

www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list.)

Streaming Webcast of the Public Workshop: The morning session but not the afternoon session of this public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by 5 p.m. EDT, March 14, 2014. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after March 24, 2014. If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit http://www.adobe.com/go/connectpro_overview. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcript will also be available approximately 45 days after the public workshop on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.)

SUPPLEMENTARY INFORMATION:

I. Background

Cataract surgery is the most commonly performed elective procedure in the United States with over 3 million patients being implanted with an IOL. Over the past two decades, IOLs have undergone significant design changes allowing them to correct for a spectrum of visual distances and refractive errors. As IOL technology evolves, some endpoints for the evaluation of the technology are also evolving. Endpoints and strategies for assessing the relative safety and

effectiveness of these innovative lens designs are in various stages of development. At this workshop, not only will some of these novel endpoints and the challenges with assessments of these endpoints be identified, but these endpoints also will be prioritized for further discussion, development, and validation. Breakout sessions following the didactic portion of the workshop will allow for more in-depth group discussions of potential approaches to address these challenges.

The workshop seeks to involve industry and academia in addressing the challenges in the development of novel endpoints for premium IOLs. By bringing together all of the relevant stakeholders, which include clinicians, researchers, industry representatives, and regulators, to this workshop, we hope to facilitate the improvement of regulatory science in this rapidly evolving product area.

FDA and AAO recognize the unique opportunity this workshop provides for all stakeholders of the ophthalmic device community and that the knowledge and education provided from this workshop will further strengthen our mission of protecting the public health.

II. Topics for Discussion at the Public Workshop

Topics to be discussed at the public workshop include, but are not limited to:

- Safety assessments for premium IOLs and how they could differ from those for monofocal IOLs.
- Patient-Reported Outcome (PRO) measures and the need to develop and validate them for assessing the safety and effectiveness of premium IOLs.
- Objective assessments of accommodation and their challenges.
- Subjective assessments of accommodation and Extended Depth of Focus (EDF) and their challenges.

These topics will be presented by experts in the associated area and the afternoon will allow for more in-depth discussions of the given topics in small breakout sessions.

Dated: December 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Statement of Delegation of Authority

Notice is hereby given that I have delegated to the Inspector General, Office of Inspector General, the authority vested in the Secretary of Health and Human Services under section 1116(e)(1) of the Social Security Act (42 U.S.C. 1316(e)(1)) to conduct reconsiderations of disallowances of any item or class of items for which Federal financial participation is claimed under section 1903 of the Social Security Act (42 U.S.C. 1396b) for the establishment or operation of a Medicaid Fraud Control Unit. This authority may be redelegated to the Principal Deputy Inspector General. This delegation excludes the authority to issue regulations.

This delegation is effective upon date of signature.

Dated: December 12, 2013.

Kathleen Sebelius,

Secretary.

[FR Doc. 2013-30160 Filed 12-18-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering (NIBIB) Announcement of Requirements and Registration for the 2014 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 DEBUT 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 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 and accomplishments of undergraduate students.

DATES: The competition begins December 19, 2013.

Submission Period: January 27, 2014 to May 29, 2014, 11:59 p.m. EDT.

Judging Period: June 10, 2014 to July 25, 2014

Winners announced: August 12, 2014

Award ceremony: October 2014, Biomedical Engineering Society Conference (exact date to be announced at <http://www.nibib.nih.gov/training-careers/undergraduate-graduate/design-biomedical-undergraduate-teams-debut-challenge>.)

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

SUPPLEMENTARY INFORMATION:

Subject of Challenge Competition: The NIBIB DEBUT Challenge solicits design projects that develop innovative solutions to unmet health and clinical problems. Areas of interest for the biomedical engineering projects include, but are not limited to: diagnostics, therapeutics, technologies for underserved populations and low resource settings, point-of-care systems, precision medicine, preventive medicine, and technologies to aid individuals with disabilities.

Rules

1. Who can win: To be eligible to win a prize under this challenge, an individual on the Student Team must

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

(b) Meet all the conditions below for eligibility to compete under this challenge.

2. Who can compete: This is a team challenge. To be eligible to compete in this challenge, an individual must:

(a) 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 2013–2014 academic year;

(b) Have his/her own active Department of Better Technology (DOBT) account that he/she has created at https://dashboard.dobt.co/sign_in.

(c) 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 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;

(d) Acknowledge understanding and acceptance of the DEBUT challenge rules by signing the *NIBIB DEBUT Challenge Certification Form* found at <https://www.nibib.nih.gov/sites/default/files/NIBIB%20DEBUT%20Certification%20Form.pdf>. 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;

(e) Be 13 years of age or older.

(f) Not be a Federal employee acting within the scope of their 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; and

(g) Comply with all the requirements under this section (Section 2).

3. 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 or be reimbursed for costs associated with participation in the award ceremony 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.

4. By participating in this challenge, each individual agrees to abide by all rules of this challenge and the *Terms of Participation* located at https://contests.dobt.co/terms_of_participation.

5. 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.

6. Each Student Team may submit only one entry into this challenge through one member of the Student Team appointed as “Team Captain” by that Student Team. The Team Captain will carry out all correspondence regarding the Student Team’s entry. The

Team Captain must be a citizen or permanent resident of the United States.

7. The Team Captain will submit a Student Team’s entry on behalf of the Student Team by following the links and instructions at <https://contests.dobt.co/debut2014/> and certify that the entry meets all the challenge rules.

8. 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/>.

9. Individuals who are younger than 18 must have their parent or legal guardian complete the *Parental Consent Form* found at <https://www.nibib.nih.gov/sites/default/files/Parental%20Consent%20Form.pdf>.

10. 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 each member of the team was enrolled full-time in an undergraduate curriculum during at least one semester or quarter of the academic year 2013–2014, and describing clearly any contribution from the advisor or any other individual outside the Student Team.

- The *NIBIB DEBUT Challenge Certification Form* (downloadable from <https://www.nibib.nih.gov/sites/default/files/NIBIB%20DEBUT%20Certification%20Form.pdf> completed with the printed names, indication of U.S. citizenship or permanent residency, dates, and signatures of each individual member of the Student Team.

- Completed *Cover Page* (downloadable from <https://www.nibib.nih.gov/sites/default/files/NIBIB%20DEBUT%20Cover%20Page.pdf> listing project title and team member information.

- 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, certification form, parental consent form, 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.

- A completed *Parental Consent Form*, accessible at <https://www.nibib.nih.gov/sites/default/files/Parental%20Consent%20Form.pdf>, for each individual on the Student Team who is under the age of 18.

11. 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, 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.

12. All entries must be submitted by the challenge deadline, May 29, 2014, 11:59 p.m. EDT. 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, or 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.

17. NIBIB reserves the right to cancel, suspend, modify the challenge, and/or not award a prize if no entries are deemed worthy.

Prize: The 1st, 2nd, and 3rd place prizes will be \$20,000, \$15,000, and \$10,000, respectively, to be distributed only among the members of the winning Student Team eligible to win a prize in this challenge. The prize will be distributed equally among the prize-eligible Student Team members, i.e., students who are either citizens or permanent residents of the United States. Each prize-eligible member of the winning Student Teams must provide his/her bank information to enable electronic transfer of funds. Six honorable mentions will also be awarded, without an accompanying monetary prize or travel reimbursement.

Winning Student Teams will be honored at the NIBIB DEBUT Award Ceremony during the 2014 Annual Meeting of the Biomedical Engineering Society (BMES) in San Antonio, Texas in October 2014. 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 prize-eligible members of the Student Team to attend the award ceremony. While members of a winning Student Team who are neither citizens nor permanent residents of the United States are welcome to attend the award ceremony and their names will be listed among the winners, they cannot be reimbursed for their travel and related expenses.

Travel must comply with National Institutes of Health policy and applicable laws and regulations (<http://www.gsa.gov/portal/content/104790>) 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, and 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 entries 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?

Additional Information: For more information and to submit entries, visit <https://contests.dobt.co/debut2014/>.

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: December 13, 2013.

Belinda Seto,

Deputy Director, National Institute of Biomedical Imaging and Bioengineering.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Literature Selection Technical Review Committee.