NOT RESEARCH INVOLVING HUMAN SUBJECTS WORKSHEET

Purpose: This worksheet serves as a tool to assist in distinguishing projects that do not require official determinations and when to seek additional consultation for the activities listed in the Department of Defense Instruction (DoDI) 3216.02 (Glossary, Part II) that are not research involving human subjects.

This worksheet should be used with AFMSA/SGE-C Guidance Memorandum 2016-0002G: Guidance on Activities That May Be Research Involving Human Subjects, and the specific references listed for each item below.

1. Do the activities involve any experimental medical products or devices that are subject to the Food and Drug Administration (FDA) regulations in Title 21 Code of Federal Regulations (CFR) Part 312 or Part 812?
   a. Yes: **STOP.** *Contact your institution's IRB for guidance.*
   b. No: Proceed to item 2

2. Are the activities carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease in Service members and other mission essential personnel under force health protection programs of the Department of Defense (DoD), including health surveillance pursuant to 10 United States Code (USC) section 1074f and the use of medical products consistent with DoDI 6200.02?
   a. Yes: Skip to item 9
   b. No: Proceed to item 3

3. Are the activities authorized health and medical activities as part of the reasonable practice of medicine or other health professions undertaken for the sole purpose of patient treatment?
   a. Yes: Skip to item 9
   b. No: Proceed to item 4

4. Are the activities performed for the sole purpose of medical quality assurance consistent with 10 USC section 1102 and DoD Manual (DoDM) 6025.13?
   a. Yes: Skip to item 9
   b. No: Proceed to item 5

5. Are the activities performed solely for an operational test and evaluation project defined in 10 USC section 139(a)(2)(A) as "the field test, under realistic combat conditions, of any item of (or key component of) weapons, equipment, or munitions for the purpose of determining the effectiveness and suitability of the weapons, equipment, or munitions for use in combat by typical military users; and the evaluation of the results of such test"?
   a. Yes: Skip to item 9
   b. No: Proceed to item 6

6. Are the activities performed solely for assessing compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units, including such activities as occupational drug testing, occupational health and safety reviews, network monitoring, and monitoring for compliance with requirements for protection of classified information?

a. Yes: Skip to item 9
b. No: Proceed to item 7

7. Are the activities, including program evaluation, customer satisfaction surveys, user surveys, outcome reviews, and other methods, designed solely to assess the performance of DoD programs where the results of the evaluation are only for the use of Government officials responsible for the operation or oversight of the program being evaluated and are not intended for generalized use beyond such program?
a. Yes: Skip to item 9
b. No: Proceed to item 8

8. Are the activities surveys, interviews, or surveillance activities and related analyses performed solely for authorized foreign intelligence collection purposes, as authorized by DoD Directive (DoDD) 5240.01?
a. Yes: Proceed to item 9
b. No: Skip to item 11

9. Do the activities have any aims or purposes other than those identified?
a. Yes: Skip to item 11
b. No: Proceed to item 10

10. Will any data or specimens collected from the activities be used for research purposes to contribute to generalizable knowledge?
a. Yes: Proceed to item 11
b. No: **STOP.** *No further action is required. Activities are defined as Not Research Involving Human Subjects in the Glossary, Part II of the DoDI3216.02.*

11. **STOP.** *Consult your institution's IRB and/or EDO about the appropriate review processes for official determinations of not human subjects research, exempt human subjects research, or non-exempt human subjects research requiring IRB approval.*

Notes:
1. In accordance with DoDI3216.02_AFI40-402, Enclosure 3, section 3.a.(1)(a), the Air Force authorizes only AFMSA/SGE-C, IRBs, and Exempt Determination Officials to make official determinations regarding whether activities are not research involving human subjects, exempt human subjects research per 32 CFR 219.101(b), and research involving human subjects that requires IRB approval prior to initiation per 32 CFR 219.

2. 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. Investigators are not authorized to make the determinations for their own activities (DoDI3216.02_AFI40-402, Enclosure 2, Section 11.c).

3. This worksheet is <u>not</u> intended to assist investigators and research coordinators (e.g., Program Managers) in making official determinations of whether an activity is research involving human subjects. Investigators and research coordinators should opt to send a project for official determination if there is any doubt that the activity "may be" research involving human subjects.
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References:

(a) 21 CFR 219, *Protection of Human Subjects*
(b) 21 CFR 312, *Investigational New Drug Application*
(c) 21 CFR 812, *Investigational Device Exemptions*
(d) DODI 3216.02, *Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research*
(e) DoDI3216.02_AFI40-402, *Protection of Human Subjects and Adherence to Ethical Standards in Air Force Supported Research*
(f) DoDI6200.02, *Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs*
(g) DoDD 5240.01, *DoD Intelligence Activities*
(h) DoDM6025.13, *Medical Quality Assurance (MQA) and Clinical Quality Management in the Military Health System (MHS)*
(i) 10 USC 1074f, *Medical Tracking System for Members Deployed Overseas*
(j) 10 USC 1102, *Confidentiality of Medical Quality Assurance Records: Qualified Immunity for Participant*s
(k) 10 USC 139, *Director of Operational Test and Evaluation*