

VA Salt Lake City Health Care System (VASLCHCS)
CHECKLIST: OPERATIONAL ACTIVITY, QUALITY ASSURANCE/IMPROVEMENT (QA/QI) OR RESEARCH?

Instructions: In accordance with [VHA Handbook 1058.05](#), “VHA Operations Activities¹ That May Constitute Research”, VASLCHCS employees may conduct certain operations activities which may or may not constitute research. Whenever the research versus non-research status of an operations activity may be in question, a determination of the status must be made.

Please submit this form to the VASLCHCS Research Office by sending a scanned, signed copy to caroline.phinney@va.gov. Please reference the [VHA Operations Activities that May Constitute Research](#) decision tree for an overview of how a decision between research and non-research activities is determined.

Project Title: Brain Injury Data Sharing

Responsible Project Lead: Jacob Kean, PhD

Email: jacob.kean@va.gov

Department: IDEAS

Role/Title: Research Scientist

CONDITIONS TO BE CONSIDERED FOR DETERMINATION OF RESEARCH VS. NON-RESEARCH OPERATIONS		
NOTE: If answers to questions 1 through 10 are marked “ TRUE ” the project is more than likely not research. <i>For answers that are marked “false,” please provide an explanation in the text fields below regarding how this project may still be QA/QI.</i>	TRUE	FALSE
1) The project is designed and/or implemented for internal VA purposes in support of the VA mission(s).	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2) The findings are designed to be used by and within VA (or by entities responsible for overseeing VA).	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3) The project is not designed for the purpose of contributing to generalizable knowledge. ²	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4) The project is not designed to produce information that expands the knowledge base of a scientific discipline (or other scholarly field). ²	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5) The project is not funded or otherwise supported as research by the Office of Research and Development (ORD) or any other entity.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6) The project does not involve administration, dispensing and/or use of any drugs, devices and/or biologics.	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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7) The project does not involve design characteristics typically reflective of research, e.g.: <ul style="list-style-type: none"> • Double-blind interventions • Use of placebo controls • Prospective patient-level randomization to clinical interventions not tailored to individual benefit 	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8) The proposal includes provisions to ensure that the safety, rights, and welfare of patients and staff are appropriately protected as applicable. ³	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9) The project is not intended to meet the requirements set forth by a masters program (or other university level degree program) that requires “research” be conducted.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
10) The activity will not be 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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>

PROJECT DESCRIPTION	
Reason for Project	<input type="checkbox"/> Locally initiated <input checked="" type="checkbox"/> Mandated by Joint Incentive Fund
In the following fields, please provide enough information about the proposed project that a reviewer understands why and how the work will be performed. Please define all acronyms.	
<p>Objective(s): <i>What is the purpose of the project? What are the issues/questions being addressed and why?</i> The goal of the proposed project is to leverage DAVINCI and PCORnet infrastructures to link DoD, VHA and private sector data streams to establish a patient-centric, longitudinal federated data source across the complete care horizon for service members with TBI. A federated data source like the one created by this project allows DoD/VA an uncommon perspective: a look into the civilian sector care practices for Servicemembers and Veterans, which is not a general description but a view of the care at the level of the individual – akin to the view of a business who learns what its customers buy from a competitor. The power of this information holds enormous potential to guide future planning and provision of services, improve patient satisfaction, and inform policy development to benefit Servicemembers and Veterans with TBI.</p>	
<p>Methodology: <i>How will the work be conducted and where? Who will be involved? Please be detailed in how the work will be conducted including data collection and analyses.</i> Goals: 1. Support cross-system identification of TBI care needs and cooperative balancing of system resources to improve access to care for service members and veterans with TBI. 2. Enable cross-system, within-patient comparisons and support between-group comparisons on national outcomes and benchmarks between VA and DoD systems and private-sector counterparts.</p> <p>Project Plan:</p>	

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Facilitate DaVINCI uptake of Armed Forces Health Surveillance Center (AFHSC) and VA National Physical Medicine and Rehabilitation Program Office/VACO TBI surveillance file and VA TBI Registry, respectively.

Create harmonized VA/DoD TBI data file that includes unique cases.

Identify DoD and VA data sources, including enrollment, demographics, and inpatient, outpatient, and laboratory utilization, from DaVINCI data stores for each diagnosed TBI case.

Generate an irreversible anonymous (“hash”) code from each Servicemember or Veterans’ identifying information (e.g., SSN, first name, last name, and date of birth).

Provide “hash” code to the lead network informaticists at REACHnet, the New Orleans-based PCORnet node.

Receive REACHnet network IDs for records matching the “hash” coded identifiers.

Evaluate the federated data source linkage using descriptive statistics.

Characterize Servicemembers’ and Veterans’ DoD, VA and civilian sector healthcare use and diagnoses.

Report the characterization of utilization and descriptions of outcomes and apply business operations and medical outcomes queries speaking directly to the JIF identified aims.

Project Team:

Mary Jo Pugh, Megan Vannemann, Scott DuVall, Jay Tucker, Lidia Kridelbaugh, Jacob Kean

Impact/Significance: *What will be done with resulting information?* We are developing a how-to protocol describing the steps that we took to complete the linkage and the resulting population overlap.

Signature of Responsible Project Lead⁴: _____ **Date:** 06-23-2020

Print Name of Responsible Project Lead: Jacob Kean

FOR VASLCHCS OFFICE USE ONLY BELOW THIS LINE

VASLCHCS ACOS/R&D Determination:

☐ **Not Research.** The ACOS/R&D has determined that based on the responses above and the proposed project description, approval by an IRB or other review committee is not needed. The project is considered to be non-research VHA operations activity. If the results of this project are presented or published they cannot be presented as research, nor does it have research approval.

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☐ **Research Project.** As designed this project requires review by an IRB or other appropriate review committee *prior* to initiation. Please refer to caroline.phinney@va.gov for guidance.

☐ Additional information is needed to make a determination. See comments below.

ACOS/R&D Comments:

VASLCHCS ACOS/R&D Signature: _____ **Date:** _____

Reference:

[VHA Handbook 1058.05](#): VHA Operations Activities That May Constitute Research

¹Examples of operations activities include activities designed for internal VA purposes, including routine data collection and analysis for operational monitoring, evaluation and program improvement purposes, VHA system redesign activities, patient satisfaction surveys, case management and care coordination, policy and guidance development, benchmarking activities, Joint Commission visits and related activities, medical use evaluations, business planning and development such as cost-management analyses, underwriting, and similar activities.

²Any change made before, during, or after implementation that results in an intent to expand the knowledge base of a scientific discipline or scholarly field of study, or otherwise contribute to generalizable knowledge, constitutes research and must be submitted to an IRB or other pertinent review committee.

³Potential risks (including physical, psychological, social, financial, privacy, and confidentiality, and other foreseeable risks) associated with non-research operations should be evaluated and appropriate protections established to mitigate them.

⁴Please note it is the responsibility of this individual and/or each VA author and coauthor (in cases of publication) to retain a copy of this form signed by the ACOS/R&D for a minimum of 5 years after publication and in accordance with any applicable records retention schedules. A copy will also be retained by Research Service.