Coulter-Drexel Translational Research Partnership Program
2017-18 Request for Proposals

Important Dates

- **December 1, 2016**: One-page Pre-proposal due through the Drexel’s [InfoReady Funding Portal](#). Faculty members are required to meet with Kathie Jordan, Coulter Program Director prior to submitting a pre-proposal.
- **January 4, 2017**: Invitations to faculty to submit Coulter-Drexel Translational Research proposals from selected LOIs.
- **January 16- March 10**: Coulter Workshop series
- **March 17, 2017**: Proposals due through the [InfoReady system](#), 5:00 p.m. Detailed instructions on the content of the proposal will be provided in the invitations to faculty sent in January.
- **April 5, 2017**: 1st Oral Presentation to Oversight Committee, Business Case Review
- **April 14, 2017**: Invitations sent to selected faculty to submit research plan and budget.
- **May 12, 2017**: Research plan and budget due at 5pm. Further details on submission process will be supplied in the April invitation.
- **May 25, 2017**: 2nd Oral Presentation to Oversight Committee, focusing on research plan, killer experiment and project milestones.
- **June 1, 2017**: Award announcements
- **July 1, 2017**: 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 suffering from any disease or condition, in any size market, in any country around the world. The program provides non-dilutive research funding to develop medical device, diagnostic and therapeutic solutions, including digitally-enabled technologies, 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 Drexel Office of Technology Commercialization, 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 from a
College of Medicine, Nursing or Public Health and at least one Co-PI 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. The clinical Co-PI's job responsibilities must include direct contact with patients or patient data. 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 Office of Technology Commercialization in developing a strategy to protect 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

In order to enhance Drexel University’s Translational Research Partnership with the Kimmel Cancer Center Consortium at Thomas Jefferson University (TJU), joint teams are encouraged to apply for Coulter-Drexel TP funding in cancer diagnostics and therapeutics.

Budget Period and Amount

Coulter-Drexel TP project funds are granted for a one-year period. Budgets have historically ranged from $60K-230K of direct costs 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.

Step 1: Pre-proposal Submission Guidelines

Deadline: December 1, 2016, 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, kj39@drexel.edu, with three times that you are available, prior to December 1, 2016.

Body of the Pre-proposal:

The pre-proposal is a one-two page narrative which should include the following topics. 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. Pre-proposals that do not conform to these guidelines may not be reviewed.

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. For each, briefly describe their area of expertise and what their proposed role on the project will be. Keep in mind that project teams must be comprised of at least one faculty member who is developing the technology and one practicing clinician, at least one of which must have a faculty appointment at Drexel.

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, potential for reduction in costs, and the likely future trends relevant to the problem, etc. Why is this problem unresolved?

4. Standard of Care
How is the clinical problem/unmet need currently addressed? What is current standard of care? Describe current protocols for management of the problem/unmet need. What specialized diagnostic or therapeutic tools (drugs, devices or equipment) are currently used to address the problem/unmet need?

5. Value Proposition

How will your envisioned product address the problem/unmet need better than the standard of care or other emerging approaches? 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. Technical solution

What is your proposed product or method that will solve this problem? What is unique or innovative about it? What tangible components or services will be sold/deployed? How will your product change or improve patient care?

7. Enabling Technology

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? What preliminary data suggests that your technology will work in the way you predict, and be safe and effective? What other technology/components will be required to create your envisioned product?

8. 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, http://drexel.edu/commercialization/drexel-community/process/, to the Office of Technology Commercialization, in order to qualify for pre-proposal 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 4, 2017.

Step 2: Full Proposal Submission Procedure

Deadline: March 17, 2017, Full Proposals due at 5pm

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. Complete details regarding the full proposal will be sent to invited faculty by January 4.

The **Coulter workshop series**, held from 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.

### Step 3: Research Work Plan and Budget

**Deadline: May 8, 2017, Research Plan and Budget due at 5pm.**

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 Friday, April 8, 2016 to faculty who are invited for this step.

#### Post Award

All award recipients, including clinical investigators, will be required to submit quarterly progress reports using the quarterly report form and to meet once monthly with the Coulter Program Director and advisors. 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.

### 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 above mentioned 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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