Clinical Research Methods

in Speech-Language Pathology and Audiology

Third Edition

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Third Edition

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Preface

This book is intended for speech-language pathology and audiology students as well as practicing professionals who wish to learn more about conducting clinical research and its application to the professions. In line with first and second editions of this text, more speech-language pathologists and audiologists are being asked to conduct research due to increased interest in evidence-based practice and demands for accountability.

Revisions to the Third Edition

As with the first and second editions of this text, many of the chapters include a general orientation to research design and statistical analysis, followed by specific discussion of various types of research methods and conclude with a chapter focusing on the acquisition of research grants. Furthermore, the utilization of discussion questions at the end of each chapter functions as a guide to focus learning and prompt further inquiry for the reader.

Major changes for the third edition include the following: (1) includes many

references to and quotations from the ASHA and AAA Codes of Ethics (ASHA, 2016 and AAA, 2018); (2) updated list of databases and sources for research in communication sciences and disorders (CSD); (3) examples to follow regarding integration of citations into a literature review; (4) updated discussion of types of qualitative research currently being used; (5) additional and updated examples of qualitative research published in speechlanguage pathology; (6) expanded discussion of the generalizability of qualitative research; (7) expanded discussion of types of mixed method designs; (8) additional and updated examples of mixed method designs published in speechlanguage pathology; (9) additional review of textbooks regarding evidence-based practice published in CSD; (10) expanded discussion of the levels of measurement and specific scales of measurement, including the importance of reliability and validity in research; and (11) more than 15 new references regarding grants acquisition and related topics (grant seeking, grant proposal writing, and grant management).

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David L. Irwin, PhD, CCC-SLP, FASHA Norman J. Lass, PhD, FASHA Mary Ellen Koay, PhD, CCC-SLP, FASHA Jennifer Whited, PhD, CCC-SLP

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Research Grants



CHAPTER OUTLINE

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LEARNING OBJECTIVES

Upon completion of this chapter, the reader will be able to:

- Identify the three phases of the grants acquisition process
- Identify reference sources available for the seeking of grants from federal and private agencies
- List general principles of the grant-seeking process
- Discuss preliminary considerations in grant proposal writing
- Identify the major sections of a research grant proposal
- List and define the major categories in the budget section of a research grant proposal
- Differentiate direct costs and indirect costs associated with a research grant proposal
- Discuss the sources of ideas/problems for research projects
- Identify basic principles of grant proposal writing
- List some suggestions for grant proposal writing
- Identify the characteristics of a fundable research grant proposal
- Describe the grant proposal review process

Introduction

There is a strong association between research activities and grants. Without grants from the government and private sector, much of the research in communication disorders (and, for that matter, in many fields) would not be possible. In addition to any available internal funds, for those involved in research, it is essential to locate a specific external source(s) of support for their activities. For example, a university professor or hospital audiologist or school speechlanguage pathologist who has an interest in a specific communication disorder and wishes to pursue a research project to learn more about the disorder, may find that funds are not available within her/ his agency to support the necessary personnel, equipment, materials, travel, and other items that are needed to conduct the research. The only feasible approach for obtaining funds for the research may be through external sources (such as the federal government or private foundations), and the only way to obtain external support is to write a grant proposal to a particular funding agency. Moreover, the importance of grants is further accentuated in academia, where support for research activities is essential for conducting research, and conducting research is essential for publications in scholarly journals, which, in turn, are essential for the awarding of tenure, which is essential for maintaining one's position in a university. Therefore, grants may be the mechanism for job stability and may play a major role in the "publish or perish" philosophy in institutions of higher education.

The Grants Acquisition Process

Acquiring grant support may appear to the uninitiated as somewhat "mystical" in nature. However, in reality, there is nothing magical about the grants acquisition process. In fact, it is a systematic process that can be considered in three phases: grant seeking, grant proposal writing, and grant management. First, the investigator seeks sources of support whose mission and interests coincide with the goals and nature of his or her project. Next, the investigator writes a grant proposal following the guidelines established by the sponsoring agency. Finally, if a grant is awarded, the investigator manages the research project, including the expenditure of awarded funds.

Grant Seeking

Grant seeking involves searching for a source of funding for a specific research project, thus matching the nature of the topic with the objectives of the support source. There are various sources of external support for research projects, the largest being the federal government. In addition, national organizations and private corporations are potential sources for competitive grants.

Foundations are another major source of support in the private sector. A foundation is a nongovernmental, nonprofit organization whose funds and programs are managed by its own trustees or directors and established to maintain or aid educational, charitable, or other activities serving the common welfare, primarily through the awarding of grants. There are different types of foundations, but the type that serves as the primary source of support for research projects is the independent foundation.

In addition to *extramural* (outside the institution) *funding* sources, colleges and universities provide support for research in the form of relatively small grants as "seed money" for starting new research projects. These *intramural* (inhouse) *funds*, although relatively small, are essential for collecting preliminary data and providing the foundation for external funding. They can be a very important component in the decisions for funding made by outside agencies.

Numerous references are available to locate potential funding sources in both the public and private sectors. Much of this information can be found online, most of it free and some fee-based. The following are representative samples of references available for grant-seeking purposes.

■ Catalog of Federal Domestic Assistance (CFDA) (http://www .cfda.gov) is a valuable reference source to learn about relevant federal programs, eligibility requirements, and application deadlines. It provides access to a database of all available federal programs that can be searched in a number of ways, including key words, agency, applicant eligibility, type of assistance, and several other factors. There is a category specifically for finding grants that would be of most relevance to seekers of support for research activities. There is also a CFDA User Guide that can be downloaded.

- Foundation Center (http://www .foundationcenter.org) collects, organizes, and communicates information on U.S. philanthropy; provides education and training on the grant-seeking process; and allows public access to information and services through its website, print, and electronic publications, library/learning centers, and a national network of Cooperating Collections. Included on its website are general and specialized information retrieval tools.
- Foundation Directory Online (https://fconline.foundationcenter .org) developed by the Foundation Center, is part of an online subscription set of databases providing access to information on grant makers and their giving interests. Searches include text-based foundation searches, grant searches, and IRS 990 searches. (IRS 990 forms are the tax forms completed by foundations that contain information on awarded grants, including recipients and titles of projects funded, which could be very useful information to grant seekers.)
- infoEd Global's Sponsored
 Programs Information Network
 (SPIN) (http://www.infoedglobal.
 com is a computer database containing information on grant opportunities from federal and private sponsoring agencies. The database is targeted primarily to institutions of higher education. infoEd Global, the company that maintains the SPIN database, also offers an alert service called SMARTS, which sends e-mail messages whenever there is a match between the grant seeker's choice of key words and the funding programs

- in the *SPIN* funding opportunities database. This website indicates that their database is the world's largest database of sponsored funding opportunities (over 40,000 opportunities from more than 10,000 global sponsors). Subscription required.
- *Grants.Gov* (http://www.grants .gov), a central storehouse for information on grant programs offered by federal grant-making agencies, allows grant seekers to electronically find and apply for competitive grant opportunities from these federal agencies. Those interested in research grants can: (a) register for e-mail notification of grant opportunities; (b) access, download, complete, and submit active grant application packages; and (c) check the status of grant applications submitted via Grants.gov.
- *GrantSelect* (http://www.grant select.com) provides an extensive list of funding opportunities from state and federal government agencies (including National Institutes of Health [NIH], National Science Foundation [NSF], Centers for Disease Control and Prevention [CDC], and others), corporations, foundations, research institutes, and other nonprofit organizations. Grant seekers can subscribe to the entire research grants database or choose from customized segments, including Arts and Humanities, Biomedical and Health Care, Children and Youth, Community Development, International Programs, and others.
- Guidestar (http://www.guidestar .org) allows grant seekers to search for information on nonprofit organizations, including foundations. It provides general information as well as specifics, including founda-

- tions' current IRS Form 990, income range, contact information, mission, programs, goals, boards of directors, grants awarded, and other relevant information.
- Pivot (formerly Community of Science) (http://pivot.cos.com) is a resource for hard-to-find information critical to scientific research and other projects across all disciplines. It provides grant seekers the opportunity to search a comprehensive resource for funding opportunities. It also contains prepopulated scholar profiles worldwide to match a given institution's profiles against funding opportunities and to find potential collaborators from among the scholar profiles.
- Society of Research Administrators (SRA) International (http://www.srainternational.org/sra03/grantsweb/index.cfm) is a source for finding funds available from local, state, federal, and international governments. It also contains information to locate private funding for projects, including links to foundations, nonprofit centers, and charities.
- grantsNet (http://www.hhs.gov/grantsnet) is an Internet application tool created by the Department of Health and Human Services (HHS) for finding and exchanging information about HHS and other federal grant programs. In support of its mission, HHS is the largest grant-awarding agency in the federal government.
- *Ed.Gov* (http://www.ed.gov), the website of the U.S. Department of Education (ED), contains answers to frequently asked questions about funding opportunities; information on and instructions

for completing grant application packages; application packages for ED grant competitions that are currently open; announcements of grant competitions; all programs and competitions under which ED has invited or expects to invite applications for new awards; deadlines for the submission of applications; and the Guide to ED Programs, which describes all programs administered by ED (including the National Institute on Disability and Rehabilitation Research [NIDRR]). It also provides a search tool to find ED programs relevant to grant seekers' interests.

- National Science Foundation (http://www.nsf.gov/) is an independent federal agency created by Congress " . . . to promote the progress of science; to advance the national health, prosperity, and welfare; to secure the national defense." This website includes information about research projects that NSF has funded since 1989 by searching the Award Abstracts database. The information includes abstracts that describe the research as well as names of principal investigators and their institutions. The database includes both completed and current research projects.
- National Institute on Deafness and Other Communication Disorders (NIDCD), a member of the National Institutes of Health (NIH), is mandated to conduct and support behavioral and biomedical research and research training in the normal and disordered processes of voice, speech, language, balance, smell, and taste. The Institute also conducts and supports: research and research training related to special behavioral and biomedical problems associated

- with people who have communication impairments or disorders; and efforts to create devices which substitute for lost and impaired communication and sensory functions. The extramural program funds research and training opportunities at universities, medical centers, and other institutions throughout the United States and abroad through research grants, career development awards, and other mechanisms.
- American Speech-Language-Hearing Association (http://www .asha.org) contains information on research grants offered by the American Speech-Language-Hearing Foundation (http://www. ashfoundation.org) and federal agencies (including the National Institutes of Health, Agency for Healthcare Research and Quality, Department of Education, National Science Foundation, Centers for Disease Control and Prevention, and U.S. Department of Veterans Affairs) as well as private foundations and organizations (http://www .asha.org/research/grants-funding/ Funding-for-Researchers.htm). Also included on this website is information and suggestions on the grants acquisition process, including grant seeking and grant proposal writing. A bimonthly subscription to the ASHA Access Academics and Research E-Newsletter (http:// www.asha.org/publications/enews/ accessacademics.htm), which serves the specific needs of researchers, including information, resources, services, educational opportunities, as well as funding, research, and grant opportunities, is available at this website.

■ American Academy of Audiology (AAA) (http://www.audiology.org) contains information on research grants offered jointly by the Academy (AAA) and the Academy of Audiology Foundation (AAF) (http:// www.audiology.org/about/foundation) to support research, education, and public awareness in audiology and hearing science, as well as other sources, including federal agencies, private foundations, and national organizations in hearing and balance. (http://www.audiology. org/education/research/funding/ Pages/default.aspx) In support of this goal, the AAA and the AAF provide research funding through the Research Grants in Hearing & Balance Program and the New Investigator Program.

The American Academy of Audiology Foundation and the American Academy of Audiology will make grants for research projects with a duration of one year. Grants of up to \$10,000 will be made based on the merit of the research project. In addition, grants may be made for basic research or clinical/applied research. Applicants must have been granted a doctoral degree in audiology (Au.D.) or hearing science (Ph.D.) within the past five years of their application for funding and must be formally associated (faculty, staff, or otherwise) with a non-profit public or private institution in the United States or Canada, with no significant source of research funding (e.g., no federal funding from NIH or NSF), and a mentor with expertise in the research area to be investigated and who will be prepared to foster the advancement of the grantee in the development and conduct of the research.

- American Hearing Research Foundation (http://americanhearing.org) funds research in hearing and balance disorders. It awards an average of five to ten research projects per year, with an average grant of approximately \$20,000. Priority is given to investigators early in their careers who need seed funds to generate results and data that can be used to support later applications for larger grants (e.g., NIH or NSF grants) in the future. This site has links to a research grant application as well as a list of former recipients and their research topics from 1996 through the present.
- Capita Foundation (http://www .capitafoundation.org) is dedicated to the support of cutting-edge innovative auditory research worldwide. The majority of Capita Foundation grants fund early stage research and projects by early career research scientists, allowing them to produce the preliminary results needed to secure grants from the NIH and other major funders. Grant applications are welcomed from scientists conducting research in line with the Foundation's mission statement to "support innovative research that works toward the prevention and cure of hearing disorders."
- http://www.federalgrantsand contracts (http://www.federalgrantsand contracts.com/about.aspx) is a comprehensive biweekly review of the latest funding opportunities across all federal agencies. It covers relevant grant opportunities announced each week, provides information on upcoming grant initiatives, and offers news on standing cyclical grant competitions.

It researches many online and print channels of federal information and resources, and provides specific information on scope, deadline, funds, eligibility, and contact needed to start the grant application process.

www.tgci.com) offers training programs that include information, resources, best approaches, tips, and insights to avoid trial-and-error learning. These training programs provide an overview of the entire proposal development process, highlighting the key elements that make proposals competitive. Also addressed is an understanding of federal application guidelines and design of a proposal development work plan.

Other reference sources on research grants include the following directories. Information on their availability can be obtained via online searches (e.g., Google) as well as at other websites (e.g., Amazon.com).

- Annual Register of Grant Support_
 is a directory of grant and fellowship programs of foundations,
 governmental agencies, as well as
 business, professional, and other
 organizations.
- Directory of Biomedical and Health Care Grants includes U.S. and international grant programs of governmental agencies, foundations, corporations, and professional organizations.
- *Directory of Research Grants* contains a listing of grant opportunities from federal agencies as well as U.S. and international foundations, corporations, government agencies, and other organizations.

- Included are grants for fellowships, basic research, equipment, building construction/ renovation, and other program types.
- *Taft Foundation Reporter* provides comprehensive profiles and gives analyses of America's major private foundations in annual grants to nonprofit organizations. It contains information on corporate foundations and direct giving programs.

General Principles of Grant Seeking

The following are some general principles applicable to the grant-seeking process:

- Search databases of existing grants from relevant funding agencies
- Know a funding agency's mission and what types of topics of research that it wishes to fund
- Match an agency whose goals fit your research project topic
- Contact the contact person (program officer) to discuss your proposed project in order to determine its feasibility for support. Additional information on the grant-seeking process is provided by Bauer (2017) and Licklider (2012).

Grant Proposal Writing

Preliminary Considerations

Once the grant-seeking phase has been completed and the agency located as a potential funding source for the proposed research project, the next major step is to write the grant proposal. However, before the writing begins, there are some preliminary considerations:

- 1. Obtain an application from the sponsoring agency's website.
- 2. Carefully review the agency's guidelines (located in the application material) for the relevant grants program, which should contain the following important information:
 - suggested format for the proposal,
 - any necessary appendices,
 - deadline dates,
 - any applicable cost-sharing requirements for the applicant,
 - allowable indirect cost rates,
 - criteria used to judge each proposal
 - relative weighting of each factor in the criteria.

The guidelines should be followed exactly as specified. If any of the above information is missing from the guidelines, or if there are questions about the guidelines, the sponsoring agency's contact person (whose name, e-mail and/or postal address, as well as, and telephone number are listed in the application material) should be contacted for clarifications.

The Grant Proposal

The grant proposal usually contains the following major sections:

Introduction

Problem Statement (Needs

Assessment)

Objectives

Methodology

Budget

Writing a research grant proposal is somewhat similar to writing a manu-

script for publication in a journal or a master's thesis or a doctoral dissertation, because all include a review of the pertinent literature, a statement of purpose of the research, and a description of the methodology to study a proposed purpose or problem. However, since a research grant proposal is written before the proposed research is conducted, it includes a budget section requesting funds to conduct the research.

The Budget

The major categories of the budget usually include the following:

- *Personnel*—the people who will be working on the project, including the principal investigator and other personnel, as well as the amount of time they will be working on the project.
- Fringe Benefits—whenever grant funds are used to pay salaries and wages, associated fringe benefits must also be charged to the grant. The fringe benefit rate and percentage usually includes social security, unemployment /worker's compensation, retirement, and health insurance. It is a percentage of the base salary of the persons working on the research project and will vary from institution to institution.

Once the salary amount is determined, fringe benefits are calculated as a percentage of the total salary for each individual or category of emloyee. These percentages are intended to provide adequate funding to cover the actual fringe benefit costs that will be charged to sponsors.

■ *Travel*—funds to travel to professional meetings to present the findings of the research project and,

depending on the nature of the research, may include funds to travel to collect data and other related research activities.

- Equipment—any necessary instrumentation to conduct the research. For many organizations, equipment is defined as any item with a unit acquisition cost of \$5,000 or more and a life span of two or more years (NIH) [or a lifespan useful for more than one year (NSF)].
- *Supplies*—needed supplies and materials.
- *Contractual*—any necessary contractual agreements with other agencies or individuals as part of the research project.
- *Other*—other items not covered in the previous six categories.
- *Total Direct Costs*—the sum of the seven budget categories previously listed.
- *Indirect Costs*—expenditures not included directly in any of the budget categories previously listed, such as the cost of heating/cooling; electricity; maintenance; security of facilities used for the research project; the processing of paperwork for purchases associated with the project; administrative costs; and other related expenses.
- *Total Project Costs*—the total cost of the research project, including all direct and indirect costs.

It should be noted that grant proposals need not include all seven budget categories previously listed. Only budget items that can be justified because they relate directly to the methodology should be included in the proposed budget for the research project.

The Idea/Problem

A fundable proposal includes a good idea/ problem that is expressed well and with an appropriate plan for implementation. The idea/problem for a research grant proposal should ask an important theoretical or applied question(s) capable of being systematically studied. A few questions to ask and answer about the idea/problem for a research study are as follows:

- Is it important (regarding discovery, improvement, or application of knowledge)?
- Is it timely today?
- Is it capable of being investigated (regarding the availability of personnel, expertise, techniques, instrumentation, facilities, etc.)?

Ideas/problems for a research project come from various sources, including the following:

- the applicant's previous experiences (e.g., teaching, research, clinical practice, administration, etc.);
- the applicant's literature reading and familiarity with the area of investigation;
- unresolved problems in the applicant's field of study;
- potential applications of previous research findings; and
- priority areas for funding established by sponsoring agencies.

Unsolicited and Solicited Proposals

An *unsolicited proposal* is one that is written without any specific guidelines