DoD Guidance for IRB Analysts, Members, & **Investigators**

PURPOSE

This guidance is to be used by IRB staff, members, and investigators as guidance to facilitate the USC IRB review of protocols where an USC Investigator is conducting, supporting, or collaborating with the federal Department of Defense (DoD). The use of DoD-affiliated personnel as participants and/or their data or specimens requires DoD approval and oversight. DoD-affiliated personnel are defined as: Service members, Reserve Service members, National Guard members, DoD Civilians, and DoD Contractors. This guidance is based on updates shared with the USC HRPP and reflects the DoD Instruction (DODI) 3216.02, "Protections of Human Subjects and Adherence to Ethical Standards in DOD-Conducted and-Supported Research."

REQUIREMENTS

In **all** cases, USC investigators who intend to conduct research or support or collaborate with the DoD in research activities must reach out to the DoD Service Component for instruction and guidance regarding DoD Service Components' review requirements prior to submission to the USC IRB. If an application is submitted to the USC IRB prior to consultation with the respective DoD Service Component, the IRB staff will return the application to the investigator so that the investigator can include any DoD specific requirements in accordance with the DoDI 3216.02. Applications will not be reviewed until and unless they contain DoD specific requirements or notice that no such requirements exist.

DoD Components:

Under Secretary of Defense for Research and Engineering (USD R&E): Human Research Protections (DOHRP) -DCTO (S&T)

Defense Advanced Research Projects Agency (DARPA) website: Defense Advanced Research Projects Agency (darpa.mil)

Department of the Airforce: Airforce Component Office for Human Research Protections (includes Air National Guard) (usaf.pentagon.af-sq.mbx.afmsa-sqe-c@health.mil)

Department of the Army: Army Human Research Protections Office (includes Army National Guard and Army Reserves) (usarmy.ncr.hqda-otsg.mbx.otsg-ahrpo@health.mil)

Defense Health Agency (DHA): Office of Research Protection (dha.hrpp@health.mil)

Department of Navy: Human Research Protection Program (Navy, BUMED, Marines): (usn.ncr.bumedfchva.mbx.DON-HRPP@health.mil)

Defense Threat Reductions Agency (DTRA): Research and Development Directorate (Research and Development (dtra.mil))

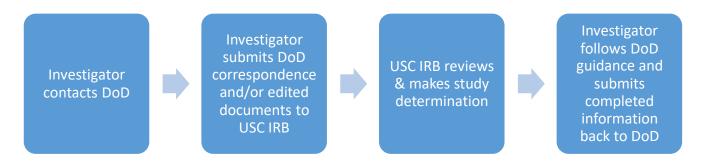
U.S. Army Medical Research Development Command (USAMRDC): Office of Human Research Oversight (OHRO): (usarmy.detrick.medcom-usamrmc.other.hrpo@health.mil)

United States Special Operations Command (USSOCOM): Research Protections (hrpp@socom.mil)

Uniformed Services University of the Health Sciences (USUHS): Human Research Protection Program: (*IRB1@usush.edu*)

SUBMISSION TO USC IRB

Investigators, when submitting to the USC IRB, please upload any correspondence and/or edited documents from the DoD Service Component in iStar section 40.1. The USC IRB will make the final determination (exempt, expedited, full board) following USC policies for study determination. Following USC's determination process, the DoD may require the investigator submit their protocol back to the DoD Component for approval/concurrence/acknowledgement prior to implementation of the study.



Process continues based on requirements of DoD and USC IRB until Approval.

