

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

	RESEARCH	QUALITY IMPROVEMENT	PROGRAM EVALUATION	
INTENT	<input type="checkbox"/> Intent of project is to develop or contribute to generalizable knowledge (e.g., testing hypotheses)	<input type="checkbox"/> Intent of project is to improve a practice or process within a particular institution or ensure it conforms with expected norms	<input type="checkbox"/> Intent of project is to improve a <u>specific</u> program	
MOTIVATION FOR PROJECT	<input type="checkbox"/> Project occurs in large part as a result of individual professional goals and requirements (e.g., seeking tenure; obtaining grants)	<input type="checkbox"/> Project occurs regardless of whether individual(s) conducting it may benefit professionally from conducting the project	<input type="checkbox"/> Project not initiated by the evaluator and occurs regardless of whether individual(s) conducting it may benefit professionally from conducting the project	
DESIGN	<input type="checkbox"/> Designed to develop or contribute to generalizable knowledge; may involve randomization of individuals to different treatments, regimens, or processes	<input type="checkbox"/> Not designed to develop or contribute to generalizable knowledge; generally does not involve randomization to different practices or processes	<input type="checkbox"/> Not designed to develop or contribute to generalizable knowledge; does not involve randomization of individuals, but may involve comparison of variations in programs	
MANDATE	<input type="checkbox"/> Activities not mandated by institution or program	<input type="checkbox"/> Activity mandated by the institution or clinic as part of its operations	<input type="checkbox"/> Activity mandated by the program, usually its funder, as part of its operations	
EFFECT ON PROGRAM OR PRACTICE EVALUATED	<input type="checkbox"/> Findings of the study are not expected to directly affect institutional or programmatic practice	<input type="checkbox"/> Findings of the study are expected to directly affect institutional practice and identify corrective action(s) needed	<input type="checkbox"/> Findings of the evaluation are expected to directly affect the conduct of the program and identify improvements	
POPULATION	<input type="checkbox"/> 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	<input type="checkbox"/> 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	<input type="checkbox"/> 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	<input type="checkbox"/> Participants may or may not benefit directly – benefit, if any, to individuals incidental or delayed	<input type="checkbox"/> Participants expected to benefit directly from the activities	<input type="checkbox"/> No benefit to participants expected; evaluation concentrates on program improvements or whether the program should continue	
DISSEMINATION OF RESULTS	<input type="checkbox"/> 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	<input type="checkbox"/> Intent to publish or present generally not be presumed at the outset of the project; dissemination of information often does not occur beyond the institution evaluated; 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	<input type="checkbox"/> 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	

	filling a gap in scientific knowledge or supporting, refining, or refuting results from other research studies	benchmarks or base rates rather than to develop or contribute to generalizable knowledge	provide benchmarks or base rates rather than to develop or contribute to generalizable knowledge	
CLINICAL SETTINGS				
USE OF PLACEBO	<input type="checkbox"/> Use of placebo may be planned	<input type="checkbox"/> Comparison of standard treatments, practices, techniques, processes – placebo would NOT be used		
DEVIATION FROM STANDARD PRACTICE	<input type="checkbox"/> May involve significant deviation from standard practice	<input type="checkbox"/> 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, which 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 312.3(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.

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 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. This concept is relevant even though by design information is collected in a systematic way often identified as research. The results of said evaluations should not be considered applicable to populations other than that under evaluation. Publication or presentation is allowed but results must not be inferred is generalizable to a broader population.

If however, quality improvement evaluations that involve 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 this activity 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) would be acceptable. If however, results were considered for presentation outside of the local environment at a national meeting, or published in a medical journal in an attempt to generalize results this would be considered human subject research and need review by the relevant IRB. In other words you may report your findings but suggestion of their impact beyond the local environment or population would be considered research and require IRB review.

Program Evaluation:

Program evaluation is the inquiry into past, present, and potential programs to understand or clarify their need, working process or impact. When the purpose of the evaluation is to provide internal 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. However, in this case, it is expected that if one gathers data from human subjects through direct or indirect interaction for purposes of this type of evaluation, it is done with the highest level of regard for ethical standards and policies.

Program evaluation is considered human subjects research when the intent is to contribute to generalizable knowledge or there is a possibility that the resulting data will be used to contribute to generalizable knowledge. Thus, the activity may lead to publishing results in scholarly research journals or making presentations outside your institution. The assumption being that publishing/disseminating the findings generalizes the data.

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

The Principal Investigator should evaluate their project with consideration of this tool and the definitions provided.

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

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 or HSRC for review prior to continuing the project.

Signature of Principal Investigator

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
(or their designee)

Date

Print Name of Appropriate Authority
(or their designee)

Position

QA Program Evaluation Research Tool
CF-195, Effective 4-26-2010

Working Document: University of Wisconsin-Madison Health Sciences IRBs, version date 11/2/08
Authors: Nichelle Cobb & D. Paul Moberg
Adapted by The Evaluation Center, University of Colorado Denver, 07/09

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 or HSRC using the appropriate forms available on the website:

COMIRB: <http://comirbweb.uchsc.edu/portal/>

HSRC: <http://comirbweb.uchsc.edu/hsrc/>