

**Department of Veterans Affairs
Tuscaloosa VA Medical Center**

Human Research Protection Program SOP # 12

May 7, 2007

**Annual Research Training Requirements
and Review of Investigator Qualifications to Conduct Research**

1. POLICY

The Tuscaloosa VA Medical Center (TVAMC) Human Research Protection Program (HRPP) is guided by the ethical principles set forth in the Common Rule, Food and Drug Administration (FDA) regulations, and the Belmont Report. With the increased complexity of research and the advent of new technologies it is imperative that all VHA personnel involved in human subject research have and maintain the appropriate expertise through education, training, and experience. Such a level of education and expertise is essential in a human research protection program that strives to provide the highest level of protection to its human subjects.

It is the TVAMC HRPP policy that all individuals reviewing, conducting or supporting human research, regardless of appointment mechanism (full-time, part-time, or Without Compensation [WOC]), must demonstrate and maintain sufficient knowledge of the ethical principles and requirements for protecting research participants and adhere to mandatory training to ensure their understanding of the protection of the rights, safety, and welfare of human subjects in research and the ethical conduct of research. This standard operating procedure (SOP) establishes written procedures on the requirements for the IRB review of investigator qualifications and annual training requirements for individuals involved in the HRPP or research.

2. RESPONSIBILITIES

The TVAMC Medical Center Director has ultimate responsibility for ensuring the protection of human subjects by authorizing the TVAMC HRPP to require and maintain accurate and up-to-date records of the mandatory annual training for individuals involved in research and the HRPP.

Coordinator of R&D and Administrative Officer of R&D are responsible for assuring that all personnel involved in research and the TVAMC HRPP fulfill the requirements for annual training and for providing additional training, lectures, and orientation as needed.

TVAMC Institutional Review Board (IRB) is responsible for reviewing the qualifications, past education and experience (i.e. curriculum vitae or biosketch) of all investigators and personnel involved in research and the ensure that the requirements for annual training have been met, as outlined in this HRPP SOP.

Investigators and All Individuals Involved in HRPP are responsible for submitting a CV or biosketch to the IRB, maintaining the annual training requirements, submitting the certificates of training to the IRB office on a timely and annual basis, and for applying the ethical principles and standards, Federal regulations, professional standards and policies to their work in research and the protection of human subjects in research. All individuals are required to understand and apply their obligation to protect the rights and welfare of research participants.

3. DEFINITIONS

- a. **Curriculum Vitae (CV):** A CV is a short account of one's career, education, qualifications, publications, and presentations. CVs tend to provide great detail about academic and research experiences.
- b. **Biosketch:** The biosketch is a 2-3 page form provided by funding agencies (i.e. NIH or VA) that include the pertinent information from one's CV in regard to education, qualifications, publications and research experiences.

4. PROCEDURES

- a. **Research Qualifications and Annual Training:** The TVAMC HRPP and IRB evaluates and contributes to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants in the following ways (described in more detail below): 1) by carefully reviewing the investigators' CV/biosketch at the time of initial review or time of addition to an active approved study, 2) by requiring minimum annual training requirements for all investigators and research staff, and 3) by providing additional educational opportunities for investigators and research staff.
- b. **HRPP Requirement for CV/Biosketch:** All persons involved the HRPP must submit a CV/biosketch to the IRB office prior being appointed to membership on an HRPP committee (i.e. IRB or R&D Committee) and prior to conducting research. This includes (but is not limited to) all HRPP office personnel, investigators, study coordinators, research assistants, research trainees, HRPP administrative support staff, and members/alternates of the IRB and R&D Committee, regardless of whether they are compensated, without compensation (WOC), or IPAs. For all staff engaged in research, a CV/biosketch must be submitted at the time of initial review of their first research study or at the time that the individual is added to a study. These CV/biosketches are kept on file by the IRB office for review at the time of membership appointment or research study review. In the review of the CV/biosketch, the IRB requires that of all investigators involved in a research study should have the requisite knowledge, understanding and experience relevant to their specific roles in the research project. If the IRB believes that the investigators do not have the qualifications or resources to conduct a research project and to assure that the rights and welfare of subjects are protected, they will disapprove the study. The IRB may consider investigators' collaborations with other professionals who have the required expertise and who agree to serve as co-investigators, consultants, preceptors or mentors as a means to provide additional expertise and qualifications needed to conduct the study.

- c. **Mandatory Annual Research Training Requirements:** All staff involved and/or responsible for the oversight of the HRPP and all staff involved in research must receive appropriate training. This list of staff included (but is not limited to) all VA Research Office personnel, investigators, study coordinators, research assistants, research trainees such as house officers and students, research administrative support staff, and members of the IRB and Research & Development Committee, regardless of whether they are compensated, without compensation (WOC), or IPAs. The training listed below is required and in accordance with VHA regulations and is intended to enhance the knowledge, understanding and experience of individuals responsible for the protection of research participants. The current minimum training for FY 2007 is listed below and may be updated by the IRB or HRPP by addendum to this SOP.

NOTE: All options for fulfilling VA human research training requirements can be found at <http://www.research.va.gov/programs/pride/training/options.cfm>. The required annual training includes:

- **Protection of Human Subjects in Research Training and Good Clinical Practice.** A course, such as the one offered by CITI (<http://www.citiprogram.org/>) or an equivalent training course approved by the VA Office of Research and Development (ORD). ORD requires annual training in BOTH protection of human subjects in research and Good Clinical Practices (GCP). The CITI training modules are designed to meet BOTH of these training requirements. This curriculum includes three courses that build upon each other over three years: 1) A Basic Course for those who have never taken the VA basic course on Human Subjects Protections and GCP either through CITI. 2) CITI 101 Refresher Course, for those who have taken the VA basic course. 3) For next year, a CITI 201 Refresher Course for those who have completed the 101 Refresher Course.
 - **VA Research Data Security and Privacy** training, which is available through the VA Learning Online (VALO) Campus or the Learning Management System (LMS) at <http://www.research.va.gov/resources/policies/cybersecurity.cfm> under “Training: VA Research Data Security & Privacy”. Once you complete the course, see the specific instructions on how to download a **Certificate of Completion**. **NOTE:** This course does not replace the VA annual training requirement for Cyber Security Awareness, Ethics, or Privacy (i.e., Education Dept).
- d. **Training Certificates:** Upon completion of the requisite training, individuals must submit a copy of their certificate to the R&D Office that attests the completion of training. The certificate may also be submitted via Intra-campus mail (Mail code 151) and/or via regular mail at 3701 Loop Road East, Attn: HRPP (151), Tuscaloosa, AL 35404.

The IRB Program Support Assistant is the individual responsible for maintaining training records; however, it is the responsibility of the individual to complete the training and send the certificate of completion to the IRB Program Support Assistant. Documentation of training must be submitted to the IRB office at time of the submission of research

study proposal and initiation of a study. This document is maintained on file with the investigator's CV. Individuals who fail to complete the required training will be unable to participate in human subject research activities at this VA Medical Center.

The R&D Office will maintain records for each mandated education and training activity. It contains a list of all individuals assigned to the activity and the date each person completes the requisite training. Copies of affidavits and certificates will be kept in the employees HRPP file. These files log the training activities of all research investigators, research staff, IRB members, R&D Committee members and all other individuals responsible for human research protection. Access to these files is available to the Coordinator for R&D, Administrative Officer (AO) for R&D, Chair of R&D Committee, Chair of the IRB, and HRPP Program Administrator for periodic review and monitoring. If annual training requirements lapse, the IRB or R&D member may not participate in the meetings until the training requirement is fulfilled. If the training requirement is not met in a 30 day extension, the member is terminated from the committee. For investigators, if annual training requirements lapse, the investigator must fulfill the training requirement within 30 days otherwise their study(ies) will be placed on administrative hold (i.e. no new patients can be entered) until IRB review for determination of study closure or suspension can be made.

- e. **Additional HRPP Educational Opportunities:** Additional educational opportunities are provided on a regular basis by the TVAMC HRPP in the form of 1) orientation of all HRPP SOPs by the C/R&D or AO of research prior to serving as an IRB or R&D Committee member; 2) local CME-approved lectures, retreats, or workshops; 3) computer based training and certification programs (such as NCI, CITI, NIH); and 4) off-site annual meetings offered by organizations such as Public Responsibility in Medicine and Research (PRIM&R,) VA, ARENA, and ORO sponsored programs. Investigators, researcher coordinators, IRB and R&D members, and research staff are encouraged to attend these meetings and educational grants through the affiliated nonprofit research corporation (TREAC) provide a limited number of travel grants for individuals to attend off-site meetings. In addition, investigators are encouraged to send research coordinators to off-site training on how to manage a clinical trial and to have their experienced research coordinators take the certification exam (a limited number of travel grants and fees for the training and exam can be provided through TREAC).

5. **REFERENCES**

- VHA Handbook 1200.5
- VA R&D PRIDE <http://www.research.va.gov/programs/pride/training/options.cfm>
- Collaborative IRB Training Initiatives (CITI) (<http://www.citiprogram.org/>)
- **Veterans Health Administration (VHA) Privacy Policy** Training Web Site <http://www.vhaprivacytraining.net/frame.htm>.
- **VA Research Data Security and Privacy** <http://www.research.va.gov/resources/policies/cybersecurity.cfm>
- **Ethics Training.** <http://vaww.sites.lrn.va.gov/vacatalog/default.asp>

6. ATTACHMENTS

None

7. RESCISSIONS

IRB Standard Operating Procedures dated July 1, 2004.

8. REVIEW DATE

January 1, 2012

Signature on File in R&D Office

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