

# San Francisco VA Medical Center Research Determination

**Definition of activities that may or may not constitute research (See Addendum A)**  
[\(VHA Handbook 1058.05, Oct 28, 2011\)](#)

**Project submission for non-research operations activities determination:**

<b>Project Title:</b>			
<b>SFVAMC Project Leader:</b>		<b>Phone/Pager:</b>	
		<b>Email:</b>	
<b>SFVAMC Project Contact (if different than above):</b>		<b>Phone/Pager:</b>	
		<b>Email:</b>	
<b>Overall Project Leader (if different than SFVAMC PL):</b>		<b>Phone/Pager:</b>	
		<b>Email:</b>	

<b>Project Summary</b> <i>(please provide a paragraph describing the purpose of the project)</i>
<b>Project Procedures</b> <i>(please provide an overview of the procedures for the project. You may attach a more detailed project plan to this form)</i>

<b>Answering "NO" to either of the below questions constitutes RESEARCH and the project protocol must be submitted to IRB for approval</b>	
<b>Study Design</b>	<b>Response and Justification</b>
Is the Operations Activity <b>designed</b> (and/or implemented) for <b>internal VA purposes in support of the VA mission(s)</b> ?	<input type="checkbox"/> Yes <input type="checkbox"/> No  <b>If yes, please provide justification here:</b>
Are the activity's <b>findings designed to be used by and within VA</b> (or by entities responsible for overseeing VA)?	<input type="checkbox"/> Yes <input type="checkbox"/> No  <b>If yes, please provide justification here:</b>
<b>Answering "YES" to any of the below questions constitutes RESEARCH and the project protocol must be submitted to IRB for approval</b>	
Is the activity <b>designed</b> for the purpose of contributing to <b>generalizable knowledge</b> ?	<input type="checkbox"/> Yes <input type="checkbox"/> No  <b>If no, please provide a well-justified operations need for the design of the project here:</b>

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Is the activity <b>designed</b> for the purpose of expanding the <b>knowledge base</b> of a <b>scientific discipline</b> or scholarly field of study?	<input type="checkbox"/> Yes – designed as research <input type="checkbox"/> No – designed as a non-research operations activity
Is the activity funded or supported <b>as research</b> ?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the activity a <b>clinical investigation</b> as defined under Food and Drug Administration ( <b>FDA</b> ) regulations?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the activity include <b>double-blind interventions</b> ?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the activity include <b>placebo controls</b> ?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the activity include <b>prospective patient-level randomization</b> to a clinical intervention <b>not tailored to individual patient benefit</b> ?	<input type="checkbox"/> Yes <input type="checkbox"/> No

<b>Individuals conducting non-research operations activities (as well as the relevant program office, network, or facility) incur a particular obligation to ensure that the safety, rights, and welfare of affected patients and staff are appropriately protected.</b>	
<b>Risks and Prevention</b>	<b>Response/Comment</b>
Have the safety, rights and welfare of affected patients and staff been thoroughly evaluated?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Can it be stated that <b>NO</b> potential risks (beyond nominal risks) have been identified? (This includes physical, psychological, social, financial, privacy, confidentiality and other reasonable foreseeable risks associated with project participation or inclusion).	<input type="checkbox"/> Yes , <b>Please explain:</b>  <input type="checkbox"/> No, <b>Discuss appropriate protections to mitigate risks:</b>

By signing this document the signer affirms that the information above is the truth to the best of their knowledge at this time. It has been acknowledged by the signer that documentation of non-research status is (i) required prior to peer-reviewed publication, and (ii) encouraged whenever non-research status may be questioned.

SFVAMC Project Leader: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
(Printed name)

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The project named below has been reviewed by the following authority and it has been determined that this Operations Activity is NOT RESEARCH. Institutional Review Board (IRB) and VA Research and Development Committee (R&DC) approval are not required.

Project Title:

SFVAMC Project Leader:

Facility Director (or designee)

Printed name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

If signed by a designee, print Facility Title of designee here:

**NOTE: Per VHA Handbook 1058.05 (10/28/2011), Publication or presentation outside VA of findings from non-research operation activities or other non-research activities does not, in and of itself, constitute research. However, further dissemination of this information requires additional documentation and approval which can be obtained by completing Addendum B.**

For continued approval of this project as a non-research operation, the project/operation cannot be modified in a way in which it will then constitute research. This can be determined by assessment of the questions below:

Study Design	Justification/Explanation
Has the activity <b>AS DESCRIBED AND APPROVED ABOVE</b> been <b>supplemented or modified before, during, or after implementation</b> in order to produce information to expand <b>the knowledge base of a scientific discipline</b> or scholarly field of study or otherwise <b>contribute to generalizable knowledge</b> ?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Has the purpose of the activity <b>changed</b> so that it is <b>now designed or intended</b> to expand the <b>knowledge base of a scientific discipline</b> or scholarly field of study or otherwise <b>contribute to generalizable knowledge</b> ?	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Answering "YES" to any of the above questions constitutes RESEARCH and the project protocol must be submitted to IRB for approval</b>	

As above, if at any time the project changes in such a way that these questions are affirmed, then it must be formally re-submitted for review as per facility policies and procedures.

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## Addendum A

### Definition of activities that may or may not constitute research

[\(VHA Handbook 1058.05\)](#)

**Operations Activities:** Operations activities are certain 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. **Operations activities may or may not constitute research.**

**Non-research Operations Activities:** 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 when it is designed and implemented for internal VA purposes. **Thus, quality assessment and quality improvement activities including routine data collection and analyses associated with VA activities such as case management and care coordination, policy and guideline development, benchmarking activities and medication use evaluations do not typically constitute research in and of themselves.**

**Operations Activities Constituting Research:** An operations activity may or may not constitute research depending on whether the activity is designed to produce information to expand the knowledge base of a scientific discipline (or other scholarly field of study). The activity is designed to contribute to generalizable knowledge if the conceptualization, plan or implementation of the activity is supplemented or modified in order to produce information that expands the knowledge base of a scientific discipline (or other scholarly field of study). **For example, if an operations activity is designed to include collecting "extra" data or performing "extra" analyses not needed for internal operations purposes in order to produce information that expands the knowledge base of a scientific discipline (or other scholarly field of study), then the activity constitutes research.**

**Research:** Research is a systematic investigation (including research development, testing, and evaluation) designed to develop or contribute to generalizable knowledge. **Thus, for purposes of this Handbook, and in accordance with the definition of generalizable knowledge, research may be defined as a systematic investigation designed to produce information to expand the knowledge base of a scientific discipline (or other scholarly field of study).** *NOTE: Research typically involves the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question to expand the knowledge base of a field of study.*

**Generalizable:** For purposes of this Handbook, generalizable knowledge is information that expands the knowledge base of a scientific discipline or other scholarly field of study. Systematic investigations designed to develop or contribute to generalizable knowledge constitute research. Thus, systematic investigations designed to produce information to expand the knowledge base of a scientific discipline or other scholarly field of study constitute research.

**Systematic Evaluation:** A systematic investigation is an activity that is planned in advance and that uses data collection and analysis to answer a question. Although research must include systematic investigation, non-research operations activities also include systematic investigation to ensure reliable outcomes. **Systematic investigation does not, in and of itself, define research.** *NOTE: Examples of systematic investigations that may or may not constitute research, include (but are not limited to) activities involving questionnaires or surveys; observations; focus groups; interviews; analyses of existing data; analyses of biological specimens; medical chart reviews; epidemiologic reviews or analyses; program evaluations; and quality assessment, quality improvement, and quality management.*

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## Addendum B

### San Francisco VA Medical Center 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 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:

Co-Author Signature:

Date:

Co-Author Name:

VA Duty Station:

Co-Author Signature:

Date:

Co-Author Name:

VA Duty Station

#### Attestation of Designated Program Office or Facility Official

As the designated representation of the VHA Program Office or Facility listed below, I have reviewed the activities reported in the publication and attest that these activities did not constitute research as described in VHA Handbook 1058.05.

Signature of Designated Official

Date:

Printed Name

Title

San Francisco VA Medical Center

*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.*