AIR FORCE HRPO INFORMATION SHEET

Human Subjects Research:

Roles and Responsibilities during DoD-Supported Extramural Research

Section 1: Regulatory Requirements, Human Subjects Research (HSR) Protection

a. The Department of Defense (DoD) requires specific language in FAR-based contracts or "other comparable agreements" (e.g., grants, assistance agreements, and cooperative research and development agreements) whenever efforts include, or might include, HSR. Such language instructs awardees to specific requirements and responsibilities during all periods of performance. In particular, DFARS clause **252.235-7004** (attached at the end of this Information Sheet) alerts performers that any research which involves human subjects is to be reviewed and approved by a Human Research Protection Official (HRPO). This HRPO review is to be completed prior to a DoD-supported performer conducting the contracted research activity.

b. Prime awardees have a non-delegable responsibility to oversee timely execution of DoD-supported research. They will ensure required contract clauses and responsibilities [to include required HRPO language], flows down to subcontractors who support HSR. In addition to inspection and acceptance of the contracted deliverable(s), external performers also agree to the following:

1) Allow DoD representatives to independently review and inspect all aspects of the awardee's research. Given that this may include access to identifiable information or protected health information, all research participants must be made aware of this requirement, i.e., via the informed consent.

2) Allow DoD representatives to prohibit research that is determined to present unacceptable hazards or is found to be non-compliant with DoD regulatory requirements.

3) Applies to all HSR matters, whether or not an institutional review board (IRB) has determined the effort to be exempt from Common Rule requirements.

c. HRPO must perform an administrative review of the research before the activities that involve human subjects can begin (e.g., human subject recruitment and related data collection). Accordingly, the HRPO must do the following:

1) Concur with the non DoD institution's review and approval whenever activities have been determined to be (a) research not involving human subjects or (b) research involving human subjects per the regulatory provisions of 32 CFR Part 219.

2) Confirm the institution has a Federal assurance if conducting non-exempt research. If DoD institutions are engaged in the extramural research, they must have a DoD Assurance.

3) Review the research protocol for compliance with Part 3.6 of DoD Instruction (DoDI) 3216.02 "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and Supported Research," in order to accept the non DoD IRB's determination of level of risk. This will ensure that the study is compliant with applicable Federal and DoD regulatory requirements prior to commencement of research activities.

4) Review and accept IRB-approved substantive changes [to an approved research protocol] before they are implemented.

5) When applicable, ensure the non DoD IRB conducts an appropriate continuing review at least annually.

6) When research involving human subjects is conducted in a foreign country, confirm the non DoD IRB confirmed all applicable national laws and requirements of the foreign country have been met, the IRB considered any unique or cultural sensitivities in the location where the research will take place and that the IRB had knowledge of the local context for the foreign research population that will be targeted for recruitment.

Section 2: Requirements for Approval of Extramural Human Subjects Research

a. **Federal Assurance of Compliance**. Each institution engaged in non-exempt human subjects research must have a current Department of Health and Human Services, Office for Human Research Protection (OHRP) FWA or DoD Assurance. An IRB review [by one of the IRBs listed on the institution's assurance] or identified in an Institutional Agreement for IRB Review *must* be provided. To avoid delays in the HRPO approval process, verify that the external performer(s)/ institutions engaged in the research have active assurances.

b**. Investigator Qualifications.** Alignment of the Principal Investigator (PI) and documentation of human subjects protection training for all engaged personnel will be provided to the HRPO. Such description will assist in the determination of which institutions are engaged in the research.

c. **Recruitment of Military Personnel**. Letters of support from Commanders of the affected military facility [or units in which recruitment will occur or the study will be conducted] is a regulatory requirement. Some military sites may also require that study volunteers seek written permission from their supervisor prior to research participation. **Note:** Special considerations pertain to recruitment process for military personnel. The chain of command must not be involved in the recruitment of military personnel and cannot encourage or order Service members to participate in a research study. For greater than minimal risk research, DoDI 3216.02 requires that an ombudsman be utilized when conducting group recruitment briefings with active duty personnel.

Section 3: HRPO Submission and Administrative Review Process

a. Research programs supporting the non DoD conducted research (the DoD Program Manager/Program Officer or their designee) are to submit proposals [those selected for funding or receiving DoD support] to the DAF HRPO to initiate administrative review. The DAF HRPO "Extramural Initial Submission Checklist" can be found at the link in the footer. **Note:** The non DoD investigator, with input from DAF programs supporting the activity, will supply required checklist data to enable HRPO review to begin.

b. The PI must complete all the information requested on the Initial Submission Checklist. Any questions related to information that is unknown should be discussed with the DAF HRPO during completion either via email or phone prior to submission to HRPO.

c. Work described in the research protocol must directly relate to the DoD-supported activities identified via the Statement of Work. Adding new DoD-supported activities [to an existing protocol] is generally not permitted. If such a design element is presented, pre-coordination with the HRPO, prior to submitting to the non DoD IRB, will ensure DoD requirements are met.

d. Once the full submission is received by HRPO a pre-review for compliance with Federal, DoD, State or host nation regulatory requirements will be completed. Any outstanding issues to bring the protocol into compliance will be coordinated with the DAF technical team as well as the non DoD investigator.

252.235-7004 Protection of Human Subjects

As prescribed in 235.072(e), use the following clause:

PROTECTION OF HUMAN SUBJECTS (JUL 2009)

(a) *Definitions*. As used in this clause—

(1) “Assurance of compliance” means a written assurance that an institution will comply with requirements of 32 CFR Part 219, as well as the terms of the assurance, which the Human Research Protection Official determines to be appropriate for the research supported by the Department of Defense (DoD) component (32 CFR 219.103).

(2) “Human Research Protection Official (HRPO)” means the individual designated by the head of the applicable DoD component and identified in the component’s Human Research Protection Management Plan as the official who is responsible for the oversight and execution of the requirements of this clause, although some DoD components may use a different title for this position.

(3) “Human subject” means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information (32 CFR 219.102(f)). For example, this could include the use of human organs, tissue, and body fluids from individually identifiable living human subjects as well as graphic, written, or recorded information derived from individually identifiable living human subjects.

(4) “Institution” means any public or private entity or agency (32 CFR 219.102(b)).

(5) “Institutional Review Board (IRB)” means a board established for the purposes expressed in 32 CFR Part 219 (32 CFR 219.102(g)).

(6) “IRB approval” means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements (32 CFR 219.102(h)).

(7) “Research” means a systematic investigation, including research, development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of 32 CFR Part 219, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities (32 CFR 219.102(d)).

(b) The Contractor shall oversee the execution of the research to ensure compliance with this clause. The Contractor shall comply fully with 32 CFR Part 219 and DoD Directive 3216.02, applicable DoD component policies, 10 U.S.C. 980, and, when applicable, Food and Drug Administration policies and regulations.

(c) The Contractor shall not commence performance of research involving human subjects that is covered under 32 CFR Part 219 or that meets exemption criteria under 32 CFR 219.101(b), or expend funding on such effort, until and unless the conditions of either the following paragraph (c)(1) or (c)(2) have been met:

(1) The Contractor furnishes to the HRPO, with a copy to the Contracting Officer, an assurance of compliance and IRB approval and receives notification from the Contracting Officer

that the HRPO has approved the assurance as appropriate for the research under the Statement of Work and also that the HRPO has reviewed the protocol and accepted the IRB approval for compliance with the DoD component policies. The Contractor may furnish evidence of an existing assurance of compliance for acceptance by the HRPO, if an appropriate assurance has been approved in connection with previous research. The Contractor shall notify the Contracting Officer immediately of any suspensions or terminations of the assurance.

(2) The Contractor furnishes to the HRPO, with a copy to the Contracting Officer, a determination that the human research proposed meets exemption criteria in 32 CFR 219.101(b) and receives written notification from the Contracting Officer that the exemption is determined acceptable. The determination shall include citation of the exemption category under 32 CFR 219.101(b) and a rationale statement. In the event of a disagreement regarding the Contractor's furnished exemption determination, the HRPO retains final judgment on what research activities or classes of research are covered or are exempt under the contract.

(d) DoD staff, consultants, and advisory groups may independently review and inspect the Contractor's research and research procedures involving human subjects and, based on such findings, DoD may prohibit research that presents unacceptable hazards or otherwise fails to comply with DoD procedures.

(e) Failure of the Contractor to comply with the requirements of this clause will result in the issuance of a stop-work order under Federal Acquisition Regulation clause 52.242-15 to immediately suspend, in whole or in part, work and further payment under this contract, or will result in other issuance of suspension of work and further payment for as long as determined necessary at the discretion of the Contracting Officer.

(f) The Contractor shall include the substance of this clause, including this paragraph (f), in all subcontracts that may include research involving human subjects in accordance with 32 CFR Part 219, DoD Directive 3216.02, and 10 U.S.C. 980, including research that meets exemption criteria under 32 CFR 219.101(b). This clause does not apply to subcontracts that involve only the use of cadaver materials.