HRPP RESOURCES AND ANNUAL REPORTING REQUIREMENTS

1. POLICY

The Birmingham VA Medical Center (BVAMC) 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 BVAMC 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

BVAMC 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 BVAMC 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 all research activities including the IRB activities.

Chief of Staff, Research and Development (ACOS/R&D) and Administrative Officer R&D (AO, R&D) are responsible for assuring that annual review of resources is conducted and reported to the BVAMC Director through the Chief of Staff (COS) and for making recommendations to the BVAMC Director for additional HRPP resources, when needed. In addition, the ACOS/R&D and AO, R&D 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

See HRPP SOP #24 – HRPP Definitions
4. **PROcedures**

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

On an annual basis the AO, R&D reviews the HRPP resources. This includes a breakdown from 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. This review includes a conclusion of whether or not the BVAMC 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 may make recommendations for changes in resources based on this review by the A/O. The A/O’s review is based on annual reports by the IRB, RDIS report, and the Safety Committee annual report. These reports are submitted with the minutes for review and approval by the Chief of Staff and the Director.

The IRB Chair submits an annual report to the R&D Committee judging 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 and/or members. The IRB Chair may make recommendations based on these concerns or findings to the ACOS/R&D, AO, R&D 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 survey findings include 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 survey is reported as part of the annual report to 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, ACOS/R&D, AO, R&D, Chief of Staff, or Director.

c. **Budgeting and Accounting Records**

Budget and accounting records concerning VA-administered research funds are maintained by Research fiscal service. An annual report of grant expenditures is prepared by the Budgeting Analyst of Research Service, and submitted annually through the Director to VA Office of R&D, and is also reported annually to the R&D Committee by the ACOS of Research.

The IRB FTE allocation and salary support is prepared by fiscal service and the AO 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.

*Supersedes version dated June 26, 2013*
5. REFERENCES

VHA Handbook 1200.05 Requirements for the Protection of Human Subjects in Research

6. ATTACHMENTS

None

7. RESCISSIONS


8. REVIEW DATE

February 1, 2021.

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