OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, DC 20301-1200

MAY 3 2005

HEALTH AFFAIRS

MEMORANDUM FOR DIRECTOR OF THE TRICARE MANAGEMENT ACTIVITY
DIRECTOR OF THE DEPARTMENT OF DEFENSE EDUCATION ACTIVITY
INTERIM PRESIDENT, UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
DIRECTOR, DEFENSE MANPOWER DATA CENTER

SUBJECT: Training Requirements for Authorization of Eligibility to Engage in HSPP Activities

Under the management plan for the Human Subject Protection Program, all personnel involved in the program, including Component Designated Official (CDO) Oversight Office staff, Institutional Officials, IRB members, administrative staff, and investigators must complete initial and annual refresher training (listed in attached information paper) to be eligible to participate in activities under the purview of the HSPP. These activities include the support, review or conduct of research involving humans.

Obtaining authorization of eligibility to engage in HSPP activities includes meeting the training requirements and verifying training for certification. The training requirements may be tailored to the needs of the individual with approval by the CDO. Once training is complete, forward documentation to the CDO's Oversight Office at the contact address on the information paper. Once training is verified and approved by me, an "Authorization of Eligibility to Engage in Human Subject Protection Program (HSPP) Activities" notification will be sent to the institutional officials and their designated research administrators with a copy to the authorized individual(s).

Initial training and authorization is valid for one (1) year. Annual refresher training needs to be completed before the one (1) year anniversary of the initial or previous training in order to assure continuous eligibility. Refresher training extends authorization for one (1) year from the date the training is completed. There will be a six (6) month transition period (through November 1, 2005) to allow affected individuals time to complete the training and refresher training requirements.

Ellen P. Embrey

Ellen P. Embrey
Deputy Assistant Secretary of Defense
Force Health Protection and Readiness

Attachment

Training Requirements for Authorization of Eligibility to Engage in Human Subject Protection Program (HSPP) Activities

Training requirements vary according to each individual's role in the HSPP. The following activities are considered appropriate forms of training:

A. Initial Training for Investigators, Research Staff, and Students (Choose one)

Participation in the CITI online "Course in the Protection of Human Research Subjects (basic version)." Institution ID: USD (Personnel & Readiness) (www.citiprogram.org).

Participation in "Investigator 101" offered by the Applied Research Ethics National Association (ARENA) (www.primr.org).

Participation in "IRB 101" offered by ARENA (www.primr.org).

B. Initial Training for IRB Members and Individuals with Exemption Approval Authority (Choose one)

Participation in the CITI online "Course in the Protection of Human Research Subjects (IRB member version)." Institution ID: USD (Personnel & Readiness) (www.citiprogram.org).

Participation in "IRB 101" offered by ARENA (www.primr.org).

C. Initial Training for Institutional Officials

Institutional Officials who are signatory officials for their institution should complete the OHRP training module for Assurances (www.hhs.gov/ohrp/education).

Note: HHS regulation 45 CFR 46, Subpart A is identical to DoD regulation 32 CFR 219.

D. Initial Training for IRB Administrators and Chairs. Choose one each from list B & C.

E. Annual Refresher Training (Choose one)

Participation in the CITI online "Refresher Course in the Protection of Human Research Subjects." Institution ID: USD (Personnel and Readiness) (www.citiprogram.org)

Attendance at the Public Responsibility in Medicine and Research (PRIM&R) Annual Conference (www.primr.org).

Attendance at an OHRP sponsored regional conference (www.hhs.gov/ohrp).

Participation in any initial training activity listed in A or B above.

Participation in programs sponsored by USUHS IRB, Component Designated Official (CDO) Oversight Office, or other DoD offices with approval by the CDO.

F. Certified IRB Professionals

Individuals who are currently certified by the Council for Certification of IRB Professionals are not required to complete additional training as long as they remain certified. For more information, visit www.primr.org/certification/overview.html

Additional training will be added when identified and approved by the CDO. Please send suggestions or requests for the most recent list to Caroline Miner at (703) 575-2677; fax (703) 824-4216; or Caroline.miner.ctr@deploymenthealth.osd.mil.