ASHP Research and Education Foundation

New Investigator RESEARCH GRANT

Application Policies and Guidelines

Application Instructions

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

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Fostering New 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. If you decide to pursue funding, 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 senior investigator that focuses on a timeline for development of the application. An applicant needs to understand that quality specific aims and study methods take 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. Although the National Institute for Allergy and Infectious Diseases tutorial on grant writing is geared to development of a National Institutes of Health grant submission, it still provides valuable information for any grant writer. The quality of the application can be enhanced greatly by seeking review by experienced researchers who are not involved with the study.

Although it is impossible to adequately discuss all aspects of grant writing through these tips, there are several areas that new investigators should pay attention to as they write an application. In this tip, a few key aspects of grantsmanship – adherence to instructions, budget justifications, and timeline development – will be addressed.

One important aspect of grant submission is adherence to the application instructions. When the investigator reviews the application and instructions to develop the grant preparation timeline, guide them to also pay close attention to issues such as page limits and font size. In many cases, funding agencies will return, without review, applications that do not adhere to application instructions. If a grant application has a budget justification section, the applicant should carefully justify requested funds in relation to the project. Rather than simply listing a research assistant, the budget justification should explain to the reviewer the assistant’s role on the project. If the grant program requires a timeline for the project, provide a tabular or graphic timeline that describes key activities on a monthly basis. Reviewers do not find statements such as “the study will be completed over a 12-month period” to be adequate timeline descriptions.

One of the most common mistakes made by grant applicants is underestimation of the time required to complete each of the institutional steps required for a successful application. Investigators often underestimate the time required for review by the investigator team, submission of the protocol and consent to the IRB, requesting letters of support, and submission of the entire grant application to the institution’s grants management office. Many new investigators are often unaware that a grants administration process exists in their institution. However, this is a critically important piece that cannot be overlooked. All grant applications should be submitted to the grants administration office in advance of submission to the funding agency. The research team should allow adequate time for completion of the grants administration process. If this process is overlooked, it can delay or prevent submission of the grant. If the research team determines that a grant will be pursued, the investigator and the research advisor should meet with a grants officer early in the process to learn about the institution’s policies and procedures related to grants administration. The grant officers can also offer expertise about numerous aspects of sponsored projects accounting that must be addressed when a grant application is submitted, such as budget preparation and indirect cost rates.
Fostering New Investigators Tip

Securing departmental and institutional support for a potential research project is 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 Institutional Review Board (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 if a grant submission occurs.

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


Grant Program Description

The ASHP Research and Education Foundation (ASHP Foundation) is offering a research grant program that will support practice-based research, related to the ASHP/ASHP Foundation Pharmacy Practice Model Initiative (PPMI), conducted by pharmacist new investigators. Practice-based research affects a wide range of practice model 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 new investigators’ 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. The PPMI is driven by a set of assumptions, beliefs, and recommendations from the November 2010 ASHP/ASHP Foundation PPMI Summit. The overarching goal of the PPMI is to increase pharmacist participation on patient care teams as the professional who is responsible and accountable for patients’ medication-related outcomes while delegating all medication distribution functions that do not require
clinical judgment to qualified pharmacy technicians and technology. Submission of studies that evaluate the pharmacy practice models in hospitals and health systems - such as the utilization of technology, role delineation changes for the pharmacists and non-pharmacists, or improving the patient care opportunities for pharmacists – is invited. Applicants can find the beliefs, assumptions and recommendations from the PPMI Summit in the PPMI Web Resource Center and other PPMI-related resources. Clinical studies, including pharmacokinetic studies and medication effectiveness studies, are not supported through this program.

Vision
As the philanthropic arm of ASHP, our vision is that:

Patient outcomes improve because of the leadership and clinical skills of pharmacists, as vital members of the health care team, accountable for safe and effective medication use.

Mission
The mission of the ASHP Foundation is to improve the health and well-being of patients in health systems through appropriate, safe and effective medication use. We will accomplish this by:

- Sponsoring high-impact practice research leading to advances in patient outcomes.
- Educating and developing pharmacists and pharmacy staff as leaders and clinicians.
- Providing funding and programs that optimize the medication-use system and advance the direct and accountable patient care role of pharmacists.
- Encouraging innovation and adoption of best practices and new patient safety and quality initiatives.
- Providing recognition and support to diffuse best practices in research, education and practice.
- Establishing partnerships, collaborations and strategic alliances to inform our mission and advance common goals.

Critical Issues
The following critical issues are paramount to the ASHP Foundation’s achievement of its mission and vision:

1. Facilitate and strongly support the pharmacy profession in advancing pharmacy practice models that foster pharmacists’ leadership and accountability for patient outcomes;
2. Create demand for new models of pharmacy practice that leverage the expertise and unique abilities of pharmacists; and
3. Drive the advancement of the technical, human, and leadership competencies of pharmacists and pharmacy staff in complex and rapidly changing organizations.

Applications for this research grant program are required to include: (1) measurable objectives that relate to practice-based research that focuses on advancing pharmacy practice models; (2) rigorous research methods that support the study objectives; (3) mentoring activities between a senior investigator/advisor and the new investigator; (4) a description of the impact that the results of the project will have on advancing pharmacy
practice models; (5) a description of the potential to generalize findings to other health care facilities; (6) interdisciplinary collaboration; and (7) an organized plan for prudent use of grant funds. Preference will be given to research projects with the potential to yield strong scientific evidence that can be used to advance pharmacy practice models.

### Eligibility

- The proposed research must focus on the advancement of pharmacy practice models and be conducted by a pharmacist new investigator. The principal investigator must be a new researcher within five (5) years of completion of his/her terminal degree or postgraduate training or have professional experience greater than five years and no more than two (2) externally funded research projects as a principal investigator. The principal investigator must be a licensed pharmacist and multidisciplinary research teams are strongly encouraged.

- 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 strong research track record as the senior investigator. History of publication of original research in peer-reviewed biomedical journals and receipt of extramural grant funding will be used to evaluate the senior investigator’s research track record.

- A biostatistician should be included as a member of the research 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, or exemption from review, has been received.

- Individuals who previously served as a principal investigator on any ASHP Foundation grant are eligible to apply if all work, including journal submission of the study findings, on the previously funded research is complete. If a tie score occurs during the grant review process, the grant will be awarded to the applicant(s) who has/have not received a grant from the ASHP Foundation previously.

- Not-for-profit organizations, for-profit entities, and government agencies are eligible to apply to this program. If a for-profit entity or government agency is a grant recipient, the monetary award provided by the ASHP Foundation must be received and managed by a 501(c)3 not-for-profit organization. Applicant organizations must be in the United States of America to be eligible for the grant.

- Members of the ASHP and ASHP Foundation boards of directors as well as ASHP and ASHP Foundation staff are not eligible to serve as a member of the investigator team for this research grant program.

- The research must comply with the [NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research](https://grants.nih.gov/policy/women少数民族_inclusion.htm) that was amended in October 2001.
• 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 24 months from project initiation.

• Senior investigators cannot apply for more than one grant in an application cycle.

Fostering New Investigators Tip

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 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 new investigator is organizing his/her research. The investigator should give serious consideration to attending an institutional program on conducting human subjects research.

In a previous edition of Tips for Conducting Quality Pharmacy Resident Research, the role of the Institutional Review Board (IRB) was addressed. Protection of human subjects is addressed under Title 45, Part 46, of the Code of Federal Regulations. 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 Code of Federal Regulations also contains detailed information on expedited review. A list of research categories that the Secretary of the Department of Health and Human Services has determined may be reviewed through an expedited review is also available.

It is critical that the new investigator and his/her research advisor discuss the IRB review process with representatives of the institution’s IRB.

Funding Information

Two (2) $20,000 grants will be awarded. Grants will be awarded to pharmacist new investigators to provide funding for specific practice-based research related to advancing pharmacy practice models 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 direct costs.

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

Grant Recipient Responsibilities

- The grant period of activity will begin upon notice of grant award by the ASHP Foundation and will expire 24 months after this initial notification.

- Following initial disbursement of funds, the grantees must submit Quarterly Research Reports to the ASHP Foundation that address:
  
  - 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 system-generated 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;
o A summary of all protocol modifications and documentation of IRB review and approval of such modifications; and
o 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 system-generated 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 grantees do 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 a system-generated 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.
- If the findings of the above named study are presented at a national pharmacy meeting, ASHP retains the right of first refusal for presentation of the study and its findings at an ASHP meeting. If the study and its findings are presented at a medical or multidisciplinary meeting, the grantee should apply to also present the study and its findings at the ASHP Midyear Clinical Meeting that follows presentation at 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.
- The ASHP Foundation should be notified by the principal investigators when articles containing the study findings are published.
- 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.
- The recipient institution is responsible for the actions of its employees and other research collaborators, including third parties, involved in the proposed research. The recipient institution will inquire into and, if necessary, investigate and resolve promptly and fairly all instances of alleged or apparent research misconduct related to this ASHP Foundation-sponsored research in accordance with federal regulations on research misconduct (see 42 CFR part 93, “Public Health Service Policies on Research Misconduct.”) and the U.S. Department of Health and Human Services Grants Policy Statement (see http://www.ahrq.gov/fund/hhspolicy.htm).
The recipient institution must report promptly to the ASHP Foundation any incident of alleged or apparent research misconduct involving ASHP Foundation-sponsored research that it judges as warranting investigation and must advise the ASHP Foundation of any decision to initiate an investigation. The recipient institution must also notify the ASHP Foundation if it intends to close a case at the inquiry or investigation stage based on an admission of responsibility, settlement, or for any other reason.

If a misconduct investigation has been initiated, the recipient institution must take any necessary steps, in addition to its normal and ongoing responsibilities under the grant, to protect human subjects, protect the scientific integrity of the project, provide reports to the ASHP Foundation, and ensure the proper expenditure of funds and continuation of the project during the investigation, if appropriate.

If the recipient finds research misconduct by anyone working on ASHP Foundation-supported research, whether at its organization or at a third-party organization, the recipient institution must assess the effect of that finding on the ability to continue that project, as originally approved, and must promptly request ASHP Foundation prior approval of any intended change of PI or other key personnel. In addition, the ASHP Foundation may withdraw approval of the principal investigator or other key personnel, disallow costs associated with the invalid or unreliable research, suspend or terminate, in whole or in part, the grant award.
Full Application Selection Criteria

The full applications for the grant will be evaluated using the selection criteria listed below.

**Overall Funding Priority Score = ________ (1-9)**

Using the following rating scale, reviewers will provide an overall priority score to reflect their overall assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved. This score represents the reviewers overall assessment of the application and is not based only on the criteria-based score described below.

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Additional Guidance on Strengths/Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>1</td>
<td>Exceptional</td>
<td>Exceptionally strong with no weaknesses</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
<td>Outstanding</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td>Very strong with only some minor weaknesses</td>
</tr>
<tr>
<td>Medium</td>
<td>4</td>
<td>Very Good</td>
<td>Strong but with numerous minor weaknesses</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
<td>Strong but with at least one moderate weakness</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weaknesses</td>
</tr>
<tr>
<td>Low</td>
<td>7</td>
<td>Fair</td>
<td>Some strengths but with at least one major weakness</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
<td>A few strengths and a few major weaknesses</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
<td>Very few strengths and numerous major weaknesses</td>
</tr>
</tbody>
</table>

*Minor Weakness:* An easily addressable weakness that does not substantially lessen impact.
*Moderate Weakness:* A weakness that lessens impact.
*Major Weakness:* A weakness that severely limits impact.

**Criteria Based Score = ________ (0-100)**

Using the following criteria, reviewers should provide an overall score to reflect their assessment of the study: rationale; objectives; significance and innovation; investigators and environment; study methods; and scope and timeline.

**Specific Aims and Hypothesis (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? Is the research question clear and well-defined? Are the overall objectives original and innovative? Are the objectives measurable? Is the number of objectives reasonable based on available funding?
Rationale and Significance (10 points maximum):
Do the investigators clearly explain why this study should be undertaken? Does this study address an important problem? 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 gaps in the existing evidence base and propose how the proposed study will fill those gaps? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? Do the investigators identify the next logical stages of research beyond the current application?

Fostering New Investigators Tip

Once the investigator 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:

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.

Innovation (10 points maximum):
Is there a justification within the background section about the research field that led to the proposed study? Is the project original and innovative? For example, does the project challenge existing paradigms or clinical practice or address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches or methodologies, tools, or technologies for this area? If the study is not innovative but is essential to move the field forward, does the applicant discuss this in the proposal? What will be the effect of this study on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigators and Environment (15 point maximum):
Are the principal investigator and other key personnel appropriately trained and well suited to carry out this work? Is the proposed work appropriate to the experience level of the principal investigator and the other members of the research team, including the senior investigator, if applicable? Do the
principal investigator and the research team bring complementary and integrated expertise to the project? Is the research team interdisciplinary in its composition? Is a biostatistician included on the research team? Is there evidence of a commitment to collaboration within the research team? Does the scientific environment in which the work will be done contribute to the probability of success? Does the proposed study benefit from unique features of the scientific environment, or subject population, or employ useful collaborative arrangements? Is there evidence of institutional support?

**Approach (40 points maximum):**
Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well-integrated, well-reasoned, and appropriate to the aims of the project? 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 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?

**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? 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?

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### Fostering New Investigators Tip

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

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### Additional Review Considerations
In the written review and during the review call, reviewers will also address protection of human subjects, inclusiveness, patient privacy and safety protections, and budget/budget justification.

**Protection of Human Subjects from Research Risk:**
Do the investigators adequately address human subjects protections?

**Inclusiveness:**
Does the research plan address gender, racial and ethnic minority balance?

**Privacy and Security Protections for Patients:**
Do the investigators adequately address patient privacy and safety issues?
Budget:
Are the proposed budget and budget justifications reasonable, and is the requested period of support appropriate in relation to the proposed research?

Fostering New Investigators Tip

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 new investigators 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 investigator and the advisor select an appropriately narrow research question that addresses an important practice issue. For investigator 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 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 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

Fostering New Investigators Tip

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**
- **Measurement, Part 1**
- **Measurement, Part 2**

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 Touchette
- **Intervention Design, Implementation and Evaluation** by Dr. Lourdes Planas
- **Bias: Considerations for Research Practice** by Dr. Tobias Gerhard
- **Validity and Reliability of Measurement Instruments Used in Research** by Drs. Carole Kimberlin and Almut Winterstein
ITEMIZED APPLICATION INSTRUCTIONS

Project

- The study must relate directly to advancing pharmacy practice models in hospitals and health systems as described in the Grant Program Description section.
- Funds may be requested for a maximum period of 24 months.
- Total amount requested may not exceed $20,000 for a 24-month period.

Principal Investigator

- Self-explanatory. Please note: Members of the ASHP and ASHP Foundation Board of Directors, as well as ASHP and ASHP Foundation staff are not eligible to serve as a member of the investigator team for this research grant program.
- Self-explanatory, if applicable.
- Degree(s)
- Position title.
- Institution/Organization name.
- Physical mailing address at place of employment.
- Business telephone number at place of employment.
- Email address that is most commonly used for frequent communication.
- Percent effort is the total percentage of the investigator’s time that he/she 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, his/her percent effort would be 10%.

Senior Investigator

- Self-explanatory. Please note: Members of the ASHP and ASHP Foundation Board of Directors, as well as ASHP and ASHP Foundation staff are not eligible to serve as a member of the investigator team for this research grant program.
• Self-explanatory, if applicable.

• Degree(s)

• Position title.

• Institution/Organization name.

• Physical mailing address at place of employment.

• Business telephone number at place of employment.

• Fax number at place of employment.

• Email address that is most commonly used for frequent communication.

• Percent effort is the total percentage of the investigator’s time that he/she 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, his/her percent effort would be 10%.

• Pharmacy license information. This includes: state, license number, and expiration date.

**Sponsoring Institution and Grant Officer**

• Not-for-profit organizations, for-profit entities, and government agencies are eligible to apply to this program. If a for-profit entity or government agency is a grant recipient, the monetary award provided by the ASHP Foundation must be received and managed by a 501(c)3 not-for-profit organization. The institution must be in the United States of America to be eligible for the grant.

• The sponsoring institution is that location at which the research will be conducted. Grant checks will be made payable to the institution name listed.

• Self-explanatory.

• 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.)
• Title of the grant officer must directly reflect an appropriate individual to receive the funds and monitor their use.

• Physical mailing address of the grant officer that all grant correspondence will be sent to.

• Business telephone number of grant officer.

• Fax number of grant officer.

• Email address that is most commonly used for frequent communication.

Other Investigators

• All other professionals engaged in project for whom salary support is NOT being requested must be named here with his/her credentials, institution name and department/division, email address, and his/her percent effort dedicated to this study. If institutional in-kind contribution of time for these members of the investigator team will be required for completion of the proposed research, a support letter that confirms this institutional support should be included.

• Self Explanatory.

Detailed Budget

(a) PERSONNEL
All personnel for whom salary support is requested must be named in this section. Salary support is available only for study personnel (e.g., technical personnel; clerical personnel; and other professional personnel.) Resident salaries and fringe benefits are not allowed under this grant program. Strong consideration should be given to allocating a portion of the budget to support biostatistics consultation. 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) CONSUMABLE SUPPLIES
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) TRAVEL
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. All travel to present study findings should be supported through grant or institutional funds. Estimated costs for meeting registration fees, airfare, lodging, meals, and ground transportation must be provided.

(d) OTHER EXPENSES
All other expenses not already specified must be itemized and justified in relation to the project. Permanent equipment, facility construction or renovation, and 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) FACILITIES AND ADMINISTRATIVE COSTS
Requests for support for facilities and administrative costs rates cannot exceed 8% of the direct costs. TOTAL budget should be the same as Item I (d).

Supporting Documents Required

(a) UPLOADS
Each of the following nine headings must appear in the stipulated order:

Research Plan Components
Description of proposed research plan on no more than ten (10) pages (using 11 point font or larger, 8.5 x 11 inches paper, 1-inch margins, single spacing and single-sided pages) with numbered pages under the following headings:

1. Abstract of proposal (limit to one page with a focus on objectives and methods);
2. Specific Aims and Hypothesis
3. Rationale and Significance
4. Innovation
5. Investigators and Environment
6. Approach
   ▪ detailed study procedures;
   ▪ power calculation, if applicable;
   ▪ plans for data analysis; and
- procedures for recruitment, retention, and protection of subjects, if applicable

7. Human Subjects/Inclusiveness/Privacy

8. Scope and Timeline

9. References

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.

(b) BIOGRAPHICAL DATA

Provide a biographical sketch for each investigator. **Biographical sketches 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 [http://www.grants.nih.gov/grants/funding/phs398/biosketchsample.doc](http://www.grants.nih.gov/grants/funding/phs398/biosketchsample.doc))

(c) CERTIFICATION AND ACCEPTANCE

This certification must be signed by the principal investigator, senior investigator, and the grant officer (named in Item III).

Communications

Please select which ONE communication vehicle prompted you to apply for this program.

Applicants should receive a receipt confirmation email from the ASHP Foundation within five (5) business days of submission delivery date. If this email confirmation is not received, applicants should immediately contact the ASHP Foundation at foundation@ashp.org to verify that the submission was received.