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# Comparison Chart
# Human Participant Research vs Quality Improvement Projects[1]

The information below may be helpful to researchers when deciding if a study falls within the criteria of research requiring Research Ethics Board review. It is advisable to consult with the REB Office before starting any study activity especially if the intent is to publish the results. If the REB makes a determination that the study is a quality improvement/assurance initiative, a REB exemption letter can be issued which may be provided to the publisher if requested. Inquiries to the REB Office can be sent to: rebsubmissions@southlake.ca

| Study Design Element | Human Participant Research | Quality Improvement Project |
|---|---|---|
| Purpose | Gather facts to test a hypothesis and develop or contribute to generalizable knowledge. | Improve and understand specific, local processes or practices commonly related to cost, productivity, operations, quality, or patient experience. |
| Starting point | Answer a question or test a hypothesis that can be applied to a more general population. | Improve performance in a specific unit or population (patient or provider) in an organization. |
| Design | Systematic design with strict adherence to a protocol that does not change throughout the process. May involve randomization. | Iterative and adaptive design that may or may not be systematic. Usually does not involve randomization. |
| Beneficiaries | Clinician, researcher, scientific community, and occasionally the participant benefit. Results do not directly benefit institutional practice or programs. | Patients, staff, providers, and institution benefit. |
| Mandate | Community hospitals typically do not mandate research activities or programs. | Activities are usually mandated by institutions or clinics as part of clinical operations. |
| Impact | Designed to contribute to generalizable knowledge that may or may not benefit study participants. | Findings are expected to directly impact institutional processes or practices. |
| Measures | Measurement instruments must have estimates of reliability, validity, specificity, and sensitivity. Instruments are often complex and have a significant time burden. Protocols are followed closely, and confounding variables are measured or controlled for. Studies may occur over long periods of time (years). | Measurement instruments are generally limited, simple, easy to administer, and not overburden some to the provision of care. Iterative, rapid cycles are followed, and confounding variables are acknowledged but not measured. Timeline is commonly weeks to months. |
| Adoption of results | Little urgency to disseminate results quickly. | Results rapidly adopted into local care delivery. |
| Participants | Subset of a population without an obligation to participate. Participants must meet strict inclusion and exclusion criteria. Investigator or sponsor will calculate a sample size to determine how many participants are needed. | Most or all of the population involved in the process or practice. The responsibility to participate is a component of care, and the expectation is that most individuals participate. |
| Benefits | Participants may or may not benefit directly. | Direct benefit to system, program, or process is expected although participants may not receive direct benefit. |

1. Chart adapted from Pat F. Bass III, MD, MS, MPH,1 John W. Maloy, JD2, How to Determine if a Project is Human Subjects Research, a Quality Improvement Project or Both, Ochsner Journal 20:56-61, 2020

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| Study Design Element | Human Participant Research | Quality Improvement Project |
|---|---|---|
| Risks | Participants may be placed at risk, and risks are stated in the informed consent document. | By design, does not increase patients' risk, with the exception of possible privacy/confidentiality concerns. Consent is implied as part of care. |
| Analysis | An a priori hypothesis is developed by the researcher/sponsor to be statistically proved or disproved. | A program, process, or system is compared to an established set of standards, outcomes, or targets. |
| Outcome | Answer a research question and statistically prove or disprove a hypothesis. Significant scientific rigor is applied. | Promptly improve a program/process/system after comparison with an established set of standards. Process validity is sought. |
| Dissemination of results | Intent to disseminate assumed at the outset of the project with results expected to develop or contribute to generalizable knowledge by filling a gap in the scientific literature. | Intent to disseminate is not assumed at the outset of the project and often does not occur beyond the institution; when results are published, the intent is to suggest potentially effective models and strategies rather than generalizable knowledge. |
| Use of placebo | Use of placebo may be planned. | Comparison of standard treatments, practices, techniques, or processes. Placebo is not used. |
| Deviation from standard practice | May involve significant deviation from standard practice. | Unlikely to involve significant deviation from standard practice. |