Coulter-Drexel Translational Research Partnership Program 2020-2021 Request for Proposals

Important Dates

- December 14, 2020: Pre-proposal due at 5pm through the Drexel's <u>InfoReady Funding Portal</u>. Faculty members are required to meet with Kathie Jordan, Coulter Program Director, prior to submitting a pre-proposal.
- **January 8, 2021:** Invitations to faculty to submit Coulter-Drexel Translational Research proposals from selected pre-proposals.
- **February March 2021**: Coulter Workshop, exact dates TBD, series of 4 workshops, offered virtually in conjunction with the Close School.
- March 22, 2021: Proposals due at 5pm. Detailed instructions on the content of the proposal will be provided in the invitations sent to faculty in January.
- April 7, 2021: 1st Oral Presentation to Oversight Committee, business case review
- April 12, 2021: Invitations sent to selected faculty to submit research plan and budget.
- May 10, 2021: Research plan and budget due at 5pm. Further details on submission process will be supplied in the April invitation.
- May 26, 2021: 2nd Oral Presentation to Oversight Committee, focusing on research plan, killer experiment and project milestones.
- June 7, 2021: Award announcements
- July 1, 2021: Funding begins

Program Description

The mission of the Coulter-Drexel Translational Research Partnership is to partner with Drexel University faculty to develop products that will save, extend, and improve the lives of patients. The program provides non-dilutive research funding to develop medical device, diagnostic, drug therapeutic and digital health solutions, and is appropriate for any faculty member who would like to see their work reach commercial markets. Our approach, working with faculty from ideation through early proof-of concept studies, includes due diligence prior to funding, and management of funded projects. The program partners with the Technology Management group of Drexel Applied Innovation, accelerating projects on the path to licensing to a start-up or strategic partner.

Eligibility Criteria

All primary investigators on a Coulter-Drexel TP sponsored project serve as Co-Principal Investigators (Co-PI's). Each proposal must include at least one clinical Co-PI whose job responsibilities include direct contact with patients or patient data, and at least one Co-PI

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holding an appointment in a scientific or engineering field, including media arts and design. At least one of the PIs must have a faculty appointment at Drexel University. In addition, Drexel University must have an ownership interest in the intellectual property that has been or will be developed from the project, and the faculty members must be actively engaged with the Technology Management group in developing a strategy to protect and license that intellectual property.

Questions about faculty eligibility should be referred to the Kathie Jordan, Coulter Program Director.

Evaluation Criteria

Evaluation of each proposal is based on the following criteria:

- Significant unmet or underserved clinical need
- Scientific merit, and substantial improvement over current solutions or standard clinical practice
- Strength and nature of the clinical collaboration
- Reasonable and achievable milestones
- Intellectual property position
- High probability of attracting follow-on funding, within 2-3 years of the Coulter award

Budget Period and Amount

Coulter-Drexel TP project funds are granted for a one-year period. Budgets have historically ranged from \$60K-230K per year. Proposals may be submitted for additional support in subsequent years, if the commercialization and research milestones from the first year were completed successfully. Renewal applications will be evaluated on a competitive basis with new applications.

Proposal Submission Guidelines

Proposal submission is a three-stage process. The first step is to submit a 1-2-page **Pre-proposal**. Selected projects will then be invited to submit a **Full Proposal** in step 2, and the **Research Plan** and **Budget** in step 3.

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Step 1: Pre-proposal Submission Guidelines

Deadline: December 14, 2020, 5pm, through the InfoReady Funding Portal.

Faculty members are required to meet with Kathie Jordan, Coulter Program Director, prior to submitting a pre-proposal. To schedule a meeting, please e-mail Kathie, kcj39@drexel.edu, with three blocks of time that you are available.

Body of the Pre-proposal:

The pre-proposal is a 1-2 page narrative, which should include the topics listed below. For the body of the text, please use Arial, 11pt font, 1" margins. Type density should confirm with standard NIH guidelines (no more than 15 characters per inch, no more than six lines per inch.) You are encouraged to use section titles and images or graphs, as necessary, to assist the reviewers in understanding your proposal. Please do not exceed two pages total, excluding references. References should not exceed one additional (third) page. Pre-proposals that do not conform to these guidelines may not be reviewed. Pre-proposals should be uploaded in PDF format, labelled "PI Last Name Coulter Preproposal 2019" e.g. "Campbell Coulter Preproposal 2018".

Introductory information

1. Non-Confidential Project Title

Provide a non-confidential title intended for a lay audience that succinctly conveys what the envisioned product is, what it does, and what problem it solves.

2. Project Team

List each of your team members and their affiliations.

Problem Statement

3. Clinical need

Describe the clinical problem or the unmet need. Use metrics, such as the number of patients affected annually, health care expenditures for treatment and/or diagnosis, and the likely future trends relevant to the problem, etc. Why is this problem unresolved?

4. Standard of Care

Describe current protocols for management of the problem/unmet need. What specialized diagnostic or therapeutic tools (drugs, devices or equipment) are used to address the problem/unmet need?

Proposed Solution

5. Value Proposition

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In **one** sentence, explain why your potential customers or stakeholders would buy your envisioned product. What will compel or drive the adoption of your product over others? How is your envisioned solution distinct and what are its advantages compared to other approaches?

6. Solution and Enabling Technology

What is your proposed product that will solve this problem? What is the innovation you have discovered or technology you have developed that will enable your envisioned product? Briefly comment on the current stage of development, i.e. what do you presently have in hand: a concept, drawings, a prototype, benchtop/in vitro data, animal data, human data? Please include at least one chart, graph or other representation of data that suggests that your technology will work in the way you predict and be safe and effective.

7. Intellectual Property

The intellectual property status, including invention disclosures, patent applications filed, shared IP ownership with others. Please note that while you do not need to have a patent application filed for your idea, you must have submitted an Invention
Disclosure Form, to the Office of Applied Innovation in order to qualify for preproposal review.

The pre-proposals will be screened by the executive committee of the Coulter-Drexel TP Oversight Committee (OC). Investigators will be invited to proceed to the next step in the application process on or before **January 8, 2021**.

Step 2: Full Proposal and Oral Presentation

Deadline: March 22, 2021, Full Proposals due at 5pm, Oral Presentation on April 7

The full proposal (no more than six pages) will build on the pre-proposal and will cover the clinical context, value proposition, business opportunity, regulatory and legal considerations, and brief overview of the budget required to reach a critical development milestone.

The **Coulter workshop series**, held for four weeks in late January through early March, is designed to assist faculty in preparing the proposals. Though not required, faculty members are strongly encouraged to participate and bring any other members of the project team. Further details about the Coulter Workshop series will be made available in December or January.

Step 3: Research Plan and Budget, 2nd Oral Presentation

Deadline: May 10, 2021, Research Plan and Budget due at 5pm. Oral Presentation, May 26.

Invited faculty members will be asked to prepare a detailed research plan and budget (4 pages total), for final review by the oversight committee. Additional details will be supplied by April 3, 2020 to faculty who are invited for this step.

Post Award

All award recipients, including clinical investigators, will be required to meet once monthly with the Coulter Program Director and advisors and to submit quarterly progress reports using the quarterly report form. Projects that are on schedule may have a reduced meeting schedule. Guidelines for the quarterly report will be sent 2-3 weeks prior to each report due date.

Full grant awardees will also be required to present one progress report to the Coulter-Drexel Oversight Committee, typically scheduled for December. Continuation of funding is dependent on Oversight Committee approval at these meetings, as well as regular meetings with the Coulter Program Director, and timely submission of quarterly reports. Faculty members are expected to work with the Technology Management group of Drexel's Office of Applied Innovation during and following Coulter program funding, to ensure that the project is licensed within 2-3 years of Coulter funding. For the purposes of Coulter program metrics, a qualified licensee is either an existing company with revenues in excess of \$10 million/year, or a start-up with leadership that has the demonstrated capacity to raise at least \$5 million in risk capital.

Due Diligence

The Coulter Program reserves the right to perform diligence on all submissions using internal, student, or external resources. Such diligence may include but is not limited to market research, patentability, reimbursement and regulatory analysis. By submitting a proposal for consideration, faculty members agree that their proposals may be reviewed by the abovementioned resources, and that they may be contacted for additional information/clarification.

Questions:

For questions regarding the award and/or preparation of proposals, please contact:

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