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MIT Medical Device Design Class 2022 Call for Proposals

Do you have a challenge that needs a new medical device?

Clinicians and corporate sponsors are invited to submit project proposals to work with teams of MIT engineering students to create prototype solutions to address an "I wish I had" need that they experience in their practice. We are actively seeking projects with mechanical and/or electronic challenges, where the problem is defined, but the solution space is open, encompassing monitoring, diagnosis, treatment, research tools, etc.

This capstone course is offered jointly between Mechanical, Electrical Engineering and the Institute for Medical Engineering and Science (IMES) for juniors, seniors and graduate students.

Taught for over a decade and a half, this course is an efficient prototype generation engine and has yielded significant results in the form of new research areas, archival papers, patents, and a few successful startups and products. More importantly, clinicians' careers have grown, collaborations have been established and many well-trained engineers have gone on to great careers in the medical device industry!

From February – May, small teams of students will work with guidance from mentors and the project proposers to follow a fast paced, efficient, 14 weeks design process, culminating in proof-of concept-prototypes. The process begins with developing a detailed understanding of the clinical need and creating a set of design requirements. The team then follows a deterministic process to create strategies, concepts and prototype solutions for testing. Final proof-of-concept prototypes will be presented in December to a clinical and industry audience. The final project report is in the form of a journal article which, ideally, is submitted to a journal or conference and may become the basis for an intellectual property (IP) disclosure.

Particularly successful projects may be invited to continue on into the spring for further development.

Upon the close of this call, course staff will review applications and identify a subset that are suitable for presentation (pitch!) to the class. Students will make the final selections and form teams after the presentations.

Key Dates

Two-page proposal deadline:	January 5, 2022
Submissions will be reviewed on a rolling basis.	
Submission via:	Course Website
Finalists notified:	January 17, 2022
Presentation to students:	February 2 & 7, 2022

Teams will be formed the week after the presentations.

Proposal Guidelines

Your proposal is limited to 2 **pdf** pages, including pictures and references, and must contain:

1. Name, affiliation and contact information (direct phone & e-mail)
2. Background on the current clinical procedure, with pictures, links to videos and references
3. Statement of clinical challenge and its significance
4. Functional requirements of desired solution, but not a description of concepts already conceived
5. Disclosure of any relevant previous work (research notes, publications or patents filed)
6. Specific resources committed to support this proposed project, including financial

We ask that proposers avoid specifying a particular solution that they have conceptualized and, rather, present the problem as clearly as possible. Experience has shown that final solutions are more creative when the team starts with a blank slate and the clinician keeps an open mind.

Projects should require the development of new mechanical and/or electronic hardware. We are not able to support pure software development projects; however, software can be part of the solution.

Each project submission must have **one** clearly defined proposer, practicing in the area of the identified need, who will serve as the project champion and interface each week directly with the students over the semester. (This person can facilitate interaction with other clinicians/personnel and resources as needed.)

We understand that many proposers have numerous ideas, but only **two** applications per proposer, per year will be accepted, so please choose carefully.

Do not hesitate to contact us to discuss shaping your proposal or to seek further guidance.

Finalist Selection Criteria

Proposals are selected for presentation to the students by applying the following criteria:

1. Is there a well-defined need? In the past, the most successful projects began with a clear goal in mind, as opposed to projects that required significant research just to understand the need.)
2. Will the students start with a clean slate? – There should be no obvious pre-existing solutions and, while proposers are encouraged to participate in idea development with teams, they should not have settled upon a particular solution or have an existing device that only needs improvement.
3. Does the problem require the creation of new electronic or mechanical hardware? – The instructors seek to identify that a solution space exists within the realm of mechanical/electrical engineering.
4. Can the solution be accomplished within time and budgetary constraints? – Working from problem to proof-of-concept device should take a student team on average 12-15 hours per week for the 14-week term. Parts, materials and custom fabricated components should not exceed a few thousand dollars.
5. Is the proposer ready to be an active team member? – Proposers must agree to frequent interaction with their teams and engaging in the design process as described in the following section.
6. Does the project seem fun and exciting? – Good design requires passion!

Proposers whose applications are selected as finalists for presentation to the class will be provided with a PowerPoint template to assist in preparing a 10 minute “pitch” to the class, which should include ample time to answer questions. The students will indicate their project preferences and the instructors will make the final selections and form teams consisting of 4 – 5 students. We aim to match students’ interest and expertise with each project’s needs.

Design Process

Once teams are formed they will follow a fast paced efficient 14-week design process consisting of:

1. Understanding the clinical challenge and crafting of mission statement
2. Prior art and literature search to understand current state of the art
3. Creating a set of *functional requirements,* capabilities that the prototype device should enable
4. Individual thought, peer review, then generation of potential strategies to solve the problem
5. Analytical modelling, bench-level prototyping and experimentation to select the strategy
6. Individual thought, peer review, then generation of specific design concepts
7. Detailed mechanical/electronic design, with emphasis placed on the *most critical module* (MCM)

8. Fabrication and testing of the MCM, fabrication of supporting modules
9. Integration, testing, "closing the design loop," i.e. evaluation with respect to hypotheses
10. Presentation and documentation, evaluation of path forward and IP

It is essential that proposers commit to becoming active team members throughout the course. Proposers commit to meeting with students, providing hospital and laboratory access to view procedures, engaging in device testing in an appropriate clinical, laboratory or industry environment and sourcing equipment.

At minimum students need direct engagement with proposers on a bi-weekly basis and proposers are expected to arrange students' access to their facilities promptly.

The fuller the participation by the proposer the more fruitful the experience!

Each student team meets weekly, outside of class, for *design reviews* with course instructors. Teams assess the past week's progress, brainstorm solutions for current design challenges and help identify the crucial tasks for the next week. Course staff serve as mentors and technical advisors. Proposers are welcome (encouraged) to join these meetings and generally enjoy participating in the design process.

Deliverables & Publications

In May teams will demonstrate their final prototype to a clinical and industry audience. Proposers are encouraged to participate in these presentations. Teams will also write a conference-ready paper to which the proposer is expected to contribute substantially and thus be an author. Many papers have been accepted for conference publication and have subsequently fostered ASME, IEEE and clinical publications.

Intellectual Property

Project proposers are required to disclose any preexisting IP related to the project.

IP is sometimes generated in this course and *it is essential that all team members keep bound, signed and witnessed design notebooks to record individual contributions*. The more engaged a project proposer is, the greater the likelihood that he or she will contribute specific claims (features) and be considered an inventor if IP is filed. (US Patent law states that merely framing the problem does not make someone an inventor.)

IP should only be filed when there is a clear path forward for a technology, commercial interest and a committed team. We are guided by the MIT Technology Licensing Office and our TLO officer Bennett Rockney.

Path Forward

All projects will be reviewed at the end of the semester and promising projects may be invited to continue via an independent project, senior thesis or graduate research. The primary focus is to evolve a proof-of-concept into a refined prototype, suitable for journal publication and presentation to investors / acquirers.

While clinicians are not required to provide financial resources for the prototyping in the fall term, further *project funding is not available.* Moving forward from a proof-of-concept is very expensive, thus teams are encouraged to seek further funding and proposers are expected to lead this effort.

Questions?

For proposal questions contact Nevan Hanumara, PhD: hanumara@mit.edu, +1.617.258.8541

The course staff can be contacted at: 2.75-staff@mit.edu

We look forward to receiving your proposals!
Prof. Ellen Roche, Prof. Gio Traverso, Dr. Nevan Hanumara, Anthony Pennes, Prof. Alexander Slocum

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