Process for Registration and Submitting an Entry

To register for this Challenge, Solvers must access the *www.challenge.gov* Web site and search for ''*Propose New Ideas For Prescription Drugs Oral Overdose Protection.*'' A registration link for the Challenge can be found on the landing page under this Challenge description.

Amount of the Prize

Up to three prizes worth a total of $15,000 ($5,000 each) will be awarded to submission(s) that satisfy all the Challenge criteria (below) and receive the highest cumulative scores.

Payment of the Prize

Prizes awarded under this Challenge will be paid by electronic funds transfer and may be subject to Federal income taxes. HHS will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

Basis Upon Which the Winner Will Be Selected

This Challenge is formulated to elicit new ideas, similar to a global brainstorm for producing a breakthrough. Submissions will be received and reviewed by the judging panel comprised of the experts in the area of prescription drug abuse research and pain management. The judging panel will evaluate each submission based on the following equally-weighted criteria:

1. Scientific foundation for the proposed idea, e.g. well-founded line of thought that is supported by the scientific literature or otherwise found to be accurate;
2. Idea novelty and originality;
3. Potential for development, including whether the submission will or is likely to:
(1) Preserve the original drug efficacy;
(2) Avoid new safety issues for the intended population of pain patients;
(3) Avoid harming a potential abuser;
(4) Be suitable for further research development and be commercially viable.

Scores from each criterion will be weighted equally for a maximum score of 120 (40 points each). Entry Materials from all submissions will be held until after the deadline is reached for a simultaneous review process. The evaluation process will begin by de-identifying the submissions and removing those that are not responsive to this Challenge or not in compliance with all rules of eligibility. NIDA reserves the right to disqualify and remove any submission which is deemed, in the judging panel's discretion, inappropriate, offensive, defamatory, or demeaning. Judges will examine all submissions in accordance with the criteria outlined above and meet to discuss all responsive submissions. Final ranking and recommendations will be determined by a vote.

Additional Information

Submission Rights

Solvers must agree that their submission is their original work, and that all proposed ideas must be the Solver's original effort. The Entry Materials must not violate or infringe the rights of other parties, including, but not limited to privacy, publicity, or intellectual property rights, or material that constitutes copyright or license infringement.

Intellectual Property (IP)

NIDA does not wish to receive or hold any IP related to submitted ideas. Solvers will retain all IP rights; however, each Solver may be asked to grant to NIDA a royalty-free non-exclusive worldwide license to use, copy for use, perform publicly, and display publicly all parts of the submission for the purposes of the Challenge. This statement serves as a notice to Solvers that granting this license to NIDA, if asked, is a condition of participation.

Liability

By participating in this Challenge, Solvers agree 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 their participation in the Challenge, whether the injury, death, damage, or loss arises through negligence or otherwise.

Indemnification

By participating in this Challenge, Solvers agree to indemnify the Federal Government against third party claims for damages arising from or related to Challenge activities. This statement serves as a notice to Solvers that they are obligated to indemnify the government as a condition of participation.

Insurance

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, solvers are not required to obtain liability insurance or demonstrate financial responsibility in order to participate in this Challenge.

Dated: May 10, 2013.

Nora Volkow,

Director, National Institute on Drug Abuse, National Institutes of Health.

[FR Doc. 2013–11689 Filed 5–15–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-Up Exclusive Evaluation Option License Agreement: In Vitro Diagnostics for Prediction of Therapeutic Efficacy in Cancer and Other Angiogenesis-Mediated Diseases

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a Start-Up Exclusive Evaluation Option License Agreement to Advanced Personalized Diagnostics, LLC, a company having a place of business in Alexandria, Virginia, to practice the inventions embodied in U.S. Provisional Patent Application No. 60/976,732, entitled ''Stably Transfected Multicolored Fluorescent Cells'', filed October 1, 2007 (HHS Ref. No. E–281–2007/0–US–01); U.S. Patent Application No. 12/060,752, entitled ''Multiplex Assay Method for Mixed Cell Populations'', filed April 1, 2008, (HHS Ref. No. E–281–2007/0–US–02); and U.S. Patent Application No. 12/802,666, entitled ''Methods of Monitoring Angiogenesis and Metastasis in Three Dimensional Co-Cultures'', filed June 10, 2010 (HHS Ref. No. E–281–2007/1–US–01). The patent rights in these inventions have been assigned to the Government of the United States of America. The territory of the prospective Start-Up Exclusive Evaluation Option License Agreement may be worldwide, and the field of use may be limited to ''The use of the Licensed Patent Rights limited to an FDA-approved Class III *in vitro* diagnostic device for prediction of therapeutic efficacy in cancer and other angiogenesis-mediated diseases.''

Upon the expiration or termination of the Start-up Exclusive Evaluation Option License Agreement, Advanced Personalized Diagnostics, LLC will have

the exclusive right to execute a Start-Up Exclusive Patent License Agreement which will supersede and replace the Start-up Exclusive Evaluation Option License Agreement, with no greater field of use and territory than granted in the Start-up Exclusive Evaluation Option License Agreement.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before May 31, 2013 will be considered.

ADDRESSES: Requests for copies of the patent application(s), inquiries, comments, and other materials relating to the contemplated Start-Up Exclusive Evaluation Option License Agreement should be directed to: Tara L. Kirby, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–4426; Facsimile: (301) 402–0220; Email: *tarak@mail.nih.gov.* A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: This technology relates to a three-dimensional co-culture system that can be used to assay cellular activity relating to angiogenesis (formation of new blood vessels) and metastasis (spread of cancer). The co-culture system is designed to mimic the *in vivo* environment of a tumor and consists of fluorescently-labeled tumor cells, endothelial cells, and other component cell types (e.g. macrophages, mast cells, fibroblasts, adipocytes, and pericytes). The co-culture system can be used to identify, monitor, and measure changes in morphology, migration, proliferation, and apoptosis of cells involved in angiogenesis and/or metastasis. The co-cultures are developed in 96-well plates to allow rapid and efficient screening for angiogenic agents and/or therapeutic agents for cancer. This technology may be used to develop diagnostic tests for personalized therapies for cancer and other angiogenesis-mediated diseases.

The prospective Start-Up Exclusive Evaluation Option License Agreement is being considered under the small business initiative launched on October 1, 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective Start-Up Exclusive Evaluation Option License Agreement and a subsequent Start-Up Exclusive Patent License Agreement may be granted unless the NIH receives written evidence and argument, within fifteen (15) days from the date of this published notice, that establishes that the grant of the contemplated Start-Up Exclusive Evaluation Option License Agreement would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Start-Up Exclusive Evaluation Option License Agreement. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 10, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013–11609 Filed 5–15–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Request for Comment on the Federal Guidelines for Opioid Treatment

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), HHS.

ACTION: Request for comment.

SUMMARY: This document is a request for comment on the revised draft of the Federal Guidelines for Opioid Treatment. These guidelines elaborate upon the Federal opioid treatment standards set forth under 42 CFR part 8.

DATES: *Comment Close Date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 60 calendar days from the date of publication in the **Federal Register**.

ADDRESSES: The draft guideline may be obtained directly from *http://www.dpt.samhsa.gov* or by contacting the Division of Pharmacologic Therapies. You may submit comments in one of four ways (please choose only one of the ways listed):

- *Electronically.* You may submit electronic comments to *DPT@samhsa.hhs.gov.*
- *By regular mail.* You may mail written comments to the following address ONLY: Substance Abuse and Mental Health Services Administration, Attention: DPT Federal Register Representative, Division of Pharmacologic Therapies, 1 Choke Cherry Road, Room 7–1044, Rockville, MD 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.
- *By express or overnight mail.* You may send written comments to the following address ONLY: Substance Abuse and Mental Health Services Administration, Attention: DPT Federal Register Representative, Division of Pharmacologic Therapies, 1 Choke Cherry Road, Room 7–1044, Rockville, MD 20850.
- *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following address prior to the close of the comment period:
- For delivery in Rockville, MD: Substance Abuse and Mental Health Services Administration, Attention: DPT Federal Register Representative, Division of Pharmacologic Therapies, 1 Choke Cherry Road, Room 7–1044, Rockville, MD 20850. To deliver your comments to the Rockville address, call telephone number (240) 276–2700 in advance to schedule your delivery with one of our staff members.

FOR FURTHER INFORMATION CONTACT: Nichole Smith, Division of Pharmacologic Therapies, CSAT, SAMHSA, 1 Choke Cherry Road, Room 7–1044, Rockville, Maryland 20857, (240) 276–2700 (phone) or email at *nichole.smith@samhsa.hhs.gov*.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. Comments received by the deadline will be available for public inspection at the Substance Abuse and Mental Health Services Administration, Division of Pharmacologic Therapies, 1 Choke Cherry Road, Rockville, MD 20850, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, phone (240) 276–2700.

Background: Federal Regulations codified under 42 CFR part 8 set forth requirements for opioid treatment programs (''OTPs''), also known as methadone treatment programs. The regulations, which were the subject of a Final Rule published in the **Federal Register** on January 17, 2001, (''Final Rule'' 66 FR 4075–4102, January 17, 2001) include standards for opioid treatment. OTPs are required to provide