



IRB Guidance: University Quality Improvement and Quality Assurance Activities

Research involving human subjects, as defined by federal regulations [inset hyperlink to definition of “human subject research” in FSH 5200], that is to be conducted under the auspices of the University of Idaho must be reviewed and approved by the University of Idaho Institutional Review Board (IRB) before it is performed. In most cases, however, University “quality improvement” or “quality assurance” activities (whether at university-wide, college, or departmental levels) that are intended solely to improve or assure the quality of programs or services provided at the University or to support the development of new programs and services at the University do not qualify as human subject research activities that require IRB review and approval under federal regulations. University quality improvement and quality assurance activities may include not only endeavors involving University faculty, staff and students and designed for the immediate benefit of the University, but also those activities engaging or required by third parties, when they are intended to inform the University’s provision of programs and services or ensure that programs and services meet established standards. The purpose of this guidance is to clarify the criteria that must be met in order for institutional activities to fall within the category of “university quality improvement/quality assurance activities” and not be, therefore, subject to oversight by the IRB.

*Should faculty, students, or staff wish to use the results of or data collected for research, in addition to the intended administrative purposes of the quality improvement and quality assurance activity, prior review and approval by the IRB will most likely be required. **Please consult with the IRB.***

Criteria for “University Quality Improvement and Assurance (Non-Research)” Determination:

Quality improvement/quality assurance activities do not require IRB review if **all of the following criteria are met:**

1. the activities are designed to:
 - a. bring about the immediate or continuing improvement of University programs or services, **or**
 - b. ensure that University programs or services are meeting regulations or standards established by outside entities and applicable to postsecondary or professional education institutions; **and**
2. the activities are managerial/administrative in nature and are not considered part of the scholarly responsibilities of faculty members or an element of the educational requirements for students
3. the data *will not* be used by either University investigators or third parties for “research” (as defined by federal human subject research regulations) in addition to the intended quality improvement/quality assurance purposes; i.e.:
 - the quality improvement/assurance activity, involving human subjects, is not undertaken to test a new, modified, or previously untested intervention, service, or program *to determine whether it is effective and can be used elsewhere, or*
 - the quality improvement activity *does not* entail the systematic comparison of standard or non-standard interventions, or
 - the quality improvement activity *does not* involve the prospective collection of data for contribution to a data repository and later use for research purposes; **and**
4. the activities involve *no more than minimal risk to the participants*; **and**
Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the activities are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Common examples of University quality improvement and assurance activities are:

- course evaluations (e.g., anonymous student evaluations of [for-credit] courses or extension classes)
- customer service or academic program evaluation surveys (e.g., dining services satisfaction surveys or departmental surveys of student interest in proposed courses)
- institutional research and assessment and strategic planning initiatives (e.g., institutional collection and assessment of data on student retention and focus groups on mandatory on-campus housing for first-year students)
- reports to and evaluations by accrediting bodies (e.g., the Northwest Commission on Colleges and Universities or the American Bar Association)
- reports to federal or state agencies for quality measurement or public health monitoring that are required by law
- initiatives in which the University, or unit of the University, collects and submits identifiable data to an outside entity that will aggregate the data with information from other institutions and report benchmarking standards to the participating institutions, unless the outside entity will also be using or sharing the data for research purposes
- initiatives in which the University, or unit of the University, permits the collection and submission of data by an outside entity that will aggregate the data with information from other institutions and report benchmarking standards to the participating institutions, when the University, or its unit, is not engaged in research

Common examples of quality improvement activities that also constitute human subject research are:

- projects in which University faculty, students, or staff propose to: collect and/or study identifiable data from a quality improvement initiative, analyze the data for general trends, and either publish a paper on his or her findings in a scientific or other professional journal or give a presentation at a scholarly conference.
- an initiative in which University units, employees, or staff submit identifiable (including coded) data to a database maintained by an outside entity that will use and/or share the data for research purposes, in addition to providing any benchmarking analyses to participating institutions.
- an initiative that is required by law, but in which the University, the relevant state or federal agency/government body, and/or a third party will be using or sharing the data for research purposes, in addition to quality measurement purposes.

Please note that other laws and regulations, such as FERPA or HIPAA, may apply to quality improvement and quality assurance activities, irrespective of whether the applicability of human subject research regulations.