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

	RESEARCH	QUALITY IMPROVEMENT	PROGRAM EVALUATION	COMMENTS
INTENT	☐ Intent of project is to develop or contribute to generalizable knowledge (e.g., testing hypotheses)	☐ Intent of project is to improve a practice or process within a particular institution or ensure it confirms with expected norms	☑ Intent of project is to improve a specific program	
DESIGN	☐ Designed to develop or contribute to generalizable knowledge; may involve randomization of individuals to different treatments, regimens, or processes	☐ Not designed to develop or contribute to generalizable knowledge; generally does not involve randomization to different practices or processes	☑ Not designed to develop or contribute to generalizable knowledge; does not involve randomization of individuals, but may involve comparison of variations in programs	
MANDATE or ENDORSEMENT	☐ Activities not mandated by institution or program	☐ Activity endorsed or mandated by the institution or clinic as part of its operations	☐ Activity endorsed or mandated by the program, usually its funder, as part of its operations	
EFFECT ON PROGRAM OR PRACTICE EVALUATED	☐ Findings of the study are not expected to directly affect institutional or programmatic practice	☐ Findings of the study are expected to directly affect institutional practice and identify corrective action(s) needed	☐ Findings of the evaluation are expected to directly affect the conduct of the program and identify improvements	
POPULATION	☐ Usually involves a subset of individuals - universal participation of an entire clinic, program, or department is not expected; generally, statistical justification for sample size used to ensure endpoints can be met	☐ Information on all or most receiving a particular treatment or undergoing a particular practice or process expected to be included; exclusion of information from some individuals significantly affects conclusions. Initial work can be limited to a smaller subgroup to identify and plan for implementation or feasibility etc. with the expectation that the practice or process will be extended to the broader population.	☑ Information on all or most participants within or affected by receiving a particular treatment or undergoing a particular practice or process expected to be used; exclusion of information from some individuals significantly affects conclusions	
BENEFITS	☐ Participants may or may not benefit directly – benefit, if any, to individuals incidental or delayed	☐ Participants expected to benefit directly from the activities	☐ No benefit to participants expected; evaluation concentrates on program improvements or whether the program should continue	
DISSEMINATION OF RESULTS	☐ Intent to publish or present generally presumed at the outset of project as part of professional expectations, obligations; dissemination of information usually occurs in research/scientific publications or other research/scientific fora; results expected to develop or contribute to generalizable knowledge by filling a gap in	☐ Dissemination of information may occur in quality improvement publications/fora; when published or presented to a wider audience, the intent is to suggest potentially effective models, strategies, assessment tools or provide benchmarks or base rates rather than to develop or contribute to generalizable knowledge. Any publication should footnote that the project was carried out as QA and did not meet the definition of research per DHHS	☐ Intent to publish or present generally presumed at the outset of the project; dissemination of information to program stakeholders and participants; may be publicly posted (e.g., website) to ensure transparency of results; when published or presented to a wider audience, the intent is to suggest potentially effective models, strategies, assessment tools or provide benchmarks or base rates rather than to develop or contribute to generalizable	

	scientific knowledge or supporting, refining, or refuting results from other research studies	regs.	knowledge. Any publication should footnote that the project was carried out as QA and did not meet the definition of research per DHHS regs.	
CLINICAL SETTINGS				
USE OF PLACEBO	☑ Use of placebo may be planned	☐ Comparison of standard treatments, practices, techniques, processes – placebo would NOT be used		
DEVIATION FROM STANDARD PRACTICE	☐ May involve significant deviation from standard practice	☐ Unlikely to involve significant deviation from standard practice		

Definitions:

Human Subjects Research

For the purposes of this policy "human subject research" is defined as an activity that meets the definition of "research" and involves "human subjects" as defined either by the Common Rule or by FDA regulations.

Research

A *systematic investigation*, including development, testing and evaluation, *designed to develop or contribute to generalizable knowledge*. Activities that meet this definition may be funded or unfunded, or may be conducted as a component of another program not usually considered research. For example, demonstration and service programs may include evaluation components, and may constitute research activities under this definition.

For the purposes of this policy, a "systematic investigation" is an activity that involves a prospective study plan which incorporates data collection, both quantitative and qualitative, and data analysis to answer a study question.

Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings.

Research as defined by FDA regulations means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for

purposes of FDA regulations. [21 CFR 50.3(c), 21 CFR 56.102(c)]

- Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act means any use of a drug other than the use of an approved drug in the course of medical practice. [21 CFR 3 12.3(b)]
- Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act means any activity that evaluates the safety or effectiveness of a device. [21 CFR 812.2(a)]
- Any activity in which results are being submitted to or held for inspection by FDA as part of an application for a research or marketing permit is considered to be FDA-regulated research. [21 CFR 50.3(c), 21 CFR 56.102(c)].

Human Subject as defined by the Common Rule

A living individual about whom an investigator (whether professional or student) conducting research obtains:

1. data through intervention or interaction with the individual, or
2. identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.]

Human Subject as Defined by FDA Regulations

Any individual who is or becomes a subject in research; either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. In the case of a medical device, a human subject/participant is also means a human on whose

specimen an investigational device is used.

Research Compared with Quality Improvement/Quality Assurance or Program Evaluation

The touchstones for separating quality improvement and program evaluation from research concern the intent of the project, the degree to which results are designed to contribute to generalized knowledge, the effect of results on program practice or processes, and the scope of dissemination of results. In general many research methods may also be used in quality improvement and program evaluation projects. In clinical settings the use of a placebo or significant deviation from standard of care is unlikely to be viewed as quality improvement or program evaluation.

Quality Improvement:

Quality improvement activities are generally pursued in order to evaluate existing local practices with a goal of documenting and correcting deficiencies. If the goal of a project is to determine success/effectiveness or failure of a given program or process and the information gained from that evaluation is used to improve the program, this is not considered research involving human subjects, even when information is collected in a systematic way, because the results of this type of activity are not considered applicable to populations other than those under evaluation. Publication or presentation is allowed but results must not be described as or inferred to be generalizable to a broader population, i.e., they may not be described as research results.

If, however, quality improvement activities involving human subjects are used to test novel services or programs for effectiveness and are presented in a more global fashion or applied to a broader population they should be considered research involving human subjects.

For example: efforts to assess current clinic practices within a hospital (i.e., local) and to modify those practices to improve effectiveness would not meet the federal definition of research even though the evaluations collected data in a systematic manner. Presentation within the local environment (i.e., to the hospital staff) and publication of the results would be acceptable, so long as results are described as quality improvement and application of the findings is clearly limited to the location where they were found. If, however, results are presented outside of the local environment at a national meeting or published in a journal using language that seeks to generalize results beyond the locality of the project or that describes the study as research, the study would be considered human subject research and need review by the relevant IRB. Another

example of research subject to IRB review would be efforts to assess current clinical practices of a number of local, unrelated entities and the aggregation of all these efforts to support a change in clinical practice beyond the local. As to each local organization, the assessment might constitute quality improvement, but when the results are aggregated to support a more generalizable recommendation, OHRP has determined that the aggregation of separate quality improvement activities constitutes research.

Program Evaluation:

Program evaluation is the inquiry into past, present, and potential programs to understand or clarify their needs, working processes, or impact. When the purpose of the evaluation is to provide feedback to the program and/or funder to improve that program, the activity is not human subject research and does not need IRB review and/or approval. Presentation of findings to the program and its funders and publication of the results would be acceptable, so long as results are described as program evaluation efforts and are clearly limited to the program to which they apply and are not described as research. Program evaluation is considered human subjects research when the intent is to contribute to generalizable knowledge. If results are presented or published using language that seeks to generalize results beyond the program studied, the study would be considered human subject research and would need review by the relevant IRB.

Examples of evaluations that would be considered research and need human subjects review include: 1) dissemination of evaluations connected to outcomes to affect the development or implementation of other programs similar in nature; and 2) evaluation undertaken to test a new, modified, or previously untested intervention, service, or program to determine whether it is effective *and can be used elsewhere*.

Even when activities constitute quality improvement or program evaluation, it is expected that the gathering of data from human subjects through direct or indirect interaction will done with the highest level of regard for the protection of human subjects and in accord with ethical standards.

The Principal Investigator should use this tool and the accompanying guidance to evaluate each project.

If any of the boxes in the research column are checked then the project must be submitted to COMIRB / HSRC for review and approval.

If the tool indicates that this is quality improvement (QI) or program evaluation (PE) only the signatures detailed below should be obtained

COMIRB document

Acknowledgment

For DNP students who will be conducting the project in their place of employment:

☐ Other institutional review board requirements needed e.g. ORRQIRP (Organizational Research Risk and Quality Improvement Review Panel) at CHCO, or other institutions IRB's
☐ Letter of compliance with institution's Health Insurance Portability and Accountability Act regulation needed

This project protocol has been reviewed and it has been determined that it meets the criteria for quality improvement or program evaluation as outlined above and is an appropriate project to be conducted within the CU College of Nursing.

_____ _____

Signature of Appropriate Authority (*or their designee*) Date

Review Committee:

Guidelines:

This document should be retained with the project file and referenced as needed.

If you have any questions or concerns that the project may include a research component, submit to COMIRB using the appropriate forms available on the website:

COMIRB: http://www.ucdenver.edu/academics/research/AboutUs/comirb/Pages/comirb-home.aspx