

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

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**Human Research Protection Program SOP #13**

**October 17, 2007**

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**INVESTIGATOR RESPONSIBILITIES**

**1. POLICY**

The Tuscaloosa VA Medical Center (TVAMC) Human Research Protection Program (HRPP) is committed to ensuring that any research involving human participants undergo Institutional Review Board (IRB) review before it is initiated. The research must be conducted at all times in compliance with all applicable regulatory requirements or determinants by the IRB. The investigator may contact the IRB office for information about whether an activity must be reviewed by the IRB, whether the review may be performed by expedited procedures, and/or whether informed consent or its documentation may be waived.

It is the policy of the TVAMC to ensure the compliance with all VA policies as well as all federal, state, and local laws and regulations. As outlined in this Standard Operating Procedure (SOP), investigators are responsible for following all TVAMC HRPP SOPs, following ethical principles and standards pertaining to research, following Good Clinical Practice guidelines defined by the Food and Drug Administration, and protecting the rights and welfare of research participants as their primary concern.

**2. INVESTIGATOR RESPONSIBILITIES**

Investigators (Principal and Co-investigators) are responsible for conducting their research in accordance with all TVAMC HRPP policies and requirements (SOPs listed below). These responsibilities include, but are not limited to, the following requirement of all investigators:

- To maintain appropriate oversight of their research protocols and research staff, including recruitment and selection of study participants, study conduct, and appropriately delegating responsibilities.
- To adhere to ethical principles as named in the Belmont Report (HRPP SOP#1).
- Employ sound study design in accordance with the standards of the discipline.
- Take actions that minimize the risk of harm to research participants and provide the IRB with an evaluation of less risky alternative, if any, and with plans for detecting harm promptly and mitigating potential injuries, as described in the protocol requirements (HRPP SOP#3).
- Document in the protocol the resources that are planned to conduct the research and to protect human participants (HRPP SOP#3)
- Seek and obtain IRB approval prior to initiating any research activities (HRPP SOP#3)

- After a participant signs informed consent, the investigator must enter a clinical warning in the research participants chart (i.e. flagged chart) as a means to indicate participation in a study and the source of more information regarding the study, unless otherwise determined by the IRB that the medical record does not require a clinical warning (i.e. flagged) to protect the participant's safety. Such determination that a medical record does not warrant a clinical flag includes, but is not limited to, 1) the study involves only one encounter; 2) the study only involves the use of a questionnaire, 3) the study only involves the use of previously collected biological specimens or data, or 4) the identification of the patient as a subject in a particular study would place the subject at greater than minimal risk. The investigator should remove the clinical warning (i.e. flag) when the patient is no longer a participant in the research study.
- Seek and obtain IRB approval prior to the expiration date through the continuing review process (HRPP SOP#6)
- Read all IRB correspondence, follow IRB Conditions for Approval, take appropriate actions and follow IRB instructions, and maintain an organized file of IRB correspondence, IRB documents, and all essential study documents.
- Do not make changes in the research protocol without prior IRB approval (HRPP SOP#4)
- Consider conflicts of interest that might affect the relationship with the participant or the outcomes of the research, and with the organization and submit a conflict of interest disclosure form at the time of initial review (HRPP SOP#9A).
- Obtain, document, and file the informed, written consent for each human subject or his/her Legally Authorized Representative or next-of-kin, unless specifically waived by the IRB (HRPP SOP#7) using the IRB stamped approved consent form, prior to allowing the participant to participate in research activities.
- Understand the difference between the informed consent process and the documentation of informed consent (HRPP SOP#7)
- Recruit research subjects in a fair and equitable manner, weighing the potential benefits of the research to the participants against their vulnerability and the risks to them (HRPP SOP#8).
- Obtain IRB approval of all recruitment materials and advertisements prior to use (HRPP SOP#8)
- Design and carry out research studies with adequate data and safety monitoring during the research and adequate data security to protect the privacy of human subjects (HRPP SOP#3 and HRPP SOP#10). In the protocol, the investigators must describe provisions to monitor the data to ensure the safety of participants.
- Adhere to all IRB reporting requirements for adverse events, serious adverse events, unanticipated events/problems, and protocol deviations (HRPP SOP#11)
- Obtain and maintain the mandatory annual training, as a means to understand when activities are subject to HRPP IRB approval, when to seek guidance, and gain knowledge of applicable federal, state, and local regulations and Good Clinical Practices, Protection of Human Subjects, Data Security, Ethics, and Privacy (HRPP SOP#12).
- Respond appropriately to participants' complaints or requests for information, in a timely manner (HRPP SOP#14)
- Follow all policies and procedures outlined by Pharmacy Service (Pharmacy SOP).

- Submit all research manuscripts pertaining to an TVAMC IRB and R&D Committee approved study to the R&D Committee for review and approval prior to publication (TVAMC CM 11-09).
- Prior to submissions, contact the IRB office to confirm the most recent versions of SOPs and forms and any other regulatory information pertaining to human participant's protection is in use.

As with all persons involved in the HRPP, Investigators may bring forward to the C/R&D, R&D AO, IRB Chair, or R&D Committee Chair any concern, suggestion, or question regarding the HRPP.

#### Research Conducted at Multi-Site Studies:

Currently, the TVAMC does not allow researchers to conduct multi-site clinical trials. However, if the TVAMC were to allow this in the future, the following procedures will be implemented. If a TVAMC Investigator were serving as the lead Principal Investigator (PI) for a multi-site study, the PI is responsible for ensuring that the research is appropriately approved and conducted at the non-TVAMC sites, and that the HRPP IRB is provided the appropriate documents from IRB reviews at those sites. The Investigator must:

- Secure approval by the HRPP IRB for the research. The protocol will include information about all other sites where the research is to be conducted. If new sites are added after approval by the IRB, research at those sites cannot begin until a modification is submitted to the IRB and all requirements of this policy are met.
- Provide a data safety monitoring plan which includes a review of all adverse events and unanticipated problems from all sites where the research is conducted. Results of the data safety monitoring must be provided to the HRPP IRB at intervals established by the HRPP IRB.
- Provide the following information to the IRB for each site where research is to be conducted:
  - The name and description of the site
  - The name of a contact person at the site with a phone number, and email address where the contact may be reached
  - Whether the site has an IRB
  - If the site has an IRB, whether or not that IRB has approved the research, or whether the site's IRB prefers to rely on the TVAMC HRPP IRB
  - Documentation that the external IRB has a Federal Wide Assurance with OHRP for federally funded studies
  - Submit to the TVAMC HRPP IRB copies of unanticipated problems from the external sites that require changes to the research or protection of participants
  - At the time of continuing review by the IRB, send a summary of data for all sites, and separately, data for the TVAMC site.
- Retain copies of the following documents in the protocol regulatory binder
  - Documentation that facilities and equipment at the external sites are adequate to conduct the research, including a plan to provide emergency care to participant
  - A copy of the initial approval of the protocol at the external sites
  - A copy of all modifications submitted and approved by the external sites, including a copy of the approval letter

- Copy of all continuing review reports submitted to the external sites, and a copy of the re-approval letter
- A copy of all adverse events occurring at the external sites.

The IRB, for multi-site studies, then has the responsibility to:

- Accept review by an external IRB only if the research could not be conducted at the site without review by the external IRB, or, if in the opinion of the TVAMC HRPP IRB, local considerations are significant and require review by an IRB of the local context
- Review data provided by PI from the data monitoring plan and require any changes to the research which will provide additional protection to participants from unanticipated risks
- Review unanticipated problems from all sites of the research and require any changes to the research which will provide additional protection to participants
- Review the data received for all sites as submitted with the TVAMC HRPP IRB Progress Report

Investigators are reminded that they are personally responsible for the careful, thoughtful execution of studies involving human subjects. Conscious disregard of subject's rights or failure to comply with all safeguards listed in the protocol will be met with severe sanctions. Non-compliance with HRPP requirements could result in suspension of approval for a particular project. Serious or continuing noncompliance may result in suspension of the investigator's privilege to conduct research at the TVAMC (HRPP SOP#18).

### **3. REFERENCES**

#### **List of TVAMC HRPP Standard Operating Procedures and Center Memos**

HRPP SOP#1 Human Research Protection Program (HRPP)  
 HRPP SOP#2 Organizational Structure of the Institutional Review Board  
 HRPP SOP#3 IRB Initial Review  
 HRPP SOP#4 Expedited Review Process  
 HRPP SOP#5 Exempt Research  
 HRPP SOP#6 IRB Continuing Review  
 HRPP SOP#7 Research Informed Consent  
 HRPP SOP#8 Participant Selection, Recruitment, and Vulnerable Subjects  
 HRPP SOP#9A Investigator Conflict Of Interest  
 HRPP SOP#9B Institutional Conflict Of Interest  
 HRPP SOP#10 Research Data Security And Privacy  
 HRPP SOP#11 Reporting Requirements  
 HRPP SOP#12 Annual Research Training Requirements  
 HRPP SOP#13 Investigator Responsibilities  
 HRPP SOP#14 Participant Outreach  
 HRPP SOP#15 DNA Research  
 HRPP SOP#16 Sponsored Research  
 HRPP SOP#17 Compliance and Quality Improvement  
 HRPP SOP#18 Allegations of Non-Compliance  
 HRPP SOP#19 HRPP Resources and Annual Reporting Requirements  
 TVAMC Center Memo 11-09 Research and Development Committee

TVAMC Center Memo 11-14 Subcommittee on Human Subjects (IRB)  
TVAMC Center Memo CS119-2 Drug Policy  
TVAMC Pharmacy SOP III-A-6 Procedure for Investigational Drugs

**4. ATTACHMENTS**

None.

**5. RESCISSIONS**

TVAMC HRPP SOP #13 Investigator Responsibilities May 7, 2007

**6. REVIEW DATE**

January 1, 2012

Signature on File in R&D Office

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