

Guidance on activities not requiring IRB review

There are many research-like activities, collectively referred to here as “QI activities”, occurring all the time in a large academic health organization like Jefferson. These include but are not limited to quality assessment and improvement activities (QI), evidence-based practice projects, analyses of business processes, employee satisfaction surveys, curricular assessments, and program evaluations. These activities may focus on students, faculty, employees, patients, and others in or served by the organization, and they may involve data-gathering procedures and analytic approaches that also can be employed in human research, but they are not considered human research and as such do not require IRB review and approval.

Key to the federal definition of research in 45 CFR 46 (the “Common Rule”) is the concept of ***generalizability***. Generalizability means that results of a research study can be generalized, or applied, to broader populations, different settings, or real-world scenarios. Because QI activities do not make this claim, they do not meet the *generalizability* criterion for human research, do not qualify as human research, and so do not fall under the regulatory requirement for IRB review.

In fact, the intent of QI activities is *not* to create generalizable knowledge, but rather to assess or improve a practice or process specifically and exclusively within the organizational domain. And where the intent of publication of results of human research studies is expected to develop or contribute to generalizable knowledge by filling a gap in scientific knowledge or supporting, refining, or refuting results from other research studies, the intent of publication of QI activities is to suggest potentially effective models, strategies, assessment tools or provide benchmarks or baseline rates rather than to develop or contribute to generalizable knowledge. Thus publication of QI activities does not make those activities *generalizable* and so does not necessitate the need for IRB review and approval.

In an effort to consolidate submission and documentation of QI activities in one place, JOHRP has established a *Non-Human Subject Research (NHSR) application* in iRIS. Individuals should submit their projects with this application in order to receive a determination as to whether their project requires IRB review or is deemed to be *not human research*.

If a project is determined to require IRB review, the individual is redirected to submit an IRB application. If the project is deemed *not human research*, a memo documenting this is provided to the individual. This memo can be presented to leadership, journal editors and conference managers as documentation that the project does not qualify as human research and does not require IRB review.

Also, the archive of these projects will serve as a central repository that can be accessed by Jeffersonians to inform future QI activities.

JOHRP strongly advises that any individual or team intending to conduct QI activities within the Jefferson organization first submit an NHSR application in iRIS and receive a memo of acknowledgment prior to beginning the project.