



Program Year 2019 (PY2019)

Request for Applications (RFA)

Key Dates:

Pre-Proposal due date: February 28, 2019
Proposals & Pitch due: Approximately July 2019*
Proposal Presentations: Approximately July 2019*
Award announcements: Approximately August 2019*
Project start date: September 1, 2019
Project end date: May 31, 2020
Quarterly report due dates: November 30, 2019, February 28 and May 31, 2020
Final report due date: June 2020

* Approximate dates will be updated on website (<http://engineering.case.edu/ebme/cctrp>)

Points of Contact:

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Program Synopsis

This is the fourth year of the third phase of the Case-Coulter Translational Research Partnership (CCTRP) to support collaborative translational research projects that address unmet or poorly met clinical needs. The CCTRP seeks to reduce the market risk of promising new clinical products arising from the research programs of BME and affiliated Case faculty. Successful projects will thus often focus on the development of prototype products, building relationships with companies, performing clinical feasibility studies, obtaining regulatory approval, and other activities that companies or business experts indicate are the essential last steps before a license can be negotiated or a startup launched. An overarching goal of the program is to foster research and development work likely leading to commercially relevant translational technologies within a three- to five-year horizon. Because the goals of all Coulter projects are to reduce market risk, all proposals are expected to reflect genuine business input, and all projects must include a “business advisor” as an important member of the decision making team.

The funding provided by the CCTRP should be considered as a “cooperative agreement” rather than a “grant”. That is, the CCTRP staff, Technology Transfer Office (TTO) staff, and the Oversight Committee (OC) are partners in the project rather than a funding agency. Faculty should (and will be expected to) take advantage of the unique resources provided by the program and to include program staff in all major decisions. Project PI’s are expected to

provide at least monthly updates on progress towards milestones, and timely quarterly reporting from the BME PI of each project will be a milestone of ALL projects and will factor into decisions about continued funding.

The CCTRP awards funding at 2 different levels, **pilot** and **full** projects:

Pilot Projects

Pilot projects up to \$25,000 can be applied for on a rolling basis but will be considered quarterly. Pilot projects will typically be for a six-month period with specific milestones defined with the intent of participation in the annual full Coulter award cycle. Apply using same instructions with a focus on the necessary steps that will position PI for a successful full CCTRP application the following year. The individual component sections can be scaled back, but the PI is responsible for making his/her case. There are no CCTRP OC presentations for pilot projects.

Full Projects

Full projects will typically be for an initial one-year period with specific milestones defined on a quarterly basis; in special circumstances, proposals can span more than one year but must be approved prior to submission. Continuation and renewal applications will be evaluated on a competitive basis with new applications, and must have a comparison of milestones achieved vs. those planned in the original award. An important part of the proposal is the commercialization opportunity and the idea or vision for the end product. Examples of preferred future outcomes include inventions, patents, improved diagnosis and treatment of disease, commercial products, licenses, commercial partnerships and start-up companies.

Stage 1 (Pre-Proposal): A pre-proposal is required by Thursday, February 28, 2019. The pre-proposal should follow the 2-page template that can be found at <http://engineering.case.edu/ebme/cctrp> (no more than 2 pages in length) and emailed to cctrp@case.edu. You will receive an email reply to each LOI submitted to confirm receipt no later than 5 p.m. Friday, March 1, 2019. If you do not receive a reply email by this time, then your LOI was not received and you should follow up with a call to one of the points of contact on the first page of this RFA.

Applicants are strongly encouraged to discuss their proposal with Steve Fening (Coulter Program Director, steve.fening@case.edu) or Andrew Cornwell (Associate Coulter Program Director, andrew.cornwell@case.edu) prior to submission.

Stage 2 (Pre-proposal Review): The pre-proposal stage will serve as a decision point to identify the proposals with the highest likelihood of success. Teams whose pre-proposals do not move to full proposals will have the opportunity to work with the CCTRP staff to strengthen their approach for a subsequent pilot proposal or for evaluation in the following year. The CCTRP OC will review pre-proposals and make recommendations on funding priority. This committee expertise includes that of professional investors, experienced entrepreneurs, medical and scientific experts, large industry, and technology transfer professionals.

Funding preference will be given to those projects in which follow-on funding from other sources and follow-on commercialization activity (i.e., licensing) is promising.

Stage 3 (C3i Program): Applicants who are invited to submit a full proposal and oral pitch are invited to participate in an educational program for applicants and their teams. The goal of this program is to provide the necessary resources, including knowledge and market research funding, for applicants to assemble the best possible full application. While not mandatory, participation is strongly encouraged as the purpose of this program is to assist faculty investigators. The program will consist of didactic sessions and group mentoring, and will be further described to those reaching this stage. Market research funding will be available although this is contingent upon participation in the program. This funding shall be used at the sole discretion of the CPD office to thoroughly

uncover any hurdles between the technology and commercialization. While not exhaustive, this diligence process will be extremely important to the success of technology.

Stage 4 (Full Proposal and Oral Pitch): Applicants accepted past the pre-proposal stage will be asked to submit a full grant application (5 page limit) and to give a brief presentation to the OC. Based on the advice of the OC, the Coulter Principal Investigator (i.e., the BME Chair) will make final funding decisions regarding each project.

Stage 5 (Project Selection): Applicants will be notified in early August on the outcome of the evaluation of their proposal. The months of August will be spent meeting with awardees to inform of award requirements in more detail, getting award accounts set up and, where necessary, to refine the project plan, resolve OC questions, address issues on which the award might be contingent, etc. Awardees should expect to possibly have interactions/support from members of the OC over the course of the award period. Proposals selected for funding can expect to begin work September 1.

Budget and Project Period

Awards up to \$200,000 will be considered if well justified. Applicants should carefully determine the funds needed to achieve well defined translational milestones. As the amount requested by a proposal increases, project milestones are expected to be increasingly related to mitigating market risk, increasingly achievable, and increasingly likely to lead to a license or startup in the short term. Funds may be used for salary support of faculty, graduate students and other research staff, but may not be used for general staff or administrative support or for tuition. Operating supplies, minor equipment items, prototyping expenses, imaging time and travel directly associated with the research activity are examples of eligible budget items. Your budget should reflect an accurate assessment of what the PI thinks is needed to take this translational research project to the next step of commercialization. It is expected that the PI participate in the project in a meaningful way, thus a significant percentage of PI effort should be allocated towards the budget. Total costs should not exceed \$200,000 for the project period of 12 months, and all requests should not be for the maximum. Only well-justified proposals will be competitive for the maximum award. Indirect costs not to exceed 15% of direct cost are to be included in the total cost budget. Carry-over of funds beyond the initial interval must be approved in advance and will be based upon attainment of milestones; extensions may be approved for a maximum of six months based on written justification by the PI. Approval for requests for extensions of funding beyond the six-month end date are not likely to be granted.

Funding Disbursement and Reporting

Project funds are released on a quarterly basis, subject to attainment of milestones and receipt of the quarterly report. The 1st Tranche beginning in September, but subsequent are contingent upon milestone-based performance (typically on a quarterly basis). The CCTRP office wants to know if a project is not working as planned, as there may be other resources available, such as expertise from the CCTRP Oversight Committee (OC). Additionally, if a milestone cannot be achieved, the CCTRP office will work with awardees to determine appropriate changes that will enable the project to get back on track. The CCTRP office aims to be flexible within this framework to do what is best for technology commercialization. It is also expected the budget will reflect uniform activity throughout the year.

Program Eligibility

Each full proposal must have co-principal investigators:

- BME co-PIs must be permanent, full-time, tenure-track faculty within the professorial ranks (assistant/associate/full) of the Case Western Reserve University BME department. Secondary faculty of the BME department may also be a co-PI. For secondary appointment consideration, respective applicants

must apply to the BME department. More details will be provided to those prospective applicants who reach **Stage 4** of the process.

- Clinical co-PIs must be full-time professional staff in one of the affiliated medical centers of Case Western Reserve University, including University Hospitals, Cleveland Clinic, MetroHealth Medical Center, and the Cleveland VA. Full-time clinical faculty in the School of Dental Medicine and the School of Nursing are also eligible as clinical co-PIs.

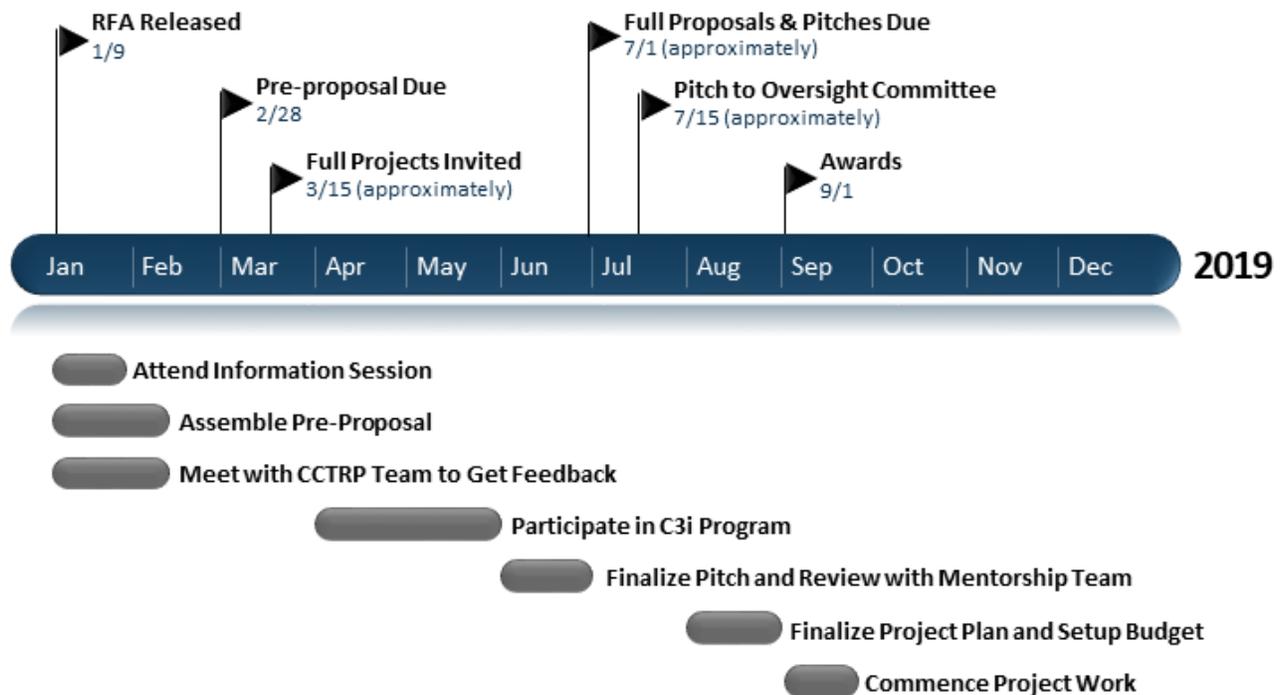
General Information

Criteria - Proposed research must relate directly to critical market-related milestones, as determined in conjunction with the project business advisor and industrial experts, which will ultimately lead to applications in health care. The objectives of the project should include an outcome that will benefit patients. Evaluation of each proposal will be on the basis of scientific merit, potential health care impact and significance, experience of the investigators, and the potential for commercialization.

IRB/AICUC - Approvals for animal and human subjects (if needed) must be completed by the time of final proposal review. The status of approvals must be clearly indicated in the proposal, and documentation of approval must be submitted prior to establishing the award accounts.

Templates – Templates are available for all 3 content submissions: Pre-proposal, proposal, and oral pitch. The template for the pre-proposal is attached to the RFA. Other templates will be made available as needed.

Timeline



Submission

Please submit all materials (pre-proposals, proposals, oral pitch) electronically to cctrp@case.edu.