ASHP Foundation
Pharmacy Practice Model Initiative
Demonstration Grants

Letter of Intent Submission Instructions

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

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A complete list of commercial supporters is available on the PPMI web site.

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Note: Completed letters of intent are due by September 27, 2013. 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 7, 2014. A description of the Letter of Intent submission process is provided on page 11. Information on the full grant program has been provided to give Letter of Intent authors complete context about the program.
I. GRANT PROGRAM DESCRIPTION

The ASHP Research and Education Foundation (ASHP Foundation) is offering a research grant program that will support demonstration projects related to the ASHP/ASHP Foundation Pharmacy Practice Model Initiative (PPMI). 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.

There is an urgent need to engage key stakeholders to create forward thinking hospital and health-system pharmacy practice models. ASHP and the ASHP Research and Education Foundation sponsored a Hospital and Health-System Pharmacy Practice Model Summit to develop recommendations for future pharmacy practice models that optimize on the use of pharmacists as the members of the multidisciplinary team who are accountable for patients’ drug therapy management.

Healthcare reform is a high national priority for the public, policymakers, payers, health professionals and healthcare organizations. This reform is being driven by multiple factors including patient and caregiver demand for higher quality and safer care at lower costs; health professionals who are pursuing safer care for our society; health professional shortages; and demographic, social and economic influences. Through the PPMI, ASHP and the ASHP Foundation are supporting the development of future practice models that are responsive to healthcare reform and the health system of the future. These practice models will be futuristic and reflect the evolution of numerous aspects of pharmacy practice in hospitals and health systems over the last 50 years including

- Adherence to standards and evidence-based practice
- Clinical pharmacy practice
- Impact of technology
- Medication distribution
- Medication-use policy and product selection
- Pharmacists’ roles as organizational leaders
- Pharmacy technician roles
- Response to the medication-use safety quality and safety movements in the U.S.

The objectives of the ASHP/ASHP Foundation Practice Model Initiative are to

- Create a framework for a pharmacy practice model that ensures provision of safe, effective, efficient, accountable, and evidence-based care for all hospital/health system patients;
• Determine patient care-related services that should be consistently provided by departments of pharmacy in hospitals and health systems and increase demand for pharmacy services by patients/caregivers, healthcare professionals, healthcare executives, and payers;
• Identify the available technologies to support implementation of advanced practice models and identify emerging technologies that could impact practice models;
• Support the optimal utilization and deployment of hospital and health-system pharmacy resources through development of a template for a practice model which is operational, practical, and measurable; and
• Identify specific actions pharmacy leaders and staff should take to implement practice model change including determination of the necessary staff (pharmacy leaders, pharmacists, and technicians) skills and competencies required to implement this model.

Applicants can find the full proceedings of the PPMI Summit in the June 15, 2011 American Journal of Health-System Pharmacy. In addition, the PPMI Resource Center contains numerous PPMI materials and resources.

The proposed practice-based research must be consistent with the vision, mission and strategic priorities of the ASHP Foundation.

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; and
• 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:

- Facilitating and strongly supporting the pharmacy profession in advancing pharmacy practice models that foster pharmacists’ leadership and accountability for patient outcomes;
- Creating demand for new models of pharmacy practice that leverage the expertise and unique abilities of pharmacists; and
- Driving the advancement of the technical, human, and leadership competencies of pharmacists and pharmacy staff in complex and rapidly changing organizations.

The following research priorities have been established by the ASHP Foundation for the PPMI Demonstration Grant Program:

Pharmacists’ Roles (Up to three $25,000 grants)
The following are priority areas related to the pharmacist’s role in advancing pharmacy practice models as the interdisciplinary team member who is responsible and accountable for patients’ medication-related outcomes:

- Comparative evaluations of the impact of inpatient pharmacist-provided core clinical services on patients’ therapeutic and safety outcomes (See the core clinical services included in the following recommendations from the PPMI Summit: B7-9, B13-16, B20-21, B23a-o, B24a-b, B25b.)

- Comparative evaluations of the impact of hospital/health-system-based outpatient pharmacist-provided core clinical services on patients’ therapeutic and safety outcomes (See the core clinical services included in the following recommendations from the PPMI Summit: B7-9, B13-16, B20-21, B23a-o, B24a-b, B25b.)

- Comparative evaluations of the impact of inpatient pharmacist-provided core clinical services on patients’ therapeutic and safety outcomes in the small and rural hospital setting (See the core clinical services included in the following recommendations from the PPMI Summit: B7-9, B13-16, B20-21, B23a-o, B24a-b, B25b.)

- Evaluations of the economic benefits of hospital/health-system pharmacist-provided core clinical services (See the core clinical services included in the following recommendations from the PPMI Summit: B7-9, B13-16, B20-21, B23a-o, B24a-b, B25b. This study must include an element that demonstrates efficient methods to track and analyze pharmacists’ clinical interventions.)
Pharmacy Technicians and Technology (Up to two $25,000 grants)
The following are priority areas related to the roles of pharmacy technicians and technology in advancing pharmacy practice models:

- Evaluations of delegation of all distributive functions that do not require clinical judgment to pharmacy technicians and technology
  (See the pharmacy technician-related assumptions, beliefs, and recommendations from the PPMI Summit.)

- Evaluations of the use of pharmacy technicians to perform clinical support functions
  (See the pharmacy technician-related assumptions, beliefs, and recommendations from the PPMI Summit.)

- Evaluations of the impact of accredited technician training programs and PTCB certification on technician effectiveness

- Evaluations of the use of existing technology systems in supporting advancement of pharmacy practice models
  (See the pharmacy technology-related assumptions, beliefs, and recommendations from the PPMI Summit.)

Pharmacist Education (One $25,000 grant)
The following is the priority area related to the role of pharmacist education in advancing pharmacy practice models:

- Evaluations of innovative residency program models that result in expansion of the number of residency-trained pharmacists who can participate as the interdisciplinary team members who are responsible and accountable for patients’ medication-related outcomes.

Applications for this research grant program should emphasize: (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) a description of the impact that the results of the project will have on advancing pharmacy practice models; (4) a description of the potential to generalize findings to other health care facilities; (5) interdisciplinary collaboration; and (6) 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.

II. ELIGIBILITY

- The proposed research must involve demonstration projects focused on the PPMI research priorities listed above. The principal investigator must be a licensed pharmacist and multidisciplinary research teams are strongly encouraged. The principal investigator must have a strong research track record as evidenced by a history of publication of original
research in peer-reviewed biomedical journals and receipt of extramural grant funding. Clinical studies, including pharmacokinetic studies and medication effectiveness studies, are not supported through this program.

- 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 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 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 18 months from project initiation.

- Senior investigators cannot apply for more than one grant in an application cycle.
III. FUNDING INFORMATION

Six $25,000 grants will be awarded. Grants will be awarded in each of the priority areas as follows:

- Pharmacists’ Roles - Up to three $25,000 grants
- Pharmacy Technicians and Technology - Up to two $25,000 grants
- Pharmacist Education - One $25,000 grant

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 in the range of $1,000 to $1,500 per project; and
- Facilities and administrative cost rates that do not exceed 8% of the total requested budget.

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

IV. GRANT RECIPIENT RESPONSIBILITIES

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

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

  - Specific plans for presentation and publication of the study findings.

- Within 60 days of submission of the Final Research Report, the grantees must submit a Final Financial Report. This report must include a complete and full accounting of the expenditure of ASHP Foundation funds related to the execution of the study.

- Any unused funds must be returned to the ASHP Foundation by the grantees.

- If, for any reason, the grantee does not complete the project, the 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, the American Society of Health-System Pharmacists retains the right of first refusal for scientific presentations that emanate from this study. If the study and its findings are presented at a medical or multidisciplinary meeting, the grantee should plan to also present the study and its findings at the ASHP Midyear Clinical Meeting that follows presentation at the medical or multidisciplinary 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. If the study results are submitted to a pharmacy journal, the American Journal of Health-System Pharmacy retains the right of first refusal for publication.

A reprint of all articles that emanate from this study should be submitted to the ASHP Foundation.

All presentations, publications, and other communications regarding this study must include the following acknowledgement: “This study was funded (or partially funded) by a research grant from the ASHP Research and Education Foundation.”

By accepting this award, the grantee will undertake all reasonable efforts to complete the study and take responsibility for fulfilling the terms described within the award letter.

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.

V. Letter of Intent Description

All interested applicants are required to upload a Letter of Intent to the ASHP Foundation by September 27, 2013. The Letter of Intent must be a PDF. 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:

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Additional Guidance on Strengths/Weaknesses</th>
</tr>
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<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>
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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 will be required 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 September 27, 2013.
VI. 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.

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<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?

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? 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?

**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?
VII. ITEMIZED INSTRUCTIONS

I. Project
   a) The study must relate directly to advancing pharmacy practice models in hospitals and health systems as described in the Grant Program Description section above.
   b) The proposed research must align with one of the three priority categories listed in the Grant Program Description section above.

II. Principal Investigator
   a) Self-explanatory. Please note: 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.
   b) Self-explanatory, if applicable.
   c) Degree(s).
   d) Position title.
   e) Institution name.
   f) Physical mailing address of place of employment, including department.
   g) Business telephone number at place of employment.
   h) Fax number at place of employment.
   i) Email address that is most commonly used for frequent communication.
   j) Percent effort is the total percentage of the investigator’s time that they will commit to this study. For example, if an investigator works 50 hours per week and expects to commit 5 hours per week to the study, his/her percent effort would be 10%.

III. Sponsoring Institution & Grant Officer
   a) 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.
   b) The sponsoring institution is that location at which the research will be conducted. Grant checks will be made payable to the institution name listed.
   c) Physical mailing address of the grant officer to which all grant correspondence will be sent.
   d) 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.)

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

f) Physical mailing address of the grant officer to which all grant correspondence will be sent.

g) Business telephone number for the grant officer.

h) Fax number for the grant officer.

i) Email address that is most commonly used for frequent communication.

IV. Other Investigators

a) 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.

V. Communications

Self-explanatory

VI. Additional Documents Required

a) Letter of Intent

The 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 Letter of Intent must be uploaded as a PDF.

Applicants should receive a receipt confirmation email from the ASHP Foundation within five (5) business days of Letter of Intent 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 letter of intent was received.