

Dated: January 18, 2013.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement of Requirements and Registration for the 2013 NIBIB Design by Biomedical Undergraduate Teams (DEBUT) Challenge

Authority: 15 U.S.C. 3719.

SUMMARY: The National Institute of Biomedical Imaging and Bioengineering (NIBIB) DEBUT Challenge is open to teams of undergraduate students working on projects that develop innovative solutions to unmet health and clinical problems. NIBIB's mission is to improve health by leading the development and accelerating the application of biomedical technologies. The goals of the challenge 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 health care, 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 and accomplishments of undergraduate students.

DATES: The competition begins January 25, 2013.

Submission Period: January 28, 2013, to June 6, 2013, 11:59 p.m. EST.

Judging Period: June 10, 2013, to July 25, 2013.

Winners announced: August 12, 2013.

Award ceremony: September 2013, Biomedical Engineering Society Conference (exact date to be announced at <http://debut2013.challenge.gov/>).

FOR FURTHER INFORMATION CONTACT: info@nibib.nih.gov or (301) 451-4792.

SUPPLEMENTARY INFORMATION:

Subject of Challenge Competition: The NIBIB DEBUT Challenge solicits entries that develop innovative solutions to unmet health and clinical problems under one of the following categories:

- Diagnostic Devices/Methods
- Therapeutic Devices/Methods
- Technology to Aid Underserved Populations and Individuals with Disabilities.

Eligibility Rules for Participating in the Competition:

1. To be eligible to win a prize under this challenge, each individual on the Student Team must

(a) Be a citizen or permanent resident of the United States;

(b) Be an undergraduate student enrolled full-time in an undergraduate curriculum during the academic year 2012-2013;

(c) Have his/her own active Challenge.gov account that he/she has created at www.challenge.gov;

(d) Form or join a "Student Team" with at least two other individuals who satisfy the criteria in (a), (b), and (c) above for the purpose of developing an entry for submission to this challenge. While it is expected that most of the individuals participating in the competition may be students from biomedical engineering departments, interdisciplinary teams including students from other fields are welcome and encouraged;

(e) Acknowledge understanding and acceptance of the DEBUT challenge rules by signing the NIBIB DEBUT Challenge Certification Form found at http://www.nibib.nih.gov/Training/Undergrad_Grad/DEBUT/NIBIB_DEBUT_Certification_Form.pdf. Each entry must include one NIBIB DEBUT Challenge Certification Form, completed with dates and the printed names and signatures of each individual member of the Student Team. Entries that do not provide a complete Certification Form will be disqualified from the challenge;

(f) Comply with all the requirements under this section; and

(g) Not be a federal employee acting within the scope of his/her employment. Federal employees seeking to participate in this challenge outside the scope of their employment should consult their ethics official prior to developing a submission.

2. By participating in this challenge, each individual agrees to abide by all rules of this challenge and the *Challenge.gov Terms of Participation* (<http://challenge.gov/terms>).

3. Each entry into this challenge must have been conceived, designed, and implemented by the Student Team. Student Teams participating in capstone design projects are especially encouraged to enter the challenge.

4. Each Student Team may submit only one entry into this challenge through one member of the Student

Team appointed as "Corresponding Student" by that Student Team. The Corresponding Student will carry out all correspondence regarding the Student Team's entry.

5. The Corresponding Student will submit a Student Team's entry on behalf of the Student Team by following the links and instructions at <http://debut2013.challenge.gov/> and certify that the entry meets all the challenge rules.

6. Each entry into this challenge must describe an original biomedical engineering project that falls into one of the following 3 categories:

(a) Diagnostic Devices/Methods e.g., sensors, imaging devices, imaging agents, telehealth, clinical laboratory diagnostics

(b) Therapeutic Devices/Methods e.g., implants, biomaterials, surgical tools, tissue engineering, drug and gene delivery

(c) Technology to Aid Underserved Populations and Individuals with Disabilities e.g., point-of-care technologies, devices/methods to address health disparities, m-health, aids for individuals with disabilities (see <http://www.ada.gov/pubs/adastatute08.htm#12102> for a definition of "disability").

The examples under the different categories above are provided for illustration but not limitation. It is possible for an entry to fit into more than one category. In such instances, Student Teams should choose the category to which the entry is most closely related.

7. Each entry must comply with Section 508 standards that require federal agencies' electronic and information technology be accessible to people with disabilities, <http://www.section508.gov/>.

8. Each individual on the Student Team 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 found at http://cphome.s3.amazonaws.com/forms/parental_consent_form.pdf.

9. Each entry must be submitted as a single pdf file and must include the following:

- Cover letter, on department letterhead, from a faculty member from the Biomedical Engineering, Bioengineering or similar department of the institution in which the Student Team members are enrolled, verifying that the entry was achieved by the named Student Team that is enrolled full-time in an undergraduate curriculum during the academic year 2012-2013, and describing clearly any contribution from the advisor or any

other individual outside the Student Team;

- The NIBIB DEBUT Challenge Certification Form (downloadable from http://www.nibib.nih.gov/Training/Undergrad_Grad/DEBUT/NIBIB_DEBUT_Certification_Form.pdf) completed with dates and the printed names and signatures of each individual member of the Student Team;

- Completed Cover Page (downloadable from http://www.nibib.nih.gov/Training/Undergrad_Grad/DEBUT/NIBIB_DEBUT_Cover_Page.doc listing project title, team member information, and challenge category the entry is submitted under;

- Project Description (not to exceed 6 pages using Arial font and a font size of at least 11 points) that includes the following 4 sections:

- (1) Abstract

- (2) Description of clinical need or problem, including background and current methods available

- (3) Design, including a discussion of the innovative aspects

- (4) Evidence of a working prototype (results/graphics obtained with the designed solution)

The 6-page limit includes any graphics, but excludes the cover page and any references. Submissions exceeding 6 pages for the project description will not be accepted. An optional 2-minute video displaying the operation of the device/method may be included. However the 6-page Project Description must be a stand-alone explanation of the project; and

- A completed Parental Consent Form, accessible at http://cphome.s3.amazonaws.com/forms/parental_consent_form.pdf, for each individual on the Student Team who is under the age of 18.

10. NIBIB will claim no rights to intellectual property. Individuals on the Student Team will retain intellectual property ownership as applicable arising from their entry. By participating in this challenge, such individuals grant to NIBIB an irrevocable, paid-up, royalty-free, nonexclusive worldwide license to post, link to, share, and display publicly the entry on the Web, in newsletters or pamphlets, and in 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. All entries must be submitted by the challenge deadline, June 6, 2013, 11:59 p.m. EST.

12. Entries must not infringe upon any copyright or any other rights of any third party.

13. By participating in this challenge, each individual agrees to assume any and all risks and waive claims against the federal government and its related entities, 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 prize challenge, whether the injury, death, damage, or loss arises through negligence or otherwise.

14. 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, individuals are not required to obtain liability insurance or demonstrate financial responsibility in order to participate in this challenge.

15. 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.

16. An individual shall not be deemed ineligible because the individual used federal facilities or consulted with federal employees during this challenge if the facilities and employees are made available to all individuals participating in the challenge on an equitable basis.

Prize: One winning Student Team will be selected for each of the three challenge categories. The winning Student Team in each category will be awarded a \$10,000 prize, to be distributed among the members of the Student Team. The prize will be distributed equally among the Student Team. Each member of the winning Student Teams must provide his/her bank information to enable electronic transfer of funds. Two honorable mentions will also be awarded in each challenge category, without any accompanying monetary prize or travel reimbursement.

Winning Student Teams will be honored at the NIBIB DEBUT Award Ceremony during the 2013 Annual Meeting of the Biomedical Engineering Society (BMES) in Seattle, Washington, in September 2013. Updated information on the BMES annual meeting can be found at <http://bmes.org/annualmeeting>. Each winning Student Team will receive, in addition to the prize, up to \$2,000 toward the travel and registration costs for the members of the Student Team to attend the award ceremony. Travel must comply with National Institutes of

Health policy and applicable laws and regulations (<http://oma.od.nih.gov/manualchapters/management/1500/>), for example:

- Air travel must be by coach class, unless an alternative is medically necessary and documented.
- If you choose to drive to the meeting instead of taking a common carrier (airplane, train or bus), you may be reimbursed at 51 cents per mile, not to exceed the cost of common carrier.
- Limousine/taxi reimbursements are provided to and from airports as well as to and from meetings. Receipts are required whenever a fare exceeds \$75 per trip.
- Per diem rates include lodging, meals, and incidental expenses (M&IE). Reimbursement for these varies by city. The current allowable room rate and the M&IE for the award ceremony location can be found at <http://www.gsa.gov/portal/category/21287>.

Honorable mention awardees are welcome to attend the award ceremony with funds from other sources; NIBIB will not provide travel reimbursement for Student Teams awarded with Honorable Mention.

Basis Upon Which Winner Will Be Selected: The winning entry in each category of the challenge will be selected 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?

The above four criteria will be weighed equally and will apply to all challenge categories. **Additional Information:** For more information and to submit entries, visit <http://debut2013.challenge.gov/>.

The NIBIB prize-approving official will be the Director of NIBIB. Prizes will be paid using electronic funds transfer and may be subject to federal income taxes. NIH will comply with the Internal Revenue Service (IRS) withholding and reporting requirements, where applicable.

Dated: January 17, 2013.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention; Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given that the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention (CSAP) Drug Testing Advisory Board (DTAB) will meet on February 11, 2013, from 10:30 a.m. to 4:30 p.m. and February 12, 2013, from 9:00 a.m. to 2:00 p.m. E.S.T. The DTAB will convene in both open and closed sessions over these two days.

On February 11, 2013, from 10:30 a.m. to 4:30 p.m., the meeting will be open to the public and will include updates on the proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs, the custody and control form, and the medical review officer certification. The meeting also will include federal drug testing updates from the Department of Transportation, the Department of Defense, the Nuclear Regulatory Commission, and the Federal Drug-Free Workplace Programs.

The public is invited to attend the open session in person or to listen via teleconference. Due to the limited seating space and call-in capacity, registration is requested. Public comments are welcome. To register, make arrangements to attend, obtain the teleconference call-in numbers and access codes, submit written or brief oral comments, or request special accommodations for persons with disabilities, please register at the SAMHSA Advisory Committee's Web site at <http://nac.samhsa.gov/Registration/meetingsRegistration.aspx> or contact the CSAP DTAB Designated Federal Official, Dr. Janine Denis Cook (see contact information below).

On February 12, 2013, between 9:00 a.m. and 2:00 p.m., the Board will meet in closed session to discuss proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs. Therefore, this portion of the meeting is closed to the public as determined by the Administrator, SAMHSA, in accordance with 5 U.S.C.

552b(c)(9)(B) and 5 U.S.C. App. 2, Section 10(d).

Meeting information and a roster of DTAB members may be obtained by accessing the SAMHSA Advisory Committee's Web site, <http://www.nac.samhsa.gov/DTAB/meetings.aspx>, or by contacting Dr. Cook.

Committee Name: Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Prevention, Drug Testing Advisory Board.

Dates/Time/Type: February 11, 2013, from 10:30 a.m. to 4:30 p.m. E.S.T.: Open; February 12, 2013, from 9:00 a.m. to 2:00 p.m. E.S.T.: Closed.

Place: Sugarloaf Conference Room, SAMHSA Office Building, 1 Choke Cherry Road, Rockville, Maryland 20857.

Contact: Janine Denis Cook, Ph.D., Designated Federal Official, CSAP Drug Testing Advisory Board, 1 Choke Cherry Road, Room 7-1043, Rockville, Maryland 20857, Telephone: 240-276-2600, Fax: 240-276-2610, Email: janine.cook@samhsa.hhs.gov.

Janine Denis Cook,

Designated Federal Official, DTAB, Division of Workplace Programs, Center for Substance Abuse Prevention, Substance Abuse and Mental Health Services Administration.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2012-1091]

Availability of Draft Environmental Assessment for the Proposed Modification of the Bayonne Bridge Across the Kill Van Kull Between Bayonne, Hudson County, NJ and Staten Island, Richmond County, NY

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability extending comment period and notice of third public meeting.

SUMMARY: This notice extends the public comment period on a Draft Environmental Assessment (Draft EA) which examines the reasonably foreseeable environmental impacts and socio-economic impacts of the proposed modification of the historic Bayonne Bridge across the Kill Van Kull between Bayonne, New Jersey and Staten Island, New York. This notice also announces a third public meeting, in Newark, NJ, on this Draft EA. Because the Bayonne Bridge is a structure over navigable waters of the United States, the proposed bridge modification would require a Coast Guard Bridge Permit

Amendment. This notice provides information on how to participate in the public comment process for the Draft EA, which includes an opportunity to submit oral or written comments at three public meetings to consider an application by the Port Authority of New York & New Jersey (PANYNJ) for Coast Guard approval of the modification to the Bayonne Bridge across the Kill Van Kull.

DATES: Written comments and related material may be submitted to our online docket via <http://www.regulations.gov> on or before March 5, 2013, or must reach the Docket Management Facility by that date.

The public meetings will be held on February 5, 2013, in Bayonne, NJ, February 7, 2013, in Staten Island, NY, and February 13, 2013, in Newark, NJ (see the Background and Purpose section below for more details). As previously noted for the first two meetings, any requests for an oral or sign language interpreter must be received by January 25, 2013. Such requests for the February 13, 2013 meeting in Newark, NJ, must be received by February 1, 2013.

ADDRESSES: You may submit comments identified by docket number USCG-2012-1091 using any one of the following methods:

(1) *Federal eRulemaking Portal:* <http://www.regulations.gov>.

(2) *Fax:* 202-493-2251.

(3) *Mail:* Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

To avoid duplication, please use only one of these four methods. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

We have provided a copy of the Draft EA (document USCG-2012-1091-0002) in our online docket at <http://www.regulations.gov>. Also, the Coast Guard First District Bridge Office at 1 South Street Bldg 1, New York, NY 10004-1466 will maintain a printed copy of the Draft EA for public review. The document will be available for inspection at this location between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays. The document will also be available for