DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE

WASHINGTON DC

6 May 2016

MEMORANDUM FOR ALL USAF RESEARCH INSTITUTIONS

FROM: AFMSA/SGE-C
7700 Arlington Blvd
Falls Church VA 20442

SUBJECT: AFMSA/SGE-C Guidance Memorandum 2016-0002G: Guidance on Activities That May Be Research Involving Human Subjects

References: (a) Title 32, Code of Federal Regulations, Part 219, *Protection of Human Subjects*
(b) Department of Defense Instruction 3216.02, *Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research*
(c) Department of Defense Instruction 3216.02_Air Force Instruction 40-402, *Protection of Human Subjects and Adherence to Ethical Standards in Air Force Supported Research*
(d) Department of Defense Instruction 6200.02, *Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs*
(e) Title 21, Code of Federal Regulations, *Food and Drugs*

1. The purpose of this memorandum is to provide guidance to Air Force Research Institutions in distinguishing activities that "may be" research involving human subjects and those that should be reviewed for official determinations of (a) not human subject research, (b) exempt research involving human subjects, or (c) non-exempt research involving human subjects that require IRB approval.

2. Reference (b) identifies a list of seven activities that are not research involving human subjects (Glossary, Part II). These activities do not meet the regulatory definition of research as defined in Section 219.102(d) of Reference (a).

a. An activity must meet the definition of "research" and "human subjects" as defined in Section 219.102(d) and Section 219.102(f) of Reference (a) to be considered research involving human subjects

(1) Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge

(2) Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

(a) Data through intervention or interaction with the individual, or

(b) Identifiable private information

b. Each of the listed activities uses the terms “sole” or “solely” to indicate that the activities have a single purpose (e.g., health and medical activities undertaken for the sole purpose of patient treatment), therefore, none of these activities are designed to develop or contribute to generalizable knowledge

c. These seven activities would not require an official determination if they will be conducted exactly as characterized, and the data/specimens from the activity will not be used in any way other than to support the primary aim identified in the Glossary of Reference (b)

3. According to Enclosure 3, section 3.a.(1)(a) of Reference (c), the Air Force authorizes only AFMSA/SGE-C, IRBs, and Exempt Determination Officials (EDOs) to make official determinations regarding whether activities are not research involving human subjects, exempt human subjects research per section 219.101(b) of Reference (a), research involving human subjects that requires IRB approval prior to initiation per Reference (a).

a. Investigators have a responsibility to obtain written determination for activities that are or may be research involving human subjects prior to initiation of the activities

b. Investigators are not authorized to make the determinations for their own activities (Enclosure 2, Section 11.c of Reference (c))

4. As a dynamic military organization, activities conducted or supported by the Air Force are often multifaceted and are aimed at improving the health of the Airmen and advancing mission effectiveness. Therefore, as a consequence, the knowledge gained from these activities may be shared in a way that is generalizable to other military and civilian populations. The following guidelines are provided to ensure research that may involve human subjects are appropriately referred to those who have the authority to make official determinations in accordance with Enclosure 3, section 3.a.(1)(a) of Reference (c).

a. Any activity in a program can involve research if it meets the regulatory definition, regardless of whether or not the primary purpose of the program is research

(1) When evaluating whether an activity or program may be research involving human subjects, these two basic questions should be asked (definitions from Section 219.102 of Reference (a) should be applied)

(a) Does it meet the definition of research?

(b) Does it involve human subjects?

b. Projects with the following designs are more likely to enter the realm of research involving human subjects and may require additional consideration during the planning stages

(1) Large multi-site projects that implement a structured protocol

(2) Divergence from standard practice or standard of care

(a) Randomization of treatment groups

(b) Any additional measures or questions added to existing evaluations to learn more about a target population to compare with other populations

c. AFMSA/SGE-C strongly recommends that investigators seek an official determination under the following circumstances, unless advised otherwise by the applicable regulatory oversight body (i.e., EDOs, IRBs, AFMSA/SGE-C)

(1) If any of the investigators indicate that they may want to have the option of using any data or specimens about the program's participants to answer a research question

(2) An investigator who desires to submit the results (whether or not they are generalizable) to a peer review journal that requires IRB approval or official determinations of not human subjects research or exempt human subjects research

(3) A student thesis or dissertation project that may involve intervention or interaction with individuals or the use of data or specimens from a program

(4) Observational studies where investigators will obtain data about living individuals in either a public or private setting

(5) A pilot study where investigators will test research procedures on a target population to prove a concept to inform the design of future studies (Note: This does not include receiving consultations from subject matter experts or stakeholders about how the procedures/tools should be developed based on their expert opinions.)

(6) Operational tests of equipment or software that collects and analyzes data about the individuals who use them

(7) Secondary analysis of data for research purposes provided that the data is not available as part of the public record and/or a public access database (i.e., does not require any special access/login requirements, passwords, or data use agreements)

(8) A multi-site project where the standard of care is being altered

Note: The range of activities identified in paragraph 4 is not intended to be an all inclusive list.

5. This guidance is not intended to assist investigators and research coordinators (e.g., Program Managers) in making official determinations of whether an activity is research involving human subjects, rather, if an activity "may be" research involving human subjects.

a. Investigators and/or research coordinators (e.g., Program Managers) should be conservative in their approach and should opt to send a project for official determination if there is any doubt that the activity "may be" research involving human subjects

b. If there are any questions about the applicability of regulatory definitions or review processes, investigators should seek consultation from EDOs, IRBs or AFMSA/SGE-C

Note: This guidance should not be used for activities involving the use of experimental medical products or devices that are subject to the Food and Drug Administration (FDA) regulations in References (d) and (e).

6. Direct questions regarding this guidance memorandum to Dr. Rochelle Collantes (E-mail: mariarochelle.s.collantes.ctr@mail.mil/(703) 761-8115/DSN 761 or Ms. Megan McFarland (E-mail: megan.e.mcfarland.ctr@mail.mil/(703) 761-8056/DSN 761).

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Attachment:
Not Research Involving Human Subjects Worksheet