BMEidea 2019 Guidelines

Please review these carefully prior to submitting.

General Information

Since 2005, the BMEidea competition has recognized innovative biomedical engineering design with high commercial potential and social impact. The competition is open to both graduate and undergraduate students. Strong BMEidea submissions define a problem and demonstrate the development of a device, product, or technology designed to solve it. Examples include but are not limited to: surgical devices, home health care devices, diagnostic, therapeutic, and preventative applications, rehabilitative and assistive technologies, or other innovations that will have a substantial impact on clinical care and patient outcomes.

Multidisciplinary teams are encouraged to apply and may include graduate and undergraduate students from diverse fields such as business, nursing, physical therapy, life sciences, physical sciences, or other related disciplines. Inter-institutional collaborations are also encouraged; in these cases we require a faculty advisor from each institution. **Each team must include at least one engineering student.**

BMEidea awards are presented each year at the MD&M East Medical Device Trade Show and Convention. Competition winners will receive cash awards ($10,000 first place, $5,000 second place, and $2,500 third place) as well as access to resources to be used for further development and commercialization of their products. *Cash prizes will be disbursed to each of the winning team's departments to be allocated at the discretion of the faculty advisor.* In addition, the first place institution will get to display the BMEidea trophy in their winning department for the year.

VentureWell is grateful to our longtime sponsors and partners of the competition: The Lemelson Foundation; MD&DI (Medical Device & Diagnostic Industry), a publication of UBM Americas; the Biomedical Engineering Society (BMES); the National Science Foundation (NSF); and the Council of Chairs of Bioengineering and Biomedical Engineering Programs.

Who is Eligible?

Graduate and undergraduate student teams at colleges and universities are eligible. Each team must include at least one engineering student. Teams are encouraged to incorporate members from diverse fields such as business, law, medicine, dentistry, nursing, physical therapy, life sciences, physical sciences, or other related disciplines. Projects should focus on a new health-related technology, be invented by students, and address a real clinical need. There is a limit of one entry per department and up to three entries per institution, and it is up to each department to coordinate which entries are submitted. Inter-institutional collaborations are also encouraged; we require a faculty advisor from each institution.

How are Entries Evaluated?

BMEidea competition entries will be judged on the following criteria:

1. Technical feasibility
2. Clinical utility
3. Economic feasibility and market potential
4. Novelty and patentability
5. Potential for commercialization

The categories for product designs may include, but are not limited to:

1. Surgical tools and technologies
2. Therapeutic applications
3. Diagnostic applications
4. Rehabilitative and assistive technologies
5. Home healthcare
6. Healthcare information systems/digital health systems

Intellectual Property Policies

VentureWell supports teams as they work toward commercialization of their inventions. Ownership of discoveries or inventions resulting from activities financed by VentureWell grant and/or competition prize funds will be governed by grantee institutions' intellectual property policies. If a school does not have an intellectual property policy, then the institution must develop an agreement that establishes ownership of ideas resulting from student teamwork.

Team members should have rights and access to all intellectual property, subject to the rules of their home institutions, unless assigned to others in exchange for support, sponsorship, or funding. Teams will be encouraged to retain a significant and motivating interest in their project results.

Please read and understand your institution's Intellectual Property policy before submitting an application. VentureWell takes no financial or ownership interest in the projects recognized by these competitions.

Submitting an entry to this competition for recognition of innovative design will necessitate public announcement of project summary, including photos and/or videos, for the 1st, 2nd and 3rd place winners as well as any honorable mention teams. Teams are advised to address intellectual property filings prior to submission and will be given one week from notification of award before the public announcement will be made.

Required Advisors

Your Faculty Advisor and Department Chair must verify their support of your competition application via VentureWell's online tool (verification for Faculty Advisor is waived if she or he is also the applicant).

Faculty Advisor -- A Faculty Advisor must verify his/her support of this competition entry. The Faculty Advisor is the faculty/staff member taking primary responsibility for the project at the institution. Students cannot serve as Faculty Advisors. Should your competition entry be selected as a winner, cash prizes will be disbursed to your team's department to be allocated at the discretion of your Faculty Advisor. Please allow several days for the faculty advisor to respond. The application CANNOT be submitted without his/her support.

Department Chair -- The Department Chair oversees the lead project department (usually the Faculty Advisor's department). This person may be Chair or your institution's equivalent (provost, etc.) Verification of support from this person demonstrates a level of institutional commitment to your project.

To ensure timely approval of your application by your institution, VentureWell recommends notifying your advisors of your intention to submit a competition entry 3-4 weeks in advance of the deadline, and share your application with them prior to submission.

How to Apply

All applications must be submitted online. Anyone on the team may serve as the applicant on a submission. ALL deadlines end at 11:59 pm Eastern Time unless otherwise indicated. To start, you'll need to have a VentureWell account. Creating an account is easy and anyone can do it. To access an existing account or to create a new one, click here. You may start, save, stop and return to your online application at anytime before submitting.

Preparing Your Application: Required and Optional Components Overview

As part of the online application process, you will be prompted to upload the following components into your submission:

- **Required application components combined together in a single PDF**: title page, narrative, letter of support, and key team member resumes. The following naming convention for this PDF is required: "TeamName_University_BMEidea" (be sure to use YOUR OWN information for the fields in orange)

- **Optional appendices combined together in a single PDF** (up to five appendices in total). The following naming convention for this PDF is required: "TeamName_University_BMEideaAppendices" (be sure to use YOUR OWN information for the fields in orange)

- **Required 3-minute video** (weblink) describing your project and demonstrating you have achieved a working prototype. *Optional*: up to 3 additional links may be included (websites, video links, articles, etc.)

Details on each of these components are provided below.

Required Application Components Detail

The following documents are required as part of your BMEidea application and must be included in the following order, combined together in a single PDF:

1. Title page (1 page)
2. Narrative (no more than 10 pages)
3. Letter of support
4. Key team member resumes (limit of three pages per resume)

Title Page (Required): Please create a title page with the following information. Your title page is NOT included in the 10-page limit for your narrative.

- Name of team/name of venture
- University
- List of student team members including name, degree sought, and year of expected graduation for each person

Narrative (Required): The narrative may not exceed 10 pages in length (double-spaced, 12 point font). Please include any images referenced in your narrative in the body of the narrative, NOT as appendices. Please prepare a narrative description that includes the following:

- Executive summary (one page). An outline of the strategy for commercialization and opportunity statement. *See below for additional details*.

- Description of the problem to be solved (one page). What is the problem you have solved? What are the clinical, market and/or industry needs that you intend to address?

- Project objective statement (one page). How does your team intend to address the problem? How does your final design fit into the existing medical/healthcare system and solve the problem?

- Competition and differentiation (1/2 page). What is currently being used to solve the problem and/or what are the anticipated alternate methods that could be in competition with you in the future? Why will people choose your solution over others?

- Documentation of the final design (one page). Be sure to include applicable standards and a risk analysis.

- Prototype of the final design (one page). Paste graphical representations and photographs in the document and provide a link to a video. If the current team was not involved from the beginning, specify what work your team has done vs. what progress has been made by others (other students or other individuals) prior to this current team's involvement.

- Proof that the design is functional and will solve the problem (one page). Include test data, market research, or pre-clinical/clinical trials.

- Results of a patent search and/or search for prior art, assessment and patentability (one page). Two excellent resources for this search are www.uspto.gov and your institution's technology transfer office.

- Describe the anticipated regulatory pathway (510(k) vs. PMA, etc.) (1/2 page). Include information to support your proposed approach. How has the FDA treated analogous devices?

- Reimbursement (1/2 page). Do you expect your device to be reimbursable by Medicare/Medicaid? Why or why not?

- Estimated manufacturing costs (1/2 page). Provide detailed per unit cost breakdown, including volume discount, for components, final assembly, quality assurance, etc.

- Potential market and impact (one page). Who would your customers be (i.e., who will be purchasing the product) and who would the end users be (i.e., who would be using the product)? If possible, quantify the number of potential users and the benefit they would receive from use of the product. Define the potential market size, selling price, and distribution channels. What is the societal and/or economic impact of your solution?

- * *What's in an* **executive summary**? An executive summary summarizes all of the above and serves as a stand-alone justification for why this idea should be pursued. Be sure to address the essentials, including:

  - Problem: What is the problem you aim to solve?
  - Solution: How will you solve it?
  - Competition and differentiation: What are alternate methods of solving the problem or anticipated methods that could be in competition with you in the future? Why will people choose your solution over others?
  - Technical Feasibility: Have you done it and can it be done?
  - Regulatory and Reimbursement: What FDA approvals will be required? What Medicare/Medicaid strategy is needed?
  - Sales and Marketing: What is the estimated size of the market (with rationale)? Who is the buyer/customer/user? Who will they buy it from? At what pricing?
  - **Hint**: Write your full proposal first, then use that information to complete the Executive Summary.

Letter of Support (Required): A letter of support demonstrating that your project is student-led is required. If your project or venture is a continuation of work started by other students and/or faculty before you, the letter should describe the proportion of the design in which your current team has been involved. The letter can be from a faculty advisor, mentor, or industry partner.

Key Team Member Resumes (Required): Resumes should be no more than three pages each, and are required only for key team members.

Required Video

A brief video (up to three minutes) is required. Your video should address the following:

- Technical feasibility: demonstrate that the prototype works or otherwise describe the function of the device.

- Product pitch: make a compelling case that the device is innovative and impactful. State the problem that's being solved, why your device/solution is better than what currently exists, and the impact of your team's solution.

Videos may be uploaded into the proposal via YouTube or another similar web-accessible site. VentureWell reserves the right to use submitted videos for public promotional purposes such as on its website or in promotions for future BMEidea competitions. Videos should *not* contain proprietary information about the innovation. It is the team's responsibility to ensure the video is appropriate for public use.

Optional Application Components

Supporting Documents or Appendices (Optional): Up to five appendices may be included in your application and must be uploaded as one merged PDF. Appendices may include but are not limited to:

1. Additional letter(s) of support: one letter of support is required (see above), but additional letter(s) of support are also welcome. Effective letters of support will demonstrate the strength of the team and/or the quality of the work accomplished. They can be from industry mentors and/or faculty advisors or others who have worked with the team as applicable.
2. Images demonstrating design and/or technical feasibility (drawings, photographs, etc.)
3. A summary of prior art
4. Literature review
5. Any data collected as part of testing your technology
6. Any other relevant supporting materials

Note: Sheer volume of material is not an asset. Reviewers are directed to use supporting materials only to supplement the 10-page narrative. Therefore, key information should be included in the narrative.

Additional Videos and/or Links (Optional): In addition to the appendices mentioned above, teams may upload up to three additional links, which may include online articles, videos and/or other relevant online data.

Application Review Process, Notification and Distribution of Prizes

- Submitted applications are reviewed by external panels of reviewers made up of individuals from academia, industry, nonprofits & NGOs, and venture capital with experience in the technology areas and in the commercialization of early stage innovations.

- VentureWell notifies applicants of the status of their submissions via email within 60 days of the submission deadline.

- All prizes are awarded to the winners' universities and are considered unrestricted gifts for the purpose of research and educational initiatives related to the winning projects. There is no expectation for services rendered and no reporting required. Funds are disbursed to each of the winning teams' departments to be allocated at the discretion of the Faculty Advisor.

Congratulations, you've read the entire guidelines!

If you have any questions, please email or call us (grants@venturewell.org or 413-587-2172).