

SUBJECT: Non-Research Activities

1. PURPOSE:

As a service to MVAHCS employees, the Research Office at the MVAHCS will provide, on request, a determination that a proposed project is either a research or a non-research activity. This policy outlines the procedures to be followed to establish and document that determination.

2. DEFINITIONS:

ACOS/R: Associate Chief of Staff for Research

dACOS/R: Deputy Associate Chief of Staff for Research

Operations Activities: Administrative, financial, legal, quality assurance, quality improvement, and public health endeavors that are necessary to support VHA's missions of delivering health care to the Nation's Veterans, performing medical education, and contributing to national emergency response. Operations activities may or may not constitute research.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Generalizable knowledge: Information that expands the knowledge base of a scientific discipline or other scholarly field of study.

3. OVERVIEW:

Research is a systematic investigation designed to develop or contribute to generalizable knowledge within a scholarly field or scientific discipline. Systematic investigations may be undertaken for non-research purposes such as to improve the operational efficiency or quality of care within a hospital or health care system. These investigations are considered operations activities and are not subject to oversight by the Research & Development Committee.

An activity must meet these two criteria to be deemed a Non-Research Activity:

1. The activity is designed and implemented for internal VA purposes (i.e., its findings are intended to be used by and within VA or by entities responsible for overseeing VA); and
2. The activity is not designed to produce information that expands the knowledge base of a scientific discipline (or another scholarly field).

Activities usually considered research:

- Activities funded as research by the VA Office of Research and Development or any other sponsor
- Studies defined as clinical investigations under FDA regulations
- Studies that employ patient-level randomization
- Studies with placebo controls
- Studies that may place subjects at risk (except for privacy/confidentiality concerns)

Activities that do NOT constitute research:

- Public Health surveillance activities
- Scholarly activities such as biography, literary criticism, journalism that focus on the specific individual(s) about whom the formation is collected

4. **PROCEDURES:**

Delegation of Authority: The MVAHCS facility director delegates the authority to determine if a specific activity is research to one or more individuals who 1. has a research background and 2. has been trained to distinguish research from operational activities. The training consists of the candidate evaluating at least 7 requests for non-research determination under the direction of either the HRPP administrator or another senior researcher (e.g. ACOS/R or deputy ACOS/R).

Determination of the status of the proposed activity:

- a) Any MVAHCS employee in good standing may request that a proposed activity be evaluated for a determination of whether it constitutes research, as defined above.
- b) Requests must be received before the proposed activity begins. Research Service will not provide a retroactive determination. Any requests received after work has been conducted will be rejected without review and no determination letter will be provided.
- c) Requests must be submitted by email to vhaminresearchoffice@va.gov and include:
 - i) a brief description of the project (not to exceed one page – see sample in Appendix A); and
 - ii) a completed “Is it Research?” form (see sample in Appendix B)
- d) The request will be evaluated by an authorized individual.
 - i) If the activity is deemed to be research, the applicant will be instructed to submit the proposal for review through the IRB or RDC, as per usual procedures.
 - ii) If the activity is deemed NOT a research activity, a form letter indicating the determination (Appendix C) will be sent to the applicant, with a copy of the letter also being sent to the applicant’s direct supervisor. As a courtesy, the letter will include information on reporting and other requirements for “Operations Activities” (see sample in Appendix D). Research Service will not assume any responsibility for tracking or monitoring compliance with any of the consultation, documentation, publication or presentation requirements of findings from non-research operations activities.

5. **REFERENCES:**

VHA Program Guide 1200.21 “VHA Operations Activities That May Constitute Research” (09 January 2019)

6. **R&D COMMITTEE APPROVAL:** 07 January 2025

7. **RECISSIONS:** Minneapolis Research Service SOP R&D-019 “Non-Research Activities” (06 July 2021).

8. **EXPIRATION DATE:** N/A

9. **FOLLOW-UP RESPONSIBILITY:** Research and Development (R&D) Committee

QI Project: Biofeedback in the Chronic Pain Rehab Program (CPRP) at the Minneapolis VAMC

Background:

Chronic pain is a common condition within the VA population which can have a large impact on patient functioning and quality of life. There is support in the literature for the use of biofeedback in various pain conditions including tension type headaches, migraines, chronic pain, fibromyalgia and others as well as treatment of common comorbid conditions such as IBS and PTSD⁽¹⁾. Studies which demonstrate the benefits of multidisciplinary pain programs often include biofeedback as a modality utilized, however do not include details related to what factors equate to higher success rates with biofeedback or characteristics that would indicate more intensive biofeedback would be beneficial⁽²⁾.

Goal:

The goal of this project is to explore what specific biofeedback measures (heart rate variability (HRV), thermal, surface EMG, etc) are being improved through engagement in the MVAHCS 4 week intensive pain program (CPRP) and what areas could benefit from additional training during group sessions. In addition, we aim to identify patient characteristics that may suggest that more 1:1 biofeedback treatment would be indicated during the mainly group based program. The long term aim being to improve pain care at the Minneapolis VA.

Methods, including data to be collected:

We propose to conduct a chart review of veterans who attended the Pain Center four week outpatient behavioral program (CPRP) at the Minneapolis VA between January 2014 and January 2019. We will use the secure database of patients who attended CPRP to identify relevant cases and patient characteristics; subsequent data extraction will be performed by Lindsay Marth- occupational therapist (OT) and pain clinical specialist at the Minneapolis VA, Maggie Manning- pain center OT and Katie Norgard- OT student. We will review the medical records of each veteran using CPRS and extract the relevant biofeedback data. This will include the data collected at admission and discharge during 1:1 biofeedback evaluations and may include specific measures of HRV, thermal, surface EMG, respiratory rate, skin conductance, and pulse measures captured at various time points during the physiological profile. We will add this information to the data that is already being tracked by the CPRP database.

Analysis:

After we have extracted the data, we will use simple descriptive statistics to examine the difference in biofeedback results pre and post CPRP program and to analyze how these results compare to patient characteristics which may include age, primary pain condition, duration of pain, and pain self efficacy score.

Follow-up Plans:

These results will subsequently be used as a quality improvement analysis to adjust CPRP group education focus and 1:1 treatment appointments as indicated to maximize efficiency and effectiveness when treating patients with complex pain problems.

1. Yucha, C. & Montgomery, D. (2008). Evidence-Based Practice in Biofeedback and Neurofeedback. Wheat Ridge, CO : Association for Applied Psychophysiology and Biofeedback.

2. Townsend, CO, Kerkvliet, JL, Bruce, BK, et al. A longitudinal study of the efficacy of a comprehensive pain rehabilitation program with opioid withdrawal: Comparison of treatment outcomes based on opioid use status at admission. *Pain* 2008; 140: 177-189.

Is this project research?

Project title:

Primary contact for project:

Email address:

Phone:

Status at VA (e.g., MVAHCS staff, resident, trainee):

Supervisor:

IMPORTANT → Attach an abstract that describes the project background, purpose and methods.

	YES	NO
Is the Operations Activity designed (and/or implemented) for internal VA purposes in support of the VA mission(s) ? (i.e., Is the project primarily intended to improve local processes of care and/or patient outcomes?)		
<ul style="list-style-type: none"> ➤ Is the above question answered NO? If so, STOP HERE and contact IRBMN@VA.GOV for further review. ➤ Is the above question answered YES? Continue to next section: 		
<p><i>The following design characteristics are typically reflective of research, but in limited instances may be applicable in non-research endeavors. Please select YES or NO for each.</i></p>		
	YES	NO
1. Is the activity designed to produce information that expands the knowledge base of a scientific discipline (or another scholarly field)?		
2. Is the activity funded or supported as research ?		
3. Is the activity a clinical investigation as defined under Food and Drug Administration (FDA) regulations?		
4. Does the activity include double-blind interventions ?		
5. Does the activity include placebo controls ?		
6. Does the activity include prospective patient-level randomization to a clinical intervention not tailored to individual patient benefit ?		
7. Has the activity been supplemented or modified before, during, or after implementation in order to produce information to expand the knowledge base of a scientific discipline or scholarly field of study or otherwise contribute to generalizable knowledge ?		
8. Has the purpose of the activity changed so that it is now designed or intended to expand the knowledge base of a scientific discipline or scholarly field of study or otherwise contribute to generalizable knowledge ?		
To the best of my knowledge, the above is accurate. Signature of person conducting project	<input type="checkbox"/>	

Email this form and the abstract to IRBMN@VA.GOV.

**Department of
Veterans Affairs****Memorandum**

Date: Date

From: IRB Administrator, Minneapolis VA Health Care System

Subj: Title of Project

To: Employee

Cc: Direct Supervisor

The engagement on the part of the Minneapolis VA Health Care System as part of the referenced project has been reviewed and determined to not meet the definition of research. 45 CFR 46 102(l) defines research as “*a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge*”. *Generalizable knowledge*, as defined by VA Program Guide 1200.21 §4.a., is “*information that expands the knowledge base of a scientific discipline or other scholarly field of study*”.

1. Oversight by the IRB or other Research oversight committees *is not* required. Please be aware that for this project you do need to follow all VA privacy and data security rules governing clinical practice.
2. Research Service does not assume any responsibility for tracking or monitoring compliance with any VA guidance governing the conduct, publication, or presentation requirements of non-research (i.e. operations) activities. For more information on this guidance consult VA Program Guide 1200.21
3. Should anything in your project design change which may affect this non-research determination, please contact IRBMN@VA.GOV prior to implementing the change.
4. Please do not hesitate to contact me if there are questions or concerns regarding this determination.



for

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Publication and Presentation of Findings from Non-Research Operations Activities

(excerpted from VHA Program Guide 1200.21, Jan 19, 2017)

- a. Program Office Peer-Reviewed Publications.** Publication in peer-reviewed journals (including electronic peer-reviewed journals) of findings from non-research activities that were funded, mandated, managed, sponsored, or otherwise supported by a VHA Program Office, or that utilized Program Office data, should be documented as non-research by the relevant Program Office prior to publication.
- b. Other Peer-Reviewed Publications.** Publication in peer-reviewed journals (including electronic peer-reviewed journals) of findings from non-research activities other than those described in subparagraph 8a should be documented, prior to publication, of the non-research status of the activities by the lead VA author's Network Director (for Network operations activities) or Facility Director (for facility operations activities), or other individual designated in writing by the Network or Facility Director.
- c. Documentation Content.** Documentation content for peer-reviewed publications based on non-research activities should include:
 - (1) A copy of the manuscript to be published, including the name and VA duty station or institutional affiliation of each author and co-author.
 - (2) An attestation, signed by each VA author or co-author, that the reported findings were not derived, in whole or in part, from activities constituting research as described in this program guide.
 - (3) The signature of the documenting official. NOTE: A sample format for documentation of non-research activities is provided in Appendix A.
 - (4) Each VA author and coauthor should retain a copy of the documentation for a minimum of 6 years after publication and in accordance with any applicable records retention schedules

Example template for reporting documentation appears on following page (VHA Handbook 1200.21 Appendix A)

PROGRAM GUIDE: VHA OPERATIONS

**APPENDIX A:
[Sample Format for]
Documentation of Non-Research Activities For Publications Outside the VA**

Title of Proposed Publication:

Author Attestations

As an author of the publication referenced above (copy attached), I attest that the findings reported in the publication were not derived, in whole or in part, from activities constituting research as described in VHA Program Guide 1200.21. The project generating these findings was conceived and conducted as a non-research operations activity involving [PROJECT DESCRIPTION].

(Provide the following for each VA author.)

Lead Author Signature:

Date:

Lead Author Name:

VA Duty Station:

Co-Author Signature:

Date:

Co-Author Name:

VA Duty Station:

[ADD ADDITIONAL CO-AUTHORS' INFORMATION AS RELEVANT]

Attestation of Designated Official

As the Director or Director-designated representative of the VHA Program Office, VA Facility, or Network listed below, I have reviewed the publication and author attestation(s), and attest that findings reported in the publication did not arise from activities that constituted research as described in VHA Program Guide 1200.21.

Signature of Designated Official:

Date:

Name:

Title:

Program Office, Facility, or Network:

NOTE: Each VA author and VA coauthor should retain a copy of the documentation for a minimum of 6 years after publication and in accordance with any applicable records retention schedules.