

COMPARISON OF THE CHARACTERISTICS OF RESEARCH, QUALITY IMPROVEMENT, AND PROGRAM EVALUATION ACTIVITIES

Use the chart below if you have questions whether your project should be considered a Research, Quality Improvement activity, or Program Evaluation. If your project satisfies any of the conditions in the Research column, it should be submitted to COMIRB for review prior to implementation. COMIRB cannot provide retroactive approval after your research project commences. If you would like assistance in evaluating your project, contact COMIRB@ucdenver.edu. Additional information on what constitutes human subjects research is [available here](#).

	RESEARCH	QUALITY IMPROVEMENT	PROGRAM EVALUATION	COMMENTS
FUNDING	Funded by a research grant, award or contract, or unfunded. If funded as research, all activities supported by the funding must be considered research.	Typically unfunded. May be funded by awards specifically for quality improvement; confirm IRB requirements, if any, with funder.	Often funded by a grant, award or contract for the purpose of developing or improving a service program. If the funding specifically requires evaluation of the program, the evaluation component may be considered research; confirm with funder. May also be unfunded.	
INTENT	To develop or contribute to generalizable knowledge.	To improve a specific business practice. In a hospital, this may include improving the quality and/or consistency of care in a specific unit or the entire hospital.	To evaluate the effectiveness of a specific program in meeting the intended goals of the program.	
DESIGN	The methodologies for conducting Research, Quality Improvement, and Program Evaluation projects are similar and are all systematic. Differential aspects are provided below as a guideline.			
	<ul style="list-style-type: none"> • Hypothesis driven • Statistically rigorous • May involve a placebo • May involve significant deviation from usual care or standard practice • Multi-site or single-site • May evaluate investigational drugs or devices 	<ul style="list-style-type: none"> • Often designed as part of a cyclical program to implement, test and evaluate modest improvements in the delivery of care, or in some other business process, e.g., Continuous Quality Improvement (CQI), Plan-Do-Study-Act (PDSA) • May or may not be hypothesis driven • Usually involves modest improvements to usual care or standard practice • Rarely multi-site • Never evaluates investigational drugs or devices 	<ul style="list-style-type: none"> • Designed to evaluate whether the program was successful, and/or whether it should continue • May be multisite if evaluating a single program at multiple sites 	

PUBLICATION	Publication alone does not define an activity as research. Differential aspects are provided below as a guideline.			
	<p>Clear intent to publish results as research (e.g., in scientific journal, research poster/abstract, or other research/scientific fora).</p> <p>Publishing is presumed as part of professional, scholarly expectations and obligations.</p>	<p>Project results will be disseminated internally (e.g., within the institution, department, or practice) soon after project completion to determine if the change improved delivery of care or another business practice, and to inform business decisions and operations.</p> <p>If methodology or results are interesting, results may be published. Publication must note that the project was carried out as QI, and did not meet the definition of research per DHHS regulations. The project may not be described as research.</p>	<p>Intent to publish or present results generally presumed at the outset of the project.</p> <p>Evaluation results will be provided to the program owner and stakeholders, and to the funder.</p> <p>Unless the evaluation was carried out as research with IRB approval, any publication should note that the project was carried out as Program Evaluation, and did not meet the definition of research per DHHS regulations. The project may not be described as research.</p>	
MANDATE or ENDORSEMENT	<p>Activities conducted to fulfill academic obligations to conduct and publish research, to complete a research project as graduation requirements, or as defined by a funding award.</p>	<p>Project is endorsed or mandated by the institution or clinic as part of CQI operations.</p> <p>Project may be mandated by educational requirements (e.g., requirement to design and complete a QI project).</p> <p>To document endorsement, COMIRB may ask for a letter of support from the head of the involved clinic or department, acknowledging the project as QI.</p>	<p>Activity endorsed or mandated by program owner and funder.</p>	
IMPACT	<p>Findings of the study are not expected to immediately and directly affect institutional or programmatic practice.</p>	<p>Findings of the project are expected to immediately and directly improve an institutional practice.</p>	<p>Findings of the evaluation are expected to immediately and directly demonstrate the success and/or shortcomings of the program.</p>	
POPULATION	<p>Carefully defined through individual inclusion and exclusion criteria in the research protocol.</p> <p>Participation is voluntary.</p>	<p>Generally includes all participants of the practice in which improvements are being implemented (e.g., all patients and providers in a specific practice).</p> <p>Participation may or may not be voluntary.</p>	<p>Generally includes all stakeholders of the program being evaluated (e.g., all program clients, staff, and leaders).</p> <p>Participation in the evaluation may be voluntary for some but mandatory for others.</p>	

BENEFITS TO PARTICIPANTS	Primary benefit is from the scientific knowledge gained. Individual participants may or may not benefit directly. Benefits to others (e.g., future patients, society) is not generally immediate.	All participants are expected to benefit directly from the QI intervention.	Program clients are expected to benefit from participation in the program. Participants will not directly benefit from the evaluation of the program.	
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This table may also be used as a tool to conduct and document a self-evaluation of the project. In that case, the project leader should indicate above where the project fits on each row. If any of the boxes in the research column are checked then the project must be submitted to COMIRB for review and approval. If the tool indicates that this is quality improvement (QI) or program evaluation (PE) only, complete the rest of this form, obtain any necessary signatures, and keep this in your project records.

Acknowledgment

I have appropriately used this tool to evaluation my project entitled: _____

By my signature below, I affirm that this project meets the definition of:

Circle the appropriate term: **Quality Improvement** **Program Evaluation**

I certify that I will conduct my project in compliance with all federal, state and local laws and policies. If during the course of the project it is amended in such a way as to meet the definition of human subject research under 45 CFR 46 or 21 CFR 56 then I understand that I must submit to COMIRB for review prior to continuing the project.

 Signature of Project Leader Date Signature of Mentor (*if applicable*) Date

I have reviewed this project proposal and determine that meets the criteria for quality improvement or program evaluation as outlined above and is an appropriate project to be conducted within this Division/ Department/ School/.

 Signature of Appropriate Authority Title/Position Date
 (*or their designee*)