

**Department of
Veterans Affairs**

Memorandum

Date: August 18, 2003

From: Director, Health Services Research and Development Service (124)

Subj: Notification of Policy Changes Related to HSR&D Proposal Submissions

To: VAMC Directors (00/151)

1. **REASON FOR ISSUE:** HSR&D has implemented changes in the proposal submission limit per review cycle and Institutional Review Board Approval process effective immediately.

2. **SUMMARY OF MAJOR CHANGES:** The principal changes clarify and incorporate additional information on Investigator Initiated Research (IIR) proposal submission and Final Report requirements. Specific new information includes:

a. **Proposal Limit:** VHA HANDBOOK 1204.01, 5. Project Proposals, c. General Instructions, page 5 (2). Proposal Limit states "A proposed Principal Investigator (PI) may submit only one application to HSR&D per review cycle." Effective with the November 1, 2003 submission date, HSR&D will accept more than one application from a PI in the same cycle without a written request for an exception to the above-stated policy.

b. **Just in Time: Institutional Review Board Approval:** VHA Handbook 1204.01, Appendix B, page B-7 k and l. VA Form 10-1223 - "Report of Subcommittee on Human Studies" and VA Form 10-1086 "VA Research Consent Form and Related Documentation" [*states*] "Proposals for studies involving human subjects *will not be reviewed* unless or until approved by the VA facility's Subcommittee on Human Studies or, if none, by the institutional review board (IRB) of the affiliated university."

HSR&D has adopted the Just in Time policy of accepting proposals for review without IRB approval, consistent with Dr. Wray's announcement on the August 11 hotline call. However, HSR&D continues to require a *draft* informed consent (Form 10-1086 or a university approved form) with the proposal. Certification of completed human subjects protection training for the PI, Co-PI and key investigators is still required at the time of application. IRB approval must be received prior to the disbursement of funds.

c. **Final Reports:** VHA Handbook 1204.5 Appendix B, page B-5 section 7.b "Copies". The number of final report copies required by HSR&D has been reduced.

When submitting Final Reports to Health Services Research and Development Service (HSR&D), please submit only:

1. The original **unbound** final report (including executive summary),

2. **One** photocopy (includes reports with color printing) and
3. One electronic copy (on 3.5" diskette or CD).

3. If you have questions regarding the IIR Research Application changes, please call Martha Bryan, EdD, Assistant Director, HSR&D at 202-254-0251. For questions regarding Final Report requirements, please call Philip Crewson, PhD, Assistant Director, HSR&D at 202-254-0220.

John G. Demakis, M.D

cc: HSR&D Research Centers, COEs, and Field Stations