Tips for Writing a Research Protocol

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A brilliant advanced practitioner colleague, whose article you will find in this issue, asked whether *JADPRO* would publish her successfully funded grant application. When I asked about her motivation to become a researcher and seek grant funding after years of a successful clinical career, she had the most astonishing reply. "Physicians can be physician scientists, and I wanted to be a nurse practitioner scientist." Her motivation made me wonder how many other advanced practitioners (APs) share the same desire: To strike a balance between conducting innovative research and maintaining patient care responsibilities. Indeed, her career path seemed remarkably similar to mine.

I have known Sara M. Tinsley-Vance, PhD, APRN, AOCN®, of Moffitt Cancer Center, for years, and have been fully aware of her extensive experience in the diagnosis and management of older adults with acute myeloid leukemia. Knowledge gained through her clinical work undoubtedly drove her passion to conduct innovative symptom management and quality-of-life research. Personal connections with patients and families led to her desire to retain her clinical practice. As you can imagine, time was a barrier to balancing these two areas of her profession.

In this issue, Dr. Tinsley-Vance provides a window into her career path. She found a unique approach to achieve her goals through writing a business plan and securing research funding for protected time. Most of you who are reading this are likely wondering how to achieve a professional model similar to the one Dr. Tinsley-Vance has. In previous issues, I wrote about the differences between quality improvement projects and clinical research, and tips for publishing (Faiman, 2021, 2022), but until now, I have not covered protocol writing and the grant funding processes.

WRITING A PROTOCOL

A protocol is the detailed plan of the study and an essential component of research. The steps to take before one decides to write the research protocol can be overwhelming, but even babies need to take their first steps. Draw from your professional experiences, discuss your desire to conduct research, and you might be surprised by the support from your workplace! From topic discovery (What is your passion?) to literature review (Was this topic studied elsewhere and, if so, how was the research conducted? What methods and instruments were used?), you will likely need to assemble a research team and obtain as much support as possible for data

J Adv Pract Oncol 2023;14(4):269–270
https://doi.org/10.6004/jadpro.2023.14.4.1

Table 1. Tips for Writing a Research Protocol

Items to consider	Notes
Topic discovery	• Pick a topic you are passionate about. • Identify knowledge gaps in your area through a review of the literature. • A PubMed search will let you know if this topic has been studied before.
Consider the who, what, when, where, why, and how of your study	• Who is the population you will study, and who are the study staff involved in the research? • What is the background and significance? • When will this take place? • Where will the study be conducted? • Why are you studying this? • How will you identify and recruit patients, protect their safety, and analyze data? • If the study involves research on human subjects, obtain the institution's ethical approval.
Identify a mentor or collaborator and assemble a team	• Identify a colleague who is also interested in your area of research. They can share insights into available resources such as study staff and procedures to follow. • Many institutions require special training and certification for all investigators. • See if funding is available internally through your department, or through a larger grant source. Sometimes you can adjust your topic focus to fit within grantor guidelines.
You have identified your topic. Congratulations! Now you have to develop your protocol	• The protocol is a detailed plan of how you carry out your study. Take each part of the protocol section by section. • Background and significance: Use an attention grabber or statistic, and explain why reviewers should care about the problem you want to study. • Introduction to the problem, study rationale: Why is this problem important or innovative? • What has happened with the problem to date? Conclude with the problem statement. • Tell reviewers the solution to the problem that is proposed by the research study and how you will answer your questions.
Know your team!	• Even if you are proficient in statistics, it is helpful to have a statistician on your team to assist with sampling, statistical methods to test your hypothesis, and analysis of data. • You will likely need research assistance, nurses, and data managers to collect and input data, and file documents with the Institutional Review Board and/or grant funders.
Additional details	• Protocols will require details regarding study recruitment and informed consent: How will you recruit your subjects and inform them of the risks and benefits to participation? Protect against a potential data breach (for chart review studies).

collection and funding. See Table 1 for a brief synopsis of key considerations. You can look for funding from sources such as the National Institutes of Health, National Institute of Nursing Research, National Cancer Institute, National Comprehensive Cancer Network, or Oncology Nursing Society.

Consider adding to existing knowledge on your topic of interest by conducting your very own, well-designed research or quality improvement project. I hope to see your abstract and poster presented at a future JADPRO Live meeting, and the research outcome published in *JADPRO*!

IN THIS ISSUE

In addition to Dr. Tinsley-Vance's article on a research strategy for a quality-of-life decision-making model for older patients with acute myeloid leukemia, read about findings on the relationship between distress levels and communication needs of neuro-oncology patients in this issue. In the Review department, learn about the management of ocular toxicities in patients receiving belantamab mafodotin; although this drug was withdrawn from the US market, there may still be patients receiving it in clinical trials. You will also find an article on the complex topic of medical aid in dying, and the provider's role in this ethical dilemma. Read a case study on managing gastrointestinal stromal tumors, with an emphasis on fourth-line options. An article in this issue investigates cost analysis data on the value of oncology pharmacists. Finally, test your knowledge on a patient with neuroendocrine malignancy and liver metastases presenting with symptoms including abdominal pain, diarrhea, abdominal bloating, and weight loss. ●

References

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