



EARLY CAREER TRANSLATIONAL RESEARCH
AWARDS IN BIOMEDICAL ENGINEERING
PHASE 2 AWARDS - 2007

APPLICATION AND ADMINISTRATIVE GUIDELINES

I. APPLICATION

ELIGIBILITY

- Only recipients of Phase 1 Early Career Translational Research Awards are eligible to apply for Phase 2 Awards.
- At the time of their third semiannual progress report (18 month report due on January 31, 2007), those Phase 1 Awardees wishing to apply for a Phase 2 Award must indicate their desire to do so at the appropriate place in the 18-month progress report submitted online using the Easygrants™ system (<http://easygrants.whcf.org>).
- Phase 2 Award applicants must continue their status as 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.

APPLICANT SELECTION CRITERIA

- The External Review Committee that reviewed the initial Phase 1 applications, and that has been reviewing the semi-annual progress reports, will decide which of those Phase 1 Awardees who indicated their desire to apply will be invited to submit a Phase 2 application. This Committee is composed of experts in biomedical engineering, clinical practice, venture capital and business management.
- The selection of the Phase 1 Awardees who will be invited to apply for a Phase 2 Award will be based on the Review Committee's assessment of the status and the progress of the applicant's Phase 1 project during the first 18 months, and on the potential of the project to continue to achieve key translational research milestones during Phase 2. Only those Phase 1 Awardees who have achieved excellent progress during their Phase 1 Awards will be invited to apply for Phase 2 Awards.

APPLICATION PROCESS

- Phase 1 Awardees who indicated their desire to apply for a Phase 2 award on their 18 month progress report due January 31, 2007, and who are selected by the External Review Committee, will be notified in mid-February that they are invited to apply. It is anticipated that no more than 50% of the EC Phase 1 Awardees will be invited to apply.
- These selected Phase 2 Award applicants must complete a written application (described in more detail below) and submit that application using the online Easygrants™ system on or before March 31, 2007.
- The External Review Committee will review the written Phase 2 Award applications, and will select a subset of those applicants to be invited to give an oral presentation of their project. Applicants selected for oral presentations will be notified no later than May 15, 2007. It is anticipated that no more than 50% of those submitting written applications will be selected for oral presentations.
- The selected applicants will give an oral presentation of their project to the Committee and the Foundation in Miami, FL on June 12, 2007. One hour will be allowed for each presentation, with 20 minutes for presentation, 20 minutes for Q&A, and 20 minutes for closed Committee discussion.
- Based upon the overall assessment of the written applications and oral presentations, the Committee will select the Phase 2 Early Career Award recipients. The Award recipients will be notified of their selection no later than June 30, 2007. Phase 2 Award project funding will begin August 1, 2007

WRITTEN APPLICATION FORMAT

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 re-statement of the unmet or underserved clinical need that the project addresses, and how it addresses it;
2. a concise summary of the accomplishments achieved in the completed Phase 1 Early Career Award project;
3. a statement of the general objectives, specific aims, and key milestones of the Phase 2 project;
4. a timeline indicating key milestones and when they are expected to be achieved;
5. a detailed research plan including procedures;
6. a summary of the envisioned product(s) that might result from successful completion of the project;
7. a competitive assessment of how the envisioned product(s) compares to existing product(s) or standards-of-care that address the clinical need;
8. an intellectual property summary and a strategic plan for protecting proprietary project outcomes;
9. a strategic plan for how commercialization would be achieved;
10. a summary of the approach that will be undertaken to attract follow-on funding after the Coulter Foundation Phase 2 award funding expires.
11. no more than 2 pages of referenced publications are allowed.

II. ADMINISTRATIVE GUIDELINES

AWARD FUNDING AND DURATION

Each Award will be for \$200,000 total (Direct + Indirect Costs). The duration of the Award is for a period of one year.

COULTER FOUNDATION MENTORING

Each Phase 2 Early Career Award recipient will be assigned to a senior member of the Coulter Foundation management who has substantial experience in medical technology development, business management, and new venture creation. This individual will serve as a mentor to the awardee and their project, with the goal of helping to accelerate the transition of the project technology from the research lab to clinical practice.

CLINICAL COLLABORATORS

Because of the nature of the research supported by this award, collaboration between the Biomedical Engineering PI and a practicing clinical investigator involved in patient care 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. To insure that the clinical collaborator's involvement in the project is substantive, a minimum of 20% of the total project budget (i.e., \$40,000 from a \$200,000 budget) should directly support the clinical collaborator's laboratory for allowable budget items such as salary and fringe benefits, clinical "release time", materials and supplies, equipment, travel, and other (e.g., clinical diagnostic equipment utilization costs). The Foundation will allow exceptions to this budget allotment to the clinical collaborator, but only if there is a clear and convincing rationale for the exception, there is clear evidence that the collaboration will not be diminished, and the clinical collaborator explains in writing (as part of the application) why they do not need the funding to their lab and why the collaboration will not suffer.

PROJECT PROGRESS REPORTS AND OPERATING REVIEWS

All Phase 2 Early Career Award recipients will be required to submit a semi-annual project progress report and budget for the duration of the project. This report, which is to be a maximum of four pages in length, will be submitted electronically (online) according to the format detailed in the progress report link available through the Foundations website <http://easygrants.whcf.org>. In addition, award recipients will be expected to attend operating review meetings with Foundation personnel regarding their projects. These operating review meetings, which will be no more than twice during the duration of the project, will be held either at the Foundation offices or in association with the annual BMES meeting.

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 construction or renovation. The total project direct cost is limited to US\$200,000. Equipment is limited to US\$20,000 total.

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.

TRAVEL

Travel must be limited to North America. Applicants should include, as part of the travel budget, funds to attend the annual Biomedical Engineering Society (BMES) conference. The biomedical engineering PI will be expected to attend this conference, and to participate in sessions that will be sponsored by the Foundation and held in association with the meeting. Travel funds should also be included to attend the semi-annual operating reviews.

ACCOUNTING

All funds advanced by The Wallace H. Coulter Foundation shall be used solely for the project described in this application and in accordance with the budget approved with the application. Financial reports must be submitted to the Foundation on a semi-annual basis, as part of the semi-annual project progress report described below.

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.

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.

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 being 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.