#### **REVIEW ARTICLE**

# Funding and Other Resources for Beginning Researchers

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#### **KEYWORDS:**

Research Proposal Research Support Research Personnel Grant Writing Despite the fact that osteopathic research is essential for the continued advancement of our profession, such research is lacking. One barrier is the attainment of funding resources to launch and continue quality research studies. In the present article, the authors outline resources for the early stages of research and provide guidance for grant proposal preparation, if it is determined that external funding is needed. Free and low-cost resources for obtaining preliminary data and sources of external funds are described. An overview of grant writing and information on where to obtain training is presented. Information on proposal writing basics, tips to increase the chances of success, the grant application process, and basic proposal and budget requirements is provided. Potential funding sources appropriate for beginning investigators are listed, as well. Suggestions are offered for revising and resubmitting unsuccessful proposals.

#### INTRODUCTION

The osteopathic medical profession needs to substantially increase its engagement in clinical research if it is to remain a viable healthcare system, according to many authorities.<sup>1-14</sup> Research, both basic science and clinical, is being conducted at most osteopathic medical schools.<sup>15</sup> Researchers at these institutions are knowledgeable about how to do research and how to obtain resources. Research can also be conducted in residency programs, but at a less advanced level. However, to expand the research base, it is necessary to increase research at osteopathic medical schools and residency programs. Clinical faculty, residents, and students typically are not trained in research, as evidenced by the fact that DO researchers accounted for less than 12% of research grant awards to osteopathic medical schools between 2004 and 2009.<sup>15</sup> It is these clinicians and their trainees who must increase the research output.

Research is a multistep process that begins with developing an idea, formulating the research question, reviewing the literature, establishing the objectives and hypothesis, and constructing the methods. <sup>16</sup> As the research question is developed and refined, a comprehensive literature search helps to establish whether the idea is original, avoid unnecessary duplication, and build the background and rationale for the proposed study. <sup>16</sup> In addition to searching MEDLINE, PubMed, and other medical literature databases, many researchers use clinicaltrials.gov to identify studies that are ongoing in a particular field (thereby avoiding unnecessary

duplication), find topics for potential research, and locate collaborators.<sup>17</sup>

Some research requires few resources, including but not limited to funding, to continue and gain momentum. Educational and survey research, medical chart reviews, and analyses of existing data sets are examples of research that is not resource intensive. This article will identify some free and low-cost resources to help beginning researchers learn and understand the research process and obtain preliminary data.<sup>18</sup> It also provides guidance for proposal preparation, if it is determined that external funding is needed. If the decision to seek funding has already been made, preliminary data will be needed (even if the grant announcement says otherwise) to demonstrate the principal investigator's experience relevant to the research and describe the groundwork that is likely to lead to a successful funded project. 19,20 Gathering preliminary data may require only the free and low-cost resources described below. Despite starting with a shoestring budget or no budget at all, the investigator(s) may be able to continue to make progress while preparing to apply for funding or awaiting the sponsor's decision. Several months' lag time between the application deadline, award notification, and project start dates should be expected.21

In addition to getting money, some compelling reasons to seek external support include developing and advancing knowledge, enhancing training opportunities, contributing to the prestige of the program and institution, and furthering the investigator's career.<sup>22</sup>

A wise novice researcher will seek the advice of someone with experience in writing successful grant proposals as a mentor.<sup>23</sup> The institution's research and sponsored programs office can assist in identifying potential sources of funding

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and preparing proposals for submission,<sup>24</sup> and may also help in identifying a mentor. For those without access to such an office, local institutions of higher learning (with or without a medical school) may have altruistic faculty willing to provide advice and guidance. This article provides a blueprint for novice researchers for writing and submitting research grant proposals.

#### FINDING FREE RESOURCES

Many resources are available to reduce the expenses related to collecting data. Government databases and websites and medical charts are excellent sources of historic comparative data.

To evaluate a new drug or procedure, using historical controls instead of an active control group may be an option. Historical controls are people "followed at some time in the past or for whom data are available through records who are used for comparison with subjects being treated concurrently." A control group of living individuals may not be needed, for example, if the disease/condition and its course are well documented. Historical controls are also useful when randomization to an untreated control group is not ethical. Because of advances in medical care and changes in demographics and other factors, use of historical controls may not always be appropriate. This option should be discussed with a statistician.

Free databases are available from many federal agencies. The National Institutes of Health (NIH) maintains an extensive list of federal, nonfederal, and international databases at <a href="https://www.nlm.nih.gov/hsrinfo/index.html">www.nlm.nih.gov/hsrinfo/index.html</a>, a sample of which is presented in Figure 1.

The public registry clinicaltrials.gov is an excellent resource for those who wish to learn more about clinical trials and

#### FIGURE 1:

Sample databases linked from the NIH website

FastStats A-Z from the Centers for Disease Control and Prevention (CDC)

Health Data Interactive from the CDC's National Center for Health Statistics

Health Indicators Warehouse

Quality of Life Instruments Database

County Health Rankings

Global Health Observatory from the World Health Organization GlobalHealthFacts.org

observational studies, including specific ongoing research projects. A database containing results of completed clinical studies is also available on the site.

The National Center for Biotechnology Information (NCBI) provides access to databases and tools containing biomedical and genomic information. For example, the Bookshelf collection (<a href="www.ncbi.nlm.nih.gov/books">www.ncbi.nlm.nih.gov/books</a>) has biomedical textbooks and other scientific titles that can be searched directly or through other NCBI databases.

Individual government agency websites have additional databases. For example, the Agency for Healthcare Research and Quality (AHRQ) has links to the Medical Expenditure Panel Survey (MEPS), National Healthcare Quality Report, and United States Health Information Knowledgebase, along with a guide on which resource to use for a particular purpose (<a href="www.ahrq.gov/data/dataresources.htm">www.ahrq.gov/data/dataresources.htm</a>). The Centers for Disease Control and Prevention has many data sets on children and adults, including the National Health and Nutrition Examination Survey (NHANES) and the Behavioral Risk Factor Surveillance System. Free databases may also be available from state or local departments of health and Area Health Education Centers.

These websites and databases have varying degrees of complexity. The databases can be huge, but many have user-friendly report generators for the basics that will often suffice, such as numbers or percentages of people with a given health condition. The help of a statistician should be enlisted for complex databases without a report generator function or for more sophisticated (inferential) statistics.

Medical charts and electronic medical records are an excellent resource, provided their use is permitted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Medical chart data on diagnoses among specific populations may be obtained using ICD-9 codes. Chart data can also be obtained on medical procedures using CPT codes. Hospital medical records staff can assist with database queries. Prospective studies can often use test results data gleaned from medical records, if the tests were performed as part of standard of care. Such tests may not need to be repeated for the research.

Regardless of the source, all research involving data from human subjects, including research on existing data, requires review by an Institutional Review Board (IRB), even if informed consent is not required. The research office, IRB, or other impartial individual or entity knowledgeable about human subject protections must make this determination. The investigator does not have this authority.<sup>26</sup>

### FINDING ECONOMICAL RESOURCES

Much research requires resources other than data to bolster the success of the project. Assistance from experts, manpower, devices, equipment, laboratory tests, and internal funds can be very important assets to the research. Some sources are described below, based on the authors' experiences.

Colleges and universities are a good source of help that can be free or inexpensive. Graduate students in epidemiology, statistics, and other fields can help with the project. Many times, these students will work for low wages or free (especially if they can obtain academic credit towards their degree). Co-authorship on publications or posters is a motivating factor for collaborators. Some schools have formal programs that match students with research projects.

Representatives from pharmaceutical and equipment companies may be able to provide items for standard care (wrist braces, placebos, medications, etc.) for the control group in the study. Equipment loans can also be arranged if "old" equipment is being replaced by a state-of-the-art model. Leasing newer equipment is a less expensive than purchasing option if it will only be needed for a portion of the study.

It is unethical and possibly illegal to bill subjects' medical insurance for labs and tests conducted solely for a research study. Clinical labs and other providers should be contacted about obtaining discount or free lab tests, x-rays, etc. Providers may be willing to offer investigators a lower rate to conduct specific tests needed for research, which will help to reduce expenses.

Some medical schools and large hospitals have small amounts of money, such as departmental budgets, student or alumni scholarships, OPTI/GME (Osteopathic Postgraduate Training Institute/Graduate Medical Education) budgets, a Dean's Fund, or research reinvestment funds. Although internally funded, there may still be a competitive application process.

Those wishing to become involved in clinical research may wish to join a Practice-Based Research Network (PBRN). PBRNs focus on health care problems in the context of primary care<sup>27</sup> and collect large amounts of patient encounter data by pooling smaller volumes of information from practice sites within the network.<sup>28</sup> The PBRN at the University of North Texas Health Science Center, called the Consortium for Collaborative Osteopathic Research Development–Practice-Based Research Network (CONCORD-PBRN), has 16 member clinics.<sup>28</sup> CONCORD-PBRN uses a unique approach that distinguishes it from most other PBRNs. Physicians receive training in research design and biostatistics through a fellowship program before becoming engaged in research.<sup>29</sup>

Training in clinical research is essential for all investigators, including those joining an existing project. FDA regulations mandate that the IRB review the qualifications of clinical investigators to perform and supervise the proposed research. In so doing, the IRB is fulfilling its responsibility to ensure that risks to subjects are minimized.<sup>30</sup>

# **SOURCES OF EXTERNAL FUNDS**

Some research requires larger funding amounts to implement a quality project. Sources of funding external to hospitals and colleges and universities may need to be explored. Such sources include collaborations on ongoing research projects that have already received funding, foundations, voluntary health organizations, fellowships, and professional associations. It may be possible to find a collaborator who already has funding for a project similar to the beginning investigator's interests. Supplemental grants may be available that allow researchers or research trainees to "piggyback" onto ongoing studies.

Free federal databases of funded projects include the National Institutes of Health's Research Portfolio Online Reporting Tool Expenditures and Results (RePORTER) (http://projectreporter.nih.gov/reporter.cfm) and the National Science Foundation's NSF Award Search (www.nsf. gov/awardsearch/). RePORTER has a number of searchable fields (e.g., by city, state, and keyword) and provides the grant number; project title; principal investigator's name, e-mail, and academic title; project abstract; thesaurus (keyword) terms; grant start and end dates, and other information for each funded project. NSF Award Search contains information similar to NIH RePORTER, and includes free text search capability. There is also the newly launched Federal RePORTER (http://federalreporter.nih.gov/), which includes projects funded by NIH and other agencies, such as the Centers for Disease Control and Prevention, Congressionally Directed Medical Research Programs within the Department of Defense, Department of Veterans Affairs, and Food and Drug Administration.31

Other federal agencies and many private funding organizations provide lists of funded projects and are worth reviewing for ideas and for potential support.

The first consideration should be where to apply for funds. Funding agencies, also called funding sources or sponsors, are like sports teams in that they are seeking the best "players" among the many candidates. Internal or intramural funds are like college sports: a considerable number of positions or opportunities are available, but the money available is relatively small and there is little or no requirement for a record of previous successes. Private sponsors are like the

minor leagues: there are fewer positions or opportunities, but more money is available; the requirements for a history of success are more stringent, but not unattainable. Lastly, federal sponsors are like the major leagues: there are very few opportunities, but the rewards are much greater and the prospects are favorable only for those with a proven record of consistent success. Research proposals with data from a preliminary study are more likely to attract funding, supporting the eventual move from the minor leagues to the big leagues.

The following is an overview of types of sponsors appropriate for those who are at the beginning stages of funding exploration (in other words, not ready for the major leagues).

Private and corporate foundations are an excellent source of funds for beginning researchers. Foundations can be identified through the Foundation Center (<a href="http://foundationcenter.org/search/">http://foundationcenter.org/search/</a>), which offers beginning grantseekers free searches on the 10,000 largest U.S. foundations. Some foundations fund projects nationwide, while others have geographic or subject area restrictions.<sup>21</sup>

Corporate foundations often limit their giving to areas in which they have facilities. Corporate foundations award grants based on an ongoing relationship with the investigator and will expect him or her to conduct research in a partnership with the company. There are literally hundreds of thousands of companies, including pharmaceutical companies, with funds that may be available to individual investigators.<sup>21</sup>

There are also services that research and sponsored programs offices subscribe to on behalf of the institution, such as SPIN<sup>TM</sup>, Illinois Researcher Information Service (IRIS), and Community of Science. Search engines, such as Google and Bing<sup>TM</sup>, can also be useful in identifying foundations and other private funding agencies.

Voluntary health organizations fund health-related research, such as disease prevention (e.g., heart disease, diabetes, cancer), health education, and patient services projects. Opportunities from voluntary health organizations can be explored through a general Internet search or a more focused search using the institution's subscription to a service such as SPIN or IRIS.

The American Osteopathic Association funds both research and training (fellowship) grants. Research grants are limited to proposals to study unique characteristics of osteopathic medicine, particularly osteopathic manipulative medicine (OMM)/osteopathic principles and practices (OPP).<sup>32</sup> Fellowships are available for undergraduate (DO) students and postdoctoral osteopathic medical students (interns, residents, or research fellows). Fellowships are for conducting

and completing a research project under the direction of a faculty sponsor. Instructions and forms are available at <a href="https://www.osteopathic.org">www.osteopathic.org</a> (keyword search "research handbook"). The American Academy of Osteopathy also has a small amount of funds to support OMM/OPP research. Information is available on their website: <a href="https://www.netforum.avectra.com/eweb/DynamicPage.aspx?Site=AAO&WebCode=ResearchGrantProcess.">www.netforum.avectra.com/eweb/DynamicPage.aspx?Site=AAO&WebCode=ResearchGrantProcess</a>.

The American Association of Colleges of Osteopathic Medicine has an annual grant cycle for medical education research. Visit <a href="https://www.aacom.org/InfoFor/educators/Pages/aacomgrants.aspx">www.aacom.org/InfoFor/educators/Pages/aacomgrants.aspx</a> for details.

The Osteopathic Heritage Foundations have endowed several centers and chairs throughout the U.S. to enhance osteopathic training and medical research. Each has a specific focus, such as aging or neuromusculoskeletal disease research. The Funding Priorities section of <a href="https://www.osteopathicheritage.org/">www.osteopathicheritage.org/</a> lists specific information. While priority is usually given to researchers at the grantee institution and its OPTI partners, some endowments may have provisions for others to conduct research or obtain research training on site with a faculty mentor from the institution.

The National Center for Complementary and Integrative Health (NCCIH) within the National Institutes of Health funds research on complementary and alternative medicine (CAM) and training of CAM researchers.<sup>33</sup> Osteopathic manipulative medicine is considered a form of complementary medicine by NCCIH. NCCIH is particularly interested in funding research on the effect of CAM modalities on chronic pain processes and in supporting health and wellness. NCCIH is also prioritizing research grant applications from early stage or new investigators. More information on specific types of research career development and training opportunities are described in the Training tab on the NCCIH website.<sup>33</sup>

Some professional associations offer seed money grants for research focused on the medical specialty of the association. Eligibility is limited to members of the association or specialty college. One example is the Foundation for Physical Medicine and Rehabilitation (<a href="http://foundationforpmr.org/">http://foundationforpmr.org/</a>).

Several types of grants may be suited to the specific type of project. For example, some opportunities are for training on how to do research, while others are for the research itself. There are specific opportunities to support new ideas and/or new investigators with little or no preliminary data. These grants are available from a variety of ssponsors and therefore use various terms, such as rapid response, new investigator, early stage investigator, beginning investigator, young investigator, and scientist development or exploratory/ developmental grants. There are even grants available to

perform sophisticated analyses of existing databases (in collaboration with a statistician, of course).

The search for funding opportunities can be tailored according to the research interests and type of project. Reviewing the list of projects funded in the last few years will help to determine if the sponsor or specific funding opportunity is well matched to the proposed project.<sup>21,23</sup> For foundations, the current grantees may be listed directly on the website or in a newsletter or annual report linked via the website. 21,23 NIH grantees can be identified by combining keywords with the appropriate check boxes for funding mechanisms and fiscal years in the query function of NIH REPORTER (http://projectreporter. nih.gov/reporter.cfm). RePORTER also has data on current funding levels by NIH center or institute, disease category, location of project, and award type that will indicate what is of greatest interest to NIH. There is also the weekly NIH Guide for Grants and Contracts, available at <a href="http://grants.nih.gov/">http://grants.nih.gov/</a> grants/guide/index.html. Speaking with funded researchers and program officers at professional meetings can also provide valuable insight into current and future funding possibilities.<sup>21</sup>

### TRAINING ON GRANT WRITING

The most common way to obtain external funding is to write a grant proposal. Grant writing is a specialized skill for which training opportunities are available. The Foundation Center provides free online training on grant writing or low cost (currently under \$200) classroom training in various cities. Visit <a href="http://foundationcenter.org/getstarted/learnabout/proposalwriting.html">http://foundationcenter.org/getstarted/learnabout/proposalwriting.html</a>. Many professional society meetings include preconference workshops on grant writing. An OPTI may also provide training programs for proposal development.

There's no shortage of workshops offered for \$400 a day and more, but they're often focused on NIH proposals and therefore too advanced for beginning grant seekers. In addition, NIH in its best years was funding about 30% of grant proposals. After a combination of funding cuts and increased competition (ie, more proposals submitted) in the past few years, fewer than 14% of the most common types of research proposals were funded.<sup>34</sup> That means that over 86% of proposals were not funded.

# **GRANT WRITING BASICS**

Grant proposal writing is a process in which the investigator makes a persuasive case to the sponsor. Some experts suggest having a one-page mini-proposal or executive summary ready at all times in order to be ready to respond on short notice to new announcements. <sup>21,24</sup> Grant writing takes time, talent, training, and practice. Continuing with the sports analogy, a couch potato can't wake up one day and decide to get a college scholarship, make the minor leagues, or be a professional sports superstar.

A basic tenet of grant writing is that funding should help the investigator and/or the institution to do something bigger, better, faster, and in an innovative manner. In other words, the money should clearly make a difference in advancing a project that is already in progress. "Give us money and we'll do great things" is not an approach that is likely to succeed. Demonstrating that the activities for which funding is being requested are an integral part of an existing project will increase the chances of success and help to lay the groundwork for future funding proposals.<sup>21</sup>

It is important to make sure that the project is a good match for the sponsor's objectives. Don't "stretch" to make the idea fit. If unsure, a call (or e-mail to set up a time) to chat with a program officer at the funding agency to get their feedback (and possible buy-in to the ideas) is in order.<sup>21</sup> The research office staff or mentor can help with preparation before making the actual contact. Many foundations require that the initial contact be in the form of a letter of inquiry and do not accept telephone calls.<sup>21</sup> Guidance on how to write a letter of inquiry is available from the Foundation Center (http://grantspace.org/Tools/Knowledge-Base/Funding-Research/Proposal-Writing/letters-of-inquiry).

Proposal writing should start at least 4 months in advance of the sponsor's submission deadline. Serious writing should be well under way 3 months in advance. The most successful grant applicants allow ample time for this process and routinely share drafts with others inside and outside their immediate area of expertise at least 2 months before they submit their proposals.<sup>35</sup> All revisions should be completed no later than 1 week before the submission deadline.

The importance of writing clearly and concisely cannot be overstated.<sup>21,23,36</sup> At least one person who is not involved with the project should be asked to read and comment on the proposal (and preferably on several drafts of the proposal) at least 1 month before it is submitted to allow time for revisions.<sup>35</sup> Grant reviewers typically have several proposals to read and rate. An axiom among grant writers and reviewers is that "good writing will not save bad ideas, but bad writing can kill good ones."<sup>37</sup> Telling a good story that readers can follow and that answers the questions listed in Figure 2, will improve the chances of getting funded.<sup>36</sup>

Engaging a mentor to advise in grant writing and review drafts is extremely valuable for those new to grant writing. The mentor may have been a grant reviewer and may even have small amounts of money to support related research, as noted above. The research office can help to identify faculty with successful funding histories who can serve as grant writing mentors.

Consider partnering with a more experienced researcher as a co-PI (co-principal investigator). This will be especially helpful if the research project has multidisciplinary aspects. Regardless, a team approach is often more effective than a single PI because most research requires at least some collaboration among investigators.<sup>21</sup> Collaborators can augment the research skills and resources provided by the investigator and the institution and can reassure reviewers that a capable research team is in place.<sup>24</sup>

The time and other resources required to prepare the proposal, obtain approvals for working with human subjects and/ or their data, receive an answer from the sponsor, conduct and complete the research, and write the final report for the sponsor must all be considered.

#### PROPOSAL DEVELOPMENT

Each sponsor and funding opportunity will have specific requirements, but a good general outline is provided in Figure 2, along with questions to be kept in mind when writing a proposal.<sup>38</sup> It is imperative to think of the answers in terms of the sponsor's perspective.

It is absolutely vital to read and follow instructions carefully! A primary reason that proposals are rejected immediately or not considered for peer review is failure to comply with formatting and content requirements.<sup>23, 39</sup>

The abstract may be the most important part of a grant proposal.<sup>21</sup> It is the only part of the proposal that some reviewers read because they are assigned to conduct an indepth analysis of other proposals. For reviewers assigned to read the entire document, the abstract is the first impression they receive. The abstract should serve as a concise and accurate description that allows the project to be understood without reading the entire proposal. It should include the goals, objectives, design and methods, and relevance to the sponsor's interests. Some sponsors require the abstract to be written in lay terms.<sup>20</sup>

The introduction or background presents the problem and how it relates to the applicant's and sponsor's priorities. It elucidates how the current project logically flows from previous work and provides a bridge to the needs assessment (preliminary studies).<sup>20</sup> The needs assessment summarizes the literature in the field and the applicant's relevant work to date.<sup>21</sup> Data should be provided to document the scope of the problem and to show the expertise of the individual applicant, the research team, and/or the host institution.<sup>20</sup>

The goal (or purpose) is the overall intention and expected results of the project, linked to the identified need.<sup>20,22</sup> The objectives are specific, measurable steps that will lead to achieving the program goals.<sup>40</sup> Objectives explain who will

do how much of what by when. Specific aims are a concise list of the project objectives, e.g., to test a stated hypothesis, create a unique design, address a specific problem, or address a significant obstacle to progress in the field.<sup>20</sup> The specific aims also summarize the anticipated outcomes, usually in relation to a hypothesis.<sup>20</sup>

The plan of operation (Methods) gives reviewers substantial, detailed information about the interventions or experiments to be completed. <sup>20,22</sup> They should link directly and logically to the hypothesis and to the needs and objectives. If the aims include testing a hypothesis, it is important to clearly delineate how the procedures section will address the hypothesis. Organizing the plan so that it follows the same order as the needs and objectives section (eg, Method 1 matches Objective 1 and Need 1)<sup>22</sup> is helpful for the investigator(s) and those who will be reading the proposal.

Key personnel contribute in a significant and measurable way to the design, performance, or evaluation of the project.<sup>20</sup> Faculty, administrative staff, research assistants, consultants, and others may fit into this category. Their relevant accomplishments, such as publications and experience, should be highlighted and their role in the project (eg, PI, coordinator, statistician) described.<sup>20</sup> This information should be specific; stating that the individual is a department chair does not provide information on his/her research background. It may be helpful to include an organization chart specific to the project.<sup>41</sup> Information should be provided on the institutional commitment to the project in terms of resources, relevant work done to date, and the capacity to conduct the project. Salaries and fringe benefits for some of the project personnel, along with their office and/or laboratory space, may form part of the institutional commitment.<sup>20,41</sup>

The expected outcomes of the project should be described and related to the goals and objectives.<sup>20</sup> The outcomes section details how the results expected will contribute to solving the problem identified in the needs assessment.

Even small, private sponsors expect an evaluation component.<sup>24</sup> A strong research team, or at the very least the involvement of someone with credentials in epidemiology, statistics, or a related field, will strengthen the proposal and greatly enhance the chances of receiving funding. An experienced evaluator will ensure that the study design, sample size, and analyses are appropriate for the stated hypotheses and anticipated results.<sup>23</sup> For projects that involve an intervention, such as a health education program or clinical study, evaluation during the project is crucial. Without evaluation, there is no accurate way to determine whether the intervention is having a positive effect, a negative effect, or no effect at all.<sup>40</sup> The evaluation plan should include measurements/instruments, data collection and analysis, potential project challenges and

### FIGURE 2:

Basic proposal outline and questions to answer

# A. Abstract (Summary)

- 1. What is the problem or need to be addressed?
- 2. What are the overall goals and objectives of the project?
- 3. What research design will be used?
- 4. What are the planned methods?
- 5. Why is the project important to the funder?

# B. Introduction (Background)

- What need will the project address or what problem will it solve?
- 2. How is the project relevant to the health of the target population?
- 3. Needs Assessment (Preliminary Studies)
- 4. What data are available to demonstrate the need?
  - a. Literature review
  - b. Studies conducted by the investigator
  - c. Government reports
  - d. Task force or advisory committee recommendations

### C. Goal

- 1. What is the overall purpose of the project?
- 2. How is it linked to the needs assessment?
- 3. How is it linked to the funder's goals?

# D. Objectives (Specific Aims)

- 1. What are the specific, measurable objectives (aims)?
- 2. Do the objectives specify who will do how much of what by when?
- 3. Do the objectives specify results and how they will be measured

# E. Plan of Operation (Experimental Design and Methods)

- 1. Where will the project be conducted?
- 2. What will the investigator do that matches the type of activity the sponsor is interested in funding?
- 3. How will the investigator conduct the study?
- 4. What study design has the investigator selected?
- 5. How will data be collected, stored, and analyzed?

# F. Key Personnel

- 1. Who will do the project?
- 2. What are their qualifications relevant to the proposed activities?

#### F. Institutional Commitment

- 1. What resources (employees, data, space, equipment, etc.) will the institution contribute?
- 2. What other, similar projects have the investigator and the institution done successfully?

# H. Expected Outcomes

1. How is the project expected to improve the health of the target population?

#### I. Evaluation

1. How will success be measured both during the project and at the end of the funding period?

#### J. Timeline

1. What is the timeline for the project, including data analysis?

# K. Dissemination

- 1. How will the results be shared with others?
  - a. Presentations
  - b. Publications
  - c. Websites

### L. Resources and Facilities

- 1. What resources are already available?
- 2. What is the institution's capacity to conduct and complete the project?
- 3. What resources are needed?

### M. Project Continuation

- 1. How will the work continue after funding ends?
  - a. Other grants
  - b. Incorporated into the institutional budget (specify in support letter)
  - c. Program income

### N. Budget and Narrative/Justification

- 1. How do the expenses link to project goals, objectives, and activities?
- 2. How much money is being requested?
- 3. What is being provided by the institution?

proposed solutions, evaluation resources, and the intervals at which evaluations will be conducted.<sup>42</sup>

A timeline for project tasks, including evaluation and dissemination, should be included. The timeline can be something as sophisticated as a PERT chart or Gantt chart<sup>20</sup> or as simple as a table or spreadsheet with quarterly milestones. The timeline should be an overview rather than an exhaustive list of every task. If space and technical capabilities allow, the lead person for each task should be listed.

Dissemination is a key component of any project. The sponsor needs to be assured that the results of the project will be communicated to others interested in addressing the problem, not be put on a shelf and forgotten. The professional society meetings at which posters or papers will be presented and journals to which manuscripts will be submitted should be stated specifically.<sup>43</sup>

The sponsor wants to know that the money will be well spent, the institution and the PI are truly committed to the project, and that the project will not end when the funding does. The project continuation or sustainability plan addresses these issues. <sup>23,44</sup> Among the most common ways to ensure project sustainability are to incorporate the activities into routine practices (and possibly the organization's budget), create a toolkit that is then provided to others for a fee, or to apply elsewhere for funding. For the latter, it is important to be as specific as possible about sources of continuation funding. The continuation or sustainability section is the sequel to the story that's been told throughout the proposal. <sup>36</sup>

Although the budget is the least favorite part of the proposal for some applicants, it is one of the most important parts for the sponsor and the reviewers. First, it is important to stay within the budget limits and types of allowable expenses for the funding opportunity.<sup>21, 23</sup> The project activities should be feasible given the budget considerations, and the budget should accurately reflect what is needed without overestimating or underestimating.<sup>21</sup> A clear, concise budget narrative (or budget justification) should be provided.<sup>21, 23</sup>

The budget is the estimated finances required to complete the project. It is an important part of the proposal and can make or break the chances of getting funded. A carefully prepared budget can help those who make the funding decisions to understand the project.<sup>21, 23</sup> It can also reassure them that the investigator understands the project.<sup>36, 41</sup> This does not mean that it is necessary to agonize over every hour potentially devoted to the project or to prepare an exhaustive list of every paper clip the project may require. The budget is a reasonable approximation of costs, typically divided into the following categories<sup>41</sup>: personnel (salaries and fringe benefits),

consultant costs, supplies, equipment, travel, patient costs, and contractual costs.

Many find it helpful to start by estimating all but the personnel expenses rounded to the nearest \$1,000. Personnel expenses should be estimated more accurately, in part because they may be the largest component. Next, resources that are needed and those that are already in place should be identified. For those with access to a research and sponsored programs office, the staff can provide guidance on which items must be exact and those that can be estimated and can often provide examples of other proposal budgets and narratives. Most institutions have policies requiring internal approvals for all proposals.<sup>21</sup> Starting the budget preparation and review process early, eg, as soon as the specific aims are finalized, will help this process to go smoothly and quickly. Approvals are required several days or even weeks in advance of the sponsor's submission deadline.

Direct costs are everything associated with the project to which a specific dollar amount can be assigned.<sup>21,41</sup> This includes personnel (inside the institution), consultants (outside the institution), expendable supplies, equipment, travel, etc. It is important to provide accurate salary and fringe benefit information for everyone listed, including those listed as "To Be Hired." Fringe benefits are part of direct costs and include vacation and sick time, health insurance, retirement contributions, etc.<sup>45</sup> Fringe benefits are usually a composite rate of the various benefits, which may vary depending on job category (faculty, postdoctoral fellow, staff, etc.). Stipends are also taxable as income by the federal government.<sup>45</sup> Local payroll taxes may also have to be deducted by the institution. The research office for should be consulted for specific information.

In-kind contributions are existing funds or staff time provided by the institution in support of the project. The most common example is salaries and fringe benefits. For example, if the principal investigator is dedicating 30% to the project, but only 20% of his/her salary and fringe benefits is requested in the proposal budget, then there is a 10% in-kind contribution from the institution. <sup>21, 23</sup> This should be stated in the budget justification to emphasize the institution's commitment <sup>21</sup> and, as previously noted, that the sponsor is not being asked to "give us money and we'll do great things." Policies regarding what may be included as an in-kind contribution or must be part of the request for funding from the sponsor vary among institutions. <sup>21</sup> Any proposed in-kind contributions should therefore be specified in the budget that is submitted for institutional approvals.

Indirect costs (also called overhead or facilities and administrative (F&A) costs) are those costs that are not easily

identified as being related to a particular project, but are nonetheless important and necessary to the administration of the project. Examples include utilities, maintenance, grant accounting, and payroll processing. Indirect costs are calculated as a percentage of some or all of the direct costs. The percentage varies, depending on factors such as sponsor policies, institutional policies (eg, for clinical trials sponsored by pharmaceutical companies), or the rate negotiated between the institution and the federal government. If the sponsor has a policy that allows only a certain indirect cost rate or no indirect costs at all, documentation of this should be provided along with the budget and budget narrative when submitting the materials for internal approvals.

Tips for proposal budget calculations are provided in Figure 3.

A carefully prepared budget will help to plan the project and manage it once funding is secured. Budget planning can help to avoid unpleasant surprises in the future by ensuring that all project expenses have been considered and provided for.<sup>21</sup>

For a tutorial on budget basics, visit <a href="http://foundationcenter.org/getstarted/tutorials/prop\_budgt/pbb\_descrip.html">http://foundationcenter.org/getstarted/tutorials/prop\_budgt/pbb\_descrip.html</a>.

### THE APPLICATION PROCESS

In many cases, funding must go to an institution, rather than an individual.<sup>21</sup> The institution is the steward of the money on behalf of the individual investigator. Significant additional lead time may be required to obtain permission to submit a proposal through an institution of which the investigator is not a full-time employee.

As noted above, there may be internal deadlines in addition to those set by the funding agency. Faculty members and department chairs rarely have the authority to sign or submit on behalf of the institution.<sup>21</sup> The office of research and

# FIGURE 3:

How to work backwards from a fixed amount for budget calculations

- Tip 1: If the sponsor has a total allowable cost for salaries and fringe benefits, to calculate base salaries to allow for fringe benefits at a rate of 30% (for example):
  - total divided by 1.30 = base salary amount
- Tip 2: If the sponsor has a fixed total budget, to calculate direct costs to allow for indirect costs at a rate of 10% (for example):
  - total divided by 1.10 = direct costs subtotal

sponsored programs can identify who has the authority to sign and who is responsible for obtaining the signature(s).

Other items that may be required before the proposal can be submitted, all of which take varying amounts of time to obtain, are listed in Figure 4.<sup>21</sup>

Letters of commitment, sometimes called support letters, are needed when a formal arrangement with another institution will be required if the proposal is funded, when consultants will participate in the project, or when an external entity will be providing access to a key resource (e.g., equipment or a particular population).<sup>21</sup> It is not uncommon for the requestor to provide a draft letter of commitment that contains the specific information on the expected contribution. Letters from elected officials are not necessary unless the purpose of the project is service delivery to their constituents.

The investigator should meet with the staff in the research and sponsored programs office and/or the faculty mentor early and often. They can help identify funding opportunities,

#### FIGURE 4:

Additional proposal elements

### Letters of commitment

- Collaborator(s)/Mentor(s)
- Consultants (required as part of the proposal by some sponsors)
- Department chairs/Program directors
- Other "higher ups," such as the dean and/or president

Statement of Intent for multi-institutional proposals\*

Certificate of Confidentiality/Nondisclosure Agreement for collaboration with other scientists outside the institution\*

Other institutional policies and procedures

- Internal approvals for the activity itself from department chair(s)
- Internal approvals of the budget and budget justification (described above)
- Faculty sponsor or full-time faculty member as principal investigator for trainees and other nonfaculty
- \*It can take several weeks to obtain the required signatures from the official at each institution.

provide guidance on budgeting, help with forms and other aspects of the application process, and advise about any internal approvals and deadlines.<sup>21, 23</sup>

Depending on the sponsor, it may be possible to identify who the potential reviewers of the proposal will be. 21, 23 A simple literature search on the reviewers should be conducted. If appropriate, information from their work should be incorporated into the literature review and/or methods sections with citations to demonstrate the investigator's knowledge of the subject matter. 22, 23 The investigator may be able to recommend reviewers. 21 If so, the list can be derived from among the authors of key publications cited. The mentor should be consulted to determine if there are any researchers who should not be reviewers, usually because of a potential conflict of interest. 22 The mentor can help to craft polite wording in a cover letter to the sponsor explaining any conflicts.

#### THE WAITING GAME

Once the proposal is submitted, there is generally nothing more to do other than wait to hear from the sponsor. Contacting the sponsor's program staff or potential reviewers is not advisable, as this could be construed as an attempt to unduly influence the review process.<sup>20, 24</sup> Many proposals, especially to large funding entities, are approved, but not selected for funding.<sup>21</sup> Therefore, it is wise to refrain from making any announcements until an official award notice is received.

# WHEN THE PROPOSAL IS NOT FUNDED

First, it is important to not take it personally. 46, 47 Even experienced researchers, including those who have or had funding, do not get funded every time. 21, 23, 47 Some sponsors will only issue a generic rejection letter, while others will provide feedback. If feedback is given, the research and sponsored programs office and/or the grant writing expert can offer an objective opinion on the comments and whether the proposal should be revised and resubmitted to this sponsor. NIH and some private sponsors have program officers who can offer guidance and read between the lines of the reviewers' comments. 46, 47 It may be better to submit to another potential funder. A detailed explanation of reading, interpreting, and responding to reviewer critiques is provided in the 2008 article in *Hematology* by Chao. 47

As with the initial proposal, the sponsor's guidelines should be followed carefully when making changes. The funder may require a cover letter, a page within the proposal summarizing the changes, special formatting of revisions, or all of the above.<sup>21</sup> If the comments are useful, the appropriate changes should be incorporated into the revised proposal. If the

comments are not useful or the research team disagrees with them, the investigator should solicit help in how to respectfully and clearly address the next steps.  $^{46,\,47}$ 

#### **SUMMARY**

This article identified free and low-cost resources and provided guidance for proposal preparation. Potential funding sources appropriate for beginning investigators include:

- · Collaborators with Funding
  - National Institutes of Health's Research Portfolio Online Reporting Tool Expenditures and Results (RePORTER)
  - ° National Science Foundation's NSF Award Search
- Private and Corporate Foundations
  - o Foundation Center
  - Subscription services, if available
- Voluntary Health Organizations (e.g., American Heart Association)
- American Osteopathic Association
- American Association of Colleges of Osteopathic Medicine
- Institutional Support
  - Department budgets
  - OPTI/GME budget
  - o Dean's funds, if applicable
  - o Research reinvestment funds
- Osteopathic Heritage Foundation-funded Centers

Research studies require resources to continue and gain momentum. Compelling nonmonetary reasons to seek external support include developing and advancing knowledge, enhancing training opportunities, contributing to the prestige of the program and institution, and furthering the investigator's career. Nonfederal sponsors are more appropriate for less experienced researchers. It is essential to read and follow instructions carefully to ensure the proposal is not rejected before being assigned to peer reviewers. If the proposal is not funded, it should be revised and resubmitted. As with any acquired skill, grant writing requires practice.

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### ADDITIONAL RESOURCES

Agency for Healthcare Research & Quality. Data Sources Available from AHRQ <u>www.ahrq.gov/data/dataresources.htm</u>

American Academy of Osteopathy Louisa Burns Osteopathic Research Committee

American Association of Colleges of Osteopathic Medicine www.aacom.org/InfoFor/educators/Pages/aacomgrants.aspx

American Osteopathic Association. AOA Research Handbook www.osteopathic.org/inside-aoa/development/quality/research-and-grants/Documents/Research-Handbook-rev.07-2011.pdf

Foundation Center. Learn About Proposal Writing www.foundationcenter.org/getstarted/learnabout/proposalwriting.html

Foundation Center. Proposal Budgeting Basics www.foundationcenter.org/getstarted/tutorials/prop\_budgt/pbb\_descrip.html

National Information Center on Health Services Research and Health Care Technology (NICHSR) <u>www.nlm.nih.gov/hsrinfo/index.html</u>

National Institutes of Health, Office of Extramural Research. Developing Your Budget http://grants.nih.gov/grants/developing\_budget.htm

National Institutes of Health, Office of Extramural Research. Strategy for NIH Funding <a href="www.niaid.nih.gov/researchfunding/grant/strategy/pages/default.aspx">www.niaid.nih.gov/researchfunding/grant/strategy/pages/default.aspx</a>

National Institutes of Health. Research Portfolio Online Reporting Tool Expenditures and Results (RePORTER) <a href="https://www.projectreporter.nih.gov/reporter.cfm">www.projectreporter.nih.gov/reporter.cfm</a>

Office of Research Integrity. Writing Skills: Grantsmanship www.ori.hhs.gov/education/products/wsu/writing\_gra.html

Osteopathic Heritage Foundations Funding Priorities: Enhancing Osteopathic Training and Medical Research www.osteopathicheritage.org/AboutUs/FoundationEndowedChairs.aspx