Application Guide

2013 ASPIRE Awards in Adult Vaccine Research

A Competitive Grants Program
Supported by Pfizer

www.aspireresearch.org

ASPIRE
Advancing Science Through Pfizer – Investigator Research Exchange

Pfizer

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2013 ASPIRE Awards in Adult Vaccine Research

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Mission

The mission of the 2013 ASPIRE Awards in Adult Vaccine Research is to advance medical knowledge to better understand the burden of pneumococcal disease in adults.

Background

The burden of pneumococcal disease in the general adult population has been extensively studied; however, it is not well-defined in special populations, including subgroups with underlying disease comorbidities and/or those living in long-term community settings.

Request for Proposals

Pfizer invites investigators to apply for the 2013 ASPIRE Awards in Adult Vaccine Research through submission of innovative research proposals for evaluation of the epidemiology and burden of pneumococcal disease in adults with underlying disease comorbidities and/or those living in long-term community settings.

Key Dates

Application deadline: July 2, 2013 by 11:59pm ET
Notification of Awards recipients: September, 2013
Start of Award: October/ November 2013
Study results are expected before December 31, 2014.

**Contracts not executed by December 31, 2013 may risk loss of funding*

Eligibility *(Applicants must meet the following requirements)*

The 2013 ASPIRE Awards in Adult Vaccine Research are open to all investigators provided that specific eligibility requirements are met. Applicants currently enrolled in a fellowship or postdoctoral program are eligible provided the applicant identifies an experienced mentor.

1. Eligibility

- Applicants must have a professional degree (MD, DO, PhD, PharmD or equivalent) and reside in the United States (including Puerto Rico).
- Applications submitted by junior investigators (within 5 years of terminal training or those enrolled in a fellowship or postdoctoral program) will be afforded preferential consideration.
- Applicants currently enrolled in a residency program are NOT eligible.

2. 2013 Research Topic

Evaluating the Burden of Pneumococcal Disease in Adults in the United States

An applicant should have a strong research interest within the areas of focus and should consider the following components when developing their research proposals:

A. The burden of pneumococcal disease and serotype distribution in adults including but not limited to:

- Individuals with increased risk of pneumococcal disease including those with underlying comorbidities.

  Comorbidities may include but are not limited to:

  - Diabetes mellitus
  - Chronic obstructive pulmonary disease (COPD) or other chronic pulmonary disorder
  - Oncologic disorders
  - Chronic renal disease
  - Hepatic disease
  - Autoimmune disorders
- Those living in community settings (e.g., extended-care facilities, correctional institutions).
- Regional evaluation of pneumococcal resistance and serotype distribution.
- Carriage of Streptococcus pneumoniae in the adult population.

B. Association of pneumococcal pneumonia with influenza or other respiratory viral illnesses

C. The following topics fall outside of the scope of the ASPIRE Adult Vaccine Research Program:

- General education and / or training.
- Support for ongoing clinical programs that are part of an organization's routine operations.
- Proposals that evaluate populations outside of the United States or Puerto Rico.

Proposals whose primary objective is to financially quantify outcomes as it relates to a Pfizer product(s) are outside the scope of the program.

3. Research Expectations

Within the specified patient populations of interest, investigators are expected to:

- Generate data regarding the burden of pneumococcal disease in adults and/or evaluation of adult vaccination efforts.
- Be able to complete the research in 12 months.
- Present and/or publish the results of the study.

4. Other Funding

No other government, non-governmental, or industry-sponsored projects may cover the same work scope as the grant application to the ASPIRE Program. However, an ASPIRE Program grant may be related to other funding from foundations or government agencies, as long as there is no direct overlap. It is the responsibility of the applicant to justify the novelty of the proposal and provide evidence that the application does not overlap with any current or pending funding.

Application

Applications are to be submitted to Pfizer through an online submission website. Visit **www.aspireresearch.org** and click:

- "Awards in Vaccine Research – United States"; then click
- Open the "Apply" tab on the top of the page
- Click on "To Apply for a 2013 ASPIRE Award Click Here"
- When you select, "To apply for a 2013 ASPIRE Award Click Here", you will be routed to Pfizer's global investigator-initiated research website: www.iirsubmission.pfizer.com
- Click on "Submit an IIR Request" and follow the online instructions.

NEW USERS: If this is your first time visiting the portal you must first "Create an Account".

- Select "Create account"
- Complete:
  - User name
  - Email
  - Password
- Press Continue to "Log In"
- Complete:
  - User Profile
  - Investigator and Organization Profile
- By completing these now, it will pre-populate this same information in the profile and will be available for subsequent submissions

ESTABLISHED USERS

- Log In
  - User name
  - Password

SUBMISSION

- Select "Create New Proposal"
- PFIZER POLICY on Submission of an Investigator Initiated Research Proposal
  - Check that you have read and agree to policy
  - Under: "Please select any option from below"
    - Select IIR (Investigator Initiated Research) Program
    - Click on "initiate submission"

GENERAL

- Are you applying to a Competitive Grants Program
  - Select "Yes"
  - A dropdown list appears and select:
    - "2013 ASPIRE US Awards in Adult Vaccine Research"
- Study title (no more than 250 characters)
  - All text fields are limited, so a character count is given on all text fields
  - Add a descriptive study title of your proposal
  - At Primary Pfizer Therapeutic Area
    - Select "Vaccines" from dropdown
    - Secondary Pfizer Therapeutic Area not required

GRANT REQUEST SECTION

- Depending on type of study selected in General section, various drop downs regarding drug needed and funding will be required
- All submissions require you to upload an itemized budget
- Complete the sections requested

STUDY DETAILS (all text fields limited at 3000 characters)

- Brief Study Synopsis
  - Provide an abstract outlining your overall research proposal
- Brief Study Rationale
  - Provide a brief description of the objectives and relevance of the proposed research in advancing the medical knowledge of the burden of pneumococcal disease in adults in the United States.
    If pre-clinical was selected in General section, check if in vivo or in vitro
- If pre-clinical was selected in General section, check if *in vivo* or *in vitro*
- Identify if Pfizer drug is applied on/off local approved indication
- High Level Primary Endpoint
  - Provide a brief description of the primary endpoint for the study proposal
- Upload Study Protocol
  - Study Protocol Requirement
    - No more than 12 pages: minimum 12 pt. font with 1' margins around (not including references or itemized budget)
    - Proposals received over this limit, will not be reviewed

CONTENT

- BACKGROUND:
  - Objectives
  - Specific Aims
  - Hypothesis (es)
  - Relevance of proposed study.
- METHODS:
  - A description of study methodology including: experimental design, sample size, potential problems and possible approaches for overcoming them, justification for the involvement of any experimental animals or human subjects, and methods of data analysis. Figures and tables must be included in the body of the text..
- BRIEF DESCRIPTION OF AVAILABLE RESEARCH/LABORATORY FACILITIES

LEGAL, SAFETY, REGULATORY

- Complete section identifying relationships and responsibilities

PRIMARY SITE INFORMATION

- If completed user and investigator profile, this is automatically populated, if not COMPLETE section

UPLOAD*

- Cover letter on institution letterhead
- CV (no more than 3 pages or if NIH biosketch, no more than 4 pages)
  - Remove any personal information from CV (such as your home contact information, birth date, tax ID number or medical license number. Your business contact information should be the only contact information on your CV)
- Description of available laboratory facilities (if applicable)
- The 3 most relevant articles from the applicant's scientific publications (if applicable)
- Listing of other research support available with a description of overlap and, if applicable, a listing of consenting collaborators (including CVs)
- Bibliography of relevant references
- Itemized budget for proposed research
- For Junior investigators (within 5 years of terminal training or those enrolled in a fellowship or postdoctoral program) the following documents are required:
  - A letter of endorsement from the applicant's sponsoring department chairman, division director or equivalent which clearly identifies the applicant's mentor for the project
  - A letter of commitment from the applicant's mentor

** Online submission system has capacity to upload protocol, budget, CV and six additional attachments. Please combine additional documents if necessary.*

APPLICATION DEADLINE: July 2, 2013

Applications must be received by 11:59pm EST on July 2, 2013. Addenda, supplemental materials, changes, or updates will not be accepted after the deadline. For further information please visit **www.aspireresearch.org**

Submit questions to **questions.aspireresearch-Vaccines@pfizer.com**

Criteria for Selection – Independent, External Review Committee

The ASPIRE applications will be reviewed by an independent, external review committee comprised of medical and scientific experts. Grants will be awarded based upon:

- Scientific merit of the research proposal
- Qualifications of the applicant
- Relevance of proposed research to the program's mission
- Evidence of the applicant's strong research interest within the areas of focus
- Evidence of a suitable research environment

Conditions of the Award

Each award is subject to the following conditions, which must be agreed to by the Awardee and host institution through a Letter of Agreement with Pfizer before any funds will be disbursed.

A. Financial Administration

The ASPIRE Program grant **will be awarded to the host institution on behalf of the Awardee.** Pfizer is funding research awards up to a maximum of **$100,000 USD*** each for one year. The amount of each award includes direct costs (labor and study costs), institutional overhead costs, and indirect costs (additional expenses such as publication, software license fees, and travel costs). Pfizer does not pay overhead on indirect costs. Each payment will be made in installments according to milestones, with a maximum of 50% of the funding delivered at the beginning of the project. The last installment will be made when the final results of the study are available. **Final budgets of those studies awarded a grant will be reviewed for fair market value before the contracting process begins. A signed, executed contract must be returned prior to disbursement of funds.**

Contracts that are unable to be executed by the end of the calendar year are subject to loss of funding.

** Please note that study budgets will be evaluated separately to ensure the requested funding is commensurate with the work proposed.*

****Due to the competitive nature of these awards, Pfizer cannot provide any additional funding and/or drug support beyond what has been requested and approved by the external review panel.***

B. Use of ASPIRE Program Funding

Funds from the ASPIRE Program may be used to support the Applicant's salary and fringe benefits, technical salaries, and supplies.

C. Financial Record Keeping

A separate financial record must be maintained by the Awardee.

D. ASPIRE Program Awards Progress and Final Reports

The Awardee must submit a final report on study results to the ASPIRE Program by December 31, 2014.

Reprints of articles published or in press, should be included with all reports.

From time to time, the ASPIRE Program may ask prior Awardees for information on study progress.

E. Required Documents if Proposal is Selected for Funding

Required additional documentation if your proposal is selected for funding by the review committee (further guidance will be provided):

- Original letter documenting acceptance of support, written on institutional letterhead, signed by the Investigator
- Two copies of the Signed Research Agreement
- IRB approval documentation, if applicable
- IND documentation from local regulatory authorities, as applicable per local regulations
- W-9 form for your institution
- Certification of Study Closure Form (provided at study completion)

F. Publications

Awardees are expected to present their findings at scientific meetings or to publish them in scientific journals. All publications that result from a project supported by the ASPIRE Program must carry the following acknowledgment: *"This research was supported by the Advancing Science through Pfizer–Investigator Research Exchange program, a competitive grants program supported by Pfizer, to (name of Awardee)."*

Awardees will provide to the ASPIRE Program the opportunity to view manuscripts or abstracts a minimum of 60 days prior to submission for publication or other public disclosure.

G. Patents and Licensing

If the conduct of the research results in any invention or discovery by the Awardee that relates to a Pfizer product, the Awardee will grant to Pfizer a perpetual, royalty-free worldwide, non-exclusive license to each such invention.

H. Stipulations

1. Should the Awardee discontinue the research project or leave the designated host institution, the ASPIRE program must be notified without delay.

2. The ASPIRE Award may be transferred to another institution at the sole discretion of the ASPIRE Program, acting on the recommendation of the Review Committee. If a transfer is requested, letters from the Awardee and the new institution must be submitted to the ASPIRE Program at least 3 months before the date of the proposed transfer.

3. If the host institution or the Awardee wishes to terminate the award before its completion, an agreement between the host institution and the ASPIRE Program will be arranged. Termination will be made with the understanding that all unexpended funds will be returned to the ASPIRE Program and any unpaid balance of the award will be cancelled.

I. Serious Adverse Events (SAE) Reporting (As Applicable)

For All Studies Using a Pfizer Product and/or Device:

Pfizer requires that, within 24 hours of first awareness of the event (or immediately if the event is fatal or life-threatening), the principal investigator will report to Pfizer by facsimile any Serious Adverse Event (SAE) that occurs during the SAE reporting period in a study subject assigned to receive the Pfizer Product. In addition, for studies using a Pfizer device or Pfizer product packaged with a device, reportable events include not only SAEs but also Device Incidents and Device Near-Incidents.

- **Reporting Forms:** The principal investigator will report such SAEs using the Pfizer IIR SAE reporting form, or the approved local regulatory form (ie, FDA MEDWATCH form, CIOMS, etc.) and the *Reportable Event Fax Cover Sheet* provided by Pfizer. SAEs should be reported as soon as they are determined to meet the definition, even if complete information is not yet available.
- **Exposure During Pregnancy, Exposure During Lactation, and Lack Of Effect:** Even though there may not be an associated SAE, exposure to the Pfizer Product during pregnancy and exposure to the Pfizer Product during lactation are reportable, and lack of effect of the Pfizer Product may also be reportable. This requirement is further explained in the training material provided by Pfizer. As used in this Agreement, the term SAE will be understood to include exposure during pregnancy, exposure during lactation, and reportable instances of lack of effect.
- **Reporting Period:** The SAEs that are subject to this reporting provision are those that occur from after the first dose of the Pfizer Product through 28 calendar days after the last administration of the Pfizer Product, or longer if so specified in the Protocol. In addition, Principal Investigator should submit SAEs to Pfizer any time after the administration of the last dose of the Pfizer Product if the Principal Investigator suspects a causal relationship between the Pfizer Product and the SAE.
- **Follow-up Information:** The institution and/or principal investigator will assist Pfizer in investigating any SAE and will provide any follow-up information reasonably requested by Pfizer.
- **Regulatory Reporting:** Reporting an SAE to Pfizer does not relieve the institution and/or principal investigator of the responsibility for reporting it to the FDA or local regulatory authority, as required.