This guidance document is used to determine whether non-exempt <Human Research> subject to DOD regulations can be approved.

**All criteria in 1 must be met.** 
*Department of Defense Instruction 3216.02*

**All criteria in 2 must be met for research involving service members as subjects.**

### 1. General Criteria

<table>
<thead>
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<th>Criteria</th>
<th>Details</th>
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<tbody>
<tr>
<td>1.1</td>
<td>The investigator and research staff have been trained on DOD regulations and requirements (see Footnote 1)</td>
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<td>1.2</td>
<td>The IRB has considered the scientific merit of the research (see Footnote 2)</td>
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</table>
| 1.3      | One of the following is true:  
  - The research does not involve informed consent  
  - The disclosure for research-related injury follows the requirements of the DOD component. |
| 1.4      | One of the following is true:  
  - The research does not involve a waiver of consent for <Experimental Subjects as Defined by DOD>  
  - A waiver will be obtained from the Assistant Secretary of DOD for Research and Engineering (see Footnote 3) |
| 1.5      | One of the following is true:  
  - The research holds out the prospect of direct benefit the individual subject (see Footnote 4) |
| 1.6      | One of the following is true:  
  - The research does not involve multi-site research  
  - There is a formal agreement between organizations to specify the roles and responsibilities of each party. |
| 1.7      | One of the following is true:  
  - The research does not involve pregnant women, <Fetuses>, or neonates as subjects  
  - The research does not involve interventions or invasive procedures with more than <Minimal Risk> to subjects  
  - The research meet: “GUIDANCE: Pregnant Women (HRP-305)”, except “biomedical knowledge” is replaced with “generalizable knowledge.” |
| 1.8      | One of the following is true:  
  - The research does not involve <Children> as subjects  
  - The research meets “GUIDANCE: Children (HRP-310)” |
| 1.9      | One of the following is true:  
  - The research complies with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g |
| 1.10     | One of the following is true:  
  - The research is conducted in the United States  
  - Permission has been obtained to conduct research in each country by certification or local ethics review  
  - The investigator will follow all local laws, regulations, customs, and practices |
| 1.11     | One of the following is true:  
  - The IRB has approved an independent research monitor (see Footnote 5)  
  - The monitor has been appointed by name  
  - The research monitor has expertise consonant with the nature of risks identified within the research protocol  
  - The monitor’s duties have been determined on the basis of specific risks or concerns about the research (see Footnote 6)  
  - The monitor has the authority to stop a research protocol in progress, remove individual subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of subjects until the IRB can assess the monitor’s report |
| 1.12     | One of the following is true:  
  - The research does not involve <Prisoners> as subjects  
  - The research meets the requirements of "REGULATORY GUIDANCE: Prisoners (HRP-308)"  
  - The research is reviewed by a convened IRB  
  - A prisoner representative is present  
  - The research does not involving prisoners of war or detainees as subjects (see Footnotes 7 and 8)
The ombudsman is not associated in any way to the research.

The IRB may rely on outside experts to provide an evaluation of the scientific merit.

Service members will not receive payment for research conducted during duty hours (see Footnote 10)

The ombudsman will be present during the recruitment in order to monitor that the voluntary involvement or recruitment of the service members is clearly and adequately stressed and that the information provided about the research is clear, adequate, and accurate

The investigator will obtain DOD approval of surveys administered to service members

The determination that research is intended to be beneficial to the individual <Experimental Subject as Defined by DOD> must be made by an IRB.

Use of expedited review is prohibited. Any IRB member who disagrees with a majority approval may appeal the decision to the Secretary of DOD.

The Assistant Secretary for DOD for Research and Engineering may waive the requirements for consent when all of the following are met: (1) The research is necessary to advance the development of a medical product for the Military Services. (2) The research may directly benefit the individual <Experimental Subject as Defined by DOD>. (3) The research is conducted in compliance with all other applicable laws and regulations. The IRB may waive the consent process for subjects who are not <Experimental Subjects as Defined by DOD>.

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The research monitor may perform oversight functions (e.g. observe recruitment, enrollment procedures, and the consent process, oversee study interventions and interactions, review monitoring plans and unannounced problems involving risks to subjects or others, oversee data matching, data collection and analysis) and report their observations and findings to the IRB or a designated official

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