Program Announcement for Pulmonary Hypertension Association and the National Heart, Lung, and Blood Institute (NHLBI) Jointly Sponsored Mentored Clinical Scientist Development Award (K08) and Mentored Patient-Oriented Research Career Development Award (K23)

The Pulmonary Hypertension Association (PHA) and the National Heart, Lung, and Blood Institute (NHLBI) wish to announce a program that will provide supplemental funding to an individual who receives an NHLBI Mentored Clinical Scientist Development Award (K08) or a Mentored Patient-Oriented Research Career Development Award (K23) for research on pulmonary hypertension.

PURPOSE

PHA is offering this award as a means to facilitate the research career development of individuals pursuing a career in pulmonary hypertension. This award will provide financial support over and above that offered by the NHLBI K08 and K23 award mechanisms, which are described below. An individual may apply for either a K08 or a K23, whichever is more appropriate for the career of the applicant and the nature of the research being proposed.

The purpose of the Mentored Clinical Scientist Development Award (K08) is to support the development of outstanding clinician research scientists in the area of pulmonary hypertension. This mechanism provides specialized study for clinically trained professionals who are committed to a career in research in pulmonary hypertension and have the potential to develop into independent investigators. The award supports a 3- to 5-year period of supervised research experience that integrates didactic studies with laboratory or clinically-based research. The proposed research should have both intrinsic research importance and be a vehicle for learning the methodology, theories, and conceptualizations necessary for a well-trained independent researcher.

Because of the focus on progression to independence, the prospective candidate should propose a period of study and development consistent with this goal and his or her previous research and clinical experience. For example, a candidate with limited experience in a given field of research may find a phased developmental program lasting for 3 to 5 years, which includes a designated period of didactic training and supervised research experience, the most efficient means of attaining independence. A candidate with substantial previous research experience may require a shorter period for class work and supervised training and more time for laboratory work appropriate for the transition to independence. The entire program should be comparable in scope and rigor to meeting the requirements of an advanced research degree.

The purpose of the Mentored Patient-Oriented Research Career Development Award (K23) is to support the career development of investigators who have made a commitment to focus their research endeavors on patient-oriented research. This mechanism provides support for 3 to 5 years of supervised study and research for clinically trained professionals who have the potential to develop into productive, clinical investigators focusing on patient-oriented research in pulmonary hypertension. For the purposes of this award, patient-oriented research is defined as research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator directly interacts with human subjects. This area of research includes: 1) mechanisms of human disease; 2) therapeutic interventions; 3) clinical trials; and 4) development of new technologies. Candidates must demonstrate they have received or
will participate in courses such as: data management, epidemiology, study design, hypothesis development, drug development, etc., as well as the legal and ethical issues associated with research on human subjects.

A comparison of the K08 and K23 mechanisms appears on the final page of this document.

ELIGIBILITY REQUIREMENTS

The candidate must have a MD degree or its equivalent, must have initiated postgraduate clinical training, must identify a mentor with extensive research experience, and must be willing to spend a minimum of 75 percent of full time professional effort conducting research and research career development.

Applications may be submitted, on behalf of candidates, by domestic, non-Federal organizations, public or private, such as medical, dental, or nursing schools or other institutions of higher education. Candidates must be U.S. citizens or noncitizen nationals, or must have been lawfully admitted for permanent residence and possess an Alien Registration Receipt Card (I-151 or I-551) or some other verification of legal admission as a permanent resident. Noncitizen nationals, though not U.S. citizens, owe permanent allegiance to the U.S. They are usually born in lands that are not states but are under U.S. sovereignty, jurisdiction, or administration. Individuals on temporary or student visas are not eligible.

Former and current principal investigators of NIH research project grants (R01), program projects (P01) or center grants (P50), or of a subproject on a P01 or P50 or the equivalent are not eligible. A candidate for a K08 or K23 award may not concurrently apply for any other PHS award that duplicates the provisions of this award nor have another application pending award. K08 or K23 recipients are encouraged to apply for independent research grant support during the period of this award. Questions regarding eligibility requirements should be directed to the NHLBI contact listed at the end of this announcement.

MECHANISM OF SUPPORT

Awards in response to this program announcement will use the K08 or K23 mechanism. Planning, direction, and execution of the program will be the responsibility of the candidate and his/her mentor on behalf of the applicant institution. The project period will be 3 to 5 years. Awards are not renewable.

RESEARCH OBJECTIVES

A. Environment: The institution must have a well-established research and clinical career development program and a qualified faculty in clinical and basic research to serve as mentors. The institution must be able to demonstrate a commitment to the development of the candidate as a productive, independent investigator. And, the candidate, mentor and institution must be able to describe a multidisciplinary career development program that will maximize the use of relevant research and educational resources.

B. Program: The Award provides up to 5 consecutive 12 month appointments. At least 75 percent of the recipient’s full-time professional effort must be devoted to the program and the remainder devoted to other clinical and teaching pursuits consonant with the objectives of the award. The basic science component must develop knowledge and research skills in scientific areas relevant to pulmonary hypertension (K08).

C. Mentor(s): The recipient must receive appropriate mentoring throughout the 5-year program.
D. Allowable Costs:

**NIH-NHLBI:**

1. **Salary Support:** The NHLBI will provide salary up to a maximum of $100,000 per year for the award recipient, plus fringe benefits. The annual salary must be consistent with the salary structure of the grantee institution and the level of effort.

2. **Research Development Support:** It is anticipated that up to $30,000 per year of the NHLBI award will be used by the recipient for research-related expenses including: a) tuition, fees, and books related to career development; b) research expenses, such as supplies, equipment, and technical personnel; c) travel to research meetings or training; and d) statistical services including personnel and computer time. For the K23 award only, in exceptional cases, the Research Development Support costs may be as high as $50,000, but such costs will only be awarded in those cases where the need for such higher costs is well documented and adequately justified. Prospective candidates should contact the NHLBI to ascertain the maximum contribution for research and development support.

3. **Facilities and Administrative (F&A) Costs:** F&A costs will be reimbursed at 8 percent of the allowable direct costs contributed by the NHLBI. PHA will not reimburse F&A costs.

The applicant must submit a categorical budget to the NIH; modular budgets will not be accepted. Annual escalation, if any, will be determined by the current NHLBI policy.

**PHA:**

PHA will contribute up to total direct costs of $62,500 per year for 5 years to supplement the K08 or K23 award from the NHLBI. In the application to PHA, funds can be requested for salary and fringe benefits and research development support. PHA will not reimburse F&A costs.

1. **Salary Support:** The applicant can request salary, plus fringe benefits; however, the combined award from PHA and NHLBI for salary and fringe benefits must be consistent with the time commitment proposed for the K08 or K23 project and the institution's salary and fringe benefits scale.

2. **Research Development Support:** The applicant can request research-related expenses including: a) tuition, fees and books related to career development; b) research expenses, such as supplies, equipment and technical personnel; c) travel to research meetings or training; and d) statistical services including personnel and computer time.

3. **Facilities and Administrative Costs (F&A):** PHA will not reimburse F&A costs.

The institution may supplement the contribution of PHA and NHLBI for salary up to a level that is consistent with the institution's salary scale; however, supplementation may not be from Federal funds unless specifically authorized by the Federal program from which such funds are derived. In no case may PHA funds be used for salary supplementation. Institutional supplementation of salary must not require extra duties or responsibilities that would interfere with the purpose of the K08 or K23.
APPLICATION PROCEDURES

NIH-NHLBI:

Applications to the NIH should conform to the guidelines published in the NIH Program Announcement PA-16-191, Mentored Clinical Scientist Development Award (K08) issued April 15, 2016, or PA-16-198 Mentored Patient-Oriented Research Career Development Award (K23) issued April 15, 2016. There are also several additional documents to help applicants in preparing an application, NHLBI Model K08 and K23 Applications and Helpful Hints for Preparing K08 and K23 Applications. All documents can be accessed at:

http://www.nhlbi.nih.gov/funding/training/redbook/newintro.htm

Applicants should follow the instructions in the form PHS 398 for presenting information on ethnicity and racial breakdown of clinical populations.

Applicants should note the NHLBI recommends, but does not require, the establishment of an Advisory Committee composed of the candidate's mentor and at least two other senior faculty members to review the candidate's progress on an annual basis. Applications are to be submitted on form PHS 398 and will be accepted on or before the receipt deadline of June 12, 2016. Forms are available at most institutional offices of sponsored research and from the Office of Grants Information, Center for Scientific Review, NIH, 6701 Rockledge Drive, MSC 7710, Bethesda, MD 20892, telephone (301) 435-0714. Copies of the form may also be printed from the NIH website at the following address:


Please take note that the maximum salary budget to be requested of the NIH using form PHS 398 is $100,000. Any request over $100,000 in salary support to the NIH may be cause for rejection of the application by the Center for Scientific Review of the NIH. As a function of the overall awards program and separate and distinct from the NHLBI application, PHA will be contributing up to a total direct costs of $62,500, in addition to the amount awarded by the NHLBI under the K08 and K23 provisions. PHA contribution can be requested for salary and fringe benefits and research development support.

To identify the application as a response to this program announcement, check "YES" on item 2 of page 1 of the application and enter "PA-16-191, Mentored Clinical Scientist Development Award: Assign to NHLBI" or “PA-16-198, Mentored Patient-Oriented Research Career Development Award: Assign to NHLBI.” Applicants must obtain the SF424 (R&R) application package associated with the funding opportunity using the “Apply for Grant Electronically” button following the directions provided at www.Grants.gov.

PHA:

To apply for the PHA portion of the award, applications are to be submitted on form PHS 398, using only the Face Page (Form Page 1) and Form Pages 2, 4, and 5 and a detailed budget justification. The applicant must submit a categorical budget to PHA. Applications will be accepted on or before the receipt deadline of June 12, 2016, or October 12, 2016 for new applications and July 12, 2016 or November 12, 2016 for resubmission applications. Send the original and PHA supplemental applications to: Pulmonary Hypertension Association, Inc., Att: Michael Patrick Gray, 801 Roeder Road, Suite 1000, Silver Spring, MD 20910.

Do not send the PHA portion of the application to NIH.
REVIEW CONSIDERATION
Applications will be reviewed for completeness by the Center for Scientific Review and for responsiveness to this program announcement by PHA and by the NHLBI. Applications that are complete and responsive to the program announcement will be evaluated for scientific and technical merit by an appropriate peer review group convened at the NHLBI in accordance to the standard NIH peer review procedures. PHA will participate with the NHLBI in the selection of the peer review group. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have highest scientific merit, generally the top half of the applications under review, will be discussed, assigned a priority score, and receive a secondary review by the National Heart, Lung, and Blood Advisory Council. The applications will also receive a secondary review by PHA.

AWARD PROCESS
PHA and the NHLBI will notify the applicants of the joint action of PHA and the National Heart, Lung, and Blood Advisory Council shortly after the Council meeting in June. It is anticipated that one jointly sponsored K08 or K23 award will be made each year and the name(s) of the awardee(s) will be announced by PHA.
NHLBI Career Development Awards
Comparison of Mentored Clinical Scientist Development Award (K08) and Mentored Patient-Oriented Research Career Development Award (K23)

K08

Eligibility Requirements

Health professional doctoral degree (such as MD, DO, DVM, or equivalent).

Professional license to practice in the US.

- Basic research that may or may not involve human subjects.
  - Patient contact not required.
- US citizen, non-citizen national, or legal permanent resident of US.
- Current or former principal investigators of an NIH K01, K23, R01, P01, or P50 or of a subproject on a P01 or a P50 are not eligible.

Special Features

- 3-5 years of mentored support.
- Maximum salary of $100,000 per year plus fringe benefits with at least a 75% effort.
- Research support may be requested up to $30,000 per year.
- Special Leave may be taken to:
  - Train at another institution;
  - Train at a lower level of effort for a longer period of time; or
  - Take a leave of absence.

K23

Eligibility Requirements

- Clinical doctoral degree or its equivalent and is focused on patient-oriented research. PhDs if certified to perform clinical duties.
- Completed clinical training, including specialty and subspecialty training, if applicable, prior to receiving an award.
- Patient-oriented research that must involve human subjects.
  - Patient contact required.
- US citizen, non-citizen national or legal permanent resident of US.
- Current or former principal investigators of an NIH K01, K08, R01, P01, or P50 or of a subproject on a P01 or a P50 are not eligible.

Special Features

- 3-5 years of mentored support.
- Maximum salary of $100,000 per year plus fringe benefits with at least a 75% effort.
- Research support may be requested up to $30,000 per year or $50,000 with justification.
- Special Leave may be taken to:
  - Train at another institution;
  - Train at a lower level of effort for a longer period of time; or
  - Take a leave of absence.
CONTACTS

For questions regarding NIH eligibility requirements and the K08 and K23 application process:

Sandra Colombini Hatch, MD
Lung Biology and Disease Branch
Division of Lung Diseases
National Heart, Lung, and Blood Institute
6701 Rockledge Drive, Suite 10162, MSC 7952
Bethesda, MD 20892-7952
Telephone: (301) 435-0222
Fax: (301) 480-3557
E-mail: hatchs@nhlbi.nih.gov

For questions regarding PHA:

Michael Patrick Gray, MPH
Senior Director of Medical Services
801 Roeder Road, Suite 1000
Silver Spring, MD 20910-4496
Telephone: (301) 565-3004, ext. 770
Fax: (301) 565-3994
E-mail: medical@phassociation.org