

May 19, 2008

OVERSIGHT OF EXTERNAL CLINICAL RESEARCH MONITORING VISITS

1. **PURPOSE:** The purpose of this policy memorandum is to describe the policies and procedures for external clinical research monitoring visits conducted at the South Texas Veterans Health Care System (STVHCS).

2. **POLICY:**

a. The STVHCS will maintain a policy and standard operating procedure for the conduct of external clinical research monitoring visits to ensure protection of human subjects in research.

b. The sponsor, through the human subject research monitoring visit, must fulfill its obligation to ensure the protection of human research subjects.

c. Definitions:

(1) **External Agencies.** An external agency for purposes of this policy would include a pharmaceutical company, study sponsor, Contract Research Organization (CRO), VA Cooperative Studies Program (CSP) monitor, or other such person or organization charged with conducting a monitoring function for a given research protocol.

(2) **Investigator Records.** Investigator records include all IRB records as well as case histories or any data gathered for research purposes. IRB records include but are not limited to: copy of all proposals reviewed including amendments, investigator brochures, any supplemental information including recruitment and informational materials, consent forms, information submitted for continuing review, and all correspondence. A case history is a record of all observations and other data pertinent to the investigation on each research subject. Case histories include the case report forms and supporting data including signed and dated consent forms, any medical records including, but not limited to: progress notes of the physician, study coordinator notes, and any other study related information contained in the computerized patient record system (CPRS).

(3) **Principle Investigator (PI).** Within VA, a PI is an individual who conducts a research investigation, i.e., under whose immediate direction research is conducted, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. The PI is accountable for the proposal and the execution of the research protocol, as designed, by overseeing the performance of research staff to ensure the completion of all research activities.

(4) **Unanticipated Problems Involving Risk to Subjects and Others (UPIRSO):** Any event or information that (1) was unanticipated (e.g. not consistent with either the described risks in the research documents, or not expected as part of natural progression of subjects underlying condition-increases in frequency or severity are considered to be unanticipated) and (2) at least possibly related (e.g. intervention or interaction in the research and/or related to collection of identifiable private information in the research considered more than likely than

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not- >50% chance- that it is at least partially related) and (3) involves greater risk to subjects or others (e.g. suggests that the research places subjects or others at a greater risk of harm – including physical, psychological, economic, or social harm- than was previously known or recognized).

(5) Strategic Improvement / Quality Assurance / Quality Improvement (SI/QA/QI) For the Human Research Protection Program. The SI/QA/QI Program assesses the conduct of humans' subject research and the R&D environment to meet the objectives of the HRPP, adjusting the environment through educational and compliance activities and reduction of challenges to implementation of the HRPP.

(6) Research Noncompliance. Conducting research in a manner that disregards or violates federal regulations or institutional policies and procedures applicable to human research which can be characterized by severity of the event and the pattern of like or similar events. Noncompliance with R&D Committee, IRB and/or federal requirements may involve a range of issues from relatively minor or technical violations which result from inadvertent errors, inattention to detail, or inadequate training and supervision of research staff to more serious noncompliance violations, which pose risk to subjects or others and/or violations of their rights and welfare.

(a) Serious Non-compliance. Non-compliance that may adversely affect the subject or others safety; increase risk to subjects; violate the rights and/or welfare of participants; affect the subject's willingness to participate in research (any of which may also be an unanticipated problem), or affect the integrity of the data (which may also be scientific misconduct).

(b) Continuing Non-compliance. A pattern of recurring or ongoing instances of actions or omissions (noncompliance) which indicates an underlying deficiency in knowledge of the regulations and R&D Committee or IRB requirements, or an inability or unwillingness to comply with them. Instances may or may not constitute serious noncompliance.

3. ACTIONS:

a. Investigator records are subject to inspection and monitoring by external agencies. These site visits by external agencies may be routine or conducted for specific causes.

b. The PI and associated research staff are responsible for ensuring:

(1) The Assistant Chief for Clinical Research is notified of all outside monitoring visits.

(2) The CRO or study monitor signs in at the R&D Office and receives a visitor badge.

(3) The CRO or study monitor signs the External Monitor Agreement prior to initiation of the visit.

(4) Any potential or actual serious findings are conveyed to the investigator and the Assistant Chief for Clinical Research or designee during an exit interview.

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(5) The CRO or study monitor completes and signs the STVHCS Report of Clinical Research Monitoring Visit Form prior to departure from the facility.

(6) All External Monitor Agreement and STVHCS Report of Clinical Research Monitoring Visit Forms are forwarded to the R&D Office.

(7) All key study personnel comply with the Research Service External Clinical Research Monitoring Visits Standard Operating Procedure No. 40.

c. The Assistant Chief for Clinical Research is responsible for ensuring:

(1) All monitoring reports with potential or actual serious findings are evaluated in accordance with the STVHCS UPIRSO and Noncompliance Policies to implement the appropriate reporting mechanisms.

(2) All monitoring reports with potential or actual serious findings are forwarded to the QA Subcommittee for review and recommendations.

(3) As part of the R&D Office Strategic Improvement/ Quality Assurance / Quality Improvement Program, a summary report of all monitoring visits is forwarded to the R&D committee at least annually.

d. The Quality Assurance (QA) Subcommittee is responsible for reviewing all potential or actual serious findings and providing recommendations to the R&D Committee.

e. The R&D Committee is responsible for ensuring monitoring reports with potential or actual serious findings are considered during annual reviews of active protocols.

f. Visitor security measures:

(1) All external monitors must sign in on VA form 4793 in the Research office.

(2) A STVHCS Police Service issued, numbered and color coded Research Monitor Visitor badge will be issued to each monitor.

(3) Badges must be worn in a visible manner by all monitors.

(4) Monitors wearing a Research Monitor Visitor badge must be accompanied by a VA employee at all times.

(5) All Research Monitor Visitor badges must be returned to the Research office.

(6) The Research office will maintain accountability of all issued badges and all visitor sign in sheets. When requested, these records will be made available to the STVHCS Police Service for auditing purposes.

(7) Lost or stolen badges will be reported to the STVHCS Police Service immediately, at which time color coding of the Research Monitor Visitor badge will be changed.

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4. REFERENCES: Research Service External Clinical Research Monitoring Visits Standard Operating Procedure No. 40; Research Service Human Subjects Concerns Complaints Allegations of Research Improprieties Standard Operating Procedure No. 26; Research Service Strategic Improvement Quality Assurance Quality Improvement for the Human Research Protection Program Standard Operating Procedure No. 41; VHA Memorandum Reporting of All Study Site-Monitoring Visit Results dated Oct 14, 2004

5. RESPONSIBILITY: ACOS for Research and Development (151)

6. RESCSSION: None

7. RECERTIFICATION: June 2011

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RICHARD J. BALTZ
Center Director

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