



**EARLY CAREER TRANSLATIONAL RESEARCH**  
**AWARDS IN BIOMEDICAL ENGINEERING**  
**PHASE 1 AWARDS - 2008**

**APPLICATION AND ADMINISTRATIVE GUIDELINES**

**I. APPLICATION**

**BME CHAIR APPROVAL**

All Early Career Award applications must be reviewed and approved by the Chair/Head of the Biomedical/Bio-Engineering Department in which the applicant has a primary appointment. The method for this approval is explained and included in the online award application form. This approval must be obtained prior to final submission of the application to the Foundation, before the due date of March 14, 2008. The Foundation will not review applications that do not have this approval.

**ELIGIBILITY**

The Foundation invites applications from principal investigators (PIs) who meet the following eligibility criteria:

- The PI must be a full-time tenure-track faculty member with a primary appointment in a Biomedical Engineering Department (or other similarly-constituted, permanently-established biomedical/bio-engineering academic program) at a North American university.
- The PI must have received his or her doctoral degree no more than six years prior to submitting the application for this award.
- The PI must not hold an academic rank higher than Assistant Professor at the time of application submission.
- Only one Phase 1 Early Career Award will be allowed per awardee for the duration of this program.
- Only one application per year will be allowed but you may apply annually as long as the PI is eligible

**EVALUATION CRITERIA**

Coulter Foundation staff will review all applications to determine the eligibility of the institution, the PI, and the proposed research project. A review committee, composed of experts in biomedical engineering, clinical practice, technology transfer, venture capital and business management, will review the applications and make recommendations to the Foundation's executive committee, which will make all funding decisions. Each eligible application will be judged based upon the following criteria:

- Merit, significance and translational nature of the proposed research.
- Appropriateness and nature of any clinical collaboration.
- Significance and nature of the unmet or underserved clinical need that would be addressed by the technology developed under the project.
- Novelty of the proposed research and potential for proprietary (e.g. patent) protection of any developed technology.
- Product and commercial development potential.
- Reasonableness and achievability of specific milestones.

## **PROCESS AND FORMAT**

Applications for the Early Career Translational Research Awards in Biomedical Engineering will be accepted once each year. The 2008 applications will be due on or before March 14, 2008. It is anticipated that award recipients will be announced by June 14, 2008 and that funding will begin August 1, 2008.

All applications must be submitted electronically via the internet. Applications will open December 15, 2007. No paper or facsimile copies of the application will be required or accepted.

The first step in the application process is to sign in to the application module by creating a user name and password. Once signed-in the applicant must complete a brief form to determine eligibility for this award. If eligibility is confirmed, the applicant may then proceed to complete the application in accordance with the detailed instructions provided within the application module.

If an applicant is deemed ineligible, the reason for the ineligibility will be explained. If an applicant believes that their ineligibility is in error they should contact the Foundation to discuss.

The Foundation will maintain some flexibility on eligibility requirements in the event of remarkable extenuating circumstances. For example, if an applicant is beyond the six year post-doctoral-degree period, but had to take a leave of absence for reasons such as illness, maternity leave or military service, the Foundation may elect to waive the strict requirement on an individual basis. Applicants requesting such waivers should contact the Foundation.

Detailed application instructions are contained within the online application module. The primary part of the application the Project description, is limited to 10 pages total and must contain:

1. a statement of the general objectives, specific aims, and milestones of the project;
2. the previous research experience and accomplishments in the project area by the PI;
3. a concise review of recent research in the field;
4. a statement of the unmet or underserved clinical need that the project addresses, and how it addresses it;
5. a statement of why the project is translational;
6. a detailed research plan including procedures;

7. a timeline indicating key milestones (specific aims) and when they are expected to be achieved;
8. an intellectual property summary and a strategic plan for protecting proprietary project outcomes;
9. A summary of the envisioned product(s) that might result from successful completion of the project and a general strategic plan for how commercialization might be achieved.
10. A summary of the approach that will be undertaken to attract follow-on funding after the Coulter Foundation award funding expires.
11. No more than 2 pages of referenced publications.

## **II. ADMINISTRATIVE GUIDELINES**

### **ACCOUNTING**

All funds advanced by The Wallace H. Coulter Foundation shall be used solely for the program described in this application and in accordance with the budget approved with the application. Over-expenditures in any budget year cannot be covered with future year funds. Financial reports must be submitted to the Foundation on a semi-annual basis, as part of the semi-annual project progress report described below.

### **ALLOWABLE BUDGET ITEMS**

The allowable budget items are outlined in the categories contained in the downloadable online budget form incorporated in the online application submission process. Funds must be used to support the research described in the approved application. Allowable budget expenditures include salary and fringe benefits for project personnel, materials and supplies, equipment, travel, and other. Funds may not be used for tuition, construction, or renovation. The total annual project direct cost is limited to US\$100,000 (plus 20% indirect costs). Equipment is limited to US\$10,000 total each year.

### **AWARD FUNDING**

Each award will be for two years for an amount not to exceed \$100,000 direct cost per year. The second year of funding will be contingent upon adequate progress during the first year.

### **BUDGET CHANGES**

If it is desired to change the budget significantly (more than 30% adjustment to any budget category), a written or e-mail letter should be sent to the Foundation explaining the rationale, and permission should be obtained prior to making the change.

### **CARRYOVERS AND NO-COST EXTENSIONS**

Unexpended funds may be carried over from one award year to the next without prior written permission if the total amount to be carried over does not exceed 25% the total Direct Cost budgeted for that year. The carryover funds must be expended as originally budgeted, except as provided by the budget change provision given above. Funds in

excess of the allowed carryover limit must be returned to the Foundation unless prior written approval is obtained or a request is granted for a no-cost extension.

### **CO-INVESTIGATORS**

Because of the nature of the research supported by this award, collaboration between the Biomedical Engineering PI and a clinical investigator affiliated with a practicing clinical environment is required. Practicing clinicians often bring a sense of urgency, relevancy, and practicality to a biomedical engineering research project that enhances the translational process. The collaboration may take a number of different forms, including the clinical investigator being a co-investigator in the research or a consultant to the project, but in any event, he/she must be involved in a substantive capacity.

### **HUMAN AND ANIMAL STUDIES**

If the supported research involves the use of animal or human subjects, this should be indicated at the appropriate place in the electronic application submission, and the appropriate institutional approvals must be obtained prior to the use of said animal or human subjects.

### **INDIRECT COSTS**

The Indirect Cost is to be calculated as outlined in the downloadable online budget form incorporated in the online application submission process. Indirect cost may not exceed 20% of allowable Direct Costs. Indirect costs are not allowed on equipment.

### **INTELLECTUAL PROPERTY POLICY**

The Principal Investigator and the awardee institution shall abide by the Foundation's Intellectual Property Policy, which is as follows:

The Wallace H. Coulter Foundation (WHCF) supports translational research – research that often involves discoveries or inventions that constitute intellectual property in the form of patents, copyrights, or trade secrets. It is the desire of WHCF that such intellectual property be administered in a manner that promotes commercialization and clinical use at the earliest possible time.

Except as provided hereafter, the entire right, title and interest to any invention or discovery, which is or may be patentable under the laws of the United States or any foreign country, and which is conceived or first actually reduced to practice in the course of performance under a grant from WHCF, shall be assigned to and retained by the institution receiving the grant, unless the institution is proscribed from doing so by Federal laws or regulations. If the institution decides not to patent or otherwise develop the invention or discovery, the inventor(s) shall be free to patent or otherwise develop the invention subject to any rights that the institution may retain under its patent policy.

WHCF waives any ownership rights in the patent, or the right to an exclusive or nonexclusive license to practice or assign the invention or discovery. The granting of

an exclusive or nonexclusive license by the institution to practice the invention shall be in accordance with the institution's policy on licensing.

In order to protect patent rights or trade secrets, publication or other public disclosure of information about the discovery or invention may be withheld for a reasonable period of time in accordance with the institution's patent policy.

Institutions are expected to have formal safeguards in place for maintaining the highest ethical standards when faced with real or potential conflicts of interest relating to commercialization of discoveries or inventions developed in the course of a research project funded by WHCF. If the principal investigator(s) or any other person being supported under a grant from WHCF, has an arrangement with any organization (non-profit or for-profit), other than the institution receiving the WHCF grant or the government, that would affect patent rights, trade secrets or copyrights for inventions or discoveries arising in whole or in part from the research supported by WHCF, information concerning such an arrangement shall be disclosed in writing at the time of the grant application or at the time such arrangements are agreed upon. In addition, if the principal investigator(s) or any other person being supported under a research grant from the WHCF has any ownership interest in a business that could benefit from the research, or is an employee of such a business, this fact must also be disclosed in the application or as soon as the ownership or employment relationship arises.

#### **PRINCIPAL INVESTIGATOR RESIGNATIONS AND TRANSFERS**

In the event of the Principal Investigator's resignation or inability to continue the project, the awardee institution should contact the Foundation, which will evaluate the specific circumstances to determine the disposition of funds. If a Principal Investigator transfers to another institution he/she should contact the Foundation, which will evaluate the specific circumstances to determine if the Award is transferable.

#### **PRIVACY POLICY**

The information that you will be providing to The Wallace H. Coulter Foundation (the "Foundation") in your Early Career Translational Research Award application will be used by this Foundation to make a decision as to whether or not to fund your research. As part of this decision making process, the Foundation relies on outside advisors to assist in the review of all applications received. The Foundation will use reasonable efforts to not distribute your application beyond reviewers described above. However, the submission of your application is not made pursuant to any nondisclosure agreement with the Foundation. Moreover, the Foundation will not enter into a non disclosure agreement with any applicant. Therefore, it is incumbent on each applicant to provide the Foundation with sufficient detail to understand the research that you are requesting to be funded and at the same time not disclose any proprietary elements that may compromise your ability to obtain intellectual property protection in the future.

#### **PROJECT PROGRESS REPORTS**

All Early Career Award recipients will be required to submit a semi-annual project progress report and budget. This report, which is to be a maximum of three pages in

length, will be submitted electronically (online) according to the format detailed in the progress report link available through the Foundations website [www.whcf.org](http://www.whcf.org).

### **TRAVEL**

Travel must be limited to North America. Applicants should include, as part of the travel budget, funds to attend an annual meeting of Early Career Awardees. The biomedical engineering PI will be expected to attend this meeting, and to participate in courses and training sessions that will be sponsored by the Foundation and held in association with the meeting. These courses and training sessions will cover topics such as entrepreneurship, technology transfer, project management, intellectual property, regulatory affairs, and project/start-up financing.