**Duke MEDx-BME Undergraduate Medical Device Design Request for Applications**

# Project Eligibility

Within scope are electronic or mechanical medical devices, mobile apps, or web services. Out-of-scope projects would be those that require expensive constitutive components, biochemical assays, or wet lab facilities for development. In past years, these projects have led to functional prototypes for testing in the human simulation lab, the generation of intellectual property that has been licensed, and the development of diagnostic/therapeutic platforms that have entered clinical feasibility testing in Institutional Review Board-approved protocols.

# Support

Four-person teams will work on selected projects for at least 2 semesters. A subset of projects will be chosen for further design and prototyping during the summer semester. MEDx and BME will partner to support a budget of approximately $4000 for supplies, prototyping, summer stipends for two design fellows to work on each selected project for ten weeks, and one week of summer design team advising by Dr. Mark Palmeri, a Faculty Advisor for the Duke BME Design Fellows Program.

In order to maximize the number of projects that receive continued development, **if your** **project is selected for continued development during the summer, you are** **highly encouraged to seek matching funds (e.g. from your department) for student stipends**.

# Application Submission

Applications will be accepted on a rolling basis and project sponsors will be notified that their proposals have been accepted at least two weeks before the start of either the fall or spring semester.

Submit your proposal using this [Qualtrics form](https://tinyurl.com/MEDxRFA) or paste the following link into your browser’s address bar: https://tinyurl.com/MEDxRFA.

The application asks for the following information:

* **Contact information**
* **Problem Statement & User Needs**: Details of the clinical problem your team is addressing.
* **Existing Solutions**: Details and shortcomings/barriers of existing products or technologies that strive to solve the problem that you have described.
* **Desired Outcome**: Describe what your ideal outcome would be for this project (e.g. functional prototype; licensing deal etc.).
* **Intellectual Property**: Describe the status of the current IP and IP rights.
* **Clinical Sponsor Engagement Agreement**: Details of your student engagement plan.

If you have design drawings, photographs of prototypes, preliminary data etc., the Qualtrics form allows you to upload them as a single combined document in PDF format. Please name the file in the following format: *Clinician Last Name\_Supplementary\_Project Title.pdf*

# Proposal Review

The proposal will be evaluated for:

* Novelty / impact of clinical problem;
* Feasibility of problem to be solved by a capstone design team, considering student and supervising faculty skill and experience, time and budget; and
* Availability and excitement of clinical Faculty to engage with the student design team.

# Reporting

Students will provide formal design reports to the clinical sponsors several times each semester, culminating in a final design report, presentation of the project at the BME Design Symposium, and transfer of design prototypes to clinical sponsors.

# If you have questions

Contact Donna Crenshaw (donna.crenshaw@duke.edu), Tarun Saxena (tarun.saxena@duke.edu), or Mark Palmeri (mark.palmeri@duke.edu).

# Qualtrics Form for Project Application

# Contact Information

What is your name?

What is your email address?

Which Duke School / clinical department / division / organization are you affiliated with?

Will your School / clinical department / division / organization commit to matching funds if the project is selected for further development in the summer? (A student stipend is $4,250.)

# Problem Statement & User Needs

Please describe in detail the clinical problem your team is addressing.

Who are the stakeholders in this problem? For example, describe the patient population and the users or beneficiaries (patients, nurses, therapists, inpatient / outpatient caretakers, etc.).

# Existing Solutions

Please describe any existing products or technologies that strive to solve the problem that you have described. For each listed item, please also describe what shortcomings or barriers exist for that solution solving the problem.

# Desired Outcome

Please describe what your ideal outcome would be for this project. For example, would you like a functional prototype to support a grant application or for testing in an IRB-approved clinical study, to start a company, develop intellectual property for licensing, etc?

Do you envision the cost of developing this prototype to exceed $4000? If so, please describe why?

# Intellectual Property

Have you submitted any Invention Disclosure Forms (IDFs) or [provisional] patents with Duke Office of Licensing and Ventures that are relevant to this project proposal? If yes, please list any relevant IDF / patent titles and file numbers.

Other than IDFs / patents described above, do you think that there is novel intellectual property (IP) that could be captured in an IDF or provisional patent before engaging with a student team?

Students are not (typically) Duke Employees and therefore retain the rights to any intellectual property they develop during their involvement in a design project. (Read [this](https://olv.duke.edu/faculty-innovators/policiesprocess/) for a complete description of Duke’s IP policies and processes.) We can proactively ask students to assign to Duke their IP rights associated with their engagement in a specific project before the project starts. Would this be of interest to you? If so, please describe why.

Do you expect to take ownership of any final versions of the physical prototypes, software, etc. at the end of the design project?

# Clinical Sponsor Engagement Agreement

On average, how many hours a week will you be able to dedicate to meeting with the students to provide clinical perspective of the problem, design feedback, testing, etc.?  *(Please note that actual week-to-week engagement could vary significantly.)*

Would you be supportive of the design team submitting their work to design competitions at the end of the second semester of the project? (*No content will be publicly disclosed prior to a discussion with all contributors and Duke OLV should any contributor wish to explore filing an IDF and/or a provisional patent application.)*

Are you supportive of highlights of this project (e.g., problem statement, design descriptions, pictures, your name) being used on public-facing Duke websites or Duke MEDx websites / newsletters? (*No content will be publicly disclosed prior to a discussion with all contributors and Duke OLV should any contributor wish to explore filing an IDF and/or a provisional patent application.)*

Please include any other comments / questions that you have.