

Quality assurance, or research subject to approval?

When is approval by the cantonal ethics committee required, and when not?

Introduction

According to the definition of research in the Swiss Human Research Act, certain projects are not to be deemed to be research under the terms of this law. They are not subject to any special statutory regulation, falling only under the notion of freedom of research as per Article 20 of the Federal Constitution of the Swiss Confederation, and do not require prior approval by the authorities before being conducted. These projects include quality assurance projects (quality assurance and quality control studies).¹ Legal regulation in Switzerland thus follows an internationally applied distinction between research subject to approval and quality assurance that is not subject to approval.² Naturally the relevant data protection provisions and ethical requirements must be fulfilled even if quality assurance projects are not subject to an approval requirement.³

This guideline is designed to help you make the distinction between quality assurance projects and research projects that are subject to approval. Even so, in individual cases it can still be difficult to make a clear distinction, and grey areas and room for interpretation remain.

Legal basis in the Human Research Act (HRA)

Art. 2 Scope

¹ This Act applies to research concerning human diseases and concerning the structure and function of the human body, ...

Art. 3 Definitions

In this Act:

- a. *Research*: means method-driven search for generalisable knowledge;
- b. *Research concerning diseases*: means research on the causes, prevention, diagnosis, treatment and epidemiology of impairments of physical and mental health in human beings; ...

¹ 21 October 2009 Dispatch on the Federal Act on Research Involving Human Beings. Here the following is stated: "...Quality control studies too are to be deemed to be research only if, in addition to quality control, new, generalisable knowledge is to be acquired on a method-driven basis."

² E.g.: "Quality Improvement" project (USA, AUS) and "Clinical Audit" or "Service Evaluation" (UK).

³ C.f. Lynn J et al. The ethics of using quality improvement methods in health care. *Ann Intern Med* 2007; 146: 666-673.

Distinguishing between research and quality assurance

The most important considerations in making a distinction are related to

1. the **goal of the project**: is it designed to generate new medical knowledge, or to evaluate the effectiveness of an accepted, evidence-based practice?
2. the **purpose of the project**: is it about medical innovation, or merely about better services and more efficient care delivery structures?
3. the **generalisability of the knowledge acquired**: are the anticipated insights generalisable, or do they primarily apply to a local or regional institution or organisation (related to a specific object)?
4. the **project methodology**: is the firmly prescribed methodology necessary and sufficient to meet the scientific objective (hypothesis), or are the methods of investigation lacking definition and adapted to evaluating and optimising a local care delivery practice (observation)?

Criteria	Research: requires approval	Quality assurance: does <u>not</u> require approval	Concrete examples of quality assurance projects that do <u>not</u> require approval
Criterion 1: Goal of the project	To generate new knowledge The goal is to generate <u>new</u> knowledge. The project is designed to create evidence where there is none. Clear and innovative objective/question, often hypothesis-driven.	To apply existing knowledge The goal is to evaluate the effectiveness and/or efficiency of a practice that has been introduced and is already applied and compare this with the evidence-based standard that has already been published.	Evaluation of a process in the treatment of postpartum bleeding that was introduced on the basis of a study.
Criterion 2: Purpose of the project	Progress, better medicine for all patients The purpose is to improve the prevention, diagnosis and therapy of diseases. The focus is on patients and their entitlement to the best medicine.	Better care from an institution or organisation The focus is on an institution or organisation's care delivery structures and service processes. Quality projects are intended to evaluate and optimise their utility and/or improve their efficiency. The results are intended to benefit future patients of the institution or organisation as rapidly as possible.	Evaluation of the safety of a national recommendation based on published studies. Example: Does the risk of pulmonary aspiration increase if the period of fasting before surgery is shortened? Establishing a disease-, procedure- or product-related register without the intention to research.

<p>Criterion 3: Generalisability of knowledge</p>	<p>Generally applicable gain in knowledge without reference to a specific object</p> <p>Insights can be applied to all patients and people, independent of a specific institution and/or organisation.</p>	<p>Gain in knowledge only/primarily related to a specific institution/organisation</p> <p>Results refer “only” to the care delivery structures and service processes of a specific institution or organisation.</p>	<p>Evaluating triage of patients in an A&E department.</p> <p>Developing methods to optimise scheduling of appointments on a ward.</p>
<p>Criterion 4: Project methodology</p>	<p>Research methodology to answer a scientific question</p> <p>Study protocol setting out firm, binding methodological requirements. Inclusion and exclusion requirements clearly defined. Sufficient statistical power. Participation in the project is always voluntary.</p>	<p>Exploratory approach with adaptable parameters for evaluating a local practice</p> <p>Flexible research plan, possibly only setting down evaluation criteria. Participation is a part of patient management. As a rule covers all patients, not only a selection. Measures may even be prescribed in the law or labour regulations.</p>	<p>Evaluating the need for emergency treatments by a mobile dental clinic.</p> <p>The influence of chlorhexidine washes on the emergence of catheter-associated bacteraemia.</p> <p>Study of the effectiveness of treatment in a day clinic.</p>

Inappropriate demarcation criteria (since they apply to both research and quality assurance)

1. Gathering health-related personal data.
2. Evaluating medical outcomes.
3. Intention to publish.

Publication of results

On the grounds of transparency there is nothing barring the publication of the quality assurance project.

However, it must be clear from the publication that it is about quality assurance; the project must not be presented the same way as a research project.

Recommendations from the cantonal ethics committee

As far as possible, questions of quality assurance and research should not be mixed.

If the focus is on quality assurance, we recommend completely avoiding elements of research requiring approval.

If the intention is to publish a research project, the application must emphasise the research objective and only go into aspects of quality on a subordinate basis.

If difficulties in demarcating a planned project persist, subject to a fee you can submit a request for the cantonal ethics commission to clarify responsibility under Support/Request on the electronic BASEC platform (<https://submissions.swissethics.ch>).

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