

**Department of Veterans Affairs
Tuscaloosa VA Medical Center**

Human Research Protection Program SOP # 19

May 7, 2007

HRPP RESOURCES AND ANNUAL REPORTING REQUIREMENTS

1. POLICY

The Tuscaloosa VA Medical Center (TVAMC) Human Research Protection Program (HRPP) is committed to providing the resources sufficient for conducting activities under its jurisdiction, providing the appropriate number of Institutional Review Boards (IRBs) for the volume and types of human research to be reviewed in a thorough and timely manner, and providing resources that are necessary for human research protection, care of research participants, and safety during the conduct of the research. This TVAMC HRPP standard operating procedure (SOP) is the written policy and procedure regarding the HRPP resources (review, management, and provision of) and annual reporting requirements.

2. RESPONSIBILITIES

TVAMC Director is responsible for assuring that the HRPP is provided the resources required for providing human research protection for the activities under its jurisdiction. The TVAMC Director is responsible for ensuring that adequate administrative support, including personnel and space sufficient to provide privacy for conducting sensitive duties and storage of records, is provided for IRB activities.

Coordinator of Research and Development (C/R&D) and R&D Administrative Officer (R&D AO) are responsible for assuring that annual review of resources is conducted and reported to the TVAMC Director and for making recommendations to the TVAMC Director for additional HRPP resources, when needed. In addition, the C/R&D and R&D AO are responsible for providing appropriate educational opportunities for researchers, IRB members and IRB staff to ensure the safety of research participants (see HRPP SOP#12).

R&D Committee is responsible for an annual review of resources and for making recommendations through the Chief of Staff for additional resources (including additional IRBs), if needed.

3. DEFINITIONS

HRPP Resources include administrative personnel, consultants, computer and office equipment, budget, secure storage space, office space, space to permit private communication, access to conference rooms, and furniture. HRPP resources also include IRB, R&D Committee, and R&D Continuous Readiness Assessment Team (C-RAT) members.

4. PROCEDURES

a. Review of Resources and Evaluation of the Adequate Number of IRBs Needed

On an annual basis after the close of the fiscal year (FY), the C/R&D and R&D AO review the HRPP resources and compile a report of resources. The report includes a breakdown for the preceding fiscal year of the personnel effort and cost, total VA and other funding received, number of open protocols and initial new protocols reviewed by the IRB, space and equipment, and materials and supplies. These resources are compared to the existing published benchmarks or reports (i.e. the HSR&D MRR-00-019 FY01 report entitled “The cost of operating IRBs in the VA). The TVAMC annual report includes a conclusion of whether or not the TVAMC has enough IRBs for the type and volume of human research reviewed in a fiscal year and whether it has enough resources to support the workload (i.e. the balance of the number of studies, number of investigators, and funding levels [i.e., input] and the number of IRBs and IRB/R&D personnel [i.e. output]). The R&D Committee reviews the report and votes on whether to accept or reject the report. The R&D Committee may make recommendations for changes in resources. The report is submitted with the minutes for review and approval by the Chief of Staff and the Director.

In addition, the IRB Chair may also judge the amount of time burden on IRB members for reviews, frequency and length of IRB meetings, or complexity of research to be reviewed as indications of the need for additional IRBs. The IRB Chair may make recommendations based on these concerns or findings to the C/R&D, R&D AO or the R&D Committee for consideration and action.

b. Resources Necessary to Protect Human Participants

The IRB also conducts a survey of IRB members, alternates, R&D members, and IRB staff in regard to resources. The report of survey findings includes a review of the level of staffing considering the volume of research to be reviewed, space, materials and supplies, equipment, and training and education. The report is reported to the IRB and R&D Committee and communicated to the Chief of Staff and Director through the R&D minutes. The above survey is reviewed annually by the R&D Committee and recorded in the minutes with the report serving as an attachment. Recommendations for further evaluation or for changes in resources necessary to protect human participants may be made by the IRB, R&D Committee, or R&D C-RAT to the C/R&D, R&D AO, or Chief of Staff or Director.

c. Budgeting and Accounting Records

Budget and accounting records concerning nonprofit research corporation-administered research funds (i.e. ancillary IRB budget, IRB expenses, and HRPP expenses) are maintained by the TVAMC nonprofit corporation, Tuscaloosa Research and Education Advancement Corporation (TREAC). Industry sponsored research protocols are invoiced an IRB administrative fee for initial and continuing review. The TREAC Board of Directors review research funds and expenditures at their quarterly Board meeting. An independent auditor in accordance with federal regulations audits TREAC financial statements. The independent audit report is submitted in accordance with federal law to the Director of the Fiscal Department through the Director. An annual report on Non-Profit Corporations activities

along with the independent auditor's report is submitted to the Secretary of Veterans Affairs and to the Director.

Budget and accounting records concerning VA-administered research funds are maintained by VA fiscal service. An annual report of grant expenditures is prepared by the C/R&D and submitted annually through the Director to VA Office of R&D, and is also reviewed annually by the IRB.

The IRB FTE allocation and salary support is prepared by fiscal service and the C/R&D and reported to the R&D Committee annually and to the VISN 7 leadership upon request. The IRB FTE allocation, salary support, costs associated with research report, and grant expenditures are all reviewed by the Director prior to their release to external locations.

In addition, the HRPP administrative budget for VA staff/expenses under the Office of the Director follows the systematic process outlined in VA Center Memo (RES-04-2).

5. REFERENCES

VA Center Memo (RES-04-2)

6. ATTACHMENTS

None

7. RESCISSIONS

IRB Standard Operating Procedures dated July 1, 2004.

8. REVIEW DATE

January 1, 2012

Signature on File in R&D Office

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