



UNIVERSITY OF CALIFORNIA, SAN DIEGO  
HUMAN RESEARCH PROTECTIONS PROGRAM

## FACT SHEET

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### EBP/QA/QI Projects

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The UCSD Human Research Protections Program (HRPP) has determined that many projects involving evidence based practice (EBP), quality assurance (QA), and quality improvement (QI) are not likely to meet the definition of "research" stated in the Department of Health and Human Services Regulations for the Protection of Human Subjects at 45 CFR Part 46, Subpart A, and would, therefore, be excluded from IRB review. However, such projects will require review and certification from the HRPP Director that the project is not research and no IRB review is required.

These regulations define "research" as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

The UCSD HRPP Standard Operating Policies and Procedures define generalizable knowledge as "Activities designed (with intent) to collect information about some individuals to draw general conclusions about other individuals that are predictive of future events and that can be widely applied as expressed in theories, principles, and statements and that enhance scientific or academic understanding."

In order for a project to be certified as not research, the following must be true:

1. Implementing the practice outlined in the project will not incur patient harm.
2. The practice change outlined in the project is not new or novel and has been published elsewhere.
3. The practice outlined in the project will be implemented in a project location.
4. All staff and affected patients in the project location will be expected to participate in the project.
5. The project is not testing issues or adding research questions that go beyond common practice.
6. The project will not randomize patients into different intervention groups.
7. The project will not deliberately delay interpretation of data.
8. The project will not deliberately delay or abbreviate feedback to those who would benefit from the findings to enhance likelihood of publication.
9. The project has no funding support from an outside organization with a commercial interest in the use of the results.

To obtain certification, the following procedures must be done:

1. Complete the [EBP/QA/QI Project: Standard Application for Review Facesheets](#) (all questions in section 3 must be answered “Yes.”)
2. Submit the Facesheets via the web to the HRPP Office
3. Once the HRPP project number has been obtained, upload the signed Facesheets and the [Project Narrative](#) using [e-IRB services](#).
4. If the project is certified as not research, certification will be e-mailed to the Investigator.
5. If the project is determined to be research, a letter will be e-mailed to the Investigator noting the determination and providing additional information regarding “re-submitting” the project for convened IRB or expedited review.

For questions as to whether a project is human subjects research, please contact the Director of the Human Research Protections Program at 858-246-4777.