INFORMATION SHEET REGARDING THE DEPARTMENT OF DEFENSE (DOD) ADDENDUM TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICE'S (DHHS) FEDERALWIDE ASSURANCE (FWA) FOR THE PROTECTION OF HUMAN SUBJECTS

This information sheet is a tool for institutions receiving funds from OUSD(P&R) institutions for the purpose of conducting research with human subjects when the DoD or its employees are not involved in the conduct of the research.

The Department of Defense has different requirements than the Department of Health and Human Services. The DoD Addendum to the FWA is the DoD's way of requiring institutions that it funds to acknowledge and agree to comply with its requirements.

Below is a list of pertinent DoD requirements and a description of what they mean.

Part 2 – DoD Requirements

- **Title 32 Code of Federal Regulations Part 219 (32 CFR 219), Department of Defense Regulations, "Protection of Human Subjects"**

  This is the same as 45 CFR 46.

- **Title 45 Code of Federal Regulations Part 46, (45 CFR 46) Department of Health and Human Services Regulations, "Protection of Human Subjects," Subparts B, C, and D as made applicable by DoDD 3216.02**

  If applicable, research that is conducted using DoD funds must be done in accordance with Subparts B, C, and D as made applicable by DoDD 3216.02 even if the institution receiving funds has chosen not to apply the Subparts to its other research activities.

- **Title 21 Code of Federal Regulations 50, 56, 312, and 812, Food and Drug Administration (FDA) Regulations**

  If your research involves an FDA regulated product, you must agree to comply with all applicable FDA regulations.

- **DoD Directive (DoDD) 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-supported Research"**

  Your IRB must determine whether your non-exempt research is greater than minimal risk. If it is, the following must be adhered to:

  1. For research involving more than minimal risk to subjects, an independent medical monitor shall be appointed by name. Medical monitors shall be physicians, dentists, psychologists, nurses, or other healthcare providers capable of overseeing the

progress of research protocols, especially issues of individual subject/patient management and safety. Medical monitors shall be independent of the investigative team and shall possess sufficient educational and professional experience to serve as the subject/patient advocate.

Depending on the nature of the study, the medical monitor may be assigned to assess one or more of the following phases of a research project: subject recruitment, subject enrollment, data collection, or data storage and analysis.

2. For research involving more than minimal risk and also involving military personnel, unit officers and noncommissioned officers (NCOs) shall not influence the decisions of their subordinates to participate or not to participate as research subjects. Unit officers and senior NCOs in the chain of command shall not be present at the time of research subject solicitation and consent during any research recruitment sessions in which members of units under their command are afforded the opportunity to participate as research subjects. When applicable, officers and NCOs so excluded shall be afforded the opportunity to participate as research subjects in a separate recruitment session. During recruitment briefings to a unit where a percentage of the unit is being recruited to participate as a group, an ombudsman not connected in any way with the proposed research or the unit shall be present to monitor that the voluntary nature of individual participants is adequately stressed and that the information provided about the research is adequate and accurate.

3. Research involving use of human subjects for testing of chemical or biological agents is generally prohibited by 50 U.S.C. 1520a subject to possible exceptions for research for prophylactic, protective, or other peaceful purposes.

- **Title 10 United States Code Section 980 (10 USC 980), "Limitation on Use of Humans as Experimental Subjects"**

(a) Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless--
(1) the informed consent of the subject is obtained in advance; or
(2) in the case of research intended to be beneficial to the subject, the informed consent of the subject or a legal representative of the subject is obtained in advance.
(b) The Secretary of Defense may waive the prohibition in this section with respect to a specific research project to advance the development of a medical product necessary to the armed forces if the research project may directly benefit the subject and is carried out in accordance with all other applicable laws.

This means that research involving deception, decisionally impaired individuals, or research being done under emergency conditions where the subject is not able to provide consent may not be possible.

- **DoDD 3210.7, "Research Integrity and Misconduct"**

  Any incident of falsification, fabrication or plagiarism must be reported to the DoD Component that is funding your research.

- **DoD Instruction (DoDI) 6200.02, "Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs"**

  Use of a medical product under a force health protection program pursuant to an Emergency Use Authorization or Investigational New Drug application requires approval of the Assistant Secretary of Defense for Health Affairs (ASD(HA)).

Part 3 - DoD Component Requirements

The part 3 Component requirements are only applicable to research protocol(s) sponsored by that DoD Component. This information sheet is for research funded by OUSD(P&R) institutions. Therefore you must comply with HA Policy 05-003, which requires individuals engaged in research with human subjects to complete initial and continuing training on the protection of human subjects. If you become engaged in research with or funded by any of the other DoD Components, then their policies will also apply.