

INSTITUTIONAL REVIEW BOARD (IRB) DETERMINATION of HUMAN SUBJECT RESEARCH, EVIDENCE-BASED PRACTICE, or QUALITY IMPROVEMENT

Federal Regulations and NMC IRB policy requires review and approval of all research involving human subjects. This guideline helps determine if any project involves human subject research as defined by Federal regulations.

Defining research:

DHHS Definition of Research (45 CFR 46.102) “A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

In general, activities that contribute to **generalizable knowledge** are those with the intent is to generate conclusions that can be applied outside the immediate environment where the investigation occurred.

Defining human subject:

A human subject is defined by Federal Regulations as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.”(45 CFR 46.102(f) (1),(2))

Intervention includes physical procedures, manipulations of the subject, manipulations or changes of the subject's environment for research purposes. (i.e. exercise, use of a computer mouse)

Interaction includes communication between the investigator and the subject. This includes face-to face, mail, and phone interaction as well as other modes of communication, such as completion of a questionnaire, survey, interview procedures, or focus groups.

	HUMAN SUBJECT RESEARCH	EVIDENCED-BASED PRACTICE	QUALITY IMPROVEMENT/PROGRAM EVALUATION
INTENT	Project developed to contribute to generalizable knowledge.	Project developed to use the best available evidence to improve administrative, clinical, or educational practice.	Project developed to improve a process within an institution or improve an administrative or educational problem.
KEY FEATURES	Generates new knowledge for a discipline; assists in scientifically testing theories or interventions.	Translates new knowledge/proven method into clinical, administrative, or educational practice	Incorporates existing knowledge into improvement activities.

	HUMAN SUBJECT RESEARCH	EVIDENCED-BASED PRACTICE	QUALITY IMPROVEMENT/PROGRAM EVALUATION
COMMONALITIES & DISTINCTIONS	Systematic problem-solving approach that is inquiry driven.	Systematic problem-solving approach that is evidence driven.	Systematic problem-solving approach that is data or knowledge driven.
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 of individuals to different practices or processes.	Not designed to develop or contribute to generalizable knowledge; may be transferable to other settings
LITERATURE REVIEW	Novel research ideas supported by literature search showing gap in knowledge. Search summarizes background and provides further justification for study; guides study design.	Supported by literature review showing evidence of the best practice method; Search for one best practice method using exhaustive, systematic search	Supported by literature review showing existing knowledge of recommended improvement ideas; Search for ideas, one idea selected and tested.
SUBJECT POPULATION	Usually involves a subset of individuals; generally, statistical justification for sample size is used to ensure endpoints can be met	Information on all or most participants expected to be used; exclusion of information from some individuals significantly affects conclusions.	Information on all or most participants expected to be used; exclusion of information from some individuals significantly affects conclusions.
BENEFITS	Participants may or may not benefit directly; benefits may be incidental to current participants or delayed to future groups.	Participants are expected to benefit directly from best practice; benefit may be immediate or delayed.	Participants are expected to benefit directly from activities or program improvements; benefit is usually immediate.
RISK	None, minimal, moderate, high risk.	Usually none or minimal; if risk is moderate or high, may need to evaluate as research.	Usually none or minimal; if risk is moderate or high, may need to evaluate as research.
DATA COLLECTION	Not rapid cycle; uses tightly controlled and time-consuming protocols; requires planned resources that vary depending on project's scope. Involves tight controls for extraneous variables	Likely intermediate and not rapid cycle; uses varying resources depending on scope of project. May or may not control for extraneous variables	Rapid cycle; uses minimal to moderate time, resources, and money. Does not involve control for extraneous variables
GENERALIZABILITY	Depending on research design, results may be generalizable beyond individuals and organizations.	Results may be transferable to other settings if similar organizational context, which may have bearing on actual EBP implementation.	Results not generalizable to other organizations beyond that which the QI project was undertaken; may benefit from lessons learned.
DISSEMINATION OF RESULTS	Requires IRB Approval and reference to human subjects protection is disclosed. Opportunities are vast.	Usually requires facility permission or participants and setting are anonymous. Opportunities are growing.	Usually requires facility permission or participants and setting are anonymous. Opportunities are limited.
OVERLAPS	Informs EBP & QI; Ideas may come from QI projects that doesn't work or EBP that lacks evidence.	Informs QI; Identifies gaps in the evidence to support research	Informs EBP; Identifies gaps to support research