DEPARTMENT OF VETERANS AFFAIRS
South Texas Veterans Health Care System
San Antonio, Texas 78229

Policy Memorandum 16-27

January 26, 2016

RESEARCH STANDARD OPERATING PROCEDURES
Annual Review of Human Research Protection Program

1. **PURPOSE:** To outline the Research and Development Committee (R&D) process for conducting the annual evaluation of the function and effectiveness of the Human Research Protection Program (HRPP), including the Institutional Review Boards (IRBs).

2. **POLICY:** Annually, the Research and Development Committee will evaluate the function and effectiveness of the HRPP, including the use of the UTHSCSA's Institutional Review Boards. The review will assess the activities and effectiveness of the HRPP, and will ensure that the IRBs are meeting their responsibilities. Recommendations of the R&D Committee will be sent to the Director, and will include a recommendation for the STVHCS to continue/discontinue the use of the affiliate's IRBs as its IRB of record. The IRBs to be considered include:

a. UTHSCSA Institutional Review Board #1, Initial Reviews (DHHS Registration #IRB00000553)

b. UTHSCSA Institutional Review Board #2, Continuing Reviews (DHHS Registration #IRB00002691)

c. UTHSCSA Institutional Review Board #3, Initial Reviews (DHHS Registration #IRB00002692)

d. UTHSCSA Institutional Review Board #4, Expedited Review (DHHS Registration #IRB00009608

e. VHA Central Office IRB#1 (DHHS Registration #IRB00006332)

3. **ACTION:**

a. The Research and Development Office will make available to the R&D Committee members all information and materials that are necessary to conduct its evaluation of the HRPP.

b. The R&D Committee evaluation of the HRPP will focus on the following areas:

(1) Credentialing and training of human subject research personnel: The R&D Office will provide a summary status report of the training and credentialing status of all personnel involved in research.

(2) Resources allocated to the HRPP: The R&D Office will summarize for the R&D Committee the resources dedicated to the HRPP, including the budget, space, and administrative support staff committed to the HRPP.

(3) Quality improvement activities in the HRPP: The R&D Office will provide a summary to the R&D Committee of the year's activities and progress related to quality improvement.

(4) Compliance issues in human subject research: A summary of the compliance activities, findings, and recommendations related to human subject research will be provided by the Research Compliance Officer.

(5) Adequacy of the local (UTHSCSA) IRBs: The R&D Committee members will review the materials pertinent to the evaluation of the IRB and make a recommendation to the Director to continue or discontinue utilization of the affiliate (UTHSCSA) IRBs. Members must consider in their review an assessment of the qualifications and experience of the IRB chairs; whether the IRB and membership of the IRB are appropriate given the type research being reviewed and meet with sufficient frequency to review the amount and type of research conducted; that the IRB includes representatives, either as members or ad hoc consultants, interested in or who have experience with the vulnerable populations involved; and whether IRB policies and procedures are appropriate. Items to be considered by the R&D Committee members related to the IRB review may include:

(a) Meeting minutes that are provided and reviewed on a monthly basis

(b) Membership and chairs of IRBs 1, 2, 3, and 4

(c) Evaluations provided by VA IRB members: at least annually the VA IRB members will review the function of the IRB using the Questionnaire included in Attachment 1

(d) Written policies, procedures, instructions as provided to all investigators on the UTHSCSA web site

(e) Member observations of and experience with the IRBs during the term of their R&D membership or through contacts as investigators

(f) Any other materials requested by the members

(6) Adequacy of the VHA Central Office IRB: The R&D Committee members will review the materials pertinent to the evaluation of the VHA Central Office IRB and make a recommendation to the Director to continue or discontinue utilization of this IRB. The R&D Committee will review the following information:

(a) Membership roster

(b) Policies, procedures and instructions

(c) Minutes of the convened meeting where STVHCS protocols were reviewed

(d) A survey of STVHCS investigators who have utilized the VHA Central Office IRB

(e) Any other materials requested by the members

(7) Cooperative R&D Agreements (CRADAs): An annual summary of active CRADAs will be provided to the R&D Committee by the R&D Office. The committee's review will ensure that all CRADAs meet the VHA requirements for the protection of human subjects.

(8) Outreach activities to past, current, or prospective research participants.

(9) Goals for the HRPP in the coming year: The R&D Office, in collaboration with all components of the HRPP, will provide written goals to the R&D Committee for discussion. The R&D Committee will review and may modify these goals, and make recommendations for the implementation of processes and procedures to accomplish the goals.

4. **REFERENCES:** VHA Handbook 1200.05 Requirements for the Protection of Human Subjects in Research; VHA Handbook 1200.01 The Research and Development (R&D) Committee Handbook

5. **RESPONSIBILITY:** Associate Chief of Staff for Research (151)

6. **RECISSION:** Research Policy Memorandum 10-27, November 1, 2010

7. **RECERTIFICATION:** November 2021

JACQUELINE A. PUGH, MD
ACOS for Research and Development

Attachment (1)

IRB MEMBER EVALUATION

IRB#: _____

1. Do the IRB chairs have sufficient qualifications and experience to protect human subjects in research? ☐ Yes ☐ No
2. Are the IRB meeting materials sent to members in sufficient time to review prior to meeting ☐ Yes ☐ No
3. Are members provided all the required meeting materials? ☐ Yes ☐ No
4. Do agendas clearly indicate primary and secondary reviewers? ☐ Yes ☐ No
5. Are all members given opportunity to provide input during meeting? ☐ Yes ☐ No
6. Are all pertinent review issues being addressed in the meeting? ☐ Yes ☐ No
7. Are members with a conflict of interest asked to leave the meeting during protocol review? ☐ Yes ☐ No
8. Is there adequate discussion when there is member disagreement? ☐ Yes ☐ No
9. Do the minutes adequately reflect the protocol reviews? ☐ Yes ☐ No
10. When needed, is assistance available from other members or IRB office staff? ☐ Yes ☐ No
11. Is the membership of the IRBs appropriate given the type of research being reviewed? ☐ Yes ☐ No
12. Are there members who have sufficient experience to adequately review research involving vulnerable populations? ☐ Yes ☐ No
13. Are the IRB polices and procedures appropriate? ☐ Yes ☐ No
14. Additional Comments/Concerns:

Attachment 1