ProtocolBuilder®

Conducting a Successful Residency Research Project

Most medical schools, as part of the graduate medical curriculum, require residents to conduct at least one research project. These projects are designed to give clinicians early in their career an opportunity to manage a project, understand the importance of well-designed clinical research and to improve their communication skills. This may be the first time a resident goes through the entire process of writing a clinical research protocol that must undergo the rigorous review by their superiors and the IRB. Some institutions provide the resident with a mentor, or preceptor. But in some cases, the resident must rely on other sources for assistance, such as fellows or the medical librarian.

A successful residency research project starts with a strong, well-developed protocol. This article will highlight the key elements of a research protocol and the common pitfalls to avoid.

Start with a good idea

This is easier than it sounds and is often where a less experienced researcher may stumble. Consider a question that may come up in everyday practice or on clinical rounds with patients. It's best to brainstorm more than one question to ensure existing literature hasn't already addressed it. Even if there are published studies addressing the question, there may be additional questions that warrant further study.

Challenge your idea

Ask why is it important to conduct this particular research. Good ideas are feasible, interesting to the researcher and ethical. They should also be novel, and the resulting answer should be relevant and useful to future researchers and clinicians.

Feasibility is an important consideration for residents, since their projects are typically for one year. While the gold standard of clinical research is a prospective, randomized and controlled trial, these take much longer and require significant resources to complete. By default, then, many residency research projects are retrospective or non-interventional studies.

Consider your hypothesis

This idea needs to be expressed in the form of a question, which then leads to a hypothesis. The hypothesis should be an educated, testable prediction about what will

happen in the “experiment.” A well written and defined hypothesis is the key to developing a research protocol. With a strong hypothesis, the investigator can then define specific objectives that will answer the research question.

Review existing research

The importance of reviewing the literature cannot be overemphasized. In combing the literature, you may find many studies similar to yours have already been conducted. Medical librarians can offer significant support in researching the vast databases available. The results of this work can lead to a clearer research question, the foundation of a strong protocol.

Write a clear protocol

The protocol will guide the researcher throughout the research project. As the building block of all research, it facilitates the effective processes that are required to answer the research question. Additionally, a well-written protocol complies with regulatory requirements, including the review by the IRB.

Federal regulatory agencies have encouraged the use of a standardized approach to writing research protocols. While it is not essential that the researcher follow these in a residency project, it can be helpful to establish a well-organized and methodical process to ensure all the important elements of the project are addressed.

Additionally, establishing a habit of a systematic approach early in one’s research career will make it easier to apply for grants and other funding later.

A protocol should include these key elements:

- A synopsis — A synopsis should include the research question, the hypothesis, the objectives and the endpoints.
- Introduction and background — An introduction describes the topic of the research, the importance of the problem and why the study needs to be done. The background summarizes the research literature and describes a gap in the current knowledge that the study will address.
- Literature review — The literature review should provide a synthesis of the current literature to establish the relevance of the problem and description of the literature that supports the need for the study. It should include a description of the iterative search process, the search terms used, a list of the databases and search engines used, the publication time period searched, and dates when searches were conducted.

- Research design and methods — Studies can be prospective or retrospective, interventional or observational; quantitative or qualitative.
- Study population — Write a description of the participants you expect to include in the study. Information can include age, sex, medical history, socio-economic status, etc. This section should include exclusion, as well as inclusion, criteria. State the sample size and provide a rationale for determining the number of participants.
- Study procedures — This section describes each step of the process, including methods of recruitment, screening, enrollment, consent, specimen collection, laboratory procedures, a schedule of when participants will visit the clinic, if appropriate.
- Data collection and handling — How will you collect the data? How will it be handled and stored to ensure patient privacy? Identify each data collection instrument that will be used (published or researcher produced).
- Statistical analysis plan — Among other things, a statistical analysis plan addresses how the researcher will mitigate against various types of bias. This analysis plan should be aligned with the research design and be able to provide data that answers the original study question. Include a discussion of the limitations of the research and the generalizability of the findings.

Carrying out a research project can be a daunting task for a resident with little experience. A guided, step-by-step process can ease the burden of writing a thorough protocol. Understanding these elements will help residents ensure their protocols are clear and concise, and set the roadmap for a successful research project.