

DEPARTMENT OF VETERANS AFFAIRS
South Texas Veterans Health Care System
7400 Merton Minter Boulevard
San Antonio, Texas 78284

RESEARCH SERVICE
MEMORANDUM 05-27

December 2, 2005

Human Research Protection Program
Standard Operational Procedures

Annual Review of IRB and Recommendation to Director

1. PURPOSE: To outline the Research and Development Committee (R&D) process for conducting the 2004 evaluation of the use of UTHSCSA Institutional Review Boards as its IRB of record in conjunction with its recommendation to the Director as to whether the relationship should continue or be discontinued.
2. POLICY: Annually the Research and Development Committee will evaluate its use of the UTHSCSA's Institutional Review Boards to ensure that the IRBs are performing their responsibilities and send to the Director a recommendation to continue/discontinue the use of the affiliate's IRBs.
3. RESPONSIBILITY:
 - a. The Office of Research and Development will make available to the R&D Committee members all materials to be considered in its evaluation.
 - b. 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/discontinue utilization of the UTHSCSA IRBs.
4. PROCEDURES:
 - a. Institutional Review Boards to be considered:

Institutional Review Board #1, Non-Oncology Initial Reviews
Institutional Review Board #2, Continuing Reviews
Institutional Review Board #3, Oncology Initial Reviews
 - b. 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.

c. Items to be considered by the committee members may include:

- (1) Meeting minutes that are provided and reviewed on a monthly basis
- (2) Reports of actions and approvals granted under the expedited review procedures that are provided and reviewed on a monthly basis
- (3) Report of Director (IRB) – Expedited Reviews that are provided and reviewed on a monthly basis.
- (4) Membership and chairs of IRBs 1, 2, and 3
- (5) Evaluations provided by VA IRB members
- (6) Written policies, procedures, instructions as provided to all investigators on the UTHSCSA web site
- (7) Reports from the Compliance Office on its findings from audits of IRB files and minutes
- (8) Member observations of and experience with the IRBs during the term of their R&D membership or through contacts as investigators
- (9) Any other materials requested by the members

d. Upon completion of the evaluation, the R&D Committee will notify the Director in writing of its findings and recommendation as to whether the R&D Committee should continue to utilize the UTHSCSA Institutional Review Boards as its IRBs of record.

5. RECISSION: Research Policy Memorandum 04-27, August 2, 2004.

6. REVIEW DATE: August 2008.


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