



Request for Research and/or Human Subjects Determination

Please complete this template and upload it, along with all supporting documentation, to your project in IRBNet. *(You may need to click "Enable Editing" on the yellow bar above in order to complete this template)*

Submission Date: (Submit Templates to dha.ncr.dha-cs-mgt.mbx.hrpp@mail.mil)

1. Full Study Title:	
2. Principal Investigator	
Name (include rank)	Title
Affiliation (vendor, command, installation, etc.)	
Work email	Work phone
3. Government Project Manager	
Name (include rank)	Title
Affiliation (vendor, command, installation, etc.)	
Work email	Work phone

Investigators and Human Research Protection Program personnel use this template to assist with determining if an activity meets the regulatory definition of "research involving human subjects". Defense Health Agency (DHA) Human Research Protection Program staff members requesting additional information might contact investigators.

Research: (32 CFR 219.102(d)) – Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Human Subject: (32 CFR 219.102(f)) – Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

- (1) Data through intervention or interaction with the individual, or
- (2) Identifiable private information.

Operational Test and Evaluation (OT&E): (10 USC 139(a)(2)(A)) – OT&E means

- (i) 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
- (ii) The evaluation of the results of such test.

DoD Instruction (DoDI) 3216.02 "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research", Enclosure 3, Definitions includes a list of common DoD-conducted or supported activities that are NOT research involving human subjects.

Specific Request(s) – select the appropriate exclusion request(s) and provide a brief justification for each.

4. Not Research

Explain this request (please limit explanation to 300 words)

5. Not Human Subject

Explain this request (please limit explanation to 300 words)

6. Activities carried out solely for purposes of diagnosis, treatment, or prevention of injury or disease in Service members and other mission essential personnel under force health protection programs of the DoD, including health surveillance pursuant to section 1074f of 10 USC and the use of medical products consistent with DoDI 6200.02.

Explain this request (please limit explanation to 300 words)

7. 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.

Explain this request (please limit explanation to 300 words)

8. Activities performed for the sole purpose of medical quality assurance consistent with section 1102 of 10 USC and DoDI 6025.13 "Medical Quality Assurance (MQA) and Clinical Quality Management in the Military Health System (MHS)".

Explain this request (please limit explanation to 300 words)

9. Activities performed solely for an OT&E project where the activities and project meet the definition of OT&E as defined in section 139(a)(2)(A) of 10 USC, and as provided above.

Explain this request (please limit explanation to 300 words)

10. 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.

Explain this request (please limit explanation to 300 words)

11. 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.

Explain this request (please limit explanation to 300 words)

12. Survey, interview, or surveillance and related analyses performed solely for authorized foreign intelligence collection purposes, as authorized by DoDD 5240.01 "DoD Intelligence Activities".

Explain this request (please limit explanation to 300 words)

13. Other justification not listed previously.

Explain this request (please limit explanation to 300 words)