**Companion document for completing the SJSU exclusion worksheet:**

**Quality Improvement and Evidence-Based Practice projects**

This companion document is designed to provide additional guidance in completing the SJSU IRB Exclusion Decision Tool for faculty and students in the Doctor of Nursing Practice. This may also be useful for students completing projects as part of degree requirements in other practice-focused disciplines in the College of Health and Human Sciences. Many culminating projects in these programs involve the application of research to practice rather than generating new knowledge. Examples include quality improvement projects, projects designed to ensure adoption of evidence-based clinical practice guidelines, evaluations of programs at a single provider site, or other projects designed to improve process or practice in a specific agency/institution. This document is NOT a substitute for the exclusion worksheet; rather it addresses a few frequently asked questions pertaining to the first two questions on the worksheet. Please note that some quality improvement or site-specific evaluation activities may qualify as research that will require IRB review (e.g., funded projects, multi-site projects, and projects that involve vulnerable populations or sensitive content). Faculty advisors and students should consult with the SJSU IRB about any projects that may require full review,

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| Does it meet the federal definition of “research”? | |
| Is it a systematic investigation? | The answer ***may*** be “no” if….   * The project t is designed to move existing evidence into practice or improve the quality of care based on established/accepted quality standards (rather than to test a new intervention or develop new knowledge). * The project involves collecting patient/provider data about implementation of a practice for non-research clinical, practical, or administrative purposes. * The methods for the project are flexible and include approaches for evaluating incremental or rapid change (e.g., Plan-Do-Study-Act [PDSA] rapid cycle process improvement) |
| Is it designed to contribute to generalizable knowledge? | The answer ***may*** be “no” if….   * The project results are intended to evaluate or improve practice in a specific organization/ institution * The site has identified the problems and is seeking a solution (e.g., not a study initiated by an external investigator). * The project is focused on evaluating current practice, staff/ clinicians who provide care are responsible for the practice in the institution, and the practice/activity under evaluation is part of usual care.   The project has no funding from federal agencies or research-focused organizations. |
| Clarification about publication and generalizable knowledge. | Planning to publish a project does not necessarily mean that the project fits the definition of research. Dissemination of quality improvement, evidence-based practice, and single-site evaluation projects are often beneficial to health and human services fields. If there is an intention to publish, the project team should be comfortable with including a statement in the methods section explaining the status of the project. An example would be: “*This project was undertaken as a quality improvement initiative at [X agency or hospital] and as such was not formally supervised by the Institution Review Board per their policies.”* |

**KEY DEFINITIONS \***

*Quality Improvement*. The intent of QI projects is to improve a practice or process within a particular institution or setting. Activities are intended to improve clinical care, including but not limited to the following: improving the performance or local practice or local systems of care; improving the process of care, patient/client experience, or clinical outcome; contributing to organizational knowledge; or improving the cost of care. QI projects are typically designed to meet the needs of a specific organization and, as such, is not generalizable to other settings. If a project is conducted at multiple sites, it is likely generalizable.

*Quality Assurance and/or assessment.* Activities focus on reviewing, analyzing or evaluating patient or provider data that may identify opportunities for changes in systems or procedures that improve quality of care or activities designed to determine whether aspects of practice are being performed consistent with established standards. These activities have local and immediate application.

*Program Evaluation.* Systematic investigations designed to develop or contribute to knowledge about a specific program. These are typically not designed to contribute to generalizable knowledge, do not involve randomization, but may involve a comparison group or comparison of programs. (Some program evaluations may not qualify as research but some may; carefully review exclusion checklist and consult with IRB as needed).

*Case histories from a single patient.* This activity is not typically considered a systematic investigation.

*Evidence-based practice project*. Some projects examine processes or outcomes associated with use of evidence-based practices that have already been adopted in a given setting (i.e. it is not testing a new intervention). There is little or no controversy about whether the intervention would be beneficial to patients/clients and the project is it designed to simply move existing evidence into practice.

*Resource Utilization Review.* A project designed to evaluate the use of resources in a specific health care activity.

\* Definitions and descriptions are adapted from several sources: Bankert, E. A., & Amdur, R. J. (2006). Institutional review board: management and function. Sudbury, Mass: Jones and Bartlett,

Additional resources for determining whether a project might be considered research or not:

<https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c2>

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html>