Coulter-Drexel Translational Research Partnership Program 2024-2025 Request for Proposals

Important Dates

- Monday, December 4, 2023: Pre-proposal due at 5pm through the Drexel's <u>InfoReady</u> <u>Funding Portal</u>. Faculty members are required to meet with Jaya Ghosh (<u>ig3948@drexel.edu</u>), Coulter Program Director, prior to submitting a pre-proposal.
- **Monday**, **January 11**, **2024**: Invitations to faculty to submit Coulter-Drexel Translational Research proposals from selected pre-proposals.
- Late January March 2024: Coulter Workshop, dates TBD. Series of 4-6 workshops, offered virtually in conjunction with the Close School.
- Monday, March 25, 2024: Proposals due at 5pm. Detailed instructions on the content of the proposal will be provided in the invitations sent to faculty in January.
- Thursday, April 11, 2024: 1st Oral Presentation to Oversight Committee, business case review.
- Week of April 15, 2024: Invitations sent to selected faculty to submit research plan and budget.
- Monday, May 13, 2024: Research plan and budget due at 5pm. Further details on submission process will be supplied in the April invitation.
- **Wednesday, May 22, 2024: 2**nd **Oral Presentation** to Oversight Committee, focusing on research plan, killer experiment, and project milestones.
- Week of June 3, 2024: Award announcements.
- July 1, 2024: Funding begins.

Program Description

The mission of the <u>Coulter-Drexel Translational Research Partnership</u> 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 translational 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-Pls). Each proposal must include at least one clinical Co-Pl whose job

responsibilities include direct contact with patients or patient data, 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. 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 of Drexel Applied Innovation in developing a strategy to protect and license that intellectual property.

Questions about faculty eligibility should be referred to Jaya Ghosh, 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 translational research 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 can range from \$75K – \$200K per year. Proposals may be submitted for additional support in subsequent years if the commercialization and research milestones from the first funded 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** and make an **Oral Presentation** in step 2, and a **Research Plan + Budget** and a second **Oral Presentation** in step 3.

Step 1: Pre-proposal Submission Guidelines

Deadline: Monday, December 4, 2023, 5pm, through the InfoReady Funding Portal.

Faculty members are required to meet with Jaya Ghosh, Coulter Program Director, prior to submitting a pre-proposal. To schedule a meeting, please e-mail Jaya @ jg3948@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 pre-proposal. Please do not exceed two pages, 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 Pre-proposal 2024", e.g., "Campbell_Coulter Pre-proposal 2024".

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 currently used to address the problem/unmet need?

Proposed Solution

5. Value Proposition and Competitive Advantage

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

Comment on your intellectual property status, including invention disclosures, patent applications filed, shared IP ownership with others, etc. Please note that while you do not need to have a patent application filed or issues for your idea, you must have submitted an Invention Disclosure Form, to the Office of Applied Innovation 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 by **Monday**, **January 11**, **2024**.

Step 2: Full Proposal, 1st Oral Presentation

Deadline: Monday, March 25, 2024, Full Proposals due at 5pm, 1st Oral Presentation on Thursday, April 11, 2024.

The **Coulter workshop series**, held over 4-6 sessions in late January through early March, is designed to assist faculty in preparing their full proposals. Faculty members are strongly encouraged to participate and bring any other members (including postdocs and students) of the project team – at least one member of the applying team is requested to attend all sessions. Further details about the Coulter Workshop series will be made available in January during the invitation process.

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, reimbursement and legal considerations, and brief overview of the budget required to reach a critical development go/no-go milestone. Oral Presentation template will be provided.

Based on the Oversight Committee's review of the Full Proposal and 1st Oral Presentation, select faculty members will be invited to proceed to the next step in the application process during the **week of April 15, 2024**.

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

Deadline: Monday, May 13, 2024, Research Plan and Budget due at 5pm, 2nd Oral Presentation on Wednesday, May 22, 2024.

Invited faculty members will be asked to prepare a detailed research plan and budget (4 pages total) for final review by the Oversight Committee. Oral Presentation template will also be provided.

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 template. 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, and 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:

To set up a pre-proposal submission meeting, and/or for questions regarding the Coulter-Drexel Translational Research Partnership program, please contact:

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