Fostering New Investigators Tips
CONTENTS

Mastering the Grant Preparation Process ................................................................. 2
Institutional Review Board ....................................................................................... 3
Developing the Research Question ........................................................................ 4
Evaluating the Existing Evidence ........................................................................... 5
Approach .................................................................................................................. 5
Establishing Timelines ......................................................................................... 6
Human Subjects Protections .................................................................................. 6
Mastering the Grant Preparation Process

For most new investigators, the entire grant submission process can be overwhelming. However, the quality of the grant application will have a major impact on funding decisions. Organization is critical to the process. As you prepare to apply through this grant program, you should immediately read the entire application and make a list of each step required for completion of the application. This should be followed by a discussion between you and the senior investigator that focuses on a timeline for development of the application. Plan adequate time to develop your application, as quality research questions, objectives and methods take significant time to develop and refine.

Garnering institutional support and the grants administration process also take significant amounts of time and should be factored into the grant submission timeline. Departmental and institutional support for the research are critical to the project’s success. Most studies require some level of logistical support from within the researcher’s department and the institution. Practice based research almost always benefits from multidisciplinary involvement. As the methods for the proposed study are being developed, the research team should assess each component of the methods to determine the impact on different departments within the institution. After this assessment has been completed, an organized plan for gaining support from each of the involved departments should be developed. This plan should also address logistical issues that are critical to execution of the study. For example, will the pharmacists need education regarding the protocol? Do other departments require review by their departmental research committee prior to IRB submission? If medical records review is involved, have all HIPAA implications been addressed with the medical records department prior to IRB submission? The study methods should be revised as required to reflect the logistics discussions that occur. Along with positively impacting execution of the study, these efforts to engage other departments will be beneficial as the study is being reviewed by the IRB and by the institution’s office of grants administration. Include letters of support from key departments as appendices to your application.

[National Institute for Allergy and Infectious Diseases tutorial on grant writing](#) provides valuable information for any grant writer.

See the following articles for an in-depth discussion of research project management and writing grants:


Remember, the quality of the grant application can be enhanced greatly by seeking review from experienced researchers who are not involved with the study.
Institutional Review Board review and approval are imperative to the ethical conduct of research, to the protection of human subjects and to ensure compliance with federal regulations governing research. In the early stages of project planning, the investigators should incorporate IRB processes into the research timeline. This provides a good opportunity for the resident to become acquainted with the IRB’s procedures and review requirements. The ASHP Foundation requires evidence of IRB approval before it funds research projects and a large number of scientific journals require similar evidence prior to publication. See the Human Subjects Protections section of the ASHP Foundation’s Research Resource Center for a review of the history of IRBs and their role in overseeing research by Wesley G. Byerly, Pharm.D.

The Department of Health and Human Services (DHHS) provides information on federal regulations regarding IRBs.

One of the questions that investigators raise frequently is what type of review – expedited or full – will occur or if a study will be exempted from review. The Code of Federal Regulations § 46.101(b) contains information on those types of studies that are exempted from review.

The DHHS website also houses the federal regulations that address expedited review and a list of research categories that the secretary of DHHS has determined may be reviewed through an expedited review process.

See the following article for an in-depth discussion of institutional review boards:

Byerly, WG. Working with the institutional review board. Originally published in Am J Health-Syst Pharm. 2009; 66:176-84. © 2009, American Society of Health-System Pharmacists, Inc. All rights reserved. Posted with permission.
Developing the Research Question

The research question should be identified as early as possible in the residency year. Selection of an appropriate research question is one of the greatest challenges confronting pharmacy residents and their research advisors.

The residency year provides a relatively short period of time to conduct quality “research” and the execution of the project must be balanced with the training priorities of the pharmacy residency. It is imperative that the resident and the advisor select an appropriately narrow research question that addresses an important practice issue. For resident projects, the use of retrospective data is usually easier, given the limited time available for study completion.

Succinctly defining the research question is key to a successful resident research project. The research question should be defined as early as possible in the residency year. In their book, Designing Clinical Research, Hulley and Cummings describe the use of the mnemonic FINER(Cummings, Browner et al. 1988) in developing the research question.

**Feasible**
- Adequate number of subjects
- Adequate technical expertise
- Affordable in time and money
- Manageable in scope

**Interesting to the investigator**

**Novel**
- Confirms or refutes previous findings
- Extends previous findings
- Provides new findings

**Ethical**

**Relevant**
- To scientific knowledge
- To clinical and health policy
- To future research directions

Grant requests to ASHP Foundation should focus on research that relates to the ASHP/ASHP Foundation Pharmacy Practice Model Initiative.

Once the research question is drafted, it should be circulated to experienced researchers associated with the residency program for review. One forum for review of the research question, and other components of the proposed study, is a regular research seminar that is attended by the residents and the residency faculty, including those with research experience.

For an extensive discussion of his topic, see Dr. Earlene Lipowski’s article on developing great research questions and Dr. Kathleen Bungay’s Research Boot Camp lecture on framing research questions: Framing Your Research Question

Evaluating the Existing Evidence

Once the resident has identified a research idea, a comprehensive review of the existing evidence should be completed to develop a thorough understanding of the topic. A review of the literature can ensure that the investigators do not duplicate questions that have been answered already and it can provide insights into important unanswered questions related to the topic area.

For further discussion of the importance of the evidence review, see Dr. Kelly Smith’s article Building Upon Existing Evidence to Shape Future Research Endeavors.

Dr. Almut Winterstein discusses the literature review at length in her Research Boot Camp lecture on this topic. See:
- Literature Review, Part 1
- Literature Review, Part 2
- Literature Review, Part 3
- Literature Review, Part 4

Watch Dr. Kathleen Bungay’s Research Boot Camp lecture, Writing a Research Plan Introduction, to learn how to incorporate your evidence review into a concise rationale and significance section for your ASHP Foundation grant application.

Approach

Study design is the most important part of conducting quality research. A well-designed study enables the researcher to respond to a research question with accurate, objective and valid methods. As part of the Research Boot Camp lecture series, Dr. Almut Winterstein addresses:

- Study Designs Used for Clinical Research
- Cohort and Case-Control Studies
- Randomized Clinical Trials
- Introduction to Study Interventions
- The Scientific Method: Generalizability and Sampling, Part 1

In addition, the American Journal of Health-System Pharmacy research series contains several articles that address various aspects of research design. These include:

- An Overview of Clinical Research Design by Drs. Daniel Hartung and Daniel Touchett
Establishing Timelines

One of the most important aspects of conducting quality research – especially during a pharmacy residency – is establishment of a reasonable timeline. The research advisor should work with the resident to develop a realistic timeline that will enable completion of a quality project while undertaking the primary training responsibilities associated with their residency.

Visit the ASHP Foundation Research Resource Center to view a sample grant timeline.

Human Subjects Protections

Institutional Review Board (IRB) review and approval is imperative to the ethical conduct of research, to the protection of human subjects and to assure compliance with federal regulations governing research. In the early stages of project planning, the investigators should incorporate IRB processes into the research timeline. This provides a good opportunity for residents and other new investigators to become acquainted with the IRB’s procedures and review requirements. The ASHP Foundation requires evidence of IRB approval before it funds research projects and a large number of scientific journals require similar evidence prior to publication. A review of the history of IRBs and their role in overseeing research by Wesley G. Byerly, Pharm.D., can be found on the ASHP Foundation Web site at http://media.ashp.org/foundation/qprpart2/index.html. To listen to this presentation, click on “Quality Practice Research, Part 1.”

Dr. Byerly also provides an in-depth primer on this topic in his article, Working with the Institutional Review Board.

Access to information on federal regulations regarding IRBs can be helpful while the resident is organizing his/her research. The resident should give serious consideration to attending an institutional program on conducting human subjects’ research.