HRPO INFORMATION SHEET

Human Subjects Research: Roles and Responsibilities during DoW Supported Research

SECTION 1: REGULATORY REQUIREMENTS, HUMAN SUBJECTS RESEARCH (HSR) PROTECTION

a. The Department of War (DoW) 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 DoW supported performer conducting the contracted research activity.

b. Prime awardees have a non-delegable responsibility to oversee the timely execution of DoW supported research. They will ensure required contract clauses and responsibilities (including required HRPO language), flows down to sub-contractors who support HSR. In addition to inspection and acceptance of the contracted deliverable(s), external performers also agree to the following, whether or not an Institutional Review Board (IRB) has determined the effort to be Exempt from Common Rule requirements:

1) Allow DoW 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 DoW representatives to prohibit research that is determined to present unacceptable hazards or is found to be noncompliant with DoW regulatory 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-DoW institution's Human Research Protection Program (HRPP), Institutional Review Board (IRB) or Ethics Committee (EC) 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) Review the research protocol for compliance with Part 3.6 of DoW Instruction (DoWI) 3216.02_DAFI 40-402 "Protection of Human Subjects and Adherence to Ethical Standards in DoW-Conducted and Supported Research." This will ensure that the study is compliant with applicable Federal and DoW regulatory requirements prior to commencement of research activities.

3) Review and approve the non-DoW IRB-approved substantive modifications to previous HRPO concurred research protocols before the modifications are implemented.

4) When applicable, ensure the non-DoW IRB conducts an appropriate continuing review at least annually.

5) When research involving human subjects is conducted in a foreign country, verify that the non-DoW IRB/EC confirmed compliance with all applicable laws and requirements of each foreign country where the HSR will be conducted, and the IRB/EC considered knowledge of the local research context including cultural sensitivities in the location where the research will take place.

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 (DHHS), Office for Human Research Protection (OHRP) Federalwide Assurance (FWA) or DoW Assurance.

Investigator Qualifications. Documentation of human subjects protection training for the Principal Investigator (PI) will be provided to the HRPO. The PI is responsible for ensuring all other engaged personnel have up-to-date HSR training and are covered under the appropriate assurance. HSR training of engaged personnel is reviewed by the IRB/EC, but may be requested by HRPO through post approval compliance monitoring or for-cause audits.

DoW Support (including recruitment of DoW-affiliated personnel). If Department of the Air Force (DAF) personnel will be targeted for recruitment to participate in HSR or are providing any other support, and the supporting DAF institution does not have an established human research protection program (HRPP), the command or component leadership must establish a limited HRPP with the DAF Component Office of Human Research Protection (COHRP). The template to facilitate this requirement is available from the AFRL HRPO office.

Similarly, when other DoW Components support HSR, the DoW organization is required to have an HRPP, consistent with that Component's policies. For example, Command approval for participation of DoW-affiliated personnel and letters of support for military facility use may fulfill this requirement. **Note:** The chain of command must not be involved in the recruitment of personnel and cannot encourage DoW-affiliated personnel to participate in a research study.

b. **Additional Unique DoW Requirements.**

1) For all non-exempt HSR research, provide written documentation that the IRB considered the scientific merit of the protocol (this is often documented on the IRB approval letter, however, other IRB documentation is accepted).

2) For all exempt and non-exempt HSR research, if the project involves Artificial Intelligence (AI) enabled tools or capabilities, there must be documentation showing that the DoW Ethical Principles for AI are provided for in the protocol. See AFRL HRPO website for the *AI Use in Supported Human Subjects Research* handout.

3) For non-exempt HSR research protocols deemed greater than minimal risk that recruit DoW-affiliated personnel in a group setting the IRB must appoint an ombudsperson (without conflict of interest and not part of the study team) who must be present during recruitment. The ombudsperson will ensure recruitment and consent is voluntary and will be available to address DoW-affiliated personnel's concerns about participation.

4) For research that involves large scale genomic data (LSGD) of DoW-affiliated personnel, a DoW LSGD security review must be accomplished prior to conducting the research. The HRPO will assist with obtaining a DoW LSGD security review.

SECTION 3: AFRL REQUIREMENTS FOR APPROVAL OF EXTRAMURAL HUMAN SUBJECTS RESEARCH

a. Component programs supporting non-DoW conducted research (the DoW Program Manager / Program Officer / Technical Point of Contact or their designee) will assist the non-DoW performer in submitting awards (those selected for funding or receiving DoW support) to the AFRL HRPO office to initiate the DoW required administrative review. The AFRL "Extramural Submission Instructions" and "Extramural Initial Submission Checklist" can be found at AFRL HRPO website.

b. The PI must complete all the information requested on the AFRL Extramural Initial Submission Checklist. Any questions related to what information is required should be discussed with representatives from the AFRL HRPO office either via email, Teams, or phone. Email AFRL.IR.HRPO@us.af.mil

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

d. Once the complete submission is received by AFRL HRPO office, the review will commence to ensure compliance with Federal, DoW, State, and, if necessary, host nation regulatory requirements. Once review of the submitted protocol has been conducted, any required follow-up to be compliant with requirements will be routed to the investigator for resolution.

e. At the review completion, the HRPO will issue a concurrence or non-concurrence letter. The review process will repeat for substantive amendments, re-approval of protocols (as applicable), and closure with response emails.

INFO SHEET REFERENCES: 32 CFR 219, DOWI 3216.02 DAFI 40-402

ATTACHMENT

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 War (DoW) component (32 CFR 219.103).

(2) "Human Research Protection Official (HRPO)" means the individual designated by the head of the applicable DoW 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 DoW 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.

(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 DoW directive 3216.02, applicable DoW 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 DoW 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.

252.235-7004 PROTECTION OF HUMAN SUBJECTS CONTINUED…

(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) DoW 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, DoW may prohibit research that presents unacceptable hazards or otherwise fails to comply with DoW 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 sub-contracts that may include research involving human subjects in accordance with 32 CFR part 219, DoW 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.