VA RESEARCH & DEVELOPMENT

March 16, 2004

2003 Research Stand Down Requirements

The following was required during the 2003 Stand Down:

a.) Effective oversight of human studies research by an IRB and VA research committee will be verified.

At any site conducting human studies research, the Medical Center Director, Chief of Staff, and Associate Chief of Staff for Research (ACOS/R) (or comparable person, if the hospital does not have an ACOS/R) will review the operations of the IRB and the R&D Committee and will attest, through the VISN Director to the Chief Network Officer and the Chief Research Officer to the fact that those committees are functioning at least at the minimum level required by the Common Rule and M-3 Part I, Chapters 2, 3, and 9. These requirements include that the IRB and R&D Committees are appropriately constituted and meet on a regular enough basis to provide timely review and oversight of new and continuing protocols and review of Adverse Events and Serious Adverse Events.

b.) All individuals who are involved in human studies research will receive appropriate training in the ethical principles and accepted practices on which human studies research should be conducted.

All investigators, research coordinators and research assistants involved in human studies research and all members of the Research Office, all members of the R&D Committee, and all members and staff of a VA Institutional Review Board (IRB), exclusive of secretarial support, will complete an educational course or complete a web-based course on **both** the protection of human research subjects, as well as Good Clinical Practice (GCP). (If the University affiliate provides the VA IRB function, the affiliate will be encouraged to participate in these educational activities.) All individuals subject to this policy will be required to update their training annually, thereafter.

c.) An effective credentialing process for all individuals involved in human studies research will be verified.

Any research personnel who perform independent clinical activities (judgment based independent of the research protocol) as part of their research activities will be allowed to conduct such activities only if they are credentialed and privileged to provide those activities on patients by the standard credentialing and privileging process of the facility (e.g., doctors, clinical psychologists). All such individuals whether compensated or on a WOC appointment will be credentialed through VetPro. All other individuals involved in human studies research (whether a licensed Title 38 individual, such as a nurse, or a Title 5 employee; and whether the individual receives VA compensation or is without compensation (WOC)) will have their credentials confirmed, a scope of work established and a record of such maintained and available for review. Licensed individuals will have their license(s) confirmed yearly. Facilities will create an electronic means of tracking all WOC employees involved in human subjects research to facilitate the regular checking of these individuals against exclusionary lists.

d.) Disciplinary actions that may result from noncompliance with the ethical standards of human study oversight.

e.) All investigators involved in human studies research will be notified that that a) if they conduct research without IRB approval, it will affect their standing in the VA and b) PIs will be held responsible for ethical breaches in the conduct of their research and these problems may affect the PI's ability to do research with the VA in the future.