

RESEARCH PRIMER

Turning Your Research Idea into a Proposal Worth Funding

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INTRODUCTION

Great ideas for clinical research often originate at the bedside when clinicians are forced to make a decision about a patient's care, but an absence of published evidence complicates the decision-making process. This is typically how gaps in the literature are identified and translated into opportunities for clinical research. This scenario happens on a daily basis, possibly many times per day, in every clinical discipline. Most of these ideas will not be worthy of the time and effort required to develop and conduct a research project, but a few will come up often enough to warrant further consideration. This consideration requires self-assessment of your level of interest in the topic; assessment of the clinical need for new data and the feasibility and logistics of actually conducting the study; and assessment of local resources available to do the research. It is highly unusual to identify meaningful projects for which all the necessary resources are readily available, but the need to obtain external funding may be seen as a roadblock for novice researchers. A study that requires funding should be viewed not as a closed door to researchers new to the world of grantsmanship but rather as a necessary step that will increase the chances of research success and validate the importance of the project.

FOCUS YOUR RESEARCH IDEA

Preparing and planning for a research project can be more time-consuming than conducting the actual project itself. This process will test your resolve and dedication to the project. Novice researchers should understand that the time from inception to randomization of the first patient is typically many months, and while some waning of interest in a project is expected, so too is progress, especially when limited resources and other people are involved.

Become Familiar with the Current Evidence

Before you begin designing the definitive trial to answer your question, take as much time as is necessary for a thorough literature

review. Assistance from a research librarian or information specialist is usually helpful. This type of scoping exercise is important to confirm that your question has not already been answered and that it is relevant to others. Furthermore, a thorough understanding of the state of the evidence will provide context for your research question and likely will help to identify other gaps in the literature that might be worth addressing. This early effort will pay off when it comes time to actually write the grant application and provide context and rationale for your proposal.

Start with Honest Introspection

The first and most important question the researcher should ask, even before considering how to answer the research question, is "How interested am I in this topic?" This soul-searching exercise is important, given how challenging it can be to maintain the level of effort required to see a project through to completion. After a preliminary research plan is deemed feasible, based on an assessment of the work required, the researcher should ask the same question again. If the answer both times is "very interested", then the research program should absolutely move forward. But even if the answer is "not really", this is not a reason to be discouraged. Honest introspection is still a valuable process that may inform future research efforts.

Clarify Your Research Question

It is essential that you be able to convey your research question and project plan with as much clarity as possible. It is worth spending as much time as necessary to translate your clinical problem into a cogent research question, to ensure the reader of the grant application can easily identify the "who", "what", "where", and "how" of your research idea. The PICOT framework is useful for formulating most research questions. It will force you to clarify the patient, population, or problem (P); the intervention (I); the comparator or control (C); the outcome (O); and the timeframe in which the outcomes are to be assessed (T).^{1,2} It is important to be aware that although the PICOT

framework can be used for many types of research questions, it is not a universal framework suitable for *all* research questions. Readers should refer to previous articles in this series for guidance about specific study designs and strategies for developing a research question.^{3,4} Once the research question has been fine-tuned, the most appropriate study design to answer the question can be determined. A randomized controlled trial is often the best design to minimize bias, but there are many scenarios where other study designs are more ethically or logistically feasible or simply better suited to answer the question.⁵ For example, a retrospective study may be the most appropriate study design to describe the frequency and outcomes of drug-related adverse events, whereas a prospective cohort study may be more appropriate for questions related to prognosis or diagnostic accuracy.

The “why” of your research project is of equal importance to a well-articulated research question. The researcher who is developing a research program is often compared to a salesman, since the greatest task can be “selling” the research idea to potential collaborators, co-investigators, administrators, ethics boards, and ultimately funding agencies. A successful grant application conveys the clinical importance of the study that is being proposed, as well as the reasons why the applicant should be the one to do it and why the funding agency should fund it. This process always begins with a thorough review of existing evidence and a comprehensive understanding of the clinical landscape. In as little as a paragraph or two, the applicant must be able to describe the magnitude of the problem that he or she proposes to address, the current state of the literature pertaining to this problem, how the proposed study will fill one of the identified gaps in knowledge of the problem, and finally how the study results may affect patient outcomes or improve the care that patients receive. It is important to speak or write in tangible terms and to avoid vague statements, to convince people not only that the project can be done, but that it *should* be done. This section of the grant application can often be a deciding factor in whether or not the project is funded: if the reviewer is not convinced that this is an important study to do, it won't matter how well designed the study is.

Assess Your Expertise and Resources

One characteristic of a successful researcher is the ability to recognize his or her own limitations. No researcher is an expert in every facet of a research project, but it takes some foresight to identify the skill sets required to conduct all the tasks involved. It is imperative that the researcher consider the roles that he or she is able and willing to play and those that will have to be filled by potential co-investigators, consultants, and service providers. This is the time to start soliciting advice from local experts, colleagues, and mentors. There is no need for the novice researcher to have all the answers to logistic, feasibility, and ethical questions, but potential collaborators must be engaged to fill these roles. Many

larger institutions will have research infrastructure in place, where consultations and advice can be sought. Institutions have a vested interest in methodologically and ethically sound research and can advise novice researchers, as well as identify local experts with the necessary expertise. For example, it would not be out of the ordinary to solicit advice from methodologists, statisticians, administrators, colleagues, database technicians, and laboratory personnel in the process of assessing the feasibility of a new research project. Involving others at this stage also serves to reassure the researcher that he or she does not have to take on the entire burden of conducting the project alone. Seasoned researchers recognize the multitude of tasks that make up a research project, many of which are best delegated to and shared among collaborators with the appropriate expertise. This is how active researchers balance multiple research programs simultaneously.

The composition of the research team is of particular interest to granting agencies. Grant reviewers must be confident that the project will be completed if it is funded. The expertise and roles of each team member will be described in detail within the application. Having the complementary expertise to conduct the tasks assigned to each team member conveys foresight, planning, and confidence to the reviewer.

Develop a Synopsis of Your Study

At this stage it is useful to expand on the research question by writing a 1- or 2-page summary of what is being proposed. List the team members and include as much detail as has been generated by this time. An organized summary can be used when you start drafting the eventual study protocol, so it is helpful to organize thoughts and ideas as you would in a structured abstract, with subheadings similar to the following: Research Question, Background/Rationale, Objectives, Methods (in PICOT format), and Clinical Impact. Ensure that the summary includes a clear statement of the study aims and hypotheses to be tested. During this process, logistical questions should be considered to assess the feasibility of the proposed study. An incomplete assessment of feasibility is one of the most common reasons why studies fail to reach completion. Feasibility questions often are directed toward (but are not limited to) patient recruitment (e.g., Where are the patients? What groups of patients will be included or excluded? How many patients are needed? How many recruiting sites will be required? What kind of consent model is most appropriate?), the intervention and comparator (e.g., What exactly will be the intervention and comparator? Can/should they be blinded? Who will provide them? When should they be administered?), and data capture (e.g., What data will be collected and when? Where are the data? Who will collect them and how? How will the data be secured?). There may also be other feasibility questions to answer related to safety monitoring, analytical plans, maintenance of confidentiality, and resource utilization. All of these questions

must be well thought out and described in the grant application, so getting them down on paper early can be very helpful. Some preliminary pilot work can also be valuable at this point, to address potential recruitment challenges, the feasibility of data capture, and the development of study tools (e.g., surveys, case report forms).

These questions of feasibility are often difficult to answer, and doing so can be a daunting task for the novice researcher; however, early consultation with experts and building a team with complementary skills can alleviate some of the burden on the primary researcher. The other advantage to completing all this preliminary work is being able to identify insurmountable obstacles before a significant amount of time, effort, and other resources are wasted. The researcher will have to describe this process in the application, as the grant reviewer will most certainly be asking the same feasibility questions to ensure that the agency's dollars are not wasted on a project that cannot be completed as planned. If the project idea has survived to this point, it is time to consider the funding required to complete the project.

IDENTIFY FUNDING OPPORTUNITIES

There are literally hundreds of public and private agencies that offer funding opportunities in health care in Canada and thousands worldwide. These opportunities come from federal agencies (e.g., Canadian Institutes of Health Research), private or charitable foundations (e.g., Canadian Foundation for Pharmacy, Kidney Foundation of Canada), and industry partners (e.g., pharmaceutical industry, medical technology companies). Many Canadian institutions also offer local opportunities for research funding at the institution level or even the department level. The greatest challenge for researchers is finding out what opportunities are available. The Canadian Institutes of Health Research is a federal agency that provides funding opportunities for biomedical, clinical, health systems, and health-related research. To apply to one of the many funding opportunities available through this agency, researchers must be affiliated with an eligible Canadian institution or organization. Private or charitable foundations (e.g., Kidney Foundation of Canada, Canadian Heart and Stroke Foundation) that provide relevant funding opportunities are sometimes more difficult to identify. However, the search for these opportunities can be well worth the effort, as there may be less competition, and many of these granting agencies have specific opportunities for allied health professionals.

Finding out what opportunities are available is sometimes the most difficult part of applying for funding. Given the competitive nature of grant funding, it is a great advantage to be aware of funding opportunities beyond the more common (and highly competitive) federal and local funding streams. Two web-based searchable databases can be particularly helpful in keeping up with funding opportunities. The Community of Science funding opportunities database (<http://pivot.cos.com/>) is a

comprehensive source that tracks over 400 000 funding opportunities from private foundations, public agencies, national and provincial governments, and corporations. Membership is required to access the database, but most Canadian institutions or their affiliated universities have memberships available for faculty and staff. The Community of Science also maintains a database of researcher profiles and their expertise, which can be filtered geographically and institutionally to identify potential collaborators according to skill set. Imagine Canada (www.imaginecanada.ca) is another organization that maintains a searchable web-based database of funding opportunities for Canadians. The Imagine Canada database is subscription based. Funding agencies typically put out a call for applications only once or twice per year, so a general awareness of funding agencies that align with your research interests and their deadlines is useful when planning a research project.

Large corporations, including pharmaceutical companies, are for-profit entities that will occasionally consider funding small studies or providing contributions in-kind for studies partially funded by other means. Contributions in-kind may include the provision of a drug for a clinical trial or laboratory work such as the determination of drug concentrations from tissue samples for a study. These opportunities may be made known only through network ties with the company, and a common interest in the research question is typically required. The websites of some pharmaceutical companies state whether they support investigator-initiated trials and, if so, the application process. Before funds are accepted from any source, care should be exercised in relation to ownership of the data, study conduct, knowledge dissemination, and conflict of interest.

Align Study Objectives with Those of the Granting Agency

Almost all granting agencies are motivated by the vision of the organization they represent. It is the applicant's responsibility to choose a funding opportunity that aligns with his or her own research goals. Furthermore, it is in the researcher's best interest to describe, within the grant application, *how* the research objectives align with the foundation's or agency's goals. Quite often, researchers must reshape their research question to "fit" the agency's call for proposals. The funding body's objectives are usually listed in the call for applications or on its website.

Funding agencies consider many logistic variables when they are awarding grants. These may include the type of project proposed (e.g., clinical trials versus quality assurance projects), the research subject area (e.g., specific disease states or populations), the geographic area (the province or country where the research will take place), the investigator's level of experience (e.g., grants for young investigators), and the investigator's affiliation with a professional society (for example, only members of the Canadian Society of Hospital Pharmacists [CSHP] are eligible to apply for

CSHP Foundation grants). Eligibility criteria will be listed in the call for applications or on the agency's website and are typically fully enforced.

Once a researcher has identified a potential funding opportunity, the time has come to contact the grant officer, an important step that is often overlooked. Typically, a grant officer is assigned to each funding opportunity within an agency. The role of the grant officer is to discuss research ideas with potential applicants and advise them about the application process. Quite often, a discussion with the grant officer will provide insight with respect to the agency's enthusiasm toward the topic of the proposed research. Soliciting advice about how to frame the research project to highlight alignment of common goals can sometimes help in gauging the agency's interest in funding a particular project.

WRITE THE RESEARCH PROPOSAL

Once the funding opportunity has been identified, researchers must review the guidance for applicants, which can usually be found on the agency's website. These instructions for completing the application usually reiterate the eligibility requirements and the vision of the granting agency, detailing exactly what is required at each stage of the application. Most granting agencies will not entertain applications that do not follow the instructions for applicants, so it is imperative that applicants be familiar with what is expected of them. This is also an opportunity for applicants to budget their time for the application. Most applications require signatures from co-investigators and administrators, a curriculum vitae for each co-investigator, and perhaps even letters of support from department heads or supporting entities. Some agencies will ask for a letter of intent to be submitted before the full application. Curricula vitae may have to be reformatted to conform with the agency's expectations, and letters of support may need to be solicited from program directors and key stakeholders. Both of these activities will take time, so it is better to plan for them at the outset. It is difficult to predict how much time should be budgeted for writing the grant application itself. The complexity of the project and the application process are major variables. For novice researchers with other professional responsibilities, 1 to 6 months is likely an appropriate range to budget for grant preparation.

A grant application is an exercise in communication. Even though the applications of private funding agencies and foundations are typically shorter than those of government granting agencies, it can be more challenging to communicate ideas clearly when there is less room to do so. Examples of successful grant applications should be reviewed, if possible. Many funding agencies post such examples on their websites. Most applications follow the same basic template: a cover letter, an abstract, a list of project-specific aims, the background and context for the research, the research plan (including the methods and analytical plan), the significance of the work, and a financial budget with justification and timeline. Other required components may include a section

on ethical considerations, a biographical sketch and role delineation for each investigator, letters of support from collaborators, letters of ethics approval from local research ethics boards, and references. Typically, the first sections to be read by reviewers are the abstract and background. As a result, before the reviewer reads the actual study protocol, first impressions have already been formed, on the basis of the research question, alignment between the applicant's and the agency's aims, the significance of the project in the context of the literature review, and the work done by the investigators to support the application. Therefore, it is incumbent on the applicant to clearly communicate the importance and value of the proposal in these sections.

The research plan is a more detailed and complete description of each specific study aim. Sufficient detail is required for the reviewer to see not only *what* will be done, but also *how* it will be done. This principle pertains to patient selection, intervention preparation and delivery, data management, and the analytical plan. The reviewer may interpret vague plans and intentions that are not spelled out in detail as incomplete and a sign of insufficient planning. Assumptions made (e.g., in relation to sample size calculations, anticipated recruitment rates, or availability of data to be collected) must be justified to show foresight. If preliminary work has been done, it should be described. Such preliminary work might include local audits to describe the current state of care or the magnitude of the problem, informal surveys to describe clinical equipoise among care providers, systematic literature searches, and scoping exercises. These tasks may be undertaken during vetting of the research idea, and describing these activities to the reviewer shows your level of interest in the topic and your dedication to the project. Key features of a strong grant application are listed in Box 1.⁶⁻⁸

Prepare the Budget

The best advice to novice researchers preparing the budget for their first grant application is to be honest and practical. Reviewing budgets from colleagues' applications can be helpful. It is more common for studies to be stopped early or scaled back because of insufficient funding than for studies to be completed with excess funds remaining. The problem of a lack of funds can be avoided by resisting the urge to cut corners before the study even begins. Provided that the funding you are requesting is not greater than what the agency allows in the call for applications, you are more likely to be successful trying to justify the expected expense than downplaying it. Justification of the budget is paramount. Typically, the budget is broken down into specific line items related to salaries for personnel, equipment, services, supplies, travel, and institutional overhead. An itemized document that justifies each line item eliminates guesswork for the reviewer. Quotes for laboratory, transportation, storage, translation, statistical, and other services can typically be added here or in an appendix. Reviewers are usually researchers themselves and have

Box 1: Key Considerations for a Successful Grant Application

Research question

- The research question, specific aims, and hypothesis to be tested are clearly stated.
- The research question is valid, innovative, and worthwhile.
- The research question addresses an identified gap in the literature and builds on the existing knowledge base.

Project summary

- The project summary is clear, concise, and complete.
- The review of the literature summarizes the current knowledge base on the topic and identifies a gap that can be addressed by the study.
- The goals of the study proposed are clearly aligned with those listed in the call for applications and the vision of the funding agency.

Study methodology and research plan

- The research plan will definitively answer the research question.
- The methodology is sound, not overly ambitious, and feasible.
- The sample size and assumptions made are justified.
- The analytical plan is feasible and appropriate.

Study time frame

- The study timeline is feasible.
- The applicant has supplied some data showing that the study can be completed within the timeframe allowed (e.g., patient recruitment rates, letters of support from service providers).

Infrastructure and resources

- Local resources required for study conduct but not accounted for in the budget are available (e.g., personnel, equipment, supplies).
- If the application is successful, the institution will be able to administer the funds.
- Investigators are able to make the time commitment to complete the study.

Pilot testing and preliminary work conducted

- Evidence to support the feasibility aspects of the research is provided.
- Efforts to confirm the availability of patients to recruit and the ability to recruit them are documented.
- The intervention, case report forms, and study tools have been pilot-tested, and the pilot results reinforce the feasibility of the study.

Support of key stakeholders

- Applicants have considered who are the key stakeholders and knowledge users for their project. These may be professional societies, institutions, and not-for-profit organizations. Letters stating their support for the project, including how they would use the new knowledge generated by the project, are valuable in convincing reviewers of the importance and relevance of the project.

Study budget

- The budget is realistic and comprehensive.
- Each item in the budget has been justified.

Dissemination plan

- Dissemination of results has been planned in advance.
- Publication and conference presentations will be complemented by engagement of key stakeholders and knowledge users.
- Public involvement is typically sought by granting agencies.

Applicant and team

- Roles are appropriately delineated.
- The applicant and the team have the appropriate skill set and expertise to conduct the project.
- Novice investigators have recruited a team with the necessary experience and expertise to ensure the project can be completed.

prepared budgets before. They will notice if the cost of a research assistant is substantially different from what such a position might cost at their own institution. The budget justification allows you to answer the questions before they are asked. Always familiarize yourself with the guidance for applicants. Some agencies will

not allow funding to be used for certain expenses (e.g., travel to conferences to present your results). Ensure that the budget conforms to the constraints imposed by the funding agency. Most granting agencies will also ask that the applicant identify the institution that will administer the funds. Typically this is the

institution where the applicant is employed (a hospital, research institute, or university). If the applicant's employer is not capable of administering the funds, it may be necessary to seek an appointment or affiliation with an institution that can.

Timelines

Creating an annotated timeline is useful for 2 reasons. First, it describes the sequence of events for the reviewer, reinforcing what appears in the study methods, and forces the applicant to assign deadlines and targets for each task in the protocol. Second, it shows the reviewer that the project is expected to be completed during the timeframe delineated in the guidance to applicants. Most funding opportunities are intended for projects that can be completed within a finite period of time. For studies that are anticipated to continue beyond 1 year, a separate budget may be required for each year, whereas many funding opportunities solicit projects that can be done within 1 year. The question of study duration is therefore an important consideration for applicants.

Dissemination Plans and Public Involvement

Most grant applications now ask for a knowledge translation or dissemination plan, which increasingly includes a request to involve the public and other stakeholders. This is another area of the grant application that is underappreciated by many applicants. The granting agency definitely wants to see how the study it is funding will inform or change practice. Publication of study results is not enough to change practice.⁹ Understanding your key stakeholders and knowledge users is important when deciding how and where to concentrate your efforts. Dissemination plans should be considered on a local, national, and international level when appropriate. Abstract submissions and poster presentations at national or international meetings can increase awareness of your study results, but granting agencies are looking for novel ways to increase awareness of your research and their support. Public dissemination of study findings can be done via a web-based clinical trial registry, such as www.clinicaltrials.gov. Engagement with professional associations, local institutions, and patient support groups that have common interests can be planned in advance. Such engagement may lead to opportunities to post or publish study results on the websites or in the newsletters of relevant associations or institutions and to reach patients through webinars and community outreach programs. Identifying these collaborators as knowledge users and describing their role in knowledge dissemination can be done via letters of support within the grant application. [Editor's note: For more information about dissemination of research results, please see the Research Primer by David Edwards, starting on page 465 of this issue.]

Grant Review

Granting agencies that request a letter of intent (usually a 1- page summary of the project) in advance of the full application

usually do so to allow time to assemble a panel of reviewers whose expertise is aligned with the proposals submitted. Reviewers will evaluate proposals according to predefined criteria that are typically disclosed in the instructions to applicants. Reviewers usually focus on the following areas in their review: significance and potential impact of the proposal, originality of the research question and methods, scope of the project, background work supporting the proposal, validity of research methods, feasibility of the project, expertise and experience of the primary applicant and his or her team, and availability of resources (including the budget) to complete the project.

The review may take up to 6 months, and this valuable time should not be wasted. During this period, the applicant should prepare for both success and rejection. If the proposal is accepted, the investigators are expected to "hit the ground running". This requires preparation in terms of creating and pilot-testing study documents, ensuring that approvals to conduct the study are obtained from institutional administrators, and obtaining ethics approval if not already in place. Conversely, preparing for rejection is the best way to deal with it. Unfortunately, rejection of a first application is common but should not be a source of discouragement for applicants. The reviewers' comments that are revealed by the agency will identify areas where improvements in clarity, design, and planning may improve the chances of funding in subsequent competitions. When suggested changes are feasible, applicants are encouraged to address them and reapply during the next competition. Reapplication is looked upon favourably by reviewers and funding agencies, as it reinforces the applicant's interest in the topic, dedication to the project, and willingness to consider feedback. Success rates for second and third applications are significantly higher than those for first-time applications.

CONCLUSION

Turning a good idea into a funded research project takes significant preparation. Investigators must have a strong interest in the research topic if they are to be successful at grantsmanship and project completion. The preparation and planning done before actually filling out the grant application and efforts to align the project goals with those of the funding agency are among the most important predictors of successful grant applications.

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Previous articles in this series:

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