Program Summary
This program is offered by the Wallace H. Coulter Foundation Translational Research Partners II Program (Coulter Program) at the University of Pittsburgh to advance qualifying research projects toward commercialization of products and services that may ultimately benefit patients through significant improvements in health outcomes and reduced delivery costs.

In the 2017 cycle, we are accepting unique applications in collaboration with the following partners:
- Center for Commercial Applications of Healthcare Data
- Department of Dermatology
- Department of Plastic Surgery
- Magee-Womens Research Institute
- Pittsburgh Liver Research Center
- University of Pittsburgh Cancer Institute
- Vascular Medicine Institute

In addition, awards will be made for other general biomedical innovation areas not covered by the above collaboration.

Examples of desirable translational research projects are devices, diagnostics, healthcare IT/software, and drug delivery systems. Drug projects may be considered, providing that Coulter funding has the potential to advance the technology enough to generate commercial interest. This program differs from traditional academic grant programs in that the approach involves a systematic hands-on interaction and collaboration between the project teams and Coulter leadership throughout the course of the application and translational project funding.

Each proposal will be evaluated on the basis of scientific and clinical merit, potential health care impact and significance, addressed market, experience and potential collaboration between the investigative co-PIs, timeline and pathway to commercialization, and the potential to obtain further financial investment to translate the particular innovation to a healthcare solution.

Benefits of Participation:
- $50,000 to $100,000 investment to help de-risk your invention for commercialization
- Development of a path to commercialization for your promising invention
- Hands-on mentoring and coaching by experienced business colleagues
- Specific feedback on how your technology may fit into the healthcare industry
- Development of an awareness of opportunities and risks
- Access to and involvement with business and commercialization resources
- Development of a high quality Executive Summary, Business Plan, Development Plan, and Investment Presentation
- Opportunities to present to potential investors and licensees, including corporate partners, angel investors, venture capitalists, and technology-based economic development groups
- Networking and contacts to expand your commercialization horizons
Eligibility Criteria:
All primary investigators on a Coulter project serve as Co-Principal Investigators (Co-PIs). Each proposal must include a technical Co-PI and at least one clinical practitioner Co-PI from the Schools of the Health Sciences or UPMC, whose job responsibilities include direct contact with patients or patient data. University of Pittsburgh faculty members at the levels of assistant or research assistant professor, associate or research associate professor, and professor or research professor are eligible to apply as Co-PI’s. Instructors, fellows, research associates, predoctoral and postdoctoral researchers may also apply, providing there is a qualified faculty member who participates as a Co-PI.

For any given research group, only one award may be active at a given time. That is, if there are several research faculty members working under the umbrella and mentorship of a given faculty member, only one award may be active for the entire group, independent of whether the principal investigator on the Coulter award is the senior investigator or any of the research faculty members.

Submission Guidelines:
Proposal submission and selection is a four-stage process.

Step 1: November 15, 2016

Step 2: January 2017
- Selected Finalists to Begin Preparation of Full Proposal

Step 3: May 2017
- Full Proposal Submission Deadline – Executive Summary, Business Plan, Development Plan, and Investment Presentation

Step 4: June 2017
- Final Oral Presentation to OC for Funding Decision - Fifteen Minutes

The Coulter Oversight Committee (OC) will select the funded Coulter projects based on presentation of the full proposal for the period July 1, 2017 through June 30, 2018. A budget of direct costs will be further prepared during the development of the full proposal.

One-Page LOI Submission: Deadline - 5:00 p.m. Tuesday, November 15, 2016
In one page, the LOI should convey the unmet clinical need, market potential, uniqueness and protectable nature of your solution and business proposition, including path to market/clinical use.

The body of the LOI narrative must include:
1. A description of the unmet or poorly met clinical need
   a. The LOI should include metrics, such as:
      i. Number of patients affected annually
      ii. Health care expenditures for treatment and/or diagnosis
      iii. Likely future trend of the problem
      iv. Defined market and estimated market size

2. The proposed solution, including status
   a. The proposal must be as focused as possible on the development of an innovative technology solution for the identified problem, i.e. “translational” as opposed to “academic” (which is defined as adding to the general body of knowledge, but not product specific)
   b. Comparison to the current standard of care and other competitive considerations
   c. Successful applications would have already progressed through an initial in vivo proof of concept for their technology

3. Concise summary of preliminary data
   a. Include published articles, if any, which support the efficacy of the proposed technology; i.e., evidence that the approach would actually “work” (proof of concept) and that there would be a future clinical demand for it
4. A realistic R&D / product development timeline
   a. Include estimated time from “bench to bedside,” taking into consideration technology feasibility, proof of in vivo feasibility, product development, verification and validation, manufacturing, and regulatory/reimbursement considerations. Is this a 1-2 year project or 8-10 years to clinical use/market?

5. The proposed one-year scope of work and budget allocation for non-PI personnel, minor equipment and supplies
   a. Do not include the university overhead, at this point
   b. Please summarize previous work and grants received for this solution
   c. Include if and for how long your investigative team has worked together on this solution and other successful translational research activities

6. The Intellectual Property Status
   a. Include invention disclosures, patent applications filed, shared IP ownership with others, patents awarded and/or technologies licensed, related to the proposed technology, including third party IP
   b. Innovation Institute disclosure docket numbers for the proposed technology must be provided. Include any assessments of the strength of the Intellectual Property (such as patent searches and applications)

Written Format:
1 inch page margins, Times New Roman Font - at least 11 point size, line breaks between paragraphs. Only proposals meeting these format guidelines will be evaluated. Please include PI names and titles.

Submit online: www.engineering.pitt.edu/coulter

Evaluation:
The Coulter Leadership Team will review and evaluate the LOI proposals. Selected LOI finalists will be invited to prepare a Full Proposal during participation in a commercialization strategy development process. Investigators will be notified regarding the result of the LOI on or before Friday, January 20, 2017, along with specific and relevant feedback. It is expected that applicants working toward a full proposal submission will work closely with the Coulter TPII Program Director (CPD) and the Office of the CPD, and use other provided translational resources, in the formulation and submission of the Full Proposal.

Note that if an interesting idea or a technology is not eligible for this year’s Coulter process (i.e. it is deemed to be too early), it may be appropriate for seed support through the Center for Medical Innovation (http://www.engineering.pitt.edu/cmi/), a sister program of Coulter TPII.

Questions:
Questions about the program should be directed to Max Fedor, MBA, Coulter TPII Program Director, mfedor@innovation.pitt.edu or Lindsay Rodzwicz, Coulter Program Manager, rodzwicz@pitt.edu.