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Using Forms to Develop Research Projects

This article is the 16th in a multipart series designed to assist readers, particularly novices, in the area of clinical research. This article is focused on the process of developing a new research project. It provides tools to help those involved in beginning their own research projects.

The process of considering and then developing a new research project involves several steps. Many of those steps have been the focus of prior articles in this series. This installment is designed to provide tools to facilitate that process, namely, forms to standardize the process of developing a research question and study protocols. Experienced airline pilots and anesthesiologists have been shown to benefit from the use of checklists or standardized protocols in their jobs. Clinical research is no different. The use of forms or checklists is a practice that many experienced researchers use when developing a potential new study. Such forms can be even more useful for less experienced researchers.

The first form discussed in this article is designed to help develop and refine appropriate research questions. Research begins with the desire to know something, most often stated in the form of a research question or hypothesis. Such questions should be carefully considered and properly formatted. The elements of a properly structured research question were described in Part 1 of this series.[1] A proposed research question is then further refined in a process that considers such aspects as feasibility, relevance, and the ethics involved, which is also described in Part 1 in this series. One of the steps in that refining process is to decide whether the idea is indeed novel. This generally involves a formal literature search and other explorations on the topic. This is helpful in deciding whether the project is of sufficient importance to warrant further efforts. Performing a quality literature review is described in detail in Part 2 of this series.[2]

Once a decision is made that a research question is indeed worth pursuing, the next step is to develop a study protocol (ie, design the experiment). The second form provided in this article is intended to assist with that process. The study protocol forms the blueprint, or recipe, for actually conducting the research study. Study protocols generally contain many different elements. These include defining the independent and dependent study variables and selecting a basic study design (described in earlier articles).[3,4] Protocol decisions also include such details as how the population will be sampled and whether randomization will be performed. The process of random assignment is described in Part 5 of this series.[5]

The investigator also makes decisions regarding the study measurements that will be performed—what they are and when and how they will be performed. This information is further described in Part 6 of this series.[6] In the design phase, the investigator should consider the possibility of extraneous variables and other factors that could cause bias or confound the study results. Effort should be made to eliminate these sources of potential bias in the design phase of the study. This is described in further detail in Part 7 of this series.[7]

The basic research design selected can have unique aspects that direct or limit elements of the study protocol. For example, random assignment can occur only in prospective studies and is not an option in retrospective designs. Survey designs, retrospective chart reviews, and so forth have unique structural aspects that direct the measurements that can be made. Some of these are described in further detail in prior articles of this series.[8-10] Once the study protocol has been finalized, it must be submitted to and approved by the Institutional Review Board or equivalent. Pilot testing of all studies is recommended unless they follow well-established protocols. The results of pilot experiences often necessitate changes in the protocol before beginning the full study.

On the following pages are two forms useful for turning research ideas into actual research projects.

- The first is a one-page research-question development form. The form has multiple sections, each focusing on an important step in the process. The first step is properly formatting the research question. The next step is to refine the question, including deciding whether it is truly novel. This form not only helps to transform research ideas into proper research questions; it also helps with making decisions as to whether a project is worth pursuing.
- The second form is a two-page tool for identifying and defining the elements of an actual study protocol. Sections are included for each of the variables and measurements that generally go into protocol design. The

Research Question Development Form

(Complete each of the following sections)

What is your research question?
(Include each of the following PICO elements)
Patients (subjects)

Intervention

Comparison

Outcome

What is the null hypothesis (H_o) for the project?

What is the alternative hypothesis (H_a)?

Which is your study hypothesis?
(Be specific about what you expect the answer to your research question will be.)

What did the literature review find?
(How much related research has been published; what is known, not known, and so forth?)

Why is it an important and relevant question?
(Does it meet each of the FINER criteria?)
Feasible

Interesting

Novel

Ethical

Relevant

Research Protocol Development Form

Your name:_____

(NB: Not all sections are applicable to all studies; eg, observational studies or evaluation of a diagnostic test.)

Study Title:

Research Question:

Study Hypothesis:

Independent (Intervention) Variable(s):

Dependent (Outcome) Variables(s):

Extraneous (Potentially Confounding) Variables (list multiple):

List inclusion and exclusion criteria for your study:

Inclusion Criteria	***Exclusion Criteria***
1.	1.
2.	2.
3.	3.
4.	4.
5.	5.
6.	6.
7.	7.

Study Design *(eg, RCT, cohort, cross-sectional):*

Research Protocol Development Form (p. 2)

Name:_____

Sampling method to be used:

Random Assignment? (if yes, how?):

Study Measurements *(eg, Hct, PO_2, pain)* How measured (eg, ABG machine, VAS)

Baseline/initial:

1.

2.

3.

4.

Postintervention *When (timing)*

1.

2.

3.

4.

Are the primary study measurements or scales validated? (If so, how?)

Sample Size Calculation *(discuss with research preceptor or statistician as needed):*
How many patients will you need to perform your study and adequately answer your question?
(Sample size calculations can be done using computer programs, internet sites, or a statistician.)

These calculations generally require information about:

1. The expected rate of the outcome variable (eg, death rate) or the amount of variance (eg, standard deviation) in the dependent variable in the study population _____

1. The percentage or amount of difference (effect size) in the primary outcome measure that would be clinically significant to detect in your study _____

2. The desired alpha (usually 0.05) _____ and desired beta (usually 0.1 or 0.2) _____

How many study subjects are estimated to be needed in each group and total?

measurements to be made generally relate directly to assessing independent and dependent variables. Not every section is directly relevant to all projects (for example, some studies do not include random assignment). The terminology used on these forms (eg, study measurement validity) are discussed in detail in prior articles in this series.[6,7]

- One of the most important steps in designing a study is performing a sample size calculation a priori. This defines the number of study subjects or measurements that will be needed to have a good chance of answering the research question at the end. The process of performing sample size calculations will be addressed in a future installment in this series.[11]

No study should begin without an a priori set of directions, or blueprint, that defines each of the study variables and directs each of the study measurements and other actions. Use of forms such as these can be very helpful in converting ideas into quality research questions, deciding whether a question warrants a full project, and designing comprehensive study protocols capable of answering the question. This all needs to be done before enrolling the first study subject.

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