

RESEARCH SERVICE

April 1, 2008

RESEARCH STANDARD OPERATING PROCEDURE

Strategic Improvement / Quality Assurance / Quality Improvement for the Human Research Protection Program

1. **PURPOSE:** To outline the South Texas Veterans Health Care System (STVHCS) Research and Development Strategic Improvement / Quality Assurance / Quality Improvement (SI/QA/QI) for the Human Research Protection Program that includes the strategic planning, monitoring and auditing, education and training, and quality improvement activities involved in the protection of human research subjects. These quality improvement activities are integral components of the STVHCS Human Research Protection Program (HRPP).
2. **POLICY:**
 - a. The SI/QA/QI program will provide an ongoing, continuous and proactive strategic planning, monitoring and auditing, education and training, and quality improvement program to strengthen and reinforce various elements of the HRPP. The STVHCS human subject research program is subject to periodic assessment to ensure compliance with policies, regulations, and laws which pertain to human research protections through compliance activities. The SI/QA/QI Program is responsible for ensuring that research using human subjects is conducted in a manner that protects the safety, rights, welfare, and other interests of the human subjects enrolled in research under the applicable statutes and policies.
 - b. This program will maintain strategic planning, continuous quality improvement, integrated compliance, and quality assurance processes to assure that all aspects of the HRPP program are functioning appropriately. Modifications to the plan may be made as service and/or program needs warrant.
3. **DEFINITIONS:**
 - a. **Human Research Protection Program (HRPP).** The systematic and comprehensive approach by an organization to ensure human subject protection in all research. The implementation of any part of the program may be delegated to specific committees, individuals or entities, e.g., academic affiliate by the organization. The objective of this system is to assist the institution in meeting ethical principles and regulatory requirements for the protection of human subjects in research.
 - b. **Quality Assurance.** All those planned and systematic actions that are established to ensure that all aspects of human subjects' research are performed and the data are generated, documented (recorded), and reported in compliance with all applicable regulatory requirement(s).
 - c. **Quality Improvement.** A multidisciplinary approach to prospectively evaluating and improving processes for the protection of human subjects in research.

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- d. **Research Impropriety.** Any ethical lapse or other incorrectness involving or occurring in connection with research other than research misconduct as defined below. Examples of research impropriety include, but are not limited to, conflicts of interest, misallocation of funds, sexual harassment, discrimination, and breaches of human subjects' protections requirements.
- e. **Research Misconduct.** Fabrication, falsification, plagiarism in proposing, performing, or reviewing research, or reporting research results.
- f. **Research Noncompliance.** Conducting research in a manner that disregards or violates federal regulations or institutional policies and procedures applicable to human research (in the case of VA research it includes noncompliance with the requirements of the VA Handbook 1200.5 as applicable) which can be characterized by severity of the event and the pattern of like or similar events. Noncompliance with 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.
 - (1) **Serious Non-compliance.** Noncompliance that may: adversely affect subject safety or the safety of others; increase risks to subjects; violate the rights and welfare of participants (any of which may also be an unanticipated problem). Serious noncompliance may affect the subject's willingness to participate in research or may affect the integrity of the data (which may also be scientific misconduct).
 - (2) **Continuing Non-compliance.** a pattern of recurring (in one or more protocols simultaneously or over a period of time) or ongoing instances of actions or omissions (noncompliance) which indicate: 1) an underlying deficiency in knowledge of the regulations and IRB requirements or; 2) a possible inability or unwillingness to comply with them. Instances may or may not constitute serious noncompliance.
- g. **Strategic Improvement Planning.** A proactive, systematic, stepwise process that assesses the current situation, defines an overall vision with short- and long-term goals, identifies barriers, and elucidates what needs to be done to achieve the vision and goals.
- h. **Unanticipated Problems Involving Risk to Participant or Others (UPIRSO).** Any event or information that (1) was unanticipated and (2) at least possibly related and (3) involves greater risk to subjects or others.
 - (1) **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).
 - (2) **At Least Possibly Related:** Intervention or interaction in the research and/or related to collection of identifiable private information in the research considered more than likely than not (e.g. >50% chance), that it is at least partially related.
 - (3) **Greater Risk of Harm:** 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.

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4. RESPONSIBILITIES:

- a. **Hospital Director.** The Hospital Director is responsible for the overall assurance of protections for human participants within the SVHCS. As the designated Institutional Official, the Hospital Director can exercise the authority to suspend or terminate research as deemed necessary, including for the protection of human participants.
- b. **Research and Development Committee.** The R&D Committee as part of its oversight function is responsible for reviewing research audit reports and ensuring that opportunities for improvement are identified and addressed and noncompliance issues are resolved. The R&D Committee will utilize a subcommittee (R&D QA Subcommittee) to conduct the evaluations of quality review audits and findings.
- c. **QA/QI Subcommittee.** The QA Subcommittee is assigned by the R&D Committee to conduct the evaluations of quality review audits and findings and issues of research non-compliance or improprieties. See the Research Service Memorandum Research Quality Assurance Standard Operating Procedure No. 19 for additional details.
- d. **Associate Chief of Staff for Research and Development (ACOS for R&D).** The ACOS for R&D is delegated the responsibility for the implementation, conceptual oversight, and administrative leadership for administering the STVHCS R&D Program by the Hospital Director. As a function of these activities, the ACOS for R&D is responsible for administering the development, implementation, and maintenance of a program ensuring compliance and quality improvement for the HRPP.
- e. **STVHCS Compliance Officer.** The Compliance Officer or designee is responsible for the periodic monitoring of the HRPP, including the ongoing SI/QA/QI activities and the follow-up of corrective actions. The Compliance Officer or designee submits their findings to the QA/QI Subcommittee.
- f. **Assistant Chief for Clinical Research.** The Assistant Chief for Clinical Research is responsible for assisting the ACOS for R&D in the development, implementation, and maintenance of all aspects of the HRPP, including SI/QA/QI activities.
- g. **Principal Investigator (PI).** Each PI is responsible for providing their designated research staff with an opportunity to attend training and education provided as part of the SI/QA/QI Program and for establishing an environment conducive to implementation of the requirements of the HRPP, including SI/QA/QI initiatives. Each PI is responsible for informing the R&D Office of any concern or allegation of non-compliance or research misconduct. Each PI is responsible for providing any records and/or documents requested for auditing activities, responding to any questions that arise as a result of an audit, and providing a corrective action plan as needed to assure ongoing compliance.

5. ACTION:

- a. **Strategic Improvement Planning:** The SI/QA/QI program includes a process of strategic planning, which is performed on an annual basis. In general, the strategic planning process includes the following components:
 - (1) **Assessing the Current Situation.** An understanding of the current situation of the STVHCS HRPP aids in identifying the barriers that stand in the way of further progress.

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- (2) **Defining the Vision.** The STVHCS aspires to discover knowledge, develop VA researchers and health care leaders, and create innovations that advance health care for our veterans and the nation. With this overall vision in mind, the annual strategic planning will identify short- and long-term goals to improve the HRPP.
- (3) **Identifying the Barriers.** Potential and real barriers to effective function of the HRPP are assessed at the system level, research service level, and at the investigator microsystem level.
- (4) **Planning the Strategy.** Major goals for improvement of the HRPP will be formulated based on the understanding of the current situation and identification of barriers. These goals must be met as a demonstration of progress toward achieving the vision.
- (5) **Strategic Plan.** The strategic plan is the action plan that will be implemented to achieve the goals. Agreement to the strategic plan will be sought from all stakeholders in the research program up front. The R&D Committee will be integrally involved in the development of the annual strategic plan. The formulated strategic plan for the STVHCS Research Service will be linked to the fiscal year business plan submitted to STVHCS administration.

b. Educational Activities

- (1) **On-line Standardized Training.** All individuals involved in human subjects' research at the STVHCS are required to annually complete the Collaborative Institutional Training Initiative (CITI) Course on Good Clinical Practice and ethical principles of human subject research protection.
 - (a) The R&D Office tracks CITI training for all investigators and study staff involved in human subjects' research.
 - (b) Training must be completed before any investigator or study staff can commence any human subjects' research and must be completed annually to continue working on active research protocols.
- (2) **Investigator Handbook.** An Investigator Handbook has been developed, and is updated as needed, to provide important guideposts to policies and procedures that are critical for investigators and study staff to understand and follow in order to ensure human subjects are afforded maximum protection as participants in research. The Investigator Handbook is available in print form and on the STVHCS Research website. The handbook provides information regarding where investigators can go to find more information or to have questions addressed.
- (3) **On-site Assessment and Training for Investigators and Research Staff.** The R&D Office staff, the ACOS for R&D, and the Assistant Chief for Clinical Research are available to conduct on-site assessment and training when requested by a STVHCS Investigator, their study personnel, or the R&D Committee.
- (4) **Electronic Communication Network for Research Study Team Members.** The SI/QA/QI program has a Research Study Members email group of all active human subjects' investigators, study coordinators, and other key study personnel. This

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establishes an ongoing method for regular feedback and dialogue between the R&D Office, principal investigators, and key research coordinators involved in the day-to-day implementation and operational functions of human research projects.

- (5) **Monthly Education and Training Sessions for Research Study Team Members.** The ACOS for R&D and the Assistant Chief for Clinical Research routinely conduct needs assessments and review of newly drafted documents and/or procedures for investigator and study staff training opportunities. Monthly interactive training sessions are conducted to disseminate new information. Handouts for each training session are provided to all Research Study Team Members, and are posted on the Research Service website for future reference.
 - (6) **Clinical Research Training Course.** The STVHCS participates with the UTHSCSA in providing an 8-hour training course on “Conducting Clinical Research”. All personnel involved in human subjects’ research at the STVHCS are strongly encouraged to participate in this course, which is offered 3 times per year.
 - (7) **IRB Training Sessions.** IRB forums which review policies and procedures for IRB submissions are held on a regular basis. Dates and times for the sessions are posted on the UTHSCSA IRB website and attendance by STVHCS investigators and study staff is encouraged.
- c. **Research Service Performance Measures.** The R&D Office has established a performance dashboard for monitoring the effectiveness of administrative processes and procedures related to the research program, including those that are applicable to the HRPP.
- (1) **Timeliness of Processes.** The R&D Office monitors time from a request or initial receipt to the date of completion or approval for a number of processes involved with human subjects research (e.g. research privileges, WOC applications, educational verification, protocol administrative pre-review, protocol review by R&D, protocol data security review, safety committee review, privacy review, protocol continuing reviews).
 - (2) **Access to Research Resources.** The R&D Office provides a number of resources for investigators and study staff. Access to these resources are monitored on an ongoing basis (e.g. space utilization, common use equipment, statistical support, computer support)
 - (3) **Research Productivity.** In an effort to continually expand research activities available to STVHCS patients, and the number and types of new proposal submissions are monitored on a regular basis (e.g. investigator initiated, new investigator, industry sponsored, VA and NIH funded projects).
 - (4) **Training.** Training initiatives are monitored on a monthly basis to assure targets for training are met or exceeded.
 - (5) **IRB Communication.** IRB minutes, protocol consent forms, and UPIRSOs from the IRB are monitored for prompt review and reporting.
 - (6) **Investigator Satisfaction.** Feedback from investigators regarding the level of service and satisfaction with the R&D Office will be solicited on a regular basis to continually identify areas for improvement.

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d. PROCEDURES FOR RESPONDING TO QUESTIONS, CONCERNS, COMPLAINTS, AND ALLEGATIONS OR REPORTS OF NON-COMPLIANCE WITH HRPP

REQUIREMENTS: Additional information regarding the review and processing of complaints, concerns, or research related allegations of improprieties are detailed in Research Service Standard Operating Procedure No.26 Human Subjects Concerns Complaints Allegations of Research Improprieties. Any allegation or report of noncompliance which arises will be handled as follows:

- (1) Any employee of the STVHCS or member of a research team who becomes aware of a violation, or who believes there may be a violation of IRB or HRPP regulations, requirements or determinations is required to provide a prompt report to the R&D Office. In addition, participants in human research studies, their designated representatives, or members of their community are also encouraged to report any questions, concerns, complaints, comments, or suggestions to the R&D Office.
- (2) Regardless of the source of the complaint, all allegations and reports of non-compliance (whether minor, serious, or continuing) which involve potential risk to subjects or others, will be reported to the R&D Chairman and the IRB Director for immediate evaluation and action.
- (3) The IRB and R&D Chairs or his/her designee, in collaboration with the ACOS for R&D and the Assistant Director for Clinical Research, ensures appropriate response to each alleged impropriety.
- (4) If an allegation or report of non-compliance was confirmed, but was neither serious nor continuing, the ACOS for R&D and the Assistant Chief for Clinical Research will take corrective actions, as required, to remedy the non-compliance and will report these corrective actions back to the R&D Committee and the IRB.
- (5) If an allegation or report of non-compliance was confirmed and was either serious or continuing, the issue will be presented to the IRB and R&D Committee and corrective actions are voted on. All actions taken are at the institutional level and appropriate for the circumstances, and the final course of action is entirely dependent on the nature, severity, and degree of seriousness of the findings. The ACOS for R&D and the Assistant Chief for Clinical Research will implement any recommended corrective actions as required to remedy the non-compliance and will report these corrective actions back to the R&D Committee and the IRB.
- (6) Any written responses to concerns/complaints will be forwarded to the Director's Office. Established guidelines of the Patient Advocate Program Policy Memorandum 003-04-02 and all related VHA regulations will be followed when completing written replies for the Director's signature.
- (7) The Hospital Director will follow all required VA policies, including VHA 1200.5, for reporting to regulatory agencies.

e. MONITORING AND REPORTING UPIRSOs:

- (1) Principal Investigators are required to follow UTHSCSA IRB policies and procedures regarding the problems that require prompt reporting to the IRB.

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- (2) The UTHSCSA IRB Office will communicate to the ACOS for R&D when a problem is determined to represent an unanticipated problem involving risks to participants or others (UPIRSO).
- (3) The ACOS for R&D will report all UPIRSOs to the QA/QI Subcommittee, which will evaluate the report and make recommendations to the R&D Committee.
- (4) If the UPIRSO meets the criteria for reporting to the Office of Research Oversight (ORO) or other regulatory agencies, the UPIRSO will be reported by the Hospital Director, along with a copy of the letter sent by the UTHSCSA IRB to regulatory agencies and institutional officials. The Hospital Director will follow all required VA policies, including VHA 1200.5, for reporting to regulatory agencies.
- (5) External safety reports received by the PI are individually reviewed for possible UPIRSO reporting to the IRB by the PI. If external safety reports are determined to not be UPIRSOs, they are summarized in the continuing review report. External safety reports received by the R&D Office from the sponsor are forwarded to the PI for evaluation. Summaries of the external safety reports are reviewed as part of the IRB and R&D continuing review process.

f. OVERSIGHT OF EXTERNAL MONITORS

- (1) 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, and are an important component in the protection of human subjects.
- (2) The Assistant Chief for Clinical Research is to be notified of all monitoring visits by external monitoring agencies as soon as they are scheduled.
- (3) The CRO or study monitor must sign the External Monitor Agreement form and return it to the R&D Office prior to initiation of the visit.
- (4) The CRO or study monitor will complete and sign the "STVHCS Report of Clinical Research Monitoring Visit" form prior to departure from the facility.
- (5) Any potential or actual serious findings must be conveyed to the investigator and the Assistant Chief for Clinical Research or ACOS for R&D, or designee during an exit interview.
- (6) All monitoring reports with potential or actual serious findings will be forwarded to the QA Subcommittee for review. These monitoring reports will also be forwarded to the R&D Committee at the time of continuing review for the protocol.
- (7) The Assistant Chief for Clinical Research will forward a summary report of all monitoring visits to the R&D committee at least annually.
- (8) The Compliance Officer or his/her designee, as part of the routine research protocol audit, will review external monitoring reports of STVHCS investigators to ensure that the R&D Office was notified of the visit and all potential or actual serious findings were communicated.

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- (9) For additional information refer to Research Service Memorandum External Clinical Research Monitoring Visits Standard Operating Procedure No. 40.
- g. **PROCEDURES FOR COMPLIANCE AUDITS:** Compliance audits for the HRPP are conducted by the STVHCS Compliance Office. See the STVHCS CBI Human Research Protection Program Policy (Policy Service Memorandum 003-07-01) for additional details. Standardized audit forms/procedures will be used for each audit activity to ensure consistency of reviews. This does not preclude the use of an improved evaluation instrument if there are program/policy changes or the findings dictate the need. Areas to be monitored may include, but are not limited to, the following:
- (1) **Compliance Audits of R&D Office Project Files.** R&D Office files are audited to ensure completeness of records, including original applications, UTHSCSA-IRB documentation, and investigator communications.
 - (2) **Compliance Audits of Investigator Records and Practices.** Human research protocols at the STVHCS will be periodically audited by the Compliance Officer or designee to ensure adequacy of record security, data management, operational procedures, informed consent process, reporting of adverse events, adequacy of consent forms, compliance with inclusion/ exclusion criteria, and management of deviations from the protocol. These audits may be randomly selected or for-cause audits.
 - (3) **Compliance Audits of Medical Record Documentation.** Documentation of the Informed Consent process, including the scanning of consent documents and 10-9012 Investigational Drug Record forms within the medical records of human research participants at the STVHCS, will be audited by the Compliance Officer.
 - (4) **Compliance Audits of the R&D Committee and its' subcommittees (e.g. UTHSCSA IRB).** The Compliance Officer will audit the R&D Committee and all subcommittees' functions and adherence to applicable guidelines, regulations, and standards that govern human research. These evaluations will be reported at least annually to the R&D Committee. Periodic evaluations will be conducted of the UTHSCSA IRB composition, operational procedures, and compliance with applicable regulations as they apply to the conduct of VA research.
 - (5) **Compliance Audits of VA Training Records.** The R&D Office database which documents the annual training required for human researchers ("Overview of Good Clinical Practices" and "HIPAA Privacy Training") will be audited by the Compliance Officer for training compliance.
- h. **ASSURANCE OF APPROPRIATE OVERSIGHT OF IRB:** A key procedure for ensuring compliance and quality improvement for the HRPP is effective two-way communication and careful oversight of UTHSCSA IRB activities. Specific oversight is accomplished as follows:
- (1) The R&D Office maintains electronic access to UTHSCSA IRB data pertaining to VA-related projects. If at any time electronic access is unavailable, paper copies of IRB records pertaining to VA research will be provided by the IRB as needed.

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- (2) A VA representative (e.g., Research Compliance Officer or Assistant Chief for Clinical Research) attends, as an observer, a minimum of 75% of UTHSCSA IRB meetings in order to monitor appropriate review and oversight of VA-related projects.
- (3) The minutes of all UTHSCSA IRB meetings are presented for review at R&D Committee meetings.
- (4) The R&D Committee monitors the qualifications and experience of new IRB chairpersons through a survey tool provided to each VA member of the IRB. Results of the surveys are summarized and presented annually to the R&D Committee for review and recommendations.
- (5) The Compliance Officer or designee monitors specific IRB activities from a compliance standpoint as follows: (a) appropriateness of IRB membership and experience in the context of research under review, (b) participation of representatives and/or advocates for vulnerable populations, (c) adequacy of IRB policies and procedures, (d) appropriate monitoring of adverse events, (e) timeliness of review process, (f) appropriateness of number of IRBs in relation to workload volume, and (g) the thoroughness of the review process. The Compliance Officer or designee completes the Research Compliance Audit Tool on at least a quarterly basis and submits the results to the QA Subcommittee and the Compliance Executive Board for review.
- (6) Regularly scheduled meetings are held between VA (ACOS for R&D, Assistant Chief for Clinical Research, R&D Office Staff) and UTHSCSA IRB officials (IRB Director, IRB Assistant Director, IRB Office Staff) in order to maximize communication, facilitate collaboration, and ensure compliance with all HRPP requirements.
- (7) Following R&D Committee review, any requirements for approval, which are in addition to those required by the IRB, are communicated to the PI and the IRB.

i. QUALITY ASSURANCE RELATED TO RESEARCH PUBLICATIONS

- (1) The Compliance Officer or designee will periodically review publications of STVHCS investigators to ensure that proper IRB approval were in place for these studies.
- (2) The Compliance Officer or designee will periodically review publications of STVHCS investigators to ensure disclosures of identified conflicts are present in any protocol related publications or presentations, if required.
- (3) The ACOS for R&D or designee, as part of the annual research productivity analysis, will review publications of STVHCS investigators to ensure appropriate acknowledgement of VA involvement as per VHA Handbook 1200.1. See Research Service Memorandum Research Productivity and Quality Assurance for Research Publications Standard Operating Procedure No.38 for additional details.

j. COMPLIANCE AUDIT AND MONITORING DOCUMENTATION:

- (1) On at least a quarterly basis, the Compliance Office will provide a written summary of compliance audits and monitoring activities to the R&D QA Subcommittee. The R&D QA Subcommittee will provide to the R&D Committee on at least a quarterly basis the

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compliance audits and monitoring activities and any recommendations for actions or improvement activities to the R&D Committee.

- (2) The minutes of all R&D QA Subcommittee meetings will be forwarded for discussion and review at the R&D Committee.

k. PROCEDURES FOR REPORTING TO REGULATORY AGENCIES:

- (1) Research-related events may require notification of Regulatory and Oversight agencies. These include, but are not limited to findings of serious or continuing noncompliance with the regulations for the protection of human subjects or with the requirements of the IRB; any unanticipated problems involving risks to subjects or others (e.g., death of healthy volunteers participating in research); and suspension or termination of IRB approval (e.g., associated with unexpected harm, research not being conducted in accordance with the IRB's requirements).
- (2) The IRB Director, or ACOS for R&D through the Medical Center Director as the Institutional Official for the HRPP, will report all actions requiring reporting to non-VA regulatory agencies such as the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA) if investigational devices or drugs are involved, and/or any other federal agencies overseeing research who require separate reports from OHRP.
- (3) The ACOS for R&D through the Medical Center Director as the Institutional Official for the HRPP, will report all actions requiring reporting to Regional Office of Research Oversight (ORO) as specified in the Office of Research Oversight (ORO): Action Memorandum "What to Report to ORO" dated Sept 8, 2005, and VHA handbook 1058.1.
- (4) Breaches in information security will be reported to the VHA Information Security Officer (ISO).
- (5) Reports to regulatory agencies shall be made as soon as possible after recognition of a reportable event and within the maximum allowable time required by the applicable regulatory body.
- (6) Reports to regulatory agencies by the STVHCS and UTHSCSA IRB will be copied to the reciprocal office.
- (7) For additional information regarding reporting to regulatory agencies refer to Research Service Memorandum Correspondence and Communication between Components of the Human Research Protection Program and Regulatory Agencies Standard Operating Procedure No.37.

l. COMPLIANCE WITH CHANGES IN HRPP POLICIES AND REGULATIONS:

Institutional officials responsible for the HRPP (i.e., ACOS for R&D, Assistant Chief for Clinical Research, R&D Committee Chair, Compliance Officer, AO for R&D) will closely monitor all policies and regulations which pertain to HRPP compliance requirements. Strategies for effective monitoring will be as follows:

- (1) Selected officials, as appropriate, will participate in recurring training in order to remain cognizant of all changes in HRPP policies and regulations. When changes are identified, they will be promptly reflected in local policies and procedures at the STVHCS and

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quickly disseminated to institutional officials, members of research review committees, and human research personnel via the STVHCS Investigator Handbook, R&D website and through ongoing educational activities.

- (2) Communications from the VA Office of Research and Development, the VA Office of Research Oversight (ORO), and the VA Center on Advice and Compliance Help (COACH) will be closely monitored in order to maintain a keen awareness of changes in HRPP policies and regulations so that compliance can be maintained.

6. REFERENCES:

VHA Handbook 1200.5 "Requirements for the Protection of Human Subjects in Research" dated July 15, 2003;

Office of Research Oversight (ORO): Action Memorandum "What to Report to ORO" dated Sept 8, 2005;

VHA handbook 1058.1 "Reporting Adverse Events in Research to the Office of Research Oversight" dated November 19, 2004

STVHCS CBI Human Research Protection Program Policy (Policy Service Memorandum 003-07-01);

Research Service Memorandum Human Subjects Concerns Complaints Allegations of Research Improprieties Standard Operating Procedure No.26;

Research Service Memorandum External Clinical Research Monitoring Visits Standard Operating Procedure No. 40;

Research Service Memorandum Research Productivity and Quality Assurance for Research Publications Standard Operating Procedure No.38;

Research Service Memorandum Correspondence and Communication between Components of the Human Research Protection Program and Regulatory Agencies Standard Operating Procedure No.37

- 7. RESPONSIBILITY:** ACOS for Research and Development (151)

- 8. RECISSION:** None

- 9. RECERTIFICATION:** April 2011

//signed//
PETER C. MELBY, M.D.
ACOS for Research and Development