Office of the Under Secretary of Defense (Personnel & Readiness)
Researcher Responsibilities

The Office of the Under Secretary of Defense for Personnel and Readiness requires that all research investigators (principal investigators as well as co-principal investigators) engaged in research with one of its institutions explicitly acknowledge and accept responsibility for protecting the rights and welfare of human research subjects as stated therein.

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1. I understand that the rights of the subjects take precedence over the needs of the research and I will protect the rights of human research subjects and will comply with the following: the Belmont Report, 32 CFR 219; 10 USC 980; DoDD 3216.02; where applicable 45 CFR 160 and 164; where applicable 45 CFR 46 (Subparts B, C, and D) under the authority of the DoD; and other Federal, State and local laws as they may relate to proposed human subjects research.

2. I am aware of the Joint Ethics Regulation, DoDI 5500.7-R, specifically areas addressing investigators relationships with sponsoring companies including monies received for research protocols. I understand that financial and other conflicts of interest must be reported to the EDO and/or IRB.

3. I understand that I must have either (a) a written exemption determination from my Exemption Determination Official (EDO) (b) an approval letter from a DoD IRB, or (c) written DoD concurrence with a nonfederal IRB review prior to initiating research.

4. I shall promptly report to the approving authority (EDO or IRB) proposed changes in a research activity and shall ensure that such changes in approved research, during the period for which approval has already been given, are not initiated without proper authority review and approval except when necessary to eliminate apparent immediate hazards to the subject.

5. I will ensure that all subjects, or their representatives, are fully informed of the nature of the research to include potential risks to subjects and I will obtain informed consent from each as required.

6. I will maintain study records for 3 years after the study is closed or for 6 years if the study is regulated by the Health Insurance Portability and Accountability Act.

7. I will respect the privacy of subjects. I shall protect confidential information given to me and advise subjects in advance of any limits upon my ability to ensure that the information will remain confidential.

8. I am aware and will complete the training required by the OUSD(P&R) HRPP prior to initiating research.

9. I will report immediately to the approving authority (EDO or IRB) any unanticipated problems involving risks to subjects or others in research.

Applicable to Biomedical Research Investigators

1. I understand and accept the responsibility for protecting the rights and welfare of human research subjects under the FDA regulations 21 CFR 50, 21 CFR 54, and 21 CFR 56 if applicable.

2. I will not enroll a subject into a study until the study has been approved by the appropriate authority and, when appropriate, the subject's primary care physician has granted approval for him/her to enter a study.

3. I am responsible for assuring the quality of each subject's consent in accordance with current federal regulations. This will include ensuring that any "designee" who obtains consent on my behalf is completely conversant with the protocol and is qualified to perform this responsibility.

4. I will maintain a Study File that must be kept for three years following completion of the study if no IND/IDE used. If IND medication or IDE appliances are used, the file must be kept for 2 years after FDA approval and can then be destroyed; or if no application is filed or approved, until 2 years after the study is discontinued and FDA notified.

5. I will report immediately to the IRB any unanticipated adverse events.

With my signature, I acknowledge that I have read and understand the responsibilities stated above and will comply with them. I understand that if I fail to comply with any of these responsibilities, all protocols for which I am an investigator may be suspended.

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Investigator Signature *Date*

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Print *(First Name)* *(Middle Initial)* *(Last Name)*

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Mailing Address

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(*City*) (*State/Province*) (*Zip/Country*)

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Phone Number *Email Address*