



Pharmacy Practice Advancement Demonstration Grants

Application Policies and Guidelines

The ASHP/ASHP Foundation Pharmacy Practice Advancement Demonstration grant was made possible through the generous support of several corporations and the Henri R. Manasse Legacy Fund.

PROGRAM TIMELINE AT-A-GLANCE:

- Letter of Intent (LOI) Application Available: July 25, 2017
- LOI Submission Deadline: October 3, 2017
- Invited Full Application Deadline: February 6, 2018
- Grantees Announced: April 2018

Administered by the ASHP Research and Education Foundation

©Copyright 2017
ASHP Research and Education Foundation
All rights reserved

I. Table of Contents

Grant Program Description3

Eligibility.....4

Funding Information5

Grant Recipient Responsibilities6

Letter of Intent Description8

Full Application Selection Criteria10

Note: Completed letters of intent are due by October 3, 2017. Following review of Letters of Intent, the ASHP Foundation will invite submission of full grant applications from selected applicants. Full applications will be due on February 6, 2018.

II. GRANT PROGRAM DESCRIPTION

The ASHP Research and Education Foundation (ASHP Foundation) is offering a research grant program to support demonstration projects related to practice advancement, consistent with the ASHP/ASHP Foundation Practice Advancement Initiative (PAI) and Ambulatory PAI. The overarching goal of these initiatives 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.

Proposed Timeline for the 2017-2018 Program Offering

- Submission materials available: July 25, 2017
- Letter of Intent deadline: October 3, 2017
- Full application available: Fall 2017
- Full application deadline: February 6, 2018
- Grantees announced: April 2018

The proposed demonstration projects must be aligned with:

- The vision, mission and strategic priorities 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, available on the [PAI Web Resource Center](#).

Submission of studies that evaluate pharmacy practice advancement initiatives and programs in hospitals, health systems, and ambulatory settings is invited. The practice advancement demonstration project should be futuristic and reflect the evolution of numerous aspects of pharmacy practice over the last 50 years including:

- Adherence to standards and evidence-based practice
- Pharmacists' direct patient care roles in acute and ambulatory care settings
- Impact of technology to advance pharmacist patient care roles
- Medication-use policy and product selection
- Pharmacists' roles as organizational leaders
- Enhanced pharmacy technician roles
- Response to the medication-use safety quality and safety initiatives in the U.S.

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.

III. ELIGIBILITY

Applications for this demonstration grant program are required to include:

- The proposed research must include:
 - Demonstration projects that are focused on the practice advancement research priorities listed above;
 - Measurable objectives;
 - Rigorous research methods that support the study objectives;
 - 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.
- Clinical studies, including pharmacokinetic studies and medication effectiveness studies, are not supported through this program.
- The principal investigator must be a licensed pharmacist and interprofessional research teams are strongly encouraged. **The principal investigator and other members of the research team MUST have strong research track records as evidenced by a history of publication of ORIGINAL RESEARCH in peer-reviewed biomedical journals and receipt of extramural grant funding.**
- A biostatistician must be included as a member of the research team and a portion of the budget should be allocated 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.

Individuals who served as principal investigators on previous ASHP Foundation grants are eligible to apply if all work, including publication of 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 previously received a grant from the ASHP Foundation.

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](#).
- 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.

IV. FUNDING INFORMATION

Up to two \$75,000 grants will be awarded.

Grants will be awarded 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 should not exceed \$1,500; 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.

V. 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 disbursement.
- 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 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.
- If, for any reason, the grantee does not complete the project, the principal 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, ASHP 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 interprofessional meeting, the grantee should plan to also present the study and its findings at the ASHP Midyear Clinical Meeting that follows presentation at the medical or interprofessional meeting. All travel 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. AJHP 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.
- 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.

VI. Letter of Intent Description

All interested applicants are required to upload a Letter of Intent to the ASHP Foundation by October 3, 2017. The Letter of Intent must be a PDF uploaded into the electronic application system. 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 (Table 1)

| Table 1: Required Sections for the Letter of Intent Submission |
|--|
| Specific Aims and Hypothesis |
| Rationale and Significance |
| Innovation |
| Investigators and Environment |
| Approach |
| Scope and Timeline |

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>Minor Weakness: An easily addressable weakness that does not substantially lessen impact.</p> <p>Moderate Weakness: A weakness that lessens impact.</p> <p>Major Weakness: 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. Prior to submission of a full application, applicants are encouraged to participate in a webinar that describes the grant program requirements and expectations. **The letter of intent must be submitted by 11:59 p.m. Eastern Time on October 3, 2017.**

VII. Full Application Selection Criteria

The full applications for the grant will be evaluated using the selection criteria listed below. Applicants should consider these criteria when developing letters of intent.

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 aims consistent with the specific grant program focus and the strategic priorities of the ASHP Foundation?
- Is the research question clear and well-defined?
- Are the overall objectives original? 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 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?
- 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?
- Do the principal investigator and the research team bring complementary and integrated expertise to the project?
- Research Team: 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?
- Environment: 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?

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?

Overall Funding Priority Score = _____ (1-9)

Using the rating scale included in the LOI section, 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.