



## General Information

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) and VentureWell have come together to support and expand DEBUT, a competition that recognizes undergraduate excellence in biomedical design and innovation. DEBUT challenges teams of students in undergraduate biomedical education to solve real world problems in healthcare. Prizes of up to \$20,000 will be awarded, with a total prize purse of \$65,000. Strong DEBUT submissions will demonstrate a mastery of analytical and design skills and capabilities; the ability to manage the product development process; the ability to work effectively in teams; and technical communication skills. Submissions will be judged on the following criteria:

- Significance of the problem being addressed
- Impact of proposed solution on potential users and clinical care
- Innovative design
- Working prototype

Additional prizes will be awarded to entries that also demonstrate:

- Market potential and economic feasibility
- Patentability

In addition, five honorable mentions will be awarded without any cash prizes.

The deadline for submission is **May 31, 2018**. Winners will be announced on **August 24, 2018**.

Winning teams will be honored at an award ceremony during the Annual Meeting of the Biomedical Engineering Society.

All applications must be submitted online and the call for applications is now open. We strongly recommend that you read these guidelines in full before applying.

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## Introduction

In past years, undergraduate student teams have applied separately to NIBIB's DEBUT challenge and to the VentureWell BMEStart competition. In 2016, the two organizations formed a public/private partnership called the DEBUT challenge, allowing student teams to submit one application and giving teams more chances to win a prize in recognition of their technology solution.

NIBIB's goals, specifically, are:

- 1) to provide undergraduate students valuable experiences such as working in teams, identifying unmet clinical needs, and designing, building and debugging solutions for such open-ended problems;
- 2) to generate novel, innovative tools to improve healthcare, consistent with NIBIB's purpose to support research, training, the dissemination of health information, and other programs with respect to biomedical imaging and engineering and associated technologies and modalities with biomedical applications; and
- 3) to highlight and acknowledge the contributions of biomedical engineering to advancing healthcare.

VentureWell's goals for the competition are to challenge undergraduates to learn, practice, and demonstrate their technical, creative, and innovative capabilities by addressing a real clinical need and documenting the promise of

- 1) technical, economic and regulatory feasibility;
- 2) technological innovation; and
- 3) potential for commercialization of the solution described.

Strong DEBUT submissions will define a healthcare 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, technologies for underserved populations and low resource settings, point-of-care systems, precision medicine, or other innovations that will have a substantial impact on clinical care and patient outcomes.

DEBUT is open to undergraduate students only (teams with graduate students on them should consider applying to VentureWell's [BMEidea competition](#)). Students enrolled in senior biomedical engineering capstone design courses are especially encouraged to apply to DEBUT. Multidisciplinary teams are also encouraged to apply and may include 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 bioengineering/biomedical engineering student. See full eligibility requirements for each sponsor under rules of participation for NIBIB and VentureWell prizes.

Team members have rights 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.

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## Competition prizes

Five DEBUT prizes will be awarded. Prize categories and amounts are listed below.

NIBIB-sponsored prizes include:

- First prize: \$20,000
- Second prize: \$15,000
- Third prize: \$10,000

VentureWell-sponsored prizes are made possible with support from The Lemelson Foundation, in partnership with IEEE EMBS, the Biomedical Engineering Society (BMES), and the Council of Chairs of Bioengineering and Biomedical Engineering Programs.

They include:

- Venture prize: \$15,000
- Design Excellence prize: \$5,000

In addition to these prizes, five DEBUT honorable mentions will be awarded. Honorable mention recognition does not include a cash prize.

Applying teams must indicate which prizes they wish to be considered for as part of the application process. Teams may choose to be considered for NIBIB prizes only, VentureWell prizes only, or all prizes. The rules for participation for each sponsor's prizes are outlined below. It is the team's responsibility to check and abide by the rules of any and all prizes for which they wish to be considered.

Each winning team will be awarded one prize only.

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## Rules for participation for NIBIB prizes

- 1) To be eligible to win a prize under this Challenge, an individual must be a member of a “Student Team” as described below, and each individual of a “Student Team”:
  - a) Must be an undergraduate student enrolled full-time in an undergraduate curriculum during at least one full semester (or quarter if the institution is on a quarter system) of the 2017-18 academic year;
  - b) Must form or join a “Student Team” with at least two other individuals for the purpose of developing an entry for submission to this challenge. Each student on the Student Team must satisfy all the requirements for competing in this challenge. While at least one Student on the Team must be from a biomedical engineering or bioengineering department (e.g., majoring in biomedical engineering or bioengineering), interdisciplinary teams including students from other fields are welcome and encouraged;
  - c) Shall be a citizen or permanent resident of the United States. Foreign students who are studying in the United States on a visa are eligible to be part of the competing Student Teams. However, they will not receive a monetary prize if they are part of a winning Student Team. See Prize section below for the distribution of prizes. As acknowledgement of their participation, however, the names of foreign students who are part of winning Student Teams will be listed among the winning team members when results are announced and at the award ceremony.
  - d) Must be a member of only one Student Team;
  - e) Must be 13 years of age or older. Individuals who are younger than 18 must have their parent or legal guardian complete the [Parental Consent Form](#).\*
  - f) Shall have agreed to be registered by the Team Captain (selected by the Student Team) to participate in the Challenge under the rules promulgated by the NIH as listed here;
  - g) Shall have complied with all the requirements set forth here;
  - h) May not be a Federal entity;
  - i) May not be a Federal employee acting within the scope of the employee’s employment and further, in the case of HHS employees, may not work on their submission(s) during assigned duty hours;
  - j) May not be an employee of the NIH, a judge of the challenge, or any other party involved with the design, production, execution, or distribution of the Challenge or the immediate family of such a party (i.e., spouse, parent, stepparent, child, or stepchild); and
  - k) Must acknowledge understanding and acceptance of the DEBUT challenge rules by signing the [NIBIB DEBUT Challenge Certification Form](#).\* Each entry must include one NIBIB DEBUT Challenge Certification Form, completed with: the printed names of Student Team members, an

indication of whether the team member is either a US citizen or permanent resident (as opposed to a foreign student on a visa), and be signed and dated by each individual member of the Student Team. Entries that do not provide a complete Certification Form will be disqualified from the challenge;

\*Forms must contain an actual signature. Handwriting-like fonts are not acceptable substitution. Forms without actual signatures will be considered incomplete and could result in disqualification from the challenge.

- 2) Each entry into this challenge must have been conceived, designed, and implemented by the Student Team without any significant contribution from other individuals.
- 3) Federal grantees may not use Federal funds to develop their Challenge submissions unless use of such funds is consistent with the purpose of their grant award and specifically requested to do so due to the Challenge design.
- 4) Federal contractors may not use Federal funds from a contract to develop their Challenge submissions or to fund efforts in support of their Challenge submission.
- 5) Submissions must not infringe upon any copyright or any other rights of any third party.
- 6) By participating in this Challenge, each individual and entity agrees to assume any and all risks and waive claims against the Federal government and its related entities (as defined in the COMPETES Act), except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from participation in this Challenge, whether the injury, death, damage, or loss arises through negligence or otherwise.
- 7) Based on the subject matter of the Challenge, the type of work that it will possibly require, as well as an analysis of the likelihood of any claims for death, bodily injury, property damage, or loss potentially resulting from Challenge participation, no individual participating in the Challenge is required to obtain liability insurance or demonstrate financial responsibility in order to participate in this Challenge.
- 8) By participating in this Challenge, each individual agrees to indemnify the Federal government against third party claims for damages arising from or related to Challenge activities.
- 9) An individual shall not be deemed ineligible because the individual or entity used Federal facilities or consulted with Federal employees during the Challenge if the facilities and employees are made available to all individuals and entities participating in the Challenge on an equitable basis.
- 10) By participating in this challenge, such individuals grant to NIBIB an irrevocable, paid-up, royalty-free, non exclusive worldwide license to post,

link to, share, and display publicly the entry on the Web, newsletters or pamphlets, and other information products. It is the responsibility of the individuals on the Student Team to obtain any rights necessary to use, disclose, or reproduce any intellectual property owned by third parties and incorporated in the entry for all anticipated uses of the entry.

- 11) NIH reserves the right, in its sole discretion, to (a) cancel, suspend, or modify the Challenge, and/or (b) not award any prizes if no entries are deemed worthy.
- 12) Each individual agrees to follow all applicable federal, state, and local laws, regulations, and policies.
- 13) Each individual participating in this Challenge must comply with all terms and conditions of these rules, and participation in this Challenge constitutes each such participant's full and unconditional agreement to abide by these rules. Winning is contingent upon fulfilling all requirements herein.
- 14) Each Student Team must appoint a "Team Captain" to carry out all correspondence regarding the Student Team's entry. The Team Captain must be a citizen or permanent resident of the United States

## **Rules for participation for VentureWell prizes**

VentureWell sponsors the Venture prize (\$15,000) and the Design Excellence prize (\$5,000). As stated in the Introduction section of these guidelines, in order to be considered for VentureWell prizes teams must meet the following:

- Consist of all undergraduate students (teams that include graduate students are not eligible for DEBUT but should consider applying for the BMEidea competition).
- Include at least one biomedical engineering or bioengineering student.
- Be working on a product that 1) solves a clinical problem; 2) features a novel and practical solution; 3) includes a description of potential intellectual property and how it could be protected; and 4) shows market potential.
- Submit a complete application package, as described in the "preparing your application" section of these guidelines.

VentureWell-sponsored prizes are awarded to each winning team's department, to be allocated at the discretion of the faculty advisor. Prizes are not awarded to individuals or ventures.

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## Intellectual property policies

NIBIB and VentureWell claim no rights to intellectual property. Team members will have the rights to all intellectual property, subject to the rules of their home institutions, unless assigned to others in exchange for support, sponsorship, or funding. NIBIB and VentureWell take no financial or ownership interest in the projects entered into this challenge. However, by checking off the box to be considered for a sponsor's prizes, your team grants to that sponsor (NIBIB and/or VentureWell), an irrevocable, paid-up, royalty-free, non exclusive worldwide license to post, link to, share, and display publicly the challenge entry (application) on the Web, newsletters or pamphlets, and other information products.

Please read and understand your institution's Intellectual Property policy before submitting an application. Teams are advised to address intellectual property filings prior to submission.

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## How to apply

All applications must be submitted online by a "Team Captain." If your team wants to compete for NIBIB prizes, the Team Captain must be a US citizen or permanent resident; if you want to compete for VentureWell prizes only, anyone on the team can be the Team Captain. To start, [click here to go to the application](#). You may start, save, stop, and return to your online proposal at any time before submitting.

Please read the "Preparing your application: required and optional components" section to make sure you correctly prepare the necessary components.

All applications must be submitted by 11:59 pm eastern time on the day of the deadline unless otherwise indicated.

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## Preparing your application: required and optional components

As part of the online application process, you will be prompted to upload the following components into your submission. Applications not containing all of these components will be considered incomplete and ineligible.

### Required Application Components

- 1) A single PDF file containing:
  - o [NIBIB DEBUT Certification Form](#)\* (you can omit this form if you do not wish to be considered for NIBIB prizes)

- [DEBUT Parental Consent Form](#)\* for any students under the age of 18 (you can omit this form if you do not wish to be considered for NIBIB prizes)
- Project narrative (see below for details)
- Faculty letter(s)

We strongly encourage the following naming convention for this PDF:

“TeamName\_University\_DEBUT” (be sure to use YOUR OWN information for the fields in blue).

- 2) A link to a 3-minute video describing your project and demonstrating you have achieved a working prototype (see below for details).

### **Optional application components:**

You may choose to include the following additional material to aid the judges’ evaluation of your project. However, the judges will mainly review the required components of your application and may consider the optional material at their discretion.

- 1) Optional supporting documents combined together in a single PDF (up to three total):
  - Support letters from stakeholders (patients, healthcare providers, industry, etc.)
  - Supporting articles, reports, etc. that present background information for your project

We strongly encourage the following naming convention for this PDF:

“TeamName\_University\_DEBUT\_Appendices” (be sure to use YOUR OWN information for the fields in blue).

- 2) Optional videos and/or weblinks up to three links can be included (websites, video links, articles, etc.).

Details on each component are provided below in these guidelines.

### **Instructions for preparing the required application components**

Please prepare the following required documents, combined together in a single PDF in the following order:

- 1) **DEBUT Certification Form**  
[Click here to download the NIBIB DEBUT Certification Form](#).\* Please fill out the requested information about the project and for each team member. Note that the form needs to be signed by all team members; leave yourself enough time to obtain all signatures. If you wish to compete only for



VentureWell prizes, and not NIBIB prizes (1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup> place prizes), you may omit this form.

2) **Parental/Legal Guardian Consent Form (for any team member under 18 years of age)**

For any/all team members under 18 years of age, the Parent/Legal Guardian Consent Form must be completed and included after the Certification Form. [Click here to download the DEBUT Parental Consent Form\\*](#). If you wish to compete only for VentureWell prizes, and not NIBIB prizes (1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup> place prizes), you may omit this form.

\*Forms must contain an actual signature. Handwriting-like fonts are not acceptable substitution. Forms without actual signatures will be considered incomplete and could result in disqualification from the challenge.

3) **Project narrative description and guidelines**

The narrative must adhere to the page limits specified below (using Arial and a font size of at least 11 points). Please include any images referenced in your narrative in the body of the narrative, NOT as appendices.

Recommended lengths for each section are included as a guide, but the total narrative must abide by the appropriate page limit below:

- Teams wishing to be considered for NIBIB prizes only: address sections 1-6 in your narrative description. Page limit: 6 pages.
- Teams wishing to be considered for VentureWell prizes (alone or in addition to the NIBIB-prizes): address all sections. Page limit: 10 pages.

The project narrative/description includes the following sections:

- 1) **Abstract** (no more than 250 words). Brief description of the problem and addressed and the solution achieved.
- 2) **Description of the problem** (1/2 page). What is the problem you have solved? What is the clinical problem or the health and/or market need that you addressed?
- 3) **Project objective statement** (1/2 page). How has your team addressed the problem? What is innovative about your approach? How does your final design solve the problem? What were the specs for your device? Note: If your entry is part of a bigger project that was started by others (other students, advisor, etc.), please clarify your specific contribution, i.e., what your team has accomplished vs. what progress had been made by others prior to your involvement.
- 4) **Documentation of the design** (1 ½ pages). Provide sufficient detail and highlight innovative aspects of your design.
- 5) **Prototype of the final design** (1 ½ pages). Include graphical representations and photographs in the document and, if available, provide a link to a video.

- 6) **Proof that the design is functional and will solve the problem** (1 ½ pages). Describe how you verified that your design reached its objectives. Include evidence such as test data, graphs, video, or comparisons to existing device outputs. How does your solution compare to other solutions/devices currently available?
- 7) **Results of a patent search and/or search for prior art, assessment and patentability** (1 page). Two excellent resources for this search are [www.uspto.gov](http://www.uspto.gov), and your institution's technology transfer office. Regarding marketplace competition, 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?
- 8) **Anticipated regulatory pathway** (510(k) vs. PMA, etc.) (1/2 page). Consider researching how the FDA has treated analogous devices.
- 9) **Reimbursement** (1/2 page). Do you expect your device to be reimbursable by Medicare/Medicaid? Why or why not?
- 10) **Estimated manufacturing costs** (1 page). Provide detailed per unit cost breakdown, including volume discount, for components, final assembly, quality assurance, etc.
- 11) **Potential market and impact** (1 page). Define the potential market size, selling price, and distribution channels. 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 potential impact the product could have (# of people who would benefit from use, etc.)

#### 4) **Letter of support from faculty member**

A letter of support is required from a faculty member from the Biomedical Engineering, Bioengineering, or similar department of the institution in which the student team members are enrolled. This letter must be written on departmental letterhead and verify the following:

- That the entry was achieved by the named Student Team. The letter must describe clearly any contribution from the advisor or any other individual outside the Student Team. Especially when the submitted entry is part of a bigger/ongoing project, the specific components designed and implemented by the competing Student Team must be clarified and distinguished from those accomplished by others.
- That each member of the team was enrolled full-time in an undergraduate curriculum during at least one semester or quarter of the current academic year.

In cases where students from multiple institutions work on a project as a multi-institutional team, we require a faculty sponsor letter from each institution.

Please combine the above 4 items into a single PDF file named "TeamName\_University\_DEBUT" (be sure to use YOUR OWN information for the fields in blue). You will upload this file during the online application submission.

### 5) **Required video**

A brief video (up to three minutes) describing your project and demonstrating you have achieved a working prototype is required.

In the video:

- Provide a brief introduction and background about the healthcare problem or unmet need that you chose to address, focusing on the technical aspects of your device;
- Describe the concept that your solution is based on, emphasizing its innovative aspects;
- Demonstrate that the prototype works and achieves its aims;
- Describe the operation of the device and its unique functions
- Make a compelling case that your device will have a significant impact on the problem you chose to address.

The content and the quality of the video are both important. Make sure that the audio is free from background noise and the volume is high enough throughout the video to be easily heard. If you have multiple speakers, make sure they can all be heard comfortably at the same volume level. Refrain from using background music that overpowers the narration. The device you present in the video must match the description in your written application and must not be an earlier version. The video is your chance to impress and engage the reviewers and to make them want to read the details of your application carefully. In addition, the video may be used for PR purposes by the sponsor for whose prizes you wish to be considered, and will be a lasting summary of your design accomplishment. Videos should not contain proprietary information about the innovation. It is the team's responsibility to ensure the video is appropriate for public use.

You will submit the link to this video (via YouTube or a similar web-accessible site) on the online form to submit your final application.

## **Instructions for preparing the optional application components**

### **Optional appendices**

Up to three optional appendices may be included in your proposal and must be uploaded as one merged PDF. Appendices may include:

- Additional letter(s) of support: one letter of support from a faculty sponsor is required (see above), but additional letter(s) of support are also encouraged. Effective letters of support will demonstrate the strength of the work accomplished. They can be from individuals who may benefit from your device, such as clinician who may use it in their practice, patients who may use your device, or industry representatives that can highlight the market need for your innovation.
- A summary of prior art
- Literature review
- Any data collected as part of testing your technology
- 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 required narrative. Therefore, key information should be included in the narrative.

The following naming convention should be used for this PDF: "TeamName\_University\_DEBUT\_Appendices" (be sure to use YOUR OWN information for the fields in blue). You will upload this file during the online application submission if you choose to include optional material,

### **Optional videos**

Up to three optional links to videos and/or websites up to three links may be included. These links can refer to online articles, videos and/or other relevant online data.

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## **Proposal review process and notification**

NIBIB prizes will be judged by a panel of NIH staff. This panel may take into consideration the preliminary technical assessment provided by external experts in the field. The final winner selections will be approved by the Director of NIBIB.

NIBIB prizes will be judged based on the following criteria:

- Significance of the problem addressed—Does the entry address an important problem or a critical barrier to progress in clinical care or research?
- Impact on potential users and clinical care—How likely is it that the entry will exert a sustained, powerful influence on the problem and medical field addressed?

- Innovative design (creativity and originality of concept)—Does the entry utilize novel theoretical concepts, approaches or methodologies, or instrumentation?
- Working prototype that implements the design concept and produces targeted results—Has evidence been provided (in the form of results, graphs, photographs, films, etc.) that a working prototype has been achieved?

VentureWell prizes 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.

In addition to the four criteria above, VentureWell prizes will take into consideration:

- Market potential and economic feasibility
- Patentability

The winners will be announced on the VentureWell and NIBIB websites, in direct emails and social media on **August 24, 2018**.

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If you have any questions, please contact us at [grants@venturewell.org](mailto:grants@venturewell.org) or call 413-587-2172.

Contact Zeynep Erim ([Zeynep.Erim@nih.gov](mailto:Zeynep.Erim@nih.gov)) with questions specifically related to NIBIB prizes.