



# New Investigator RESEARCH GRANT

## Letter of Intent and Full Application Policies and Guidelines

### **PROGRAM TIMELINE AT-A-GLANCE:**

- Letter of Intent (LOI) Application Available: July 18, 2017
- LOI Submission Deadline: September 26, 2017
- Invited Full Application Deadline: February 21, 2018
- Grantees Announced: April 2018

**Administered by the ASHP Foundation**

© Copyright 2017-2018  
ASHP Foundation  
All rights reserved

# CONTENTS

---

Grant Program Description .....	3
Eligibility .....	4
Funding Information .....	5
Grant Recipient Responsibilities .....	5
Letter of Intent .....	7
Full Application Selection Criteria .....	8
Itemized Application Instructions .....	10

## Grant Program Description

---

The ASHP Research and Education Foundation (ASHP Foundation) is offering a research grant program that will support practice-based research, conducted by pharmacist new investigators and related to advancing pharmacy practice. The primary goal of the program is to support quality research to advance pharmacy practice. A secondary goal 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 aligned with:

- The vision, mission and critical issues of the ASHP Foundation;
- The set of assumptions, beliefs and recommendations for advancing pharmacy practice from the November 2010 ASHP/ASHP Foundation Pharmacy Practice Model Initiative (PPMI) Summit or the recommendations from the March 2014 ASHP Ambulatory PPMI Conference and Summit.

Submission of studies that evaluate pharmacy practice models in hospitals, health systems, and other ambulatory settings is invited. Practice-based research affects a wide range of practice model topics; including the utilization of technology, role delineation changes for the pharmacists and non-pharmacists, or enhancing patient care opportunities for pharmacists. Applicants should utilize the recommendations from the Summits in the [PAI Web Resource Center](#) to identify relevant topics for this grant program.

Applications for this research grant program are required to include:

- Measurable objectives that relate to practice-based research that focuses on advancing pharmacy practice models;
- Rigorous research methods that support the study objectives;
- Mentoring activities between a senior investigator/advisor and the new investigator;
- Description of the impact that the results of the project will have on advancing pharmacy practice models;
- Description of the potential to generalize findings to other health care facilities;
- Interprofessional collaboration; and
- 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.

## ASHP Foundation

---

As the philanthropic arm of ASHP, our mission is to improve the health and well-being of patients in health systems through appropriate, safe and effective medication use.

The strategic priorities of the ASHP Foundation are closely aligned with the ASHP strategic plan. ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's more than 40,000 members include pharmacists, student pharmacists and pharmacy technicians. For over 70 years, ASHP has been on the forefront of efforts to improve medication use and enhance patient safety.

The ASHP Foundation pursues its mission and priorities through provision of awards, research grants, educational programs, and practice tools. The ASHP Foundation has a long track record of administering research grant, education and practitioner recognition programs that use stringent external review processes to select program recipients and participants. [Visit our website](#) to learn more about the ASHP Foundation.

## 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](#) 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.
- Preference will be given to projects that demonstrate collaboration and multi-disciplinary teams.

## Funding Information

---

Up to 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 is 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 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 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 within 120 days of submission of the Final Financial Report.
- 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.

## Letter of Intent Description

---

All interested applicants are required to submit a Letter of Intent to the ASHP Foundation by September 26, 2017. This Letter of Intent must be limited to a maximum of two pages (using 11 point font or larger, 8.5 x 11 inches paper, 1-inch margins, single spacing and single-sided pages) and should concisely describe the study’s specific aims and hypothesis, rationale and significance, innovation, and approach. Headings should be provided for each of these sections.

The following scale will be used to score Letters of Intent:

Impact	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High	1	Exceptional	Exceptionally strong with no weaknesses
	2	Outstanding	Outstanding
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
Low	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses
<p><b>Minor Weakness:</b> An easily addressable weakness that does not substantially lessen impact.  <b>Moderate Weakness:</b> A weakness that lessens impact.  <b>Major Weakness:</b> A weakness that severely limits impact.</p>			

Based on the results of external peer review of letters of intent, applicants will be invited to submit a full grant application to the ASHP Foundation. Those invited to submit a full application will be contacted by December.-

## Full Application Selection Criteria

---

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

### **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?

#### **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? *Preference will be given to projects that demonstrate collaboration and multi-disciplinary teams.*

#### **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?

**Overall Funding Priority Score = \_\_\_\_\_(1-9)**

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 above.

Impact	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High	1	Exceptional	Exceptionally strong with no weaknesses
	2	Outstanding	Outstanding
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
Low	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses
<p><b>Minor Weakness:</b> An easily addressable weakness that does not substantially lessen impact.  <b>Moderate Weakness:</b> A weakness that lessens impact.  <b>Major Weakness:</b> A weakness that severely limits impact.</p>			

**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?

## ITEMIZED APPLICATION INSTRUCTIONS

---

### Project

The study must relate directly to advancing pharmacy practice models in hospitals, health systems, or other ambulatory settings as described in the Grant Program Description section.

### Principal Investigator

- 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.
- ASHP Member ID, 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

- 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.
- ASHP Member ID, 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%.

### 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.
- 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.
- Provide: Full Name, Title & Credentials, Institution Name, Dept./Division, Email Address, and % Effort.

### **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

The biographical sketch should list all of the applicants' peer reviewed publications and should be submitted in the format acceptable by the NIH and AHRQ, links included below.

	Date Posted	Blank Format Page	Instructions and Samples
<b>General</b> Biographical Sketch Format Page – Forms Version C (use also for Fellowship Sponsor/Co-Sponsors)	11/25/2015	<a href="#">MS Word</a> (29 KB)	<a href="#">MS Word</a> (40 KB)

#### (c) CERTIFICATION AND ACCEPTANCE

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