

SOP: 603A
VETERANS AFFAIRS MEDICAL CENTER

1. POLICY (Applies to HSC only)

Under an agreement between the Board of Regents of the University of Oklahoma Health Sciences Center (HSC) and Veterans Affairs Medical Center (VAMC) Oklahoma City, the HSC Institutional Review Board (IRB) has been designated as an IRB of record for review of human participant research conducted at the VAMC in Oklahoma City.

Under a separate agreement between HSC and VAMC Muskogee, the HSC IRB has been designated as an IRB of record for review of human participant research conducted at the VAMC in Muskogee.

The Oklahoma City and Muskogee VAMC's have a separate agreement with the VA Central IRB (VA-CIRB) in Washington DC for the review and approval of VA funded clinical trials. The CIRB is listed on all applicable FWA's.

It is the policy of the HSC IRB to apply the requirements of 38 CFR Parts 16 and 17 and the VA Handbook to all VA-regulated research.

VA research is defined as research that is conducted by VA investigators (serving on compensated, without compensation (WOC), or Intergovernmental Personnel Agreement (IPA) appointments) while on VA time, utilizing VA resources (e.g. equipment), recruiting VA patients, and/or on VA property including space leased to, or used by, VA. The research may be funded by VA, by other sponsors, or be unfunded.

Specific Policies

1.1 OUHSC IRB and VAMC Research and Development

Proposed research to be conducted at the Oklahoma City or Muskogee VAMC requires prospective review and approval by both the HSC IRB and the VAMC Research and Development Committee (R&D), per applicable SOPs 401, Research Exempt from IRB Review; SOP 402, Expedited Review; or SOP 403, Initial Review – Criteria for IRB Approval.

Continuing review and amendments to on-going research conducted at the Oklahoma City or Muskogee VAMC are subject to SOPs 404, Continuing Review; and 405, Amendments; respectively.

2. SCOPE

These policies and procedures apply to all research involving human participants conducted at the VAMCs located in Oklahoma City and Muskogee, unless reviewed and approved by the VA-CIRB.

3. RESPONSIBILITY

3.1. The OUHSC IRB is Responsible For:

- 3.1.1 Protecting the rights and welfare of human participants who participate in VA-regulated research.

- 3.1.2 Including two or more VA employees as voting members of the IRB on each IRB that reviews VA research. One of these members must have scientific expertise.
- 3.1.3 Notifying the VA Medical Center Director, VA Central Office, with regard to VA research:
 - 3.1.3.1 Any adverse events that cause harm or risk of harm to human participants;
 - 3.1.3.2 Any instances of serious or continuing noncompliance; and
 - 3.1.3.3 Suspension or termination of IRB approval.
- 3.1.4 Determining that the investigator and key personnel have met all HSC IRB educational requirements.
- 3.1.5 Reporting to the Privacy Official any unauthorized use, loss, or disclosure of individually-identifiable participant information.
- 3.1.6 Reporting violations of VA information security requirements to the appropriate Veterans Health Administration Information Security Officer.
- 3.1.7 The IRB staff prepares a confidentiality agreement for the VAMC R&D Committee members to sign prior to providing copies of the HSC IRB meeting minutes to the VAMC R&D Committee.
- 3.1.8 Providing copies of the HSC IRB meeting minutes to the VAMC R&D Committee for review and approval.

3.2 VAMC R&D is Responsible For:

- 3.2.1 Identifying and recommending qualified VA employees to serve on the HSC IRB.
- 3.2.2 Providing the VAMC Research Compliance Officer (RCO) to serve as a non-voting member of the HSC IRB, as the VA human participants protections liaison to the VA R&D committee.
- 3.2.3 Approving HSC IRB minutes for VA-regulated research projects.
- 3.2.4 Reviewing VA-regulated research projects for scientific or scholarly validity and acting on any findings.
- 3.2.5 Providing a final VA R&D Approval Memorandum to Investigators after formal approval from the VAMC R&D Committee is secured.
- 3.2.6 Providing VA R&D Approval Memorandums to the HSC IRB.
- 3.2.7 Monitoring VA-regulated research activities.

3.3 Investigators Proposing to Conduct VA-regulated Research are Responsible For:

- 3.3.1 Prospectively submitting research projects, including exempt determinations for review, to the VAMC R&D prior to submission to the HSC IRB.

- 3.3.2 Submitting research projects to the HSC IRB once VAMC R&D has been submitted.
- 3.3.3 Using the appropriate VA form 10-1086 consent form.

4. APPLICABLE REGULATIONS AND GUIDELINES

38 CFR 16, 17

Department of Veterans Affairs, VHA Handbook 1200.5, July 15, 2003

5. REFERENCES TO OTHER APPLICABLE SOPS

- SOP 301, Research Submission Requirements,
- SOP 302, Administrative Review and Distribution of Materials
- SOP 401, Research Exempt from IRB Review
- SOP 402, Expedited Review
- SOP 403, Initial Review – Criteria for IRB Approval
- SOP 404, Continuing Review
- SOP 405, Amendments.

6. ATTACHMENTS

- 603A-A VA R&D Approval Memorandum
- 603A-B VA Form 10-1086 Consent Form Template
- 603A-C VA Form 10-9012 Investigational Drug Information Record
- 305-C New Study Approval Checklist

7. PROCESS OVERVIEW

- 7.1** The investigator prospectively submits a research project to the VAMC R&D Committee for evaluation for scientific or scholarly validity when the investigator utilizes VA resources and/or recruits VA patients as participants in the project. This may be done concurrently with submission to the HSC IRB.
- 7.2** Submitted documents to the IRB are processed per SOP 301, Research Submission Requirements; and SOP 302, Administrative Review and Distribution of Materials.
- 7.3** The IRB Administrator verifies the project has been submitted to the VA R&D Committee by filing the Contingent Approval VA R&D letter in the IRB file or by contacting the VA R&D Committee. Communication with the investigator occurs if the project has not been submitted to the VA R&D Committee.
- 7.4** If review of project per SOP 401, Research Exempt from IRB Review; and SOP 402, Expedited Review; indicates the project qualifies for convened IRB review, the IRB Administrator processes the project per SOP 403, Initial Review – Criteria for IRB Approval and forwards the agenda to the VAMC RCO.

- 7.5 The VAMC RCO reviews VAMC-regulated research projects to ensure VA regulations have been upheld, ensures that the VAMC research projects have been submitted to the VAMC R&D Committee for review. The RCO attends the IRB meeting to suggest changes to VAMC research projects, and to provide assistance to the IRB should VAMC issues or questions arise.
- 7.6 Final IRB approval is issued when a VA R&D Committee contingent approval letter has been received by the IRB, provided all other requested changes have been made and verified by IRB Administrator and IRB Chair or designee.
- 7.7 IRB meeting minutes are forwarded to the VAMC RCO for presentation to the VA R&D Committee when available.

APPROVED BY: _____ **DATE:** 09/01/2009

NEXT ESTABLISHED REVIEW DATE: MAY 2012