



HEALTH AFFAIRS

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, DC 20301-1200

30 October 2014

MEMORANDUM FOR OFFICE OF THE UNDER SECRETARY OF DEFENSE FOR PERSONNEL AND READINESS (OUSDP&R) INSTITUTIONS CONDUCTING OR SUPPORTING HUMAN SUBJECTS RESEARCH

SUBJECT: Continued Acceptance of OUSD(P&R) Human Research Protection Program
Training through the Collaborative Institutional Training Initiative (CITI)

The Office of the Under Secretary of Defense for Personnel and Readiness (OUSDP&R) issues Assurances for the Protection of Human Subjects (Assurance) through the Research Regulatory Oversight Office (R2O2) in accordance with DoD Instruction (DoDI) 3216.02. DoDI 3216.02, Enclosure 3, Section 5 describes the requirement for role-based training of personnel involved in the conduct, review, or approval of research involving human subjects, including the non-affiliated and prisoner representative members on the DoD Institutional Review Board (IRB) in compliance with the standards set forth by the Assistant Secretary of Defense for Research and Engineering (ASD(R&E)).

The Office of the ASD(R&E) issued a memorandum dated August 16, 2012 outlining the Minimum Education Requirements Framework (MERF) for DoD Personnel Involved in Human Research Protection. The OUSD(P&R) has adopted the updated modules offered through CITI which substantially meet these standards and those modules are available to all individuals who affiliate with OUSD(P&R) in CITI. An updated OUSD(P&R)-specific module will soon be available that captures all additional DoD-specific requirements.

OUSD(P&R) institutions should accept as satisfying the training requirements for human research protection, documentation of successful completion of the OUSD(P&R) affiliated CITI training dated 01 July 2013 and after. Personnel involved in the conduct, review or approval of research involving human subjects will only have access to MERF-compliant training through OUSD(P&R) affiliation in CITI from 20 July 2014, so all subsequent training received through this curriculum will meet the standards articulated in the MERF.

Individuals who do not have documented successful completion of training for roles that they intend to serve must complete all of the modules required for the roles from the curriculum currently available to learners who affiliate with OUSD(P&R) in the CITI program. Those modules are compliant with the MERF.

OUSD(P&R) institutions may implement more restrictive standards for meeting the MERF requirements; however, those additional requirements shall not delay the submission, review, approval and initiation of research protocols. Conditional IRB approvals shall be

provided that permit initiation of research protocols for a period of time, not less than 30 days or more than 90 days, for the individuals to complete the modules required by the institution. If the individual (Principal Investigator, Associate Investigator, Other Key Study Personnel, *etc.*) does not complete the training during that time, then the training is to be considered to have lapsed. In accordance with OUSD(P&R) Policy Guidance PG-03-001, sanctions may be imposed that restrict conduct of the study or participation by an individual study team member.

Individuals serving OSUD(P&R) institutions in oversight or review capacities (*e.g.*, IRB members, Human Protection Administrators) may not be permitted to conduct those regulatory actions independently until all required MERF-compliant training is completed successfully as evidenced by completion certificates. For additional information, please contact the R2O2 at HRPP@DHA.mil.

ECKERT.JOHN.
J.1248350624
CAPT John J. Eckert, PhD, CIP
Acting Director
Research Regulatory Oversight Office

Digitally signed by
ECKERT.JOHN.J.1248350624
DN: c=US, o=U.S. Government,
ou=DoD, ou=PKI, ou=USPHS,
cn=ECKERT.JOHN.J.1248350624
Date: 2014.10.30 10:05:00 -04'00'

cc:
DASD(FHP&R)
Director, Human Performance, Training, and Biosystems Directorate, OASD(R&E)