DEPARTMENT OF VETERANS AFFAIRS
South Texas Veterans Health Care System
7400 Merton Minter Boulevard
San Antonio, Texas 78284

RESEARCH SERVICE
MEMORANDUM 04-20

May 28, 2004

HUMAN RESEARCH PROTECTION PROGRAM

Human Research Studies Educational Program

1. PURPOSE: All individuals involved in human research must receive the training necessary to ensure human research is carried out in an ethical and safe manner. Purpose of this policy is to identify individuals for whom human research education is required, the training that will satisfy this requirement, and the procedures for confirming that individuals have met the training requirements.

2. POLICY: Individuals involved in human research studies will be required to receive appropriate training in the ethical principles and accepted practices on which human studies research should be conducted. This training meets the VA and Federal requirements for human research training.

3. ACTION:

a. Individuals Involved: The following individuals are required to complete the designated training in the protection of human research subjects and Good Clinical Practice (GCP) :

(1) All investigators and their research staffs involved in research studies involving human subjects.

(2) Members of the Research Office, exclusive of secretarial support

(3) Members of the R&D Committee

b. Course:

(1) Effective May 2004 the VA has made available an on-line course that combines both the Good Clinical Practice course and the Human Subjects Protection course. Completion of this combined course satisfies the VA human research training requirement. Current instructions will be made available through the Research Office (Q203, X15523).

(2) In lieu of the combined course, individuals may continue to take the separate GCP and human protection courses if they desire:

(a) Rochester Medical Center training program "Protecting Study Volunteers in Research," offered through the University of Texas Health Science Center Institutional Review Board or the NCI on-line course on human protection PLUS
(b) The VA Good Clinical Practice on-line course

c. Frequency: All individuals must have completed this training within the previous twelve months.

d. Documentation: Individuals completing the VA combined, VA GCP, or the NCI courses must print the certificate of completion provided at the end of each course and submit a copy to the Research Office to document completion of the training requirement. The UTHSCSA Office of the IRB will provide the Research Office the list of individuals completing the Rochester course as the list is updated.

e. Tracking: The Office of R&D will maintain the latest IRB training list and a copy of all training certificates. A database of current training dates will be maintained to track training compliance. Current training status will be verified at the time of protocol submission and at the time of the annual project review.

(1) New Protocol Submission: The principal investigator is required to submit a list of all investigators and research staff participating in the project and documentation of training. The Office of Research and Development will check the training database and documentation to insure all personnel listed have completed the required training. Final R&D Committee approval will not be given until training has been confirmed for all individuals listed on the project.

(2) Annual Protocol Review: When the annual project progress report is requested, the investigator must certify the current project personnel. The Office of R&D will verify that the training is current (within twelve months) for all personnel listed and contact the investigator if any personnel need current training. After training has been verified, the progress report will be sent to the R&D committee for approval.

(3) Non-project personnel: The Office of R&D will maintain a record of the dates of training for R&D Office staff and R&D Committee members. The Administrative Officer or designee will quarterly review the training data to initiate reminders to staff and members when training will be due and follow up to insure documentation of updated training is received.

f. Other Federal requirements: OHRP requires that responsible institutional officials complete specific OHRP on-line training modules prior to issuing a Federal-Wide Assurance. This requirement must be met prior to any FWA submissions. Office of R&D will provide the dates of training on the FWA application at the time of any resubmissions.

4. REFERENCES: Office of Research and Development, VACO, memo dated March 6, 2003.

5. RESCISSION: Research Service Policy Memorandum 03-20, dated March 6, 2003.

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