

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
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 or ENDORSEMENT	<input type="checkbox"/> Activities not mandated by institution or program	<input type="checkbox"/> Activity endorsed or mandated by the institution or clinic as part of its operations	<input type="checkbox"/> Activity endorsed or 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

Intervention includes both physical procedures by which information or biospecimens 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 that has been provided for specific purposes by an individual ~~that~~ the individual can reasonably expect will not be made public (for example, a medical record).

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

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, goal of pr-7 (y)0 (th a)JTJve smnce -5-9(n)-9 (e)4 (ss or f3 nd thewouldsi)-2 (r)-merc67 t-6 (g)gy7s arest

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 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. ~~Evaluation~~