Department of Veterans Affairs

Memorandum

Date: APR 3 0 2001

From: Under Secretary for Health (10)

Subj: Requirement for Training on Human Subjects Protection in Research: ACTION

To: Network Directors and VAHCS and VAMC Directors with VA Multiple Project Assurance Contracts (MPA)

1. Research is integral to the mission of the VA health care system. Respect for the rights, dignity, and safety of veterans who participate as research subjects must be of paramount importance to us all. The responsible conduct of research needs to be completely understood by all those engaged in the research process. All VHA institutional officials at the VISN and HCS/VAMC levels must abide by stringent ethical principles and regulatory requirements to ensure the protection of human subjects.

2. Under Federal regulations, any institution engaged in Federally-supported human subjects research must commit in writing to the protection of those subjects. This written commitment is called an Assurance of Compliance. For human subjects research supported by the Department of Health and Human Services (DHHS), the Office for Human Research Protections (OHRP) must approve the institution's Assurance before the funds can be awarded by DHHS for such research. OHRP has implemented a new Federal Wide Assurance (FWA) that VA and other Federal Departments and Agencies will implement this year.

3. VHA's Office of Research Compliance and Assurance (ORCA) is coordinating this process for VA. ORCA is helping VA Health Care Systems (HCSs) and Medical Centers (VAMCs) with VA MPA contracts apply for the new FWAs. The FWA will replace the current VA MPA Contracts and any OHRP MPAs that may be held.

4. OHRP has developed an online training course for institutional signatory officials signing the FWA. The three training modules in this course are designed to acquaint those involved in the research process with their institutional responsibilities. These modules must be completed as part of the FWA process.

The Modules are titled:

- Federal Regulations and Institutional Responsibilities
- Investigator Responsibilities and Informed Consent
- Human Protections Program Administration and IRB Responsibilities

Completion of all three modules will take about 1 hour.

5. To facilitate the training on the new FWA process, all Network Directors, HCS Directors and VAMC Directors with VA MPA Contracts should complete these three training modules by Thursday, May 31, 2001. They are short, clear, and straightforward in content. The completion of these modules will help VA clearly demonstrate that the senior executives at the VISN and HCS/VAMC levels, responsible for research programs in VA, understand the basic requirements of their responsibilities under the FWA. They are not designed to satisfy VA or NIH requirements for other training and education, such as mandated investigator training.

6. By May 31, 2001, please do the following:

   - Log on to the OHRP website section titled "Educational Materials." The address is: http://ohrp.osophs.dhhs.gov/educmat.htm
   - Log in to each of the three training modules as a signatory official and enter your name.
   - Complete all three modules. Print a certificate of completion at the end of each module.
   - Mail or fax the three certificates to the Chief Officer, Office of Research Compliance and Assurance (ORCA) (10R), 811 Vermont Ave., NW, Washington, DC, 20420. The fax number is (202) 565-9194.

7. If you have any questions or need additional information, please contact Ms. Priscilla Craig, Health Science Specialist, ORCA at (202) 565-8162.

8. Thank you for your continuing commitment and dedication to protecting VA patients who participate in research.

Thomas L. Garthwaite, M.D.

cc: Deputy Under Secretary for Health (10A)
Chief Officer Office of Research Compliance and Assurance (10R)
Chief Officer, Office of Research and Development (12)