

SUBJECT: Administration of Research Funds

1. PURPOSE:

The purpose of this SOP is to define policy, procedure, and responsibilities of the MVAHCS Research Office with respect to administration of research funds, in accordance with the references.

2. DEFINITIONS:

ACOS/R: Associate Chief of Staff for Research

dACOS/R: Deputy Associate Chief of Staff for Research

IACUC: Institutional Animal Care and Use Committee

IPA: Interagency Personnel Agreement

IRB: Institutional Review Board

PI: Principal Investigator

RDC: Research and Development Committee

SRS: Subcommittee for Research Safety

VA-NPC: VA-affiliated Non-Profit Research Corporation, per 38 USC §§ 7361–7366

WOC: Without Compensation Employee

3. OVERVIEW:

This policy concerns administration of funds used in VA research, defined in VHA Directive 1200.02 as “[...] research that is conducted by VA Investigators (serving on compensated, WOC, or IPA appointments) while on VA time or on VA property. The research may be funded by VA, by other sponsors, or be unfunded. The research must be approved by the R & D Committee before it is considered VA research and before it can be initiated.” In contrast, non-VA research is research that meets all three of these criteria: Not conducted on VA time, not conducted on VA property, and not funded by VA.

This policy applies only to situations in which the VA investigator is the awardee, and not to instances in which a VA investigator is a consultant or co-investigator on awards to non-VA researchers. This policy does not apply to non-VA research conducted by investigators dually appointed at the VA and the affiliate University.

4. PROCEDURES:

Per VHA Directive 1200.02 § 8b, the following entities may administer funds for VA research, in accordance with applicable law and VA policy:

- a) VA medical centers administer all intramural funds (38 USC § 7303(b)), all funds in the General Post Fund earmarked for research (VHA Handbook 4721), and all funds received from another Federal agency under an interagency agreement (31 USC § 1535).
- b) VA-NPCs administer all funds that the corporations receive. Medical centers may transfer any funds not appropriated to the Department to a VA-NPC (VHA Handbook 1200.17). *NOTE: If approached by a potential donor or grantor interested in supporting VA research, a VA official may not direct the donor to deposit the funds with any entity other than VA or a VA-NPC.*
- c) Affiliated schools and universities and nonprofit organizations (other than a VA-NPC) may administer funds for VA research if authorized by a VA medical center Director.

- i) Pursuant to § 4c above, for VA investigators with an affiliate University faculty appointment, NIH funding will be administered by the affiliate University. For VA investigators without an affiliate University faculty appointment, NIH funding administration will be determined on a case-by-case basis by the ACOS/R. See Attachment A for current MVAHCS policy on NIH funds.

5. COMMUNICATION WITH INVESTIGATORS:

- a) The ACOS/R will send out an email message on a yearly basis reminding investigators about the rules governing administration of research funds (See § 4 and Attachment B).

6. REPORTING REQUIREMENTS FOR INVESTIGATORS:

- a) Initiation of Research: The forms necessary to initiate a research project require the investigator to indicate both source of funding and funding administrator. Investigators filing a protocol to be reviewed by the IRB, IACUC, SRS, or RDC will be required to answer this question to secure ACOS approval for their research.
- b) Continuing Review: All Continuing Review Forms require investigators to indicate if the funding administrator has changed (See § 7b.)

7. MONITORING PROCEDURES IN RESEARCH OFFICE:

- a) Initiation of Research: All forms for initiation of new research projects are reviewed and entered into the ePROMISE system by staff in the Research office who will forward for further review any studies in which the funding administrator is not clearly listed as VA, VA-NPC, or the affiliate University. The ACOS/R or the dACOS/R will review the study and determine if the funding administrator is allowable based on the guidelines above.
- b) Continuing Review: All Continuing Review Forms include a question asking whether the funding administrator (e.g. VA, University, VA-NPC) for the project has changed since the last continuing review. If a change is indicated, the PI is asked to identify the new funds administrator.
- c) If the funding administrator has changed to anything other than VA, VA-NPC, or affiliate University, Research staff who review these forms will forward the information to the ACOS/R or the dACOS/R to determine if the funding administrator is allowable as in § 7a.

8. REFERENCES:

VHA Directive 1200.02 “Research Business Operations” (06 September 2017)

VHA Handbook 1200.17 “VA Nonprofit Research and Education Corporations Authorized by Title 38 U.S.C. Sections 7361 Through 7366” (09 May 2017)

VHA Handbook 4721 “VHA General Post Funds - Gifts and Donations” (13 August 2018)

31 USC § 1535

38 USC § 7303(b)

38 USC §§ 7361–7366

9. **R&D COMMITTEE APPROVAL:** 05 April 2022
10. **REVISIONS:** Minneapolis Research Service SOP R&D-007 “Administration of Research Funds” (04 June 2019).
11. **EXPIRATION DATE:** N/A
12. **FOLLOW-UP RESPONSIBILITY:** Research and Development (R&D) Committee

ATTACHMENT A: MVAHCS Policy on Research Awards Administration

This policy is intended to balance 3 competing interests: the Minneapolis VA Health Care System (MVAHCS) maximizing its share of research-associated Veterans Equitable Resource Allocation (VERA) dollars and the strength of its affiliated non-profit corporation (NPC), the University of Minnesota Medical School maximizing its NIH ranking, and MVAHCS investigators maximizing their compensation.

The following 3 requirements apply to all investigators with a 5/8ths or greater MVAHCS appointment, for all studies considered to be VA research*:

1. All VA awards must be administered through the MVAHCS (i.e. research office or Center for Care Delivery and Outcomes Research, CCDOR).
2. All prime NIH grants must be administered through the Sponsored Project Administration (SPA) at the University of Minnesota. Occasional exceptions may be allowed by the Associate Chief of Staff for Research (ACOS).
3. All other grants (e.g. NIH subawards, Department of Defense, foundation, industry, Agency for Healthcare Research and Quality) must be administered through the NPC. Occasional exceptions may be allowed by the ACOS in cases where an exception will further a compelling institutional priority. In these cases, the ACOS will consider investigator status (research-funded employee or clinically funded), nature of the research project (involving VA patients/resources or only investigator time), and other relevant factors.

**VA Research is any research conducted by VA Investigators (serving on compensated, WOC, or IPA appointments) while on VA time or on VA property. The research may be funded by VA, by other sponsors, or be unfunded. All VA research MUST be approved by Research & Development Committee before any work begins.*

ATTACHMENT B: Example of Annual ACOS/R Email to Investigators

1. Funds in support of VA Research* from any entity except VA **must** be administered through one of the following organizations:
 - a) **VA-Affiliated Non-Profit Corporation** (Center for Veterans Education and Research (CVRE), for studies funded by industry, foundations, or federal agencies, including NIH subawards);
 - b) **Academic Affiliate University** (University of Minnesota, for NIH prime grants);
 - c) **Another non-profit organization**, only if *specifically authorized* by the MVAHCS Director.
2. Although we can respond to RFPs or other requests to collaborate on research activities with drug or device companies, as VA employees we are NOT allowed to solicit funds from these entities. These collaborative efforts must be formalized through CRADAs (Cooperative Research and Development Agreements) which are reviewed by VA attorneys and signed by the MVAHCS Director, who is the only one authorized to sign off on proposed commitments of the medical center to a study.

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