Quality Assurance

vs.

Research

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# Quality Assurance vs. Research

## What is the Difference Between Quality Assurance and Research?

Quality assurance (QA) and research projects have many attributes in common, such as a rigorous approach to methodology, analysis and interpretation of data. However, many individuals have legitimate concerns when trying to distinguish the differences. The guidelines provided in this document are intended to lead researchers and evaluators as they determine whether their proposed activity constitutes research or QA. Ultimately, a decision on a Research Ethics Board (REB) application submission is determined.

## Definitions

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

Research asks the question “What…?”

**Quality Assurance**:Activities are undertaken to measure the effectiveness of a process, program or service, and the results of the activity are most often shared with individuals associated with the process, program or service being evaluated.

[TCPS2, Article 2.5](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/) “Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review.”

Quality Assurance asks the question “How are we doing?”

**Systematic Investigation:** An activity that is planned in advance and that uses data collection and analysis to answer a question. Although research must include systematic investigation, many non-research activities also include a systematic investigation. The systematic investigation does not, in and of itself, define research.

## Determining Differences

**It is the responsibility of the individual administering the project to ensure that appropriate judgment has been reached in regard to the requirement for REB review.** If your study is not research and does not require ethics review, it is still your moral imperative to ensure the respect for human dignity and to adhere to ethical standards, all relevant local organization policy and any other applicable standards of conduct associated with the activities or profession of practice.

If your study requires HREB review, it is the responsibility of the researcher to obtain ethics clearance prior to beginning the research. Note that retroactive ethics approval or clearance cannot be granted.

The following table will give you general guidance in categorizing QA and research. Take a moment to read through the table and answer whether or not your project matches the left or right column.

|  |  |
| --- | --- |
| **Quality Assurance** | **Research** |
| Quality assurance is a systematic approach to the review of practices and procedures in order to identify possible improvements and to provide a mechanism for bringing them about. | Research is a systematic investigation, which aims to increase the sum of knowledge. It usually involves the testing of a hypothesis or theory. |
| Quality assurance raises questions that might be answered by further research. | Research generates the knowledge that may be tested in quality assurance. |
| Quality assurance is a test of whether things are being done as well as they could/should be. It compares current practice with current standards/best practices. | Research is the act of finding the correct thing to do and identifying the most effective form of intervention. Research may help determine what is or might be best practice. |
| Quality assurance does not consider a completely new treatment but tests the adherence to a treatment that is considered to be best practice. | Research may involve a completely new treatment and usually investigates an area where there is no knowledge of the best practice. |
| Quality assurance results are local to the participant population/location/time. | Research results can be generalized to a wide population. |
| Quality assurance results are generally for internal information | Research results are generally of external information. |
| Quality assurance requires the participation of site-specific people and departments. The data relates only to the specific site or area. | Research requires the participation of patients and others outside of the specific site or area so that a representative sample can be obtained and the results generalized. |
| Quality assurance is a continuous and on-going process, which includes a follow-up after a period of time. | Research often will have a defined endpoint, which is researched when an adequate sample size has been obtained. |
| Quality assurance results are disseminated at the local or internal level to educate and publicize how to achieve best practice. | Research results are published universally to share the knowledge with a wide user base of persons. |

Some projects are not easily characterized as quality assurance/program review or research, and there isn’t any simple rule or single characteristic that differentiates quality assurance and research studies. The REB views these types of studies as existing on a continuum. That being said, the way we categorize projects may need to be further dissected to support decision making. The table on the following page helps to show the different sections of a project and how they can be better suited to one side of the spectrum or the other.

|  |  |  |
| --- | --- | --- |
| **Human Subjects** | **Research** | **Quality Assurance** |
| Purpose | Designed to develop or contribute to generalizable knowledge | Designed to implement knowledge and assess a process or program as judged by established/accepted standards |
| Starting Point | To answer a question or test a hypothesis | To improve performance |
| Design | Follows a rigid protocol that remains unchanged throughout the research | Adaptive, iterative design |
| Benefits | Might or might not benefit current subjects; intended to benefit future subjects | Directly benefits a process, system or program; might or might not benefit subjects |
| Risks | May place subjects at risk and states as such | By design, does not increase patient’s risk, with exception of possible privacy/confidentiality concerns |
| Participant Obligation | No obligation of individuals to participate | Responsibility to participate as component of process, system or program; however, no direct obligation |
| Endpoint | Answer a research question | Promptly improve a program, process or system |
| Data Collection | More intensive systematic data collection | Less intensive systematic data collection |
| Analysis | Statistically prove or disprove hypothesis | Compare program, process or system to established standards; can include statistical analysis |
| Adoption of Results | Most often, little urgency to disseminate results quickly | Results rapidly adopted into local process, system or program |
| Publication/Presentation | Obliged to share results | Encouraged to share systematic reporting of insights |

## When Quality Assurance Transforms into Research

If a researcher knows at the beginning of a study that it will serve two purposes – QA and research – then the study must undergo REB review before it commences. The study falls within the scope of TCPS2 (considered the secondary use of information):

[TCPS2, Article 2.5](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/) “If data are collected for the purposes of such activities but later proposed for research purposes, it would be considered secondary use of information not originally intended for research, and at that time may require REB review in accordance with this Policy. Refer to [Section D](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter5-chapitre5/#toc05-1d) of [Chapter 5](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter5-chapitre5/ch5_en) for guidance concerning secondary use of identifiable information for research purposes.”

If the study you are undertaking is a borderline case, or if you are still unsure and would like a more formal opinion, please contact the REB for decision making support. It is best practice to inquire rather than make assumptions. Examples of projects that could be both QA and research include:

* Implementation of a new point-of-care testing device to improve patient care and analysis of data to establish scientific evidence of the intervention’s effectiveness
* Implementation of a novel laboratory approach that has not been extensively studied
* Development of new quality assessment or measurement tools in the laboratory
* Use of patient data to develop new clinical treatment guidelines that could alter testing intervals

REB Screening Tool
The checklist is intended to be used as a pragmatic screening tool to help determine the appropriate route for REB review. That is, ***is the project research?*** If so, it should be submitted to an REB. ***Is the project quality or evaluation?*** If so, proceed with locally relevant policies for review of quality or evaluation projects.

The recommended REB review process depends on a number of factors, including local policies and level of risk, and may require further exploration on a project-specific basis. This tool has not been validated and is not intended to replace professional judgment and interpretation but was developed to help increase consistency and transparency of ethics screening processes.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Question** | **Yes** | **No** |
| 1 | Is the project funded by, or being submitted to, a research funding agency for a research grant or award that requires research ethics review? |   |  |
| 2 | Are there any local policies that require this project to undergo review by a Research Ethics Board? |   |  |
|   | If Yes to either of the above, the project should be submitted to a Research Ethics Board.If No to both questions, continue to complete the checklist. |   |  |
| 3 | Is the primary purpose of the project to contribute to the growing body of knowledge regarding health and/or health systems that are generally accessible through academic literature? |   |  |
| 4 | Is the project designed to answer a specific research question or to test an explicit hypothesis? |   |  |
| 5 | Does the project involve a comparison of multiple sites, control sites and/or control groups? |   |  |
| 6 | Is the project design and methodology adequate to support generalizations that go beyond the particular population the sample is being drawn from? |   |  |
|  | **Question** | **Yes** | **No** |
| 7 | Does the project impose any additional burdens on participants beyond what would be expected through a typically expected course of care or role expectations? |   |  |
|   | LINE A: SUBTOTAL Questions 3 through 7 = (Count the # of Yes responses) |   |   |
| 8 | Are many of the participants in the project also likely to be among those who might potentially benefit from the result of the project as it proceeds? |   |  |
| 9 | Is the project intended to define a best practice within your organization or practice? |   |  |
| 10 | Would the project still be done at your site even if there were no opportunity to publish the results or if the results might not be applicable anywhere else? |   |  |
| 11 | Does the statement of purpose of the project refer explicitly to the features of a particular program, organization or region rather than using more general terminology, such as rural vs. urban populations? |   |  |
| 12 | Is the current project part of a continuous process of gathering or monitoring data within an organization? |   |   |
|   | LINE B: SUBTOTAL Questions 8 through 12 = (Count the # of Yes responses) |   |   |

**Interpretation:**

If the sum of Line A is greater than Line B, the most probable purpose is ***research***. The project should be submitted to an REB.

If the sum of Line B is greater than Line A, the most probable purpose is ***quality/evaluation***. Proceed with the locally relevant process for ethics review, which may not necessarily involve an REB. However, if you are unsure, it is best practice to contact the REB for guidance.

If the sums are equal, seek a second opinion to further explore whether the project should be classified as research or as quality and evaluation.

***\*Source of Recommendations***: Protecting People While Increasing Knowledge: Recommendations for a Province-wide Approach to Ethics Review of Knowledge Generating Projects (Research, Program Evaluation, and Quality Improvement) in Health Care [December 2005), Alberta Research Ethics Community Consensus Initiative (ARECCI). For more information, visit the ARECCI website at [www.ahfmr.ab.ca/arecci](http://www.ahfmr.ab.ca/arecci)

## Common FAQs

### I’m not sure if my project is QA or research. Can I determine this after I begin my project?

No. Research requires REB review and approval before research begins. The CSMLS REB will never give approval after methods are initiated. You must determine the purpose of your project at the beginning of your project. If a researcher knows at the outset that the project will be done for both QA and research purposes, CSMLS REB approval is required.

### Why doesn't the CSMLS REB review all QA activities?

The CSMLS REB system was designed to provide oversight for human subjects. The system can be costly and can take an extended period of time to obtain approval for more complex research proposals. The REB is governed by CSMLS staff and run by expert volunteers. As such, requiring all QA activities be submitted would impose a heavy burden that would make some projects not feasible. The process of QA activities not requiring REB approval is consistent with health care and academic organization REBs across Canada.

### Can QA studies be published without prior REB approval?

Publication is only one of many criteria for determining whether a QA activity is also research. As a standalone concept, publication or intent to publish is not sufficient to require REB review and approval.

Even though most QA activities are not research, there is much to be learned from sharing descriptions of these non-research activities. Standards for reporting QA projects have been developed and published by [SQUIRE](http://www.squire-statement.org/). Individuals intending to publish the results of a QA project can consult these as well as other guidelines.

### What ethical oversight is appropriate for QA projects that are not intended to be research?

The CSMLS REB provides ethical oversight for research involving human subjects. There is not a system for ethical oversight of external QA activities. At a minimum, laboratories, academic programs and hospital departments should review all proposed QA activities to ensure that the risks to participants do not pass a minimal threshold and that there are appropriate protections for the individual’s privacy and confidentiality of their identifiable data.

### Is informed consent required for QA projects?

Informed consent is not required for QA projects since they pose minimal risk. As QA projects are an integral aspect of normal health care and laboratory operations, consent to be included in a QA project is part of the patient’s consent to receive care.

### What should I do if I suspect that irresponsible conduct of research has occurred?

Whether you are a student, staff member, laboratory professional, employer, faculty member, Chair or Dean, you have both a right and a responsibility to report any instances of irresponsible conduct of research involving members you uncover to the CSMLS REB.

Before reporting the offense, you should ensure that this offense would likely be considered to be the irresponsible conduct of research and not another form of misconduct or a more general performance issue.