



University of California
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Research vs. QI/QA

As an academic institution and a medical center, UCSF is required to continually evaluate and improve our clinical care and training activities through quality assurance and performance improvement. We want to help clarify when Quality Improvement (QI) and Quality Assurance (QA) activities fall under the jurisdiction of the IRB.

Both QI/QA activities and research activities use scientific methodology equally, so it is difficult to define research activities that require IRB review by the methods they employ. Other attributes ? such as publication of findings, methodological design, selection of subjects, and hypothesis testing and generating ? also do not necessarily differentiate QI/QA activities from research. These distinctions are challenging and evolving.

Research Activities: The IRB must review all research involving human subjects [1].

Definitions of research and human subjects

DHHS Regulations define *research* as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalize knowledge." (45 CFR 46.102(1) Common Rule). These activities require IRB approval when human subjects are involved.

Human subject is defined as a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (45 CFR 46.102(e)(1) Common Rule).

Additionally, the FDA regulates research involving a drug, device or biologic, and all research involving data that will be submitted to or held for inspection by the FDA (21 CFR 56.102(c)).

QI/QA Activities: QI/QA activities are designed to continuously evaluate and improve performance in a clinical area or department. At UCSF, these activities primarily include changes to clinical systems or processes, the development and implementation of guidelines, or the intersection of these activities with training and education. The fundamental goal of QI/QA activities is to improve patient care at UCSF.

Definitions of QI/QA Activities Not Requiring IRB Review

QI/QA activities meeting the following definitions do not require IRB review, as long as these activities do NOT:

- Do not pose significant risk to patients and
- Do not include testing the safety and efficacy of a drug or device in a human subject.

QA and QI activities ? clinical or procedures: Systematic, data-guided activities designed to implement promising ways to improve clinical care, patient safety and health care operations. The activity is designed to bring about immediate positive changes in the delivery of health care, programs or business practices in the local setting.

QA and QI activities ?non-clinical: Data collected with the limited intent of evaluating and improving existing services and programs or for developing new services or programs. Examples include teaching evaluations or customer service surveys.

Examples of activities that would or would not require IRB review

QI/QA Activities That Would Not Require IRB Review

Activities That Would Be Considered Research and Would Require IRB Review

Surveys whose primary purpose is to gauge the opinions and perceptions of internal and external customers (e.g., trainees, staff, patients, referring physicians, and others) for the purpose of improving the delivery of health care at UCSF. This could include patient satisfaction surveys.

A patient satisfaction survey, with identifiers, designed to broadly evaluate and report on the impact of new California health care requirements or programs.

Activities to implement or improve adherence to established/accepted standards (such as clinical practice guidelines) for the purpose of improving care at UCSF.

Activities to improve adherence to established/accepted standards (such as clinical practice guidelines) at UCSF and 3 other centers, funded by a research grant from NIH, for the purpose of demonstrating whether adherence to the standards could be improved.

Rapid cycle continuous quality improvement (CQI) activities (e.g. using common QI methodologies, such as Plan-Do-Study-Act cycles) designed to bring care at UCSF within accepted standards.

Access to UCSF medical records for data collection and analysis for the purpose of publishing on the results of care provided at the UCSF Medical Center.

If you have questions about whether or not an activity constitutes research, contact us ^[2]. Also review Quick Guide: Activities Requiring IRB Review ^[3].

Funded Activities

The determination of whether an activity is QI/QA or human subject research also can depend on how the activity is funded.

- If the activity is supported by a contract or grant for research, and involves human subjects, the investigation requires IRB approval.
- If the activity is supported by a contract or grant for quality improvement without a research component, IRB approval is not needed as long as the activity satisfies the definitions above.
- If the activity is unfunded, funded by hospital or departmental funds, and the activity satisfies the definitions above, IRB approval is not needed.

Note that QI/QA activity can be supported by both internal and external sources of funding.

Publication of the Findings of QI/QA Activities

It is expected that the findings of QI/QA activities may warrant publication from time to time.

The possibilities of publishing the findings of a QI/QA activity (as defined above) does not in and of itself obligate prior IRB review of the activity. Furthermore, sharing or generalizing the results of a QI activity does not imply that the original activity was in fact research and was conducted without appropriate review.

However, the systematic review of identifiable data collected for non-research purposes (e.g., QI/QA activities) to contribute to generalizable knowledge is considered research. Therefore, if publication of the findings of a QI/QA activity requires re-analysis of identifiable data, it will be necessary to submit an application to the IRB, most likely for expedited review under category 5.

Note that IRB approval would not be required if publication of the QI/QA activity did not require access to a data set with subject identifiers.

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[1] <http://irb.ucsf.edu/research-needing-irb-review>

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