UNIQUE REQUIREMENTS FOR WORK SUPPORTED BY THE DEPARTMENT OF DEFENSE (DOD)	SOP 11.1.03

1. Purpose

The purpose of this SOP is to provide guidance on the unique requirements that researchers must follow for work supported by the Department of Defense (DoD).

2. General Information

Research is considered to involve the DoD when the research is funded by a component of DoD, the research involves cooperation, collaboration, or any other type of agreement with a component of DoD, the research uses property, facilities or assets of a component of DoD, or the subject population will intentionally include personnel (military and/or civilian) from a component of DoD. The DoD components include, but may not be limited to, the Navy, Army, Air Force, Marines, Coast Guard, National Guard, Defense Advanced Research Projects Agency (DARPA), National Security Agency, etc.

In their work with study participants, Caltech and JPL investigators are required to fulfill all requirements of the Caltech IRB, including, but not limited to, compliance with the Department of Health and Human Services' regulations found at 45 CFR 46. Caltech investigators receiving Department of Defense (DoD) funds for experiments using study participants must also fulfill the unique requirements imposed by the DoD. This SOP describes procedures for compliance with the unique DoD requirements.

3. Training Requirements

The DoD requires continuing human subjects research education every **three years**. This requirement can be fulfilled through certification of Caltech CITI training.

4. Procedure

a. New Protocol

To ensure compliance with the DoD unique requirements, the Caltech IRB requires that work performed on a DoD award be provided as a stand-alone Caltech IRB protocol that applies only to the work with study participants described in the DoD proposal and funded by the DoD award.

Primary Review (Caltech IRB)

a. The Caltech PI must submit an IRB protocol application to the Caltech IRB. It is essential that the PI inform the Caltech IRB that work described within the application is funded by the DoD at the time the application is submitted.

b. The IRB will review and approve the protocol application in accordance with Caltech's policies and procedures.

c. The PI will receive an approval letter from the Caltech IRB, confirming protocol approval.

d. The approved protocol will be redacted to remove buildings and room numbers prior to submission to the DoD for Secondary Review. The PI will coordinate with the IRB to generate the redacted copy of the protocol.

e. The PI shall prepare all appropriate DoD IRB application form(s) and provide a copy to the IRB for review. The PI should confirm the Sponsor's need for any additional documentation, such as Scientific Review. The US Army currently requires the following additional documents, however this list is subject to change at any time by the USAMRDC:

    i. The PI must complete the HRPO Protocol Submission Form for all USAMRDC submissions.

    ii. If the protocol is Exempt, PIs should submit a completed Claim of Exemption Form and the Caltech Status Memo stating that the protocol has been determined to be exempt.

Secondary Review (DoD):

a. The PI shall confirm that the Office of Sponsored Research (OSR) or the Office of Research Compliance (ORC) will submit the redacted copy of the Caltech IRB approved protocol, a copy of the Caltech IRB approval letter, and the appropriate forms (from 2.e.) to the DoD. OSR or ORC will cc the PI and the IRB on the submission to the DoD.

b. A DoD IRB official will review and approve the protocol for the DoD. Secondary Review may take up to 3-4 months for original protocol review.

c. NO WORK can begin (i.e. no DoD funds spent) on the protocol until both *Primary* and *Secondary* Review are complete and the applications approved.

d. Failure to obtain DoD IRB approval before beginning work or implementing any change to the protocol is a violation of the DoD award/contract and will result in a non-compliance and denial of approved use of funds.

b. Protocol Modifications

All protocol modifications, annual renewals, and de-novo applications submitted to and approved by the Caltech IRB under Primary Review must also be submitted by the PI to the DoD for Secondary Review.

Should a PI later decide to modify their protocol to add work not funded by DoD, the IRB advises that the PI "duplicate" their protocol and add the amendment to the new protocol which will not require DoD review. Going forward, any changes a PI wishes to make to both protocols, will have to be provided as separate amendments, one for each protocol.

Primary Review (Caltech IRB):

a. The PI submits an application or request for amendment or personnel change to the Caltech IRB. The Caltech IRB will review and approve the request for modification in accordance with standard policies and procedures.

b. The Caltech IRB approved Protocol Modification will be redacted to remove buildings and room numbers prior to submission to DoD for Secondary Review. The PI will coordinate with the IRB to generate the redacted copy of the Protocol Modification.

Secondary Review (DoD):

a. The PI shall confirm that OSR or ORC will submit the redacted copy of the Protocol Modification along with a copy of the Caltech IRB approval letter to the DoD. OSR or ORC will cc the PI and the IRB on the submission to the DoD.

b. Inclusion of the word "Amendment" in the subject line of the email correspondence to DoD when submitting a Protocol Modification will ensure that request for changes to an approved protocol will be reviewed more quickly than a New Protocol.

c. A DoD IRB official will review and approve the protocol for DoD.

d. NO protocol modifications can be implemented (i.e., no DoD funds spent) on the protocol until both Caltech IRB Primary and DoD Secondary Review are complete and the modifications approved.

e. Failure to obtain DoD approval **before** implementing any change to the protocol is a violation of the DoD award/contract and will result in a non-compliance and denial of approved use of funds.

5. **Greater Than Minimal Risk**
The DoD no longer requires PIs to submit a DoD Research Monitor (RM) for protocols that have a Greater Than Minimal Risk determination.

6. **Multi-Site DoD Research**
The DoD requires that any institution located in the United States that is engaged in multi-site cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the U.S. The requirement applies to all research, to include studies subject to the U.S. Food and Drug Administration's regulations. The primary awardee (lead institution) of a USAMRDC-managed research proposal that includes a multi-site, cooperative effort must develop a plan for coordinating all collaborating sites' reliance on a single IRB for DoD-supported multi-site cooperative research.

7. **DoD Funded Research Conducted Outside of the United States**
If the project involves execution of all or part of the research outside of the United States, the HRPO must confirm all applicable host national laws and requirements of the foreign country

have been met and confirm the IRB considered cultural sensitivities in the setting where the research will take place. The PI must provide adequate information to the HRPO regarding national laws and requirements and the cultural context in which the research will take place. This information can be provided through completion of applicable sections of the HRPO International Research Submission Form, or through inclusion of applicable information in the protocol.

8. Protocol Non-Compliance or Institutional Action or Change in Status

a. DoD must receive notice from Caltech of all IRB actions regarding:
   i. Any non-compliance with the protocol, IRB policies, or federal regulations;
   ii. Any suspension of IRB protocol/activity; and
   iii. Any pending compliance inspection/visit by the FDA, DHHS Office of Human Research Protections (OHRP), or other government agency concerning this research, the issuance of Inspection Reports, FDA Form 483, warning letters, or actions taken by any regulatory agencies including legal or medical actions and any instances of serious or continuing noncompliance with the regulations or requirements.