VAPHS RESEARCH & DEVELOPMENT

POLICY NUMBER: 021

TITLE: Administration of Extramural Grants

1.0 PURPOSE

To define procedures governing the relationship between the VA Pittsburgh Healthcare System (VAPHS), its affiliate, the University of Pittsburgh (University) and the Veterans Research Foundation of Pittsburgh (VRFP), a VA nonprofit corporation (NPC) established under the laws of the Commonwealth of Pennsylvania and enacted under 38 USC 7361 – 7368, with the purpose of managing and administering research and education programs funded by non-VA extramural funds.

2.0 DOCUMENT HISTORY

R&D Committee Approval Date	Version	Change	Reference Section(s)	Effective Date
07/25/2017	1.0	New Policy		07/26/2017

3.0 POLICY

- **A.** It is the policy of VAPHS that the VRFP will be the prime awardee for all non-VA awards (except for NIH awards) that are received to support research activities conducted at the VAPHS when 50% or more of the resources used by the project are VAPHS resources. This includes VAPHS research performed by VA staff or Working without Compensation (WOC) employees.
- **B.** The VAPHS Research Service will continue to administer any research funded by VA Office of Research and Development (ORD).
- **C.** The University of Pittsburgh will be the prime awardee of NIH awards for which the Principal Investigator holds both a paid University of Pittsburgh appointment and a VA appointment.
- **D.** In cases where VAPHS contributes less than 50% of the resources to non-VA project, another institution may be the prime awardee of the grant; however, a subcontract or subaward must be established with VRFP to support VA activities.
- E. VRFP shall continue to administer any and all private industry funds used to conduct research at VAPHS and require execution of approved Cooperative Research and Development Agreements (CRADA) that address sharing of intellectual property rights between the sponsor and the VA.
- **F.** Regardless of whether research is primarily administered by VRFP, the VA Research Service or another institution, any research that engages VAPHS in human research, or utilizes VA

- resources must be approved by the VA Research and Development Committee and relevant subcommittees.
- **G.** Exceptions to this policy will be granted only by the Medical Center Director after review of a written recommendation by the Associate Chief of Staff for Research and Development (ACOS/R&D).

4.0 DEFINITIONS

- **A.** <u>VA Resources</u> include property leased by and/or rented by the VA, the use of VA paid staff time (VA employee or IPA employees), laboratory and office space, VA computer hardware, VA clinical resources, VA research subjects, VA data and databases, and VA equipment.
- **B.** Non-VA Awards include research funding from federal (except for funding from the Department of Veterans Affairs), state or local governmental sources, non-profit foundations, pharmaceutical or other commercial or for- profit entities or donations from private individuals.

5.0 PROCEDURE

- A. At the time of grant submission or initial budget preparation for submission of non-VA grants, Principal Investigators and VA site investigators will consult with the VAPHS Research Business Manager and ACOS R&D regarding the proper administration of research funds. The Principal Investigator or VA site investigator must provide a description of research project, proposed budget, and utilization of any VA resources as defined above. In addition, specific information regarding any proposed recruitment of VA subjects, use of VA data, VA tissue banks or repositories, space, VA clinical resource or VA equipment must be detailed. Any requests for additional VA space required for the project must be made prior to application and new space will not be provided upon funding of the application unless there has been preapproval of the request. Information about the corresponding use of resources at the University or University of Pittsburgh Medical Center (UPMC), the University of Pittsburgh or other institutions must also be provided.
- **B.** Based upon these data, the ACOS/R&D will make the determination as to the appropriate institution to be the prime awardee and submit the application to the funding agency. The following criteria will be used:
 - (1) A project will be determined to use 50% or more of VAPHS resources if any of the following criteria are met:
 - a. 50% or more of the human subjects are recruited from VAPHS.
 - b. 50% or more of the space utilized for the project is VAPHS owned or leased space, or
 - c. 50% of more of the personnel are VA or Veterans Research Foundation of Pittsburgh employees or their effort on the project is funded by Veterans Research Foundation of Pittsburgh interagency personnel agreements (IPA).
- **C.** If the PI or site PI disagrees with this determination he may appeal to the Medical Center Director for reconsideration.

- **D.** A letter of support for the application will be provided by the ACOS/R&D. This letter will reflect the determination as to the appropriate prime awardee and will document any commitments for use of VA resources. Principal investigators are also encouraged to obtain additional letters of support from clinical service line vice presidents regarding access to and use of VA clinical resources.
- E. The R&DC must review and approve all research conducted at VA Pittsburgh conducted by VA investigators (serving on a compensated, work without compensation (WOC), or Intergovernmental Personnel Agreement (IPA) appointment) while on VA time, regardless of funding source. As part of its review of projects, the R&DC will review compliance with this policy and will not approve any research project that does not adhere to these guidelines.

6.0 RESPONSIBILITY

- A. Principal Investigator or site PI: Prior to submission of an application for funding of research activities to be conducted all or in part at VAPHS, the PI/site PI must consult with the VAPHS Research Business Manager and ACOS/ R&D regarding the proper administration of research funds. The Principal Investigator or VA site investigator must provide a description of research project, proposed budget, and utilization of any VA resources as defined above. In addition, specific information regarding any proposed recruitment of VA subjects, use of VA data bases, VA tissue banks or repositories, space, VA clinical resource or VA equipment must be detailed. Any requests for additional VA space required for the project must be made prior to application and submitted to the ACOS/R&D in writing. Information about the corresponding use of resources at the University or UPMC must also be provided.
- **B.** The ACOS/R&D must review the information regarding funding source and use of VA or other resources and make a determination as to whether the VAPHS Research Service, VRFP or the University should serve as the prime awardee. The ACOS/R&D will also determine if VRFP subcontracts should be established in the event that a non-VA/non-VRFP institution is the prime awardee. The ACOS/R&D is also responsible for completing appropriate letters of support indicating that the VA will provide resources to support the proposed research project.
- C. The VRFP is responsible for assisting the investigator in preparing applications, budgets and other documents required for application submission if it is to be the prime awardee. In the event that VRFP subcontracts are required, the VRFP will assist applicants with submitting budgets and other required documents to the prime institution.
- **D.** The VAPHS Medical Center Director will hear appeals to the decision made by the ACOS/R&D as to the proper institution to serve as the prime awardee and make appropriate decisions as to the proper institution to receive the prime award.
- **E.** The R&DC will review compliance with this Directive for all new projects and disapprove applications that are in violation of this policy.

7.0 REFERENCES

38 USC 7361-7368 VHA Handbook 1200.02 VHA Handbook 1200.17 CRADA Statute -15 U.S.C. §3710a

8.0 SIGNATURES

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Gretchen Haas, PhD Research and Development Committee Chair

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Steven H. Graham, MD, PhD Associate Chief of Staff for Research and Development