



Student Projects: How to Avoid Compliance Issues
Office of Nursing Services Teleconference
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Tom Puglisi, PhD
Office of Research Oversight

Human Research Protection Requirements

38 CFR 16 –

Federal Policy (Common Rule) for the Protection of Human Subjects

VHA Handbook 1200.05 –

Requirements for the Protection of Human Subjects in Research

VHA Handbook 1058.05 –

VHA Operations Activities That May Constitute Research

VHA Handbook 1605.1 –

Privacy and Release of Information



VHA Handbook 1058.05 - VHA OPERATIONS ACTIVITIES THAT MAY CONSTITUTE RESEARCH

Research –

- A systematic investigation **designed** to develop or contribute to generalizable knowledge.

Generalizable Knowledge (for purposes of this Handbook) –

- Information that expands the knowledge base of a scientific discipline or scholarly field of study.
- Thus, systematic investigations **designed** to produce information to expand the knowledge base of a scientific discipline or scholarly field of study constitute **research**.



VHA Handbook 1058.05 - VHA OPERATIONS ACTIVITIES THAT MAY CONSTITUTE 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, conducting research and development, performing medical education, and contributing to national emergency response.
- May include **Nursing Service** evaluation projects
- Operations activities **may or may not** constitute research.



VHA Handbook 1058.05 - VHA OPERATIONS ACTIVITIES THAT MAY CONSTITUTE RESEARCH

Operations Activities that ARE NOT Research –

- Activities that are not **designed** to produce information that expands the knowledge base of a scientific discipline (or other scholarly field) do not constitute research.
- An operations activity does **not** constitute research if **both**:
 - (1) The activity **is designed** and/or 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 other scholarly field).



VHA Handbook 1058.05 - VHA OPERATIONS ACTIVITIES THAT MAY CONSTITUTE RESEARCH

Non-Research Operations Activities –

- Quality assessment and quality improvement activities designed for internal VA purposes
- Routine data collection and analysis for operational monitoring, evaluation, and program improvement purposes
- May include **Nursing Service** evaluation projects



VHA Handbook 1058.05 - VHA OPERATIONS ACTIVITIES THAT MAY CONSTITUTE RESEARCH

Operations Activities that ARE Research –

- Any operations activity whose conceptualization, plan, or implementation is **supplemented or modified** in order to produce information expanding the knowledge base of a scientific discipline or scholarly field of study.
- **Modifying or adding to** an existing non-research activity to produce information expanding the knowledge base of a scientific discipline or scholarly field of study.
- Analyzing non-research data in a **different way** to produce information expanding the knowledge base of a scientific discipline or scholarly field of study.



VHA Handbook 1058.05 - VHA OPERATIONS ACTIVITIES THAT MAY CONSTITUTE RESEARCH

Use of Operations Data for Research

- Data collected for non-research operations may subsequently be accessed and used for research
- If such data are accessed and analyzed differently in order to expand the knowledge base of a discipline (ie, contribute to generalizable knowledge), then this access and use constitutes research.
- An activity designed as non-research operations becomes research if supplemented or modified in order to expand the knowledge base of a discipline.



VHA Handbook 1058.05 - VHA OPERATIONS ACTIVITIES THAT MAY CONSTITUTE RESEARCH

Activities that ARE ALWAYS Research –

- Activities funded or otherwise supported **as research** by the Office of Research & Development (ORD) or any other entity.
- Clinical investigations as defined under Food and Drug Administration (FDA) regulations

Activities that ARE ALMOST ALWAYS Research –

- Activities using:
 - Double blind interventions
 - Placebo controls
 - Prospective patient-level randomization to clinical interventions not tailored to individual patient benefit



VHA Handbook 1058.05 - VHA OPERATIONS ACTIVITIES THAT MAY CONSTITUTE RESEARCH

CONSULT and DOCUMENT BEFORE the Project Begins

- Do **not** access **any** Protected Health Information (PHI) or other identifiable private information
 - HIPAA requires an authorization, or waiver of authorization, to access PHI for research purposes (even if the investigator has access for clinical purposes)
- If the VA Facility has a **Research Program**:
 - Contact the Research Service and/or the Institutional Review Board (IRB)
 - Affiliation Agreement with the Sponsoring Educational Institution



VHA Handbook 1058.05 - VHA OPERATIONS ACTIVITIES THAT MAY CONSTITUTE RESEARCH

CONSULT and DOCUMENT BEFORE the Project Begins

- If the VA Facility **does not** have a **Research Program**:
 - The project **cannot** constitute research – but an Operations Project may be permitted
 - Facility Director or designee may approve the project
 - A written agreement with the Sponsoring Educational Institution may be required



VHA Handbook 1058.05 - VHA OPERATIONS ACTIVITIES THAT MAY CONSTITUTE RESEARCH

Documentation Requirements

- Publication (or presentation) of findings from non-research operations activities **does not** itself constitute research.
- Publication **in peer-reviewed journals** of findings from non-research activities **REQUIRES** documentation prior to publication by
 - Relevant **VHA Program Office** if funded, mandated, managed, sponsored, or supported by a VHA Program Office or using **Program Office data**
 - Otherwise, designated Facility or Network official (depending on scope of project)



VHA Handbook 1058.05 - Sample Format for Documentation of Non- Research Activities

Title of Proposed Publication:

Author Attestation

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 Handbook 1058.05.

Provide for each VA Author and Co-Author

Author Signature:

Date:

Author Name:

VA Duty Station:

Signature of Designated Official:

Date:

Name

Title:

Program Office or Facility:

Note: Each VA author and coauthor must retain a copy of the documentation for a minimum of 5 years after publication and in accordance with any applicable records retention schedules.





Project Planning

Steps **BEFORE** Beginning the Work

K. Sue Haddock, RN, PhD

Associate Chief of Staff – Research (151)

WJB Dorn VA Medical Center

Know your facility process

Dorn VA's Process – Step 1

Develop a one page project description

- Purpose
 - For a class/academic program?
 - For an EBP or QI project?
 - For a system redesign project?
- Objectives – what you want to accomplish
- For VA or beyond?
- Brief description of methods
 - Who will be involved – patients, employees, etc.
 - What will you measure or record?
 - Risks?

The Process – Step 1a

For a class/academic program?

- Contact the VA Education Office
- Ensure an Affiliation Agreement exists
- Project may require IRB review at the Affiliate
- Affiliate IRB does **NOT** replace VA IRB

The Process – Step 2

- Contact your Research Office
 - Share description with the IRB Coordinator
 - Request determination of type of review needed
 - Complete a Differentiating Research from Other Projects Form
 - Submit form to ACOS-R

The Process – Step 3

- Determinations
 - Not research, proceed with project
 - Research – submit packet for IRB
 - Exempt
 - Expedited Review
 - Full Board Review



Working with your IRB

Kathryn Rugen, PhD, FNP-BC

Associate Chief Nurse for Education & Research

Jesse Brown VAMC

Chicago, Illinois

What is IRB?

- An **Institutional Review Board (IRB)** is a [committee](#) that has been formally designated to approve, monitor, and review [biomedical](#) and [behavioral research](#) involving [humans](#) with the aim to protect the rights and welfare of the [research subjects](#). In the [United States](#), the [Food and Drug Administration](#) (FDA) and [Department of Health and Human Services](#) (specifically [Office for Human Research Protections](#)) regulations have empowered IRBs. An IRB performs critical oversight functions for research conducted on human subjects that are ***scientific, ethical, and regulatory.***

Typically require IRB review

- Pilot studies involving individuals that are performed to refine study methodology;
- Human genetic research;
- **Retrospective medical record review;**
- **Masters thesis or doctoral dissertation;**
- Surveys, interviews or observations of individuals (including use of the Internet);
- Data or tissue banking; and
- Two or more case reports.

Types of Review

- **Exempt**
- **Expedited**
- **Full board review**



Exempt categories

- **Access to specified public use datasets**
- **Research limited to the use of commercial, de-identified non-human embryonic stem cell lines;**
- **Case reports involving the observation of a single patient whose novel condition or response to treatment**
- **Research which is limited to death records, autopsy records, or cadaver specimens**
- **Course-related activities designated specifically for educational or teaching purposes, where data is collected from and about human subjects as part of a class exercise or assignment but are not intended for use outside of the classroom (not intended to develop or contribute to generalizable knowledge)**
- **Research involves taste and food quality evaluation**

Exempt Examples

- **2 DNP capstone projects**
 - **Simulation-based Interprofessional Education in the Emergency Room**
 - **Observation of Medication Interruptions pre and post intervention**

Expedited Categories

- **Clinical studies of drugs for which a n investigational new drug application is not required and medical devices which are exemption application is not required or device is approved and being used in accordance with it approved labeling**
- **Collection of blood samples from healthy non-pregnant adults**
- **Prospective collection of biological specimens for research by noninvasive means**
- **Collection of data through noninvasive means routinely employed in clinical practice**
- **Research involving materials that have been or will collected for non-research purposes**
- **Collection of voice, video, digital or image recordings**
- **Research on individual or group characteristics or behavior (some types may be exempt)**

Expedited Examples

- **2 DNP capstone projects**
 - **Outcomes of an APRN run HF clinic**
 - **Inpatient Smoking Cessation: Bringing the program to the patient**

Full Board Review

- **Greater than minimal risk**
- **Minimal risk means that the probability and magnitude of the harm or discomfort anticipated are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.**

Training

- **Human Research Protections training every other year.**
www.citiprogram.org.
- **VHA Privacy Annually**
- **VA Information Security Awareness and Rules of Behavior Annually**
- **Information Security 201 training for Research and Development (One time Only Requirement)**

Plan for time

- **Required training takes up to 8 hours**
- **Filling out paperwork may take weeks**
- **Expedited review, may take 2+ weeks for response**
- **Plan for modifications and resubmission**
- **Total 6-8 weeks**