protective equipment, vehicles, or other hardened structures (including physical security measures such as security checkpoints).

(m) Protected Health Information (PHI).

(n) Review is not required if the author(s) intends to keep the work within the DoD in a classified or FOUO, or other status that prevents public release. Clearance requirements will be given to PIs in the information packet with their approved protocol.

22. PROPONENT

The proponent for this regulation is USCENTCOM CCSG. Units are invited to submit comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) directly to HQ USCENTCOM Attn: CCSG, 7115 South Boundary Boulevard, MacDill AFB, Florida 33621-5101.

23. ACCESSIBILITY

Publications and Forms are available on the USCENTCOM SIPRNet Releasable (REL) Portal index for downloading at the following link: Consolidated Publications Portal.

24. RELEASABILITY

There are no releasability restrictions on this publication within the U.S. Federal Government. Contact the USCENTCOM Freedom of Information Act (FOIA) Office if requested for public release under the FOIA.

25. EXPIRATION

This publication will expire in five years per USCENTCOM CCR 25-30, *Preparation of Administrative Publications*, unless revised or rescinded.

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APPENDIX A - REFERENCES

1. Department of Defense Instruction (DoDI) 3216.02, *"Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research,"* October 20, 2011. Available at: http://dtic.mil/whs/directives/corres/pdf/321602p.pdf.

2. The Belmont Report, *"Ethical Principles and Guidelines for the Protection of Human Subjects of Research,"* 1979. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

3. Health Affairs (HA) Policy 05-003, *Policy for Protection of Human Subjects in DoD sponsored research*, current version.

4. DoD Directive (DoDD) 5230.09, *"Clearance of DoD Information for Public Release*," August 22, 2008. Available at: http://dtic.mil/whs/directives/corres/pdf/523009p.pdf.

5. DoDD 5205.02, " *DoD Operations Security (OPSEC) Program*," March 6, 2006. Available at: http://dtic.mil/whs/directives/corres/pdf/520502p.pdf.

6. DoD 6025.18-R, "*DoD Health Information Management Regulation*," January 24, 2003. Available at: http://dtic.mil/whs/directives/corres/pdf/602518p.pdf.

7. USCENTCOM Regulation (CCR) 40-1, "*Quality Management (QM) in Healthcare Operations,"* 19 Feb 2016. Available at: http://rel.centcom.smil.mil/sites/CCJ6/R_DIV/RD/RDR/Pubs/40%20series/CCR%2040-1%2019%20Feb%2016.pdf.

8. Department of Defense Instruction (DoDI) 3210.7, "*Research integrity and Misconduct,"* May 14, 2004. Available at: http;//dtic.mil/why/directives/corres/pdf/321007p.pdf.

9. DoDD 6200.02, *"Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs,"* February 27, 2008. Available at: http://dtic.mil/whs/directives/corres/pdf/620002p.pdf .

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APPENDIX B - TERMS AND DEFINITIONS

1. Administrative Review. Review of a research protocol and supporting documents (e.g., safety review, scientific review, IRB minutes) related to DoD-supported research involving human subjects which ensures the institution engaged in the research involving human subjects has met the requirements of all applicable regulations and policies. This is not an IRB review.

2. Classified Research Involving Human Subjects. Research involving human subjects where protocol or other information required by the IRB for review and oversight or required or provided by the research subjects includes classified information.

3. Clinical Investigations. Any research or experiment that involve a test article, one or more human subjects, and are performed under the requirements of reference (e). Clinical investigations are a subcategory or research involving human subjects.

4. DoD-Conducted Research Involving Human Subjects. Research involving human subjects that is performed by DoD personnel. Intramural research is one type of DoD-conducted research involving human subjects.

5. DoD-Supported Research Involving Human Subjects. Research involving human subjects for which the DoD is providing at least some of the resources. 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 involving human subjects (intramural research) and research conducted by a non-DoD institution.

a. DoD-supported research in the USCENTCOM AOR that is exempt from CCR 40-6 includes surveys, focus groups, and interviews of populations that ensure participant anonymity and do not include vulnerable populations (e.g., prisoners, minors, pregnant women). This is pursuant to 45 CFR 46.101(b)(2), exemption 2 to the Federal Policy for the Protection of Human Subjects ("Common Rule"), which states:

> "Research using educational tests, survey procedures; interviews; or observations of public behavior, unless subjects are identifiable and disclosure could place them at risk. This exemption for parts involving educational tests is applicable to children. However, this exemption for parts involving survey or interview procedures or observations of public behavior does not apply to research involving children, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed".

6. Exempt Research Involving Human Subjects. Research involving human subjects where the only involvement of the human subjects in the research are in one or more of the categories identified in section 219.101(b) of Reference (j).

7. Federal Assurance. A written document in which an institution (not an IRB) commits to a Federal department of agency their compliance with the requirements set forth in the Common Rule. Institutions engaged in non-exempt research involving human subjects conducted or

supported by the DoD or other Federal departments and agencies that have adopted the Common Rule must have a Federal assurance approved or accepted by the Federal agency supporting the research.

8. HRPP. Institution's system of interdependent elements that implement policies and practices to protect human subjects involved in research.

9. Human Subject. A living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual; or identifiable private information.

a. Intervention includes both, "physical procedures by which data are gathered (e.g., venipuncture) and manipulation(s) of the subject or the subject's environment that are performed for research purposes."

b. Interaction includes, "communication or interpersonal contact between investigator and subject (whether written or verbal)."

c. 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 that has been provided by an individual for specific purposes and which the individual can reasonably expect will not be made public (e.g., medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for the information to constitute research involving human subjects."

10. Institution. An organization or entity defined in a Federal assurance or HRPP.

11. IO. The senior person authorized to establish and responsible to maintain the HRPP for the institution. Responsible for a Federal assurance and the IRBs internal to the institution, if these elements are part of the HRPP.

12. Noncompliance. Failure of a person, group, or institution to act in accordance with DoDI 3216.02, its references, or applicable requirements.

13. Non-Exempt Research Involving Human Subjects. An activity that meets the definitions of research and human subjects, but does not meet the criteria where the only involvement of the human subjects in the research are in one or more of the categories identified in section 219.101(b) of Reference (j).

14. Research. A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

15. Research Involving Human Subjects. Activities that include both a systematic investigation designed to develop or contribute to generalizable knowledge AND involving a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information. Refer to DoDI 3216.02 (page 37) for list of activities conducted or supported by DoD that are not research involving human subjects.

16. Serious Non-Compliance. Failure of a person, group, or institution to act IAW DoDI 3216.02 and its references such that the failure could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data.