OHIO UNIVERSITY

College of Health Sciences
and Professions

Distinguishing a Program Evaluation (PE) From a Research Project (RP): A Primer

DEVELOPED BY

Jennifer Horner

Associate Dean for Research and Graduate Students

Acknowledgments

Appreciation to the Office of Research Compliance administrative and professional staff who offered substantive and editorial suggestions to improve this educational document, as well as to faculty members who read and critiqued this document before it was finalized.

May 26, 2017

CONTENTS

*The hypothetical cases are offered for the purpose of contrasting PE and RP; they are for illustration purposes only.

PART I. OVERVIEW

Distinguishing Program Evaluation (PE) from a Research Project (RP) as Defined by the OHIO University IRB[1]

Abbreviations:

- PE: Program Evaluation
- RP: Research Project
- IRB: Institutional Review Board: at OHIO, (a) Social-Behavioral Committee, or (b) Biomedical Committee.
- ORC: Office of Research Compliance, Ohio University.

FAQs:

- *What is the federal definition of research?* The OHIO Office of Research Compliance in its correspondence () entitled "Distinguishing Program Evaluation from a Research Project as Defined by the IRB" (see Appendix A) wrote: "The federal definition of research includes three elements: a) involves living individuals; b) involves intervening or interacting with these individuals **or** collecting/using identifiable private information; **and** c) is a systematic investigation designed to develop or contribute to generalizable knowledge" (see Appendices B and C; and endnote 2 quoting the federal definition verbatim).

- *Does a PE meet the federal definition of research?* **NO**. In most instances, a PE is not research involving human subjects according to the federal definition, but a PE might have a research component. If the proposal combines PE and RP, the investigator must adhere to federal research regulations for the protection of human subjects as determined by the ORC/IRB..

- *Must all proposals by faculty and students that involve human participants – PE and RP – be submitted to the ORC/IRB via LEO?* **IT DEPENDS**. There are many PEs across Ohio University that do not submit to the IRB, e.g., evaluations pertaining to enhancing the quality and effectiveness of programs or specific courses, surveys of students' satisfaction and so on. PEs or pedagogical evaluations are not required to be submitted to the Office of Research Compliance/IRB ***unless*** the investigator is unclear as to whether the proposed activity is a PE or pedagogical evaluation or whether it is an RP (as per the federal definition; see endnote 2).

- *Will the ORC/IRB make the determination as to PE or RP?* **YES.** If the project is submitted through the LEO electronic IRB system, the ORC/IRB will make this determination.

- *Must all faculty and staff complete CITI human subjects training before submitting a proposal to the IRB?* **YES**.

- *Does the ORC/IRB have the authority to approve, disapprove, or request changes to your proposal?* **YES**.

- *Will the ORC/IRB determine the N, X, E, or F status of the proposal?* **YES**. Whether the IRB protocol is "exempt," "expedited," or "full board" review is determined by the ORC/IRB, not the investigator.

RESEARCH; CODE REFLECTS LEVEL OF REVIEW:

- E = exempt, 00-**E**-00
- X – expedited, 00-**X**-00
- F = full board, 00-**F**-00

NOT RESEARCH PER FEDERAL DEFINITION:

- N = not federal research, 00-**N**-00, i.e., "N" means that the proposal does not meet the federal government's definition of human subjects research in accordance with 45 CFR 46.102(d) and (f).

- *Will I receive a reference number from the ORC/IRB*? **YES**. If your proposal is a PE (and not an RP), you will receive a code with the letter N. If your proposal is an RP, the approval code will have the letter E, X, or F.

- *What if select conference organizers and publishers require an IRB determination as a condition of submission/presentation?* Should I submit a proposal to the IRB? **YES.** If—as a faculty member or a student—you are aware that select conference organizers and publishers require an IRB determination as a condition of submission/presentation—even in circumstances where you project does not meet the federal definition of research used by Ohio University as a condition of review, you should submit your proposal to the IRB. The advantage is that if the IRB has reviewed the proposed activity in advance, it will avoid delay of presentation/publication activities after the study has been completed. In this situation, submit your proposal to the Ohio University ORC/IRB and explain that your professional/scientific conference organizers and publishers require an IRB determination as a condition of submission/presentation.

- *In the federal definition of research, what does this phrase mean: "designed to develop or contribute to* ***generalizable knowledge****"?*
  To be considered "generalizable knowledge," the activity would include the following concepts:
  - Knowledge contributes to a theoretical framework of an established body of knowledge
  - Results are expected to be generalized to a larger population beyond the site of data collection or population studied
  - Results are intended to be replicated in other settings

  Source: MSU HRPP Manual Section 4-3, Determination of Human Subject Research. Retrieved April 11, 2017, from the Michigan State University website: https://hrpp.msu.edu/definitions-generalizable-knowledge

PART II. EDUCATIONAL CHART – PROGRAM EVALUATION (PE)

Main Issues (IRB/ORC Correspondence; see Appendix A)	Elements Pertinent to an IRB Proposal	Explanatory Notes
Applicability: Results narrowly applicable to the organization itself.	The PE proposal describes an evaluation of A administered by B for the purpose C The relevant organization has approved this PE.	A: Name the program; B:identify the agency or organization; C: explain the purpose of the evaluation such as "the value of (or need to change) a program, procedure or organizational practice." *Note.* If the PE proposal has a research component or if the investigator is not sure whether or not it meets the federal definition of research, the ORC/IRB will review the proposal and make this determination.
Voluntary consent: Consent is not required for proposals that are strictly PEs because evaluation of services rendered is part of routine operations.	The PE data to be analyzed will be internal to the organization and will be used exclusively to evaluate the program.	If identifiable data are used and are HIPAA-protected (or otherwise protected under state law), voluntary consent will not be required in most situations involving PEs assuming all other elements of PE are met (as summarized in this document). *Note.* A PE might include elements of research as defined by the federal regulations for protection of human subjects. If the ORC/IRB determines that the PE includes a research component, more stringent consent and confidentiality protections probably will be necessary.
Impact: Well-designed PEs inform the practitioner or entity about the value of (or need to change) a program, procedure or organizational practice; PE yields ways to improve quality.	The PE will potentially have a significant impact on quality of services offered because it will examine D in light of a variety of factors E.	D: the "outcome" of interest [the dependent measure]. E: the independent measurable variables that potentially influence the outcome of interest; for example the characteristics of the clients being served, the dates of service rendered (reflecting the dates of records accessed); and, characteristics of the services rendered. Other types of independent variables potentially relevant to the outcome of

		interest might include the frequency of visits or the cost, as well as demographic features such as age, education, socioeconomic status, family status, work history and so forth. Decide in advance how you plan to analyze the data. Typically you will use descriptive statistics (means, medians, modes, standard deviations) or correlational statistics. *Note*. The type of statistical analysis does not distinguish a PE from an RP. The statistical analysis is dictated by the question being asked, the "n" (size of sample), and the number of variables. Seek advice from your faculty advisor.
Dissemination: PEs are intended for internal dissemination and application to future incremental quality improvement in programs. However, disseminating findings from a PE might and can occur. Such dissemination, even if anticipated, does not make it research by the IRB definition unless it is *designed* to create generalizable knowledge.[3]	The PE is used *by and for* the organization to assess and improve the quality of its services. The intent of the PE is to examine specific clients, intervention programs, and procedures in order to evaluate "the value of (or need to change) a program, procedure or organizational practice; PE yields ways to improve quality."	Adhere to the design of the PE as explained to the ORC/IRB and approved by the clinical entity in which the PE will take place. If you amend a PE protocol—potentially introducing research features—always consult with the ORC/IRB in advance of implementation. You are permitted to disseminate findings of the PE, e.g., at an internal conference or a professional society. If your protocol has been reviewed by the ORC/IRB, this information should be included in any resulting paper, poster or publication.

Note. ORC's correspondence "Distinguishing Program Evaluation from a Research Project as Defined by the IRB" (March, 2017) is found in APPENDIX A of this document.

PART III. HYPOTHETICAL EXAMPLE—PROGRAM EVALUATION (PE)

Statement of the Problem

Explain the problem so that the reader knows why the evaluator is undertaking this program evaluation. A problem statement for a program evaluation typically will be framed around the *quality* (accessibility, effectiveness, efficiency, cost) of *a program, procedure,* or *organizational practice.*

If relevant, provide contextual details, e.g., X County; geography, county health rankings; type of clinic, hospital, or agency. Describe the type of clients served by age, diagnosis or other relevant characteristics.

Purpose and Applicability

This proposal describes an evaluation of the social work behavioral intervention program administered by the X County Health Clinic and staffed/supervised by licensed social workers and their graduate students from Ohio University. The behavioral intervention program of interest counsels adults with a diagnosis of depression. The purpose of the proposed program evaluation is to assess the quality of services we provide to adult female clients. The X County Health Clinic has reviewed and approved this program evaluation protocol. At its inception, the intent is to disseminate the results exclusively to the XYZ Health Clinic's division responsible for the treatment of adults with depression and to the Ohio University Social Work Program administrators. (The Health Clinic and the Program have a cooperative clinical services/clinical internship agreement.)

Source of Data

The data to be analyzed in this program evaluation will be derived from clinical records internal to the X County Health Clinic, and will be used exclusively to evaluate the behavioral health program. All records accessed for analysis will remain on the secure servers of the agency, or otherwise securely protected at Ohio University, and will be aggregated and de-identified for the purpose of reporting the results to the X County Health Clinic.

Consent

The data to be analyzed will be internal to the organization and will be used exclusively to evaluate the value and effectiveness of the program. Independent consent by each client is not required for this program evaluation, because evaluation of services rendered is part of routine operations.

Methodology

Subjects. The data we intend to analyze will be extracted from client files that are maintained as part of routine care in the social work division of the X County Health Clinic. All data will be derived from records of adult female clients with self-reported depression. All will be residents of X County. The period of interest spans five-years, January 2006 to December 2010. Any client who entered the program but who engaged in three (3) counselling sessions or fewer will be excluded from analysis. The outcomes and independent measures will be derived exclusively from the internal clinical records. No intervention or direct interaction with clients is planned.

Independent variables. In order to evaluate the factors that might influence clients' outcomes, we will systematically gather data relevant to the following independent variables: (a) the years of experience of the social worker supervising the case; (b) the total number of client visits; (c) the type(s) of intervention {such as c-1 behavioral counseling alone, or c-2 behavioral counseling + antidepressant medication). In

addition, we will extract from the record (d) the span of time (in months) each client was seen in the clinic; and, each client's demographic features such as (e) age, (f) education, and (g) socioeconomic status.

Dependent variables (outcome). The primary outcome of interest is post-treatment mood, as measured by the ABC depression scale, a standardized and valid instrument that is used routinely by the social work counsellors when evaluating patients who complain of depression. A secondary outcome is the change score (baseline to endpoint). In addition, from the clinical record, we will extract (a) clients' qualitative / subjective statements about frequency and intensity of depressive episodes, and (b) clients' qualitative statements about their satisfaction with the services rendered. As a matter of standard practice, these objective and subjective measures are recorded routinely no less than 1x/month, and will be derived from standard clinical records. In summary, baseline, interval, and post-treatment data will be gathered from the clinical record.

Statistical analysis. Based on past program utilization, we anticipate an accrual of 250 eligible client records over the five-year study period (about 50 each year). We plan to use descriptive statistics for the baseline-to-endpoint comparisons. We will conduct Pearson Product correlations among dependent (outcome) and independent variables and will compare change scores relative to type(s) of service rendered (counseling vs counseling + medication). If warranted, we will identify a small subset of dependent variables in a regression analysis to determine which, if any, predict the primary outcome.

Impact

This project will evaluate the effectiveness of social work counselling for a defined subset of the clients served by the X County Health Clinic. By analyzing the relationship of a variety of independent variables to the ultimate outcome (over a five-year period), our goal is to evaluate the quality of its services rendered to adult female clients with a diagnosis of depression by understanding whether depression is ameliorated (from baseline to endpoint) relative to client demographic profiles and program characteristics. With these data in hand, we will then make incremental changes to the program to improve its quality.

Note. This PE example is hypothetical and is presented solely to illustrate some relevant elements of a PE protocol.

PART IV. EDUCATIONAL CHART – RESEARCH PROJECT (RP)

Main Issues	Elements Pertinent to an IRB Proposal	Explanatory Notes
Applicability: Results broadly applicable beyond the particular setting; an RP is designed to contribute to generalizable knowledge. (See decision chart in Appendix C.)	By way of example, an RP proposes to include participants who have the condition of interest, in order to compare whether intervention 1 is the same or different in effectiveness from intervention 2. Note. The research questions or hypotheses determine the research design. Many different variations exist. Consult your faculty advisor.	In this example, the goal is to determine the relative effectiveness of two interventions by examining individuals with the same medical condition. a-Identify and recruit participants prospectively; define inclusion and exclusion criteria; b-Distinguish the specific interventions (these are the main independent variables in the hypothetical example in PART V below); c-Identify the dependent variables (the behaviors of interest that are expected to change as a result of the intervention(s); d-Identify and describe the measurement instruments, testing intervals, and so forth.
Voluntary consent: Research participation is voluntary. The investigator explains that the project is research; that the participant may or not benefit; that the study might involve minimal or greater than minimal risks and so on.	In all types of research including healthcare research, participants must consent to the use of their private information, typically in the form of a written "informed consent" document. Other elements of an informed consent include the purpose of the study, the expected numbers of subjects, remuneration if any; and participants' right to withdraw from the study without loss of any benefits to which they are entitled.	The informed consent document should explain to participants how the investigator plans to protect the privacy of research participants, the confidentiality of the data gathered for research purposes, and how long the data will be securely stored (minimum 3 years). In some circumstances, investigators might wish to request an alteration or waiver of the consent requirement or seek consent from a surrogate. This is only permissible if the ORC/IRB approves the waiver or surrogate consent in advance.
Impact: Well-designed and executed RPs inform scientists and practitioners of research findings that inform *theories* about why biomedical or social-behavioral phenomena	This RP is designed to contribute *new knowledge* to existing evidence. The purpose of each new RP is to replicate or improve research questions and research designs, to identify new study populations,	*Note*. The statistical analyses are dictated by the research questions or hypotheses, the size and distribution of the sample, and the types and numbers of variables. In a hypothesis-driven study—when different interventions or different groups are

occur, about *evidence* supporting or refuting therapeutic interventions, and about *clients/patients* who might or might not benefit from specific interventions.	and to examine alternative theoretical models. Therefore, an RP potentially has broad and significant impact on the basic or applied healthcare sciences or other types of research.	compared—inferential statistics are used. Seek advice from your faculty advisor.
Dissemination: RPs results are intended for wide dissemination, typically in the form of peer-reviewed publications so as to contribute to generalizable knowledge	Dissemination is essential for progress of science and its applications (e.g., evidence-based clinical practice).	Adhere to the design of the RP as approved by the ORC/IRB. Report protocol deviations to the IRB. Submit protocol amendments to the IRB in advance, and receive IRB approval prior to implementing any changes to the approved research protocol. When disseminating your findings, (e.g., at poster or platform sessions at a professional society, or in peer-reviewed publications), include the fact that the study was approved by the IRB/ORC.

PART V. HYPOTHETICAL EXAMPLE—RESEARCH PROJECT (RP)

Statement of the Problem

Explain the problem so that the reader knows why the investigator is undertaking this research project. A problem statement for a research project is framed around *what is known* (a literature review), *what is not known or understood* about the mechanism of the biomedical or social-behavioral condition, and *what factors influence* the disease or condition of interest to prevent, cause, or ameliorate it. The problem statement will articulate the *gap in knowledge* that this particular RP intends to address.

Focus the problem statement by providing contextual details, e.g., X County; geography, county health rankings; and the source of patients (e.g., community agency, hospital). Describe the population of interest by age, diagnosis or other relevant characteristics.

Theoretical Model and Generalizability

A scientific research proposal includes a theoretical model. A theory is "an abstract generalization that presents a systematic explanation about relationships among phenomena" (Polit & Beck, 2007, p. 734, as cited in Rourke et al., 2010). A theory-driven protocol asks "why?" Why does behavior change? Why do relationships between X and Y occur? If an effect is found, why is one intervention superior to another? Why, from a theoretical perspective, should we expect there to be a difference between the two chosen interventions?

A theory is important, because measuring change in the absence of theory is merely "reporting, not [-] science" (Gioiella, 1996, p. 47). Measuring change in a rigorous, controlled manner in the presence of theory *is science* and, therefore, the results are amenable to *generalization.* (See p. 4 above, explaining what is meant by the phrase in the federal definition of research "designed to develop or contribute to generalizable knowledge").

Thus, the statement of the problem and the theoretical basis for the research are essential elements of a scientific research project. These elements, in turn, lead to research questions and methodology. At the conclusion of the study, regardless of how the data "turn out," the theoretical model that has been used to guide the research hypotheses should be used to interpret the outcomes. Whether the hypotheses are affirmed or refuted, the data should be used to refine a) the research questions, b) the research design, and/or c) the theory itself.[4]

Purpose and Applicability

This proposal describes an RP regarding the behavioral intervention program administered by the X County health clinic and staffed/supervised by licensed social workers and their graduate students from Ohio University. The behavioral intervention (counselling) program is designed to ameliorate depression in adult female clients. The purpose of the proposed RP is to compare the effectiveness of two different types of interventions to determine whether behavioral counselling is more or less effective than a program that involves behavioral counseling plus antidepressant medications. The IRB/ORC and the X County health clinic have reviewed and approved this RP protocol. At its inception, the intent is to disseminate the results widely through peer-reviewed publications in hopes that we will contribute to knowledge surrounding depression in adult females representing a rural, low socioeconomic strata who are reliant on county health departments for counselling and guidance.

Research Questions

In a population of patients with depression situated in a rural area of the United States and treated by social workers over an 8-week period:

- Does behavioral therapy (counselling) alone lead to significant positive changes in mood?

- Does behavioral therapy (counselling) alone + antidepressant medication lead to significant positive changes in mood?
- Is behavioral therapy (counselling) alone more or less effective (at statistically significant levels) than behavioral therapy (counselling) + antidepressant medication?

Hypotheses

The theory guides the hypothesis (a statistical prediction about change and the direction of change, examined using an appropriate inferential statistic), e.g.,

- Null hypothesis: There will be no difference between behavioral therapy vs behavioral therapy + an Rx intervention.
- Alternative hypothesis: Behavioral therapy alone will be inferior to behavioral therapy + an Rx intervention.

Methodology

Source of data. The following sources of data will be used: 1) medical record, 2) social work clinical files, and 3) data collected exclusively for research purposes. All records acquired for analysis will be remain on the secure servers of the agency, or otherwise securely protected at Ohio University, and will be aggregated and de-identified for the purpose of disseminating the results. Per the federal regulations, the primary investigator of the RP is responsible for securely saving all research records for no less than 3 years after the completion of the study, longer if required by the funding agency or per standard practice in X County health clinic.

Consent. With clients' consent, they will be enrolled in the study after they understand the research purposes and procedures, the risks and benefits of participation (if any), and that they will be randomly assigned to one of two different therapy approaches. All consenting participants will understand that the data to be analyzed will be collected within X County health clinic, then will be relocated *in de-identified* form to Ohio University for analysis and dissemination.

Subjects. After their initial evaluation and diagnosis of depression, individuals will be invited to enroll in the research project if they meet specific inclusion criteria, e.g., >18 years of age; female; capacity to consent to research; medical clearance from primary care physician; and, not currently on antidepressant medication. Exclusion criteria will include: prior attempted suicide or psychiatric hospitalization; unable to attend at least one counselling session per week for 8 weeks. Consenting subjects will be enrolled as they enter the clinic until 100 subjects are enrolled, 50 in each group. An independent social worker will monitor each research participant's clinical status to remove the individual from the research project if warranted.

Independent variables. The main independent variables are the treatment conditions to which the consenting participants will be randomly assigned: 1) counselling only, or 2) counseling + medication.

Dependent variables. The primary dependent variables in this RP are depression severity and change in depression as measured by a reliable and validated depression scale, and cognition as measured using a reliable and validated instrument cognitive abilities instrument. Covariates are age (years) and duration of depression (months). Additional variables of interest include socioeconomic status and educational level, and number of major current medical diagnoses.

Statistical analysis. We plan to compare baselines and endpoints relative to the type of treatment (counseling alone versus counseling + antidepressant medication) using two-tailed inferential statistics. An n of 50 in each group provides adequate statistical power, using $p < .05$, meaning that if there is a difference (i.e., a true effect of an intervention), the statistic will detect it. Secondary analyses will use age and duration

of depression at baseline as covariates. Descriptive and correlational statistics will also be used to discern patterns relative to marital status, socioeconomic status, educational level, and the number of other major medical conditions.

Impact

By analyzing endpoints and change scores over the course of 8 weeks relative to either counselling alone or counselling + medication, we will fill a gap in our understanding about whether one approach or the other (or neither) offers greater value for adult female clients seeking therapy for depression at a county health department in a rural Midwest city. We will disseminate our findings in a peer-reviewed scientific journal to stimulate future research on the effectiveness of treatment for depression in patients of differing types. Our ultimate goal is to apply evidence-based approaches in the clinic to enhance quality care while reducing cost where possible. Depending on the results of the proposed study, we will make incremental changes to our counselling regimens and research designs (e.g., controlling for years of experience of our counsellors; stratification of participants by age, family status, etc.) to advance our understanding of what factors influence treatment efficacy.

Note. This RP example is hypothetical and is presented solely to illustrate some relevant elements of an RP protocol.

References (endnote[5])

APPENDIX A

Distinguishing Program Evaluation from a Research Project as Defined by the IRB

Ohio University Office of Research Compliance

[Correspondence, March 2017]

Federal definition of research used by Ohio University's Institutional Review Board:

The federal definition of research includes these elements: a) involves living individuals; b) involves intervening or interacting with these individuals or collecting/using identifiable private information; and is a systematic investigation designed to develop or contribute to generalizable knowledge.

Program evaluation (PE) with the following features does not meet this definition of research:

- **Applicability local**: Results narrowly applicable to the organization itself.
- **Voluntary consent**: Consent not required for PEs because evaluation of services rendered is part of routine operations. PE respects HIPAA-protected status of individually identifiable data.
- **Impact**: Well-designed PEs inform the practitioner or entity about the value of (or need to change) a program, procedure or organizational practice; PE yields ways to improve quality.
- **Dissemination**: PEs are intended for internal dissemination and application to future incremental quality improvement in programs. However, disseminating findings from a program evaluation might and can occur. Such dissemination, even if anticipated, does not make it research by the IRB definition unless it is *designed* to create generalizable knowledge. Thus, a well-designed PE might be generally interesting (and thus disseminated), but if the intent is not to assess a generalizable (i.e., global) question, it is not research by the IRB definition.

Ohio University, Office of Research Compliance

Location of additional guidance documents:

https://www.ohio.edu/research/compliance/human-subjects.cfm

APPENDIX B

Typical Features That Help Distinguish a Program Evaluation From a Research Project

(Horner, 2/23/17)

Characteristics	Program Evaluation (PE)	Research Project (RP)
Definition	A program is "*any set of organized activities supported by a set of resources to achieve a specific and intended result.*" Evaluation is the "*examination of the worth, merit, or significance of an object*" (CDC, 2012).	The federal definition of research includes these elements: a) involves living individuals; b) involves intervening or interacting with these individuals *or* collecting/using identifiable private information; *and* is a systematic investigation designed to develop or contribute to generalizable knowledge.
Intent	To evaluate the effectiveness, efficiency, or client and practitioner acceptance of a program, a process, a procedure, or an organizational practice.	To produce new knowledge that will advance our understanding of phenomena that impact health, illness, and healthcare delivery.
Applicability	Results narrowly applicable to the organization itself.	Results broadly applicable to the body of knowledge on which the research was based, including related theoretical models.
Benefit	Knowledge gained through PE will be used to improve a program, a process, a procedure, or an organizational practice.	Knowledge gained through a RP is not primarily intended to benefit research participants but hopefully will inform evidence-based practice (EBP) to the benefit of individual organizations and practitioners.
Approval	The organization's administration agrees it is a PE/QI project and the OHIO Office of Research Compliance or the IRB agrees that it does *not* meet the federal definition of research (coded *N*).	The Institutional Review Board (IRB) agrees the project meets the federal definition of research and approves the protocol as a RP (exempt, expedited or full board review; coded *E*, *X*, or *F*, respectively).
Standard of care	All clients receive standard of care; includes a wide variety of acceptable practices *individualized to meet the specific needs of each client*, nested under programs of care and organizational practices. Delivery of care to clients is governed by professional and institutional standards of care; deviations should be reported to the institution.	The standards for research and research ethics include social or scientific value, scientific validity, fair subject selection, favorable risk-benefit ratio, independent review, informed consent and respect for potential and enrolled subjects (Emanuel et al., 2000). RPs are governed by IRB-approved protocols; all deviations must be reported within 72 hours.
Hypothesis	Based on prior institutional and practitioner practice patterns, PEs are descriptive, not hypothesis-driven.	Based on prior knowledge and theory, RP s are typically hypothesis-driven.
Data collection	Typically retrospective, i.e., analysis of data already on hand.	Typically prospective, i.e., involving collection of data with specific research aims in mind.
Participants	Uses a convenience sample of clients or practitioners; PEs should include sufficient numbers of participants to assure representativeness.	Uses inclusion and exclusion criteria to guide participant selection; RPs must have sufficient numbers in each group or condition to assure validity (and statistical power).
Consent	Consent not required for PEs because evaluation of services rendered is part of routine operations. All PEs using medical records must adhere to HIPAA regulations and/or state law governing medical privacy.	Consent is required for RPs, unless a waiver of informed consent is granted by the IRB, because participants are volunteers who may refuse or withdraw from RP at any time without penalty (will not affect actual clinical care).
Subject assignment	No matching or randomization among participants.	Matching or random assignment of participants to different experimental conditions is common but might not always be appropriate; it depends on the

		subject availability, sampling strategy, research questions, and statistical power.
Measurement	Widely accepted clinical measurement tools are used and recorded in the client's record as a matter of routine care and good record-keeping.	Measurement tools should have known reliability and validity. Some research data may be derived from existing records; additional research data are collected solely for the RP.
Analysis	Effects on the variable of interest (e.g., behavior, health, satisfaction) are quantified and analyzed in light of *program characteristics* as well as demographic variables.	Effects on the variable of interest (e.g., behavior, health, satisfaction) are quantified and analyzed in light of *research interventions* as well as demographic variables.
Statistics	Descriptive statistics (e.g., mean, median, mode, range, SD). Tables, bar graphs and scatterplots are often used to illustrate results. Correlation coefficients may also be used to elucidate the strength of associations among variables.	Descriptive statistics are supplemented by inferential statistics, which are used to test the hypothesis at a predefined p-level or effect size. Correlation coefficients may also be used to elucidate the strength of associations among variables. Regression analysis may be used to determine whether any independent variables predict the dependent (outcome) variable.
Impact	Well-designed PEs inform the practitioner or entity about the value of (or need to change) a program, procedure or organizational practice; PE yields ways to improve quality. Because PE lacks rigorous scientific controls, PE are program specific and rarely generalizable to other settings.	Well-designed RPs contribute to theoretically driven knowledge; statistically significant findings for the sample(s) of subjects under the condition(s) of the protocol are generalizable to the population of individuals with similar characteristics. Because RP's have rigorous scientific controls, results are generalizable to other settings.
Value	Well-designed PEs have clinical value.	Well-designed RPs have scientific/theoretical value and, ideally, are applicable to clinical settings.
Dissemination	PEs are intended for internal dissemination and application to future incremental quality improvement interventions.	RPs are intended for external dissemination (via peer review journals) and contribution to future incremental research interventions.

Note. Whether or not you intend to (or actually) publish your findings is *not* the distinguishing feature of a program evaluation versus a research project.

Centers for Disease Control and Prevention. (2012, May 11). *Introduction to Program Evaluation for Public Health Programs: A Self-Study Guide.* Retrieved February 23, 2017, from https://www.cdc.gov/eval/guide/introduction/

Emanuel, E. J., Wendler, D., & Grady, C. (2000, May 24/31). What makes clinical research ethical? *JAMA* 283(20), 2701-2711. https://doi.org/10.1001/jama.283.20.2701

Federal regulations governing research: Code of Federal Regulations, title 45, part 46. *Protection of Human Subjects.* Retrieved February 23, 2017, from http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title45/45cfr46_main_02.tpl

ENDNOTES

[1] *See* OHIO Office of Research Compliance (2017, March). Distinguishing Program Evaluation from a Research Project [Correspondence]. (March 2017). (See Appendix A.)

[2] 45 Code of Federal Regulations, Part 46, Protection of Human Subjects. Definitions (45 CFR § 46.102).

> **"(d)** *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition

constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities." (45 CFR 46.102)

. . .

(f)*Human subject* means 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. (45 CFR 46.102)

Source: https://www.law.cornell.edu/cfr/text/45/46.102. Accessed April 10, 2017.

[4] What types of theory might be relevant in the context of this hypothetical example? By way of example, one might explore theories governing learning, or cognition, or the relationship of cognition and behavior, or the therapeutic benefit of the patient-counselor relationship itself (see Hayes, 2004). Alternatively, if the investigator is more interested in physiology, the relevant theory might pertain to neural mechanisms, asking a question such as, *why* does behavior change when medications affect neurotransmitters such as serotonin? (e.g., DeRubeis Siegle, & Hollen, 2008).

[5] References pertaining to theory-driven research:

DeRubeis, R. J., Siegle, G. J., & Hollon, S. D. (2008, October). Cognitive therapy vs. medications for depression: Treatment outcomes and neural mechanisms. *Nature Review Neuroscience, 9*(10, 788-796. https://doi.org/10.1038/nrn2345

Gioiella, E. C. (1996). The importance of theory-guided research and practice in the changing health care scene [Editorial]. *Nursing Science Quarterly, 9*(2), 47.

Hayes, S. C. (2004). Acceptance and commitment therapy, relational frame theory, and the third wave of behavioral and cognitive therapies. *Behavior Therapy, 35*, 639-665.

Polit, D., & Beck, C. (2007). *Nursing research: Generating and assessing evidence for nursing practice* (8th ed.). Medford, NJ: Lippincott Williams and Wilkins.

Rourke, L., Schmidt, M., & Garga, N. (2010). Theory-based research of high fidelity simulation use in nursing education: A review of the literature. *International Journal of Nursing Education Scholarship, 7*(1), Article. 11. https://doi.org/10.2202/1548-923X.1965

APPENDIX C:

A DECISION TREE FOR **RESEARCH**

1 Does my work involve LIVING individuals? → YES ← Does my work involve intervening or interacting with these individuals? OR collecting/using identifiable private information?

↓

AND

↓

2 Is my work a systematic investigation designed to develop or contribute to generalizable knowledge--for example, do I intend to disseminate my work to the public and/or scientific community via poster, presentation, publication, grant proposal, public news announcement, or other venue?

NOTE. Collecting/using/discussing/presenting data collected from living individuals that is strictly confined to the classroom for learning purposes is *not* public dissemination; therefore, it is *not* human subjects research as defined by federal regulations and does *not* require IRB pre-approval.

↓ YES → **3** IRB APPROVAL IS REQUIRED

↓ NO → No IRB Needed → Not sure? Email compliance@ohio.edu

A *single* case study (n = 1) is *not* a "systematic investigation" and *not* "designed to contribute to generalizable knowledge." Therefore, it is *not* "research" as defined by the federal regulations and does *not* require IRB pre-approval.

OU IRB Exempt Categories: http://www.ohio.edu/research/compliance/Exemption-Categories.cfm

Choose one:

"IRB-EXEMPT"	"IRB-EXPEDITED"	"IRB-FULL REVIEW"
Six possible types of research may be "exempt" from continuing review, but you must complete an IRB protocol.	Studies involving minimal risk or less and meeting one or more of 9 defined categories will be deemed by IRB to be expedited; you must complete an IRB protocol.	Protocols involving more than minimal risk must have full board review; you must complete an IRB protcol.
Submit an IRB protocol.	Submit an IRB protocol.	Submit an IRB protocol.

You must complete CITI Biomedical Research Training online BEFORE your IRB protocol can be approved.

An approved IRB protocol is a contract (mutual and binding promises) between the faculty investigator and co-investigators (including students) that is governed by federal regulations.

NOTES:

(a) A violation of or deviation from an IRB-approved protocol is serious; could lead to suspension of your research; inability to use the data; or other sanctions.

(b) Follow the IRB-approved protocol exactly. If your protocol needs to be changed, submit an amendment to the IRB.

(c) If you notice an unintentional or inadvertent deviation from protocol, report it immediately to the IRB, and work with the IRB to correct it.

Source of regulations: 45 C.F.R. 46
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

5/24/2013