



# Fostering Young Investigators Pharmacy Resident Practice-Based Research Grant

Administered by the  
American Society of Health-System Pharmacists Research and Education Foundation

## Application Instructions

*These instructions should be followed carefully. Only after all the requested information has been received will an application be considered complete and eligible for evaluation by the ASHP Foundation's Grants Review Panel. If the application is incomplete or incorrectly prepared, it may be returned without review or evaluation may be delayed until the next application period, if applicable.*

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**APPLICATIONS THAT DO NOT STRICTLY COMPLY WITH THE  
APPLICATION INSTRUCTIONS WILL BE  
RETURNED WITHOUT REVIEW.**



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## *Fostering Young Investigators Tip*

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. (Visit the [ASHP Foundation Research Resource Center](#) to view a [sample grant timeline](#).) 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 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 the 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.

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

Remember, the quality of the grant application can be enhanced greatly by seeking review by experienced researchers who are not involved with the study.

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## **I. GRANT PROGRAM DESCRIPTION**

The ASHP Research and Education Foundation (ASHP Foundation) is offering a research grant program that will support practice-based research in medication use conducted by residents in ASHP-accredited pharmacy residency programs or by residents in pharmacy residency programs that have submitted an application for ASHP accreditation. Practice-based research affects a wide range of medication-use topics including patient education; patient outcomes and effectiveness of medication therapy; health care quality; medication use in minority, elderly and other special populations; medication costs and financing; program evaluations; and access to medications. A secondary goal of the program is to develop pharmacy residents' research skills while fostering development of mentoring relationships with more experienced senior investigators. The proposed practice-based research must be consistent with the vision, mission and strategic priorities of the ASHP Foundation.



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### **Vision**

Patients receiving medication therapy in our nation's hospitals and health systems will receive care in a safe and efficient manner, leading to optimal medication outcomes.

### **Mission**

The mission of the ASHP Foundation is to improve the health and well being of patients in hospitals and health systems through appropriate, safe and effective medication use. The Foundation provides leadership and conducts education and research activities that foster the coordination of interdisciplinary medication management leading to optimal patient outcomes. Emphasis is given to programs that will have a major impact on advancing pharmacy practice in hospitals and health systems, thereby improving public health.

### **Strategic Priorities**

- Design and study of safe and effective medication-use systems
- Advancement of optimal patient medication outcomes
- Expansion of pharmacists' direct patient care and leadership roles

Applications for this research grant program should emphasize: 1) Project objectives that address practice-based research related to medication use; 2) prudent use of grant funds; 3) a sound research methodology that supports the project objectives; 4) mentoring activities between a senior investigator/advisor and the pharmacy resident; 5) interdisciplinary collaboration; 6) the potential for projects to be replicated in other health care facilities; and 7) the impact that the results of the project will have on medication use. Preference will be given to research projects with the potential to yield strong scientific evidence that can be applied to practice.

National healthcare priorities are one potential source of study questions. The [ASHP Health System Pharmacy 2015 Initiative](#) goals and objectives provide guidance on priorities for the improvement of pharmacy practice in health systems. The [Core Measures](#) and [National Patient Safety Goals](#) from The Joint Commission are also potential sources that can be used to develop practice-based research questions.

Applicants should also consider other ASHP policy documents and initiatives when selecting a research question. For example, the [ASHP Statement on Pharmacy Services to the Emergency Department](#) and the [ASHP-SHM Joint Statement on Hospitalist-Pharmacist Collaboration](#) identify potential research areas. See ASHP's [Practice and Policy Resource Page](#) for complete information on ASHP's policy documents.

In June 2007, ASHP and the ASHP Research and Education Foundation hosted a Continuity of Care in Medication Use Summit. The [executive summary](#) of the summit, which can be found on the ASHP Foundation Web site, contains a research agenda related to the use of patient-centered personal medicine lists.



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## II. ELIGIBILITY

- The proposed research must involve practice-based research in medication use that is conducted by a pharmacy resident in an ASHP-accredited residency program or a program that has applied for ASHP residency accreditation. A senior investigator must participate on the research team as a mentor/advisor. In the application process and grant progress reports, evidence must be included regarding the support and involvement of the senior investigator. For this grant program, the senior investigator assumes responsibility for compliance with all requirements of the grant program. The senior investigator does not have to be a pharmacist.
- Applicants are strongly encouraged to include an individual with a research track record as a member of the investigator team. Strong consideration should be given to allocating a portion of the budget to support biostatistics consultation.
- The proposed research must be submitted to an institutional review board (IRB) for approval. Evidence of IRB approval must be provided to the ASHP Foundation upon acceptance of the grant award. Grant funds will not be disbursed until evidence of IRB approval has been received.

### *Fostering Young Investigators Tip*

Institutional Review Board review and approval are 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 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 Web site 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 procedure.

- The research must comply with the [NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research](#) that was amended in October, 2001.



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- The research must comply with the [NIH Policy and Guidelines On the Inclusion of Children As Participants in Research Involving Human Subjects](#).
  - The study timeline should not exceed 18 months from project initiation.
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### III. FUNDING INFORMATION

Six \$5,000 grants will be awarded. Grants will be awarded to pharmacy residents to provide funding for specific practice-based research related to medication use and are not intended for long-term support of research programs. Facilities and administrative cost rates that do not exceed 8% of the total requested budget are allowed.

Funds may not be applied to:

- Resident salaries and/or benefits;
- Ongoing general operating expenses and/or existing deficits;
- Purchase of permanent equipment, facilities, or software, or other capital costs;
- Endowment contributions; and
- Stipends or loans.

Funding is generally available for:

- Salary support for study personnel including biostatisticians;
- Institutional review board fees;
- Consumable supplies and services;
- Travel essential to the conduct of the proposed project;
- Patient expenses/reimbursement;
- Travel to present project findings in the range of \$1,000 to \$1,500 per project; and
- Facilities and administrative cost rates that do not exceed 8% of the total requested budget.

Grants will be awarded to individuals and the funds will be disbursed directly to the sponsoring institution for administration.

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### IV. GRANT RECIPIENT RESPONSIBILITIES

- The grant period of activity will begin upon notice of grant award by the ASHP Foundation and will expire 18 months after this initial disbursement.
- Following initial disbursement of funds, the grantees must submit Quarterly Research Reports to the ASHP Foundation that address:



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Progress toward completion of activities included on the study timeline for the quarter in question;

Any protocol modifications and documentation of IRB review and approval of such modifications; and

A summary of all adverse events associated with execution of the study during the quarter in question and documentation of IRB review of such adverse events.

- Within 60 days of study completion, the grantees must submit a Final Research Report to the ASHP Foundation. This report must include:

A summary of the study results including statistical analysis if applicable;

Preliminary conclusions;

A summary of all adverse events associated with execution of the study and documentation of IRB review of such adverse events;

A summary of all protocol modifications and documentation of IRB review and approval of such modifications; and

Specific plans for presentation and publication of the study findings.

- Within 60 days of submission of the Final Research Report, the grantees must submit a Final Financial Report. This report must include a complete and full accounting of the expenditure of ASHP Foundation funds related to the execution of the study.
- Any unused funds must be returned to the ASHP Foundation by the grantees.
- If, for any reason, the grantee does not complete the project, the senior investigator must inform the ASHP Foundation in writing within 30 days of study termination. Within 60 days of study termination, the grantees are required to complete the Final Research Report and Final Financial Report and return any unused funds to the ASHP Foundation as described above.
- The grantees may request one grant extension. Only one extension will be granted for any study. The project must be completed and all other requirements of the grant fulfilled by the end of the extension period.
- The ASHP Foundation requires submission of the study results for presentation at a national or international scientific meeting. If submission is made to a pharmacy meeting, the American Society of Health-System Pharmacists retains the right of first refusal for scientific presentations that emanate from this study. If the study and its findings are presented at a medical or multidisciplinary meeting, the grantee should plan to also present the study and its findings at the ASHP Midyear Clinical Meeting that follows presentation at



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the medical or multidisciplinary meeting. Travel to the ASHP Midyear Clinical Meeting to present study findings should be supported through grant or institutional funds.

- The ASHP Foundation requires submission of study results to a peer-reviewed scientific journal within 6 months of study completion. If the study results are submitted to a pharmacy journal, the *American Journal of Health-System Pharmacy* retains the right of first refusal for publication.
- A reprint of all articles that emanate from this study should be submitted to the ASHP Foundation.
- All presentations, publications, and other communications regarding this study must include the following acknowledgement: "This study was funded (or partially funded) by a research grant from the ASHP Research and Education Foundation."
- By accepting this award, the grantee will undertake all reasonable efforts to complete the study and take responsibility for fulfilling the terms described within the award letter.

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### V. APPLICATION PROCESS/SELECTION CRITERIA

Grant application reviewers will use the following criteria in evaluating applications:

#### **Rationale - 10 points maximum**

Do the investigators clearly explain why this study should be undertaken? Is there an adequate review of the relevant literature included in the proposal? Does the literature review demonstrate that the investigator understands the field and has a balanced and adequate knowledge of it? Do the investigators identify the next logical stage of research beyond the current application?

#### **Significance - 10 points maximum**

Does this study address an important problem? Is there a justification within the background section about the research field that led to the proposed study? Does the reason for conducting the study challenge existing paradigms or propose new methods, techniques or technologies? Do the investigators identify gaps in the existing evidence base and propose how the proposed study will fill those gaps? If the study is not innovative but is essential to move the field forward, the applicant should mention and discuss this in the proposal. Does the investigator demonstrate how the hypothesis and research will increase knowledge in the field and relate the study to longer-term, broad, scientific objectives and to the advancement of public health?

#### **Objectives - 20 points maximum**

Are the study objectives consistent with the specific grant program focus and the strategic priorities of the ASHP Research and Education Foundation? Are the overall objectives original and innovative?



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## Fostering Young Investigators Tip

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 (Cummings SR, Browner WS, Hulley SB. Conceiving the Research Question. In: Hulley SB, Cummings SR, eds. *Designing Clinical Research*. Vol 1. 1 ed. Baltimore: Williams & Wilkins; 1988:12-17.) describe the use of the mnemonic FINER 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*

Once the research question is drafted, it should be circulated to experienced researchers for review.

Along with the research question, well defined objectives are key to the successful completion of a study. The objectives should answer the question “What are you going to do?” For a junior investigator-initiated study, the research team should not be overly ambitious with the objectives as this will affect project viability. The study should probably be limited to 2-3 objectives. However, these objectives can be designed to increase the value of the study. For example, a study that addresses outcomes data, rather than process data, could have an important impact on practice.

See the National Institute of Allergy and Infectious Diseases guidance on [writing study objectives](#).

Similar to the review of the research question, the objectives should be reviewed by experienced researchers. Hypothesis statements are developed primarily to provide a basis for statistical analysis. The National Institute of Allergy and Infectious Diseases also provides detailed information on generation of a [hypothesis statement](#).

## **Study Methods - 40 points maximum**

Do the investigators propose clear and detailed study methods? Will the methods enable the researcher to address the stated objectives and hypothesis? Do the procedures to be followed



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include, when applicable: appropriate study design; sampling techniques and a description of the population from which the sample will be recruited; controls; procedures for collection, storage and quality control of data for the major outcome, variable secondary outcomes, and other covariates; assurance of availability of subjects and/or facilities to be used; feasibility of plans for recruitment and retention of subjects; and plans for data analysis including biostatistics support? Are methods problems anticipated and alternative approaches proposed? Can the proposed study methods be replicated and generalized?

### *Fostering Young Investigators Tip*

Study design is one of the most important parts of conducting quality research. A well-designed study enables the researcher to respond to a research question with accurate, objective and valid methods. The study design that is chosen should employ the best approach to establishing a causal relationship between the intervention and the measurable outcome(s). The ASHP Foundation's Web-based Research Resource Center contains a section on [study design](#) including [information from the Oxford Centre for Evidence Based Medicine](#) that provides brief descriptions of advantages and disadvantages of several different study designs.

Consultation with a biostatistician can dramatically impact the quality of the study. Key steps that lead to a valid statistical analysis include:

- Establishing a research question
- Formulating a hypothesis
- Identifying primary and secondary outcomes
- Selecting an appropriate test
- Sampling correctly
- Collecting data
- Describing the data
- Performing the test

A brief primer on descriptive and inferential statistics, entitled [Statistics at Square One](#), is available from the *British Medical Journal*.

The [National Institute of Allergy and Infectious Diseases](#) provides insight into what grant reviewers are looking for in terms of study design.

### **Scope and Timeline - 5 points maximum**

Do the investigators justify that the proposed timeline is realistic? Is there evidence the study can be completed in the proposed time period (maximum 2 years)? Do the investigators present information to support the feasibility of the study (e.g., pilot data)? Will sufficient patients/subjects be available for completion of the project within the proposed time period?

### *Fostering Young Investigators Tip*

Visit the [ASHP Foundation Research Resource Center](#) to view a [sample grant timeline](#).

### **Personnel and Facilities - 15 points maximum**

Are the professional competencies and experiences of the investigators appropriate to execute the work required? Is there evidence of a commitment to collaboration between the research team?



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Are the facilities appropriate and adequate for the proposed project? Is there evidence of institutional support?

The application is to be completed by the principal investigators and forwarded to:

Daniel J. Cobaugh, Pharm.D., DABAT, FAACT  
Director of Research and Program Development  
ASHP Research and Education Foundation  
7272 Wisconsin Avenue, Suite 200  
Bethesda, Maryland 20814

To be accepted, the completed application must be mailed to arrive at the ASHP Foundation no later than the Close of Business on October 31, 2008. If additional space is needed for any item(s), append additional page(s) and reference with item numbers. Ten (10) copies (original plus nine) of the completed seven-page application form, with all attachments, must be submitted. Each copy must be collated in the order in which the items appear in the grant application:

- 1) Completed application form (7 pages)
- 2) Any attached pages required to complete Items 1-9
- 3) Project plan (Item 10(a) parts 1-10)
- 4) Curricula vitae for all investigators (Item 10(b))

**APPLICATIONS THAT DO NOT STRICTLY COMPLY WITH THE APPLICATION INSTRUCTIONS WILL BE RETURNED WITHOUT REVIEW.**

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### VI. ITEMIZED INSTRUCTIONS FOR GRANT APPLICATION

1. Self-explanatory.
2. Funds may be requested for a maximum period of 18 months.
3. Total amount requested may not exceed \$5,000 for an 18-month period.
4. (a,b) The pharmacy resident must be participating in an ASHP-accredited residency program or a program that has applied for ASHP accreditation.  
(c,d) Institution and the department or division in which the pharmacy resident is currently employed.  
(e-h) Self-explanatory.  
(i) Percent effort is the total percentage of the investigator's time that they will commit to this study. For example, if an investigator works 50 hours per week and expects to commit 5 hours per week to the study, their percent effort would be 10%.
5. (a,b) The senior investigator does not have to be a pharmacist. The senior investigator should have the requisite skills and experiences to supervise the resident's research activities. The individual named as senior investigator must assume primary responsibility for the study and serve as the senior investigator for



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- the entire grant period.
- (c,d) Institution and the department or division in which the senior investigator is currently employed.
- (e-h) Self-explanatory.
- (i) Percent effort is the total percentage of the investigator's time that they will commit to this study. For example, if an investigator works 50 hours per week and expects to commit 5 hours per week to the study, their percent effort would be 10%.
6. (a) The sponsoring institution is that location at which the research will be conducted. Grant checks will be made payable to the institution name listed. (b) The ASHP Foundation only makes grants to tax-exempt institutions or agencies. (c) Self-explanatory. (d-e) List the grant officer at the sponsoring institution who will be responsible for monitoring of grant fund use. Institutions with grants management divisions are required to submit the grant application to the institutional grants management division for review and sign-off prior to submission to the ASHP Foundation. For institutions that do not have internal grants management divisions, the institution must identify an appropriate entity (e.g., related healthcare foundation) to receive the funds and monitor their use. The grant officer cannot be a member of the investigator team. The grant officer cannot be a departmental support staff member (e.g., administrative assistant.) (f-h) Self-explanatory.
7. (a) All personnel for whom salary support is requested must be named in this section. Salary support is available only for study personnel (e.g. senior investigator, technical personnel; clerical personnel; and other professional personnel.) Resident salaries and fringe benefits are not allowed under this grant program. In the personnel budget justification section, provide a detailed justification that describes each individual's role. The budget justification should correspond directly to the project plan.
- (b) All consumable supplies must be itemized as to description, number, cost per unit, and total cost. If exact costs are not known, estimates must be provided. Provide a detailed justification for each budget item. The budget justification should correspond directly to the project plan.
- (c) Only travel costs essential to the conduct of the project are eligible for funding. Travel to present project findings is acceptable in the range of \$1,000 to \$1,500 per project. In the travel budget justification, provide a detailed justification for each budget item. Estimated costs for meeting registration fees, airfare, lodging, meals, and ground transportation must be provided.
- (d) All other expenses not already specified must be itemized and justified in relation to the project. Requests for permanent equipment, facility construction or renovation, or software are not eligible for funding. Provide a detailed justification for each budget item. The budget justification should correspond directly to the project plan.
- (e) Requests for support for facilities and administrative costs rates cannot exceed 8% of the total budget. TOTAL budget should be the same as Item 3.
8. (a) All other professionals engaged in project for whom salary support is not being



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requested must be named here with their official title, department/division, institution, and their percent effort dedicated to this study. (Do not list the pharmacy resident investigator and senior investigator/advisor here.)

9. This "certification" must be signed by the pharmacy resident investigator, the senior investigator/advisor, and the financial officer named in Item 5.
10. (a) Each of the ten headings must appear in the stipulated order. The abstract should summarize the proposal and is limited to one page. In developing the proposal, the applicant should provide sufficient detail in the methods section including a power analysis, if applicable, and plans for data management and analysis. A detailed description of the subject recruitment process, including the informed consent process, should be provided if applicable. The application must address the ability to recruit a sufficient number of subjects to successfully complete the study. Under "Role of the Resident Investigator and Senior Investigators," describe the role of the resident investigator and the senior investigator in serving as the co-principal investigators with responsibility for the entire project. Describe the qualifications of the each researcher according to the eligibility requirements described above. Including the abstract and references, the narrative of the project plan may not exceed ten (10) pages (using 11 point font or larger, 8.5 x 11 inch paper, 1 inch margins, single spacing and single sided pages). Applicants should strictly comply with font size, paper size, spacing and page limit requirements. Applications that do not strictly comply with the application instructions will be returned without review.  
(b) Provide a curriculum vitae (C.V.) for each investigator. In addition to the usual vital statistics, education, professional experience, and publications, each C.V. must include the individual's major research interest and a description of their research experience. **Curricula vitae must be limited to 4 pages and must be submitted in the format provided in the PHS 398 form from the U.S. Department of Health and Human Services. (See [www.grants.nih.gov/grants/funding/phs398/biosketchsample.doc](http://www.grants.nih.gov/grants/funding/phs398/biosketchsample.doc).)**

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