Program Evaluation vs. Research: Do I Need to Submit for an Exemption or IRB Approval?

There is often confusion in determining whether Program Evaluation activities fall within the category of research and require submission for an exemption from IRB review or IRB review and approval or do not.

What is Program Evaluation?

The Center for Disease Control defines program evaluation as the systematic collection of information about the activities, characteristics and outcomes of programs to make judgments about the program (or processes, products, systems, organizations, personnel, or policies), improve program effectiveness, and/or inform decisions about future program development.

Key Concepts

- Program evaluations may be considered research when there is a hypothesis or question being answered and the information being collected is designed to contribute to generalizable knowledge (i.e. beyond the context of the specific institution(s) conducting the evaluation).
- Whether these projects are research is determined by the IRBO on a case-by case-basis.
- The IRBO makes this determination by evaluating a group of factors including the purpose and intention of the project, level of risk, and methodology.
- Publishing or presenting program evaluation findings does not automatically mean the project is research.

How the IRBO Makes a Determination

If the IRBO is asked to make a formal determination, we look at a variety of questions:

First, we assess whether the project meets the **definition of research**. Then we determine if the project involves **human subjects**.

When questioning if your program evaluation needs an exemption or IRB review and approval, the project lead should ask: does the project also meet the **definition of research per the Human Subject Protection Regulations?** That is, is it a systematic investigation, including research development, testing and evaluation designed to contribute to generalizable knowledge? Program evaluation activities **are likely also not** considered human subject research when:

- They do not involve an experimental or non-standard intervention;
- Their intent is only to provide information for and about the setting in which it is conducted;
- They are conducted as part of the standard operating procedures of the setting; and
- They are (usually) not subject to peer review.

Some questions you can ask to help with these decisions:

- Is the goal of the program evaluation to test a hypothesis or answer a research question? If no, the activity is probably not research.
- Is the program evaluation intended to benefit people or communities or entities other than those from whom the data are collected? If no, the activity is probably not research.
- Is the program a routine operation in the setting? If yes, the activity is probably not research.

- Do the data gatherers have regular and routine contact with the data or the participants of the program? If yes, the activity is probably not research.
- Does the program alter the timing or frequency of standard procedures? If no, the activity is probably not research.
- Is the program part of a research project? **If yes, the activity probably is research.**

If the answer to ANY of the above suggests the activity might be research, the project should be submitted for an exemption or IRB review and approval.

Publication of findings, methodological design, selection of subjects and hypothesis testing and generating do not necessarily differentiate research from program evaluation because these attributes can be shared by both research and non-research activities. Below are elements that are common to evaluation and research projects. This list is not intended to be comprehensive and not all elements are required in order for a project to be considered research or evaluation. Rather, this list of elements can be used to assist staff in determining whether an activity involves research requiring an exemption or IRB review and approval.

Common Elements	Evaluation	Research
Intent	Intent of project is to evaluate a specific program, only to provide information for and about that program.	45CFR46.102(d): Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Belmont Report: [T]he term 'research' designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective. OHRP : "The question "what is research" frequently arises in relation to an investigator or institutional activity being planned to gather data to evaluate a specific program, such as a QA/QI activity. Although the determination as to whether the activity will contribute to 'generalizable knowledge' is often based on whether the data will be dissemination by means of publication or presentation, this should not be the sole factor used to make the determination. In general, OHRP gives guidance that if the data will be used to draw conclusions related to a larger entity then the activity is considered 'research'."
Motivation for Project	Project not initiated by the evaluator and occurs regardless of whether individual(s) conducting it may benefit professionally from conducting the project.	Project occurs in large part as a result of individual professional goals and requirements (e.g., seeking tenure; obtaining grants; completing a thesis or dissertation).
Focus	Focus on process, product, or program	Focus on population *(human subjects)*
Setting	Conducted within a setting of changing actors, priorities, resources, and timelines	Controlled setting (interaction or intervention) or natural setting (observation which may or may not include interaction or intervention)

Common Elements	Evaluation	Research
Subject Population	Group of individuals that are participants in a specific program, undergoing a particular practice or use a specific product in affiliation with an organization; exclusion of information from some individuals significantly affects conclusions.	May involve a subset of individuals; universal participation of an entire population (e.g., clinic, program, or department) is uncommon; generally, statistical justification for sample size is used to ensure endpoints can be met
Design & Desired Outcome	Designed to assess the effectiveness of or improve a process, product, or program via: - needs assessment - process, outcome, or impact evaluation - cost-benefit or cost-effectiveness analyses May involve comparison of variations in programs	Designed to answer a question or test a hypothesis to develop or contribute to the scientific storehouse of knowledge or theory within a field or contribute to a broader societal endeavor via: - procedures, component(s) or analyses, i.e. involving combining data with other projects; randomization of individuals to different processes or interventions; novel research ideas; experimental activities that are not yet known to be efficacious; expanded sites, or literature reviews May be designed to be descriptive, or prove a relationship, correlational or causation
Value	Determines merit, worth, or value	Strives to be value-free
Benefit	No benefit to participants expected; evaluation concentrates on program improvements or whether the program should continue.	Participants may or may not benefit directly – benefit, if any, to individuals is likely to be incidental or delayed.
Effect on Standard Procedures or Normal Activities	Evaluation will rarely alter the timing or frequency of the program (standard procedures)	Standard procedures or normal activities may be altered by an experimental or non-standard intervention as part of the evaluation
Funding	Directed and usually funded by the entity doing the program	May have external funding

Common Elements	Evaluation	Research
Effect on Program or Practice Evaluated	Findings of the evaluation are expected to directly affect the conduct of the program and identify improvements.	Findings of the study are not expected to directly or immediately affect institutional or programmatic practice; although they may also be used for this purpose. Activity will be used to develop a problem statement, research questions, and/or theory-based hypotheses.
Dissemination of Results	If publication results, has no impact on how the project is designed or analyzed 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 knowledge.	The desire to disseminate impacts the choice of procedures or analyses, in order to strengthen generalizability 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, grant proposals, or other research/scientific forum; results expected to develop or contribute to generalizable knowledge by filling a gap in scientific knowledge or supporting, refining, or refuting results from other research studies. Results of the project will be disseminated outside the institution for the purpose of sharing the outcomes or implications of the project, not just the process.

What If I Want to Publish the Results of My Program Evaluation?

It is entirely appropriate to disseminate results of a program evaluation, including through channels that are external to an organization such as conferences or publication. This may include presentations at meetings and publications in professional journals. Therefore, the mere intent to publish the findings of a program evaluation does not obligate submitting for an exemption or IRB review and approval as long as the publication makes it clear the publication is the result of a program evaluation as defined above.

If the project is research involving human subjects, submission for an exemption or IRB review and approval is required.

See the Prospective Data Collection Protocol Template for exempt human subjects research projects involving surveys, interviews, focus groups, benign behavioral interventions, or public observation.

See Retrospective Data or Biospecimen Review Protocol Template for projects involving retrospective chart reviews or biospecimens and no retention of identifiers.

If your project involves other human subject research activities that may require IRB review and approval of a research protocol, please see the other NIH IRP protocol templates.

If the project team wants a formal determination that the project is not research, complete the request for determination for "Not Human Subjects Research". See the "Instructions for Submitting a Request for Determination of NHSR" on the OHSRP website.

Informed by:

Oklahoma State University:
https://www.wcasa.org/wp-content/uploads/2020/03/Evaluation_Research-Paper-What-is-the-Difference-between-Evaluation-and-Research-and-why-do-we-Care.pdf

Washington University in St. Louis HRPO Research Guide (Updated July 24, 2020, v. 23):
http://online.fliphtml5.com/ikcz/ifub/#p=1

Oregon State University IRB:
https://research.oregonstate.edu/sites/research.oregonstate.edu/files/irb/comparison_research_v_non_research_v01292018.pdf

University of Connecticut IRB:
https://ovpr.uconn.edu/services/rics/irb/researcher-guide/does-evaluation-require-irb-review/

Emory University IRB: https://irb.emory.edu/guidance/getting-started/review.html