

Teacher Efficacy, Program Evaluation and Service Assessments

When do I need to submit my project to the CPHS?

OHRP refers to these projects as [Quality Improvement Activities](#).

Most Quality Improvement Activities are not designed to satisfy the definition of “research” under 45 CFR 46.102(d), “...a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge...” Therefore there is no requirement for such activities to undergo review by the CPHS. For more details, see “[When Quality Improvement Activities *do not* need to be reviewed](#)”.



However, when the project involves **introducing an untested intervention** for purposes which include both: (a) improving the quality of service delivery, and (b) collecting information about participant outcomes for the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results, such activities typically do satisfy the definition of “research”. Projects like these must undergo review by the CPHS **prior to the introduction of the untested intervention**, otherwise the information collected about participant outcomes cannot be used for establishing scientific evidence in determining how well the intervention achieved its intended results. For more details, see “[When Quality Improvement Activities must be reviewed](#)”.

When Quality Improvement Activities do not need to be reviewed:

Regulations for the protection of Human Subjects in Research do not apply to Quality Improvement Activities conducted by researchers whose purposes are **limited to**: (a) implementing a practice to improve the quality of service delivery, and (b) collecting participant data regarding the implementation of the practice for functional or administrative purposes.

Examples of implementing a practice and collecting participant or provider data for non-research functional or administrative purposes:

- A school wishes to lower reported instances of bullying. Current curriculum is active throughout the school. A researcher reviews two alternative curriculums and implements them in randomly selected classrooms throughout the school. Reported bullying is measured and compared between the students receiving current curriculum versus an alternative curriculum. The researcher documents the results and the administration publicly shares the findings as justification for selecting a new/alternative curriculum.

- A daycare program for elders wishes to assess their standard of care. A researcher implements a widely accepted capacity assessment as part of routine standard of care in order to identify patients requiring special services and staff expertise. The daycare staff will audit participant's charts in order to see if the assessments are performed with appropriate participants, and will implement additional in-service training of staff regarding the use of the capacity assessment if it finds that the assessments are not being administered routinely. The researcher documents the results and publicly shares the findings as a case-study on standard of care improvement.

When Quality Improvement Activities must be reviewed:



In certain cases, [Quality Improvement Activities may \(also\) constitute Human Subjects Research](#) when the project involves **introducing an untested intervention** for purposes which **include both: (a) improving the quality of service delivery, and (b) collecting information about participant outcomes for the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results.**

These research designs typically **do** satisfy the definition of “research” under 45 CFR 46.102(d), “...a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge...” Projects such as these must undergo review by the CPHS **prior to the introduction of the untested intervention, otherwise the information collected about participant outcomes cannot be used for establishing scientific evidence in determining how well the intervention achieved its intended results.**

Examples of implementing a practice and collecting participant or provider data for “research” purposes:

- A researcher wishes to evaluate outcomes of different curriculums which purport to lower instances of bullying and a school agrees to participate. Current curriculum is active throughout the school. A researcher reviews two alternative curriculums and implements them in randomly selected classrooms throughout the school. Reported bullying is measured and compared between the students receiving current curriculum versus an alternative curriculum. The researcher documents the results, then publically shares the research design and findings in such a way that other professionals can test, repeat and anticipate similar outcomes in similar populations.

- A researcher wishes to assess standard of care procedures at daycare programs for elders in order to identify indicators of patients requiring special services. A program agrees to participate as a pilot site. The researcher documents current standard of care procedures and then implements a capacity assessment as part of routine standard of care. The daycare staff will audit participant's charts in order to see if the assessments are performed with appropriate participants, and will implement additional in-service training of staff regarding the use of the capacity assessment if it finds that the assessments are not being administered routinely. The researcher documents/records the results, then publically shares the research design and findings in such a way that other professionals can test, repeat and anticipate similar outcomes in similar populations.

Indicators that a Quality Improvement Activity is (also) “research”:

Note: A **MAJORITY** of these indicators must be met for the activity to likely be “research”.

- ☐ The intervention is novel (untested) per the literature review documented in the protocol.
- ☐ The intervention has NOT been introduced to the subject population until the protocol has been reviewed by the CPHS.
- ☐ There is a control group or equivalent population to compare outcomes with.
- ☐ The researcher documents/records and shares the research design and results in such a way that other professionals can test, repeat and anticipate similar outcomes in similar populations.