

Kansas City VA Medical Center Research Form
Quality Assurance/Quality Improvement Project Worksheet

Section 1: Project and Reviewer Identification

Program Office or Service	GENERAL SURGERY
Title of Project/Operations Activity	Adult Intussusception: Retrospective Review Diagnosis and management.
Project Manager	Santosh Shenoy
Service Chief	ANIL . BAHADURSINGH

Section 2: Operations Activity Review

	YES	NO
1. The primary intent of the project is not peer reviewed publication and if publication of the result was prohibited, the project would still have merit as a QA/QI effort	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. There is a documented commitment in advance of data collection, to a corrective plan given any of a number of study outcome	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. The responsible staff member has both clinical supervisory responsibility and the authority to impose a corrective plan based on the outcome of the project	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. The project does not involve prospective assignment of patients to different procedures or therapies based on a predetermined plan such as randomization	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5. The project does not involve a "control group" in whom therapeutic or study intervention is intentionally withheld to allow an assessment of its efficacy	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. The project does not involve the prospective evaluation of a drug, procedure or device that is not currently approved by the FDA for general use (including "off-label" indications)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7. Human participants will not be exposed to additional physical, psychological, social or economical risks or burdens (beyond patient satisfaction surveys) in order to make the results of the project generalizable	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8. Adequate protections are in place to maintain confidentiality of the data to be collected and there is a plan for who can access any data containing patient identifiers	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9. The project is likely to improve patient care activities and/or outcomes at the Kansas City VA Medical Center alone or as a part of the VISN-15 or VHA	<input checked="" type="checkbox"/>	<input type="checkbox"/>
10. The purpose of the activity is <u>not</u> to expand the knowledge base of a scientific discipline or scholarly field of study or otherwise contribute to generalizable scientific knowledge .	<input checked="" type="checkbox"/>	<input type="checkbox"/>

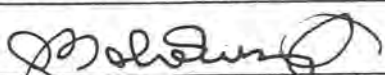
Section 4: Service Chief's Determination


The Service Chief makes one of the following final determinations:	
<input checked="" type="checkbox"/>	This qualifies as a QA/QI Project (In order for the study to be qualified as QA/QI project/effort, the answers to all above questions must be "Yes".)
<input type="checkbox"/>	This does not qualify as a QA/QI project and constitutes research (If one or more answers is "No" then this operations activity constitutes research. The activity may not be conducted until approval has been granted by the Institutional Review Board and the Research

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	& Development Committee).
<input type="checkbox"/>	Determination has been deferred pending consultation with ORD/ORO.

Section 5: Attestation and signature

I attest that this document has been completed in conformity to the requirements of VHA Handbook 1058.05 and that it accurately characterizes the attached operations activity. I acknowledge that I am required by VHA Handbook 1058.05 to retain a copy of this document and all attachments for a minimum of five years and in accordance with any applicable records retention schedules.	
Signature of Service Chief or designee	Date
 ANIL BAHADURSINGH	8-10-11


 Sanjosh Shetty

Definitions:

Generalizable Knowledge: For purposes of this VHA Handbook 1058.05, 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 constitutes research.

Clinical investigations: As defined under Food and Drug Administration (FDA) regulations clinical investigators include studies of FDA-regulated drugs, devices, and biologics, regardless of whether the investigation or comparison requires an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE), and regardless of whether the investigation or comparison involves approved or unapproved (i.e., off-label) uses.

Systematic Investigation: 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.

Excluded Activities as detailed in VHA Handbook 1058.05: Routine data collection and analysis associated with the following VA activities do not typically constitute research, in and of themselves:

(1) Quality assessment and quality improvement activities designed for internal VA purposes (as determined by the relevant Program Office, VHA Network, or VHA facility per par. 6), including routine data collection and analysis for operational monitoring, evaluation, and program improvement purposes. Examples include, but are not limited to the routine data collection and analysis activities of the following VA programs:

- (a) All Employee Surveys, Voice of VA Surveys, and similar Surveys;
- (b) Cardiac Assessment Reporting and Tracking System (CART);
- (c) External Peer Review Program (EPRP);
- (d) Home and Community Based Care Quality Initiative;
- (e) Inpatient Evaluation Center (IPEC);
- (f) Mental Health Program Evaluation Center (Northeast Program Evaluation Center, Program Evaluation