Founders Affiliate Clinical Research Program Description

Award Activation: January 1, 2012

Program Description, Eligibility and Peer Review Criteria

**Objective**
To encourage early career investigators who have appropriate and supportive mentoring relationships to engage in high quality introductory and pilot clinical studies that will guide future strategies for reducing cardiovascular disease and stroke while fostering new research in clinical and translational science, and encouraging community- and population-based activities.

This grant is not intended to fund basic science or to support senior researchers, but encourages mentoring of early career investigators.

**Science Focus**
Funding is available for research related to cardiovascular disease and stroke prevention or treatment, or to related clinical and public health problems, including multidisciplinary efforts. Proposals are encouraged on provider behavior, patient behavior, behavioral outcomes, risk factor outcomes, disease outcomes, cost benefit analyses, efforts to evaluate outcomes of patient care delivery and patient/provider and/or system compliance and adherence to recommendations, as well as pilot clinical research studies that may provide preliminary data for larger-scale investigation. Also, encouraged are studies using existing databases. Ancillary studies or a clearly defined sub-study of an ongoing clinical research study are also encouraged. There must, however, be clear justification that the proposal is a sub-study and not a piece of an already funded project.

The Founders Affiliate strongly encourages applications for projects that focus on issues related to under-represented minority groups.

**Target Audience**
- Healthcare professionals with a masters or post-baccalaureate doctoral degree, including M.P.H., R.N., Pharm.D., M.D., D.O. or Ph.D.
- Interdisciplinary research teams are eligible.

At the time of application, the applicant must:
• Meet institutional requirements for grant submission.

Individuals are not eligible to be the principal investigator if they hold or have held:

• Certain NIH awards (such as RO1, R21, PO1)
• Certain AHA awards (BGIA, SDG, EIA, GIA); or
• An award equivalent to any of the above (an independent investigator award)

 Citizenship
At the time of application, must have one of the following designations:

• U.S. citizen
• Permanent resident
• Pending permanent resident. Applicant must have applied for permanent residency and have filed form I-485 with the U.S. Citizenship and Immigration Services and have received authorization to legally remain in the U.S. (having filed an Application for Employment form I-765)
• E-3 Visa - specialty occupation worker
• H1-B Visa - temporary worker in a specialty occupation
• F-1 - Student Visa - temporary worker in a specialty occupation
• J-1 Visa - exchange visitor
• O-1 Visa - temporary worker with extraordinary abilities in the sciences
• TN Visa - NAFTA Professional

Awardee must meet American Heart Association citizenship criteria throughout the duration of the award.

Applicants are not required to reside in the United States for any period before applying for American Heart Association funding.

Mentor
All applicants must identify a mentor with an earned doctorate and a track record of high quality clinical investigation.

Location of Work
The award may be completed at any accredited institution in Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island or Vermont.

American Heart Association research awards are limited to non-profit institutions, including: medical, osteopathic and dental schools, veterinary schools, schools of public health, pharmacy schools, nursing schools, universities and colleges, public and voluntary hospitals and others that can demonstrate the ability to conduct the proposed research.
Applications will not be accepted for work with funding to be administered through any federal institution or work to be performed by a federal employee, except for Veterans Administration employees.

Funding is prohibited for awards at non-U.S. institutions.

### Budget/Annual Award Amount

**Salary/Fringe:** Up to $37,500 (50 percent) of the direct costs may be used for salaries and fringe benefits of the principal investigator, collaborating investigator(s), and other participants with faculty appointments, including an allowance of up to $5,000 for the mentor.

Institution may supplement the stipend.

**Indirect Costs:** $6,818 (included in total annual award amount)

**Project Support:** Salaries of technical personnel essential to the conduct of the project, supplies, equipment, travel, volunteer subject costs, and publication costs.

**Total Annual Award Amount:** $75,000

**Award Duration:** Two years

### Peer Review Criteria

To judge the merit of the application, reviewers will comment on the following criteria. Please be sure that you and your mentor or co-investigator fully address these in your proposal:

1. **Investigator:** Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Do the investigative team and mentor bring complementary and integrated expertise to the project? Will this grant support the investigator's further development into an independent investigator?

2. **Environment:** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is the strength and nature of the mentoring relationship appropriate? Is
there evidence of institutional support?

3. **Significance:** Does this study address an important problem broadly related to cardiovascular disease or stroke? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods and technologies that drive this field?

4. **Approach:** Are the conceptual framework, design, methods and analyses adequately developed, well integrated, well reasoned and feasible (as determined by preliminary data) and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Does the investigator have access to an appropriate population group for the study? Does the investigator address issues of statistical power when appropriate? If the proposal is for a pilot study is there a rationale for development of more definitive studies?

5. **Innovation:** Is the project original and innovative? For example: Does the project challenge existing paradigms and address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools or technologies for this area?

Applicants should never contact reviewers regarding their applications. Discussing scientific content of an application or attempting to influence review outcome will constitute a conflict of interest in the review. Reviewers must notify the AHA if an applicant contacts them.

**Restrictions**

- An investigator may not hold more than one AHA award concurrently. Exception(s): an investigator may hold two AHA grants (affiliate and national) concurrently if all three apply: 1) There will be no more than six months remaining on the initial award. 2) The projects have no overlap in specific aims. 3) There is no budgetary overlap between the two projects.

- An applicant may submit only one affiliate application per deadline. If eligible, an applicant may simultaneously submit an application to an affiliate and to the national award program. The proposed research plan may need to be adjusted based upon different length of award and dollars available. The deadline dates may be different for each submission. If both are funded, the applicant must choose one award.

- An applicant who is unsuccessful in a competition may resubmit the same or similar application three times (the original plus two resubmissions). The same or similar application submitted for the fourth time will be administratively withdrawn.