

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](mailto: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](mailto: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](mailto: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

treatment in accordance with these standards as a basis for CSAT certification. These standards address patient admission requirements, medical and counseling services, drug testing, and other requirements. The final rule also established an accreditation requirement. Each OTP is required to obtain and maintain accreditation from an accreditation organization approved by SAMHSA under 42 CFR part 8. Accreditation organizations that provide OTP accreditation under the final rule are required to apply for and obtain SAMHSA approval. Under 42 CFR 8.3(a)(3), each accreditation organization must develop a set of accreditation elements or standards together with a detailed discussion of how these elements will assure that each OTP surveyed by the accreditation organization is meeting each of the Federal opioid treatment standards. The Federal Guidelines for Opioid Treatment are intended to guide accreditation organizations in preparing their accreditation standards. In addition, the Guidelines provide useful elaborations on the regulatory standards set forth under 42 CFR part 8.

As such, the updated guidelines will assist both accreditation organizations and OTPs in complying with regulatory requirements. Prepared initially in 1997, the Federal Opioid Treatment Guidelines, originally titled *Guidelines for the Accreditation of Opioid Treatment Programs*, are being updated to reflect new information and research in the field of opioid assisted treatment. CSAT convened an expert panel to provide the draft guideline now being circulated for comment. CSAT is soliciting comments on the guideline from the public, and expects comments from OTPs, accreditation organizations, patients, the medical community and other interested parties. All comments submitted no later than 60 calendar days from the date of publication in the **Federal Register** will be considered.

**Summer King,**  
Statistician.

[FR Doc. 2013-11637 Filed 5-15-13; 8:45 am]

**BILLING CODE 4162-20-P**

## DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2013-0036]

### Cooperative Research and Development Agreement (CRADA) Opportunity With the Department of Homeland Security for the Development of a Foot-and-Mouth Disease 3ABC ELISA Diagnostic Kit

**AGENCY:** Science and Technology Directorate, Plum Island Animal Disease Center, Department of Homeland Security.

**ACTION:** Notice of intent.

**SUMMARY:** The Department of Homeland Security Science and Technology Directorate (DHS S&T), through its Plum Island Animal Disease Center (PIADC), is seeking industry collaborators to aid DHS S&T in developing an ELISA diagnostic test that is capable of obtaining a U.S. regulatory license to detect antibodies to at least one of the Foot and Mouth Disease virus (FMDV) non-structural proteins (NSP): 3A, 3B, or 3C. This new FMDV 3ABC ELISA may be used in the event of a real or suspected outbreak of Foot-and-Mouth Disease (FMD) in order to differentiate infected from vaccinated, non-infected animals (DIVA).

The role of the industry collaborator(s) in this CRADA will be to develop and validate the FMDV 3ABC ELISA assay in collaboration with DHS S&T and the United States Department of Agriculture Animal and Plant Health Inspection Service Foreign Animal Disease Diagnostic Laboratory (USDA APHIS FADDL) at PIADC, and with other U.S. laboratories that are associated with USDA, such as the National Animal Health Laboratory Network (NAHLN). Components of a prototype assay, developed by USDA, Texas Veterinary Medical Diagnostic Laboratory, and a 3rd party fee-for-service contractor, will be made available to the industry collaborator(s). The goal of the CRADA is to submit a data package to USDA APHIS Center for Veterinary Biologics (CVB) in order to obtain a U.S. regulatory license for use under the direction of USDA administrators of the FMDV 3ABC ELISA in the U.S. (See CVB Veterinary Services Memorandum No. 800.73 for "General Requirements for Immunodiagnostic Test Kits for the Detection of Antibody or Antigen.") The assay must also successfully identify and test a reference panel of sera provided by OIE (World Organisation for Animal Health) as tested in a U.S. Reference Laboratory, e.g., USDA APHIS FADDL.

DHS S&T is seeking CRADA collaborators that own or have access to the technological components for, have the technological expertise in, and have proven track records of success in the fields of diagnostic test kit research, development, and the obtaining of USDA licensure for the detection of antibodies to viral antigen(s). CRADA collaborators must indicate if they are currently or may be funded by the Federal government, and, if yes, they must include a discussion of how proposed CRADA work and Federal government-funded work would not be duplicative.

The proposed term of the CRADA can be up to thirty (30) months.

**DATES:** Submit comments on or before June 17, 2013.

**ADDRESSES:** Mail comments and requests to participate to Dr. Angela Ervin, (ATTN: Angela Ervin, 245 Murray Lane SW., Washington, DC 20528-0075). Submit electronic comments and other data to [Angela.Ervin@hq.dhs.gov](mailto:Angela.Ervin@hq.dhs.gov).

#### FOR FURTHER INFORMATION CONTACT:

*Information on DHS CRADAs:*  
Marlene Owens, (202) 254-6671.

#### SUPPLEMENTARY INFORMATION:

##### Assay Requirements

1. Ideally a competitive ELISA (an assay in which a molecule in the test sample competes against a reagent provided in the kit for binding to the target) for FMDV NSPs that will differentiate FMDV infected from FMDV vaccinated animals (DIVA) (specifically cattle) and can be made commercially by the CRADA partner or by another entity and upon request by USDA APHIS, be supplied to USDA APHIS FADDL and accredited state laboratories within the National Animal Health Laboratory Network.

2. The ideal assay will have the following characteristics:

a. Diagnostic sensitivity of at least 96% for all seven major serotypes of FMDV, including detection of cattle antibodies to FMDV within 7 to 10 days post-infection.

b. Diagnostic specificity of at least 96%, ideally >99% with respect to viruses that cause FMDV look-alike clinical signs, such as Vesicular Stomatitis Virus, Swine Vesicular Disease Virus, Bovine Rhinovirus, Seneca Valley Virus.

c. Compatibility with serum samples from U.S. national cattle (beef and dairy) and domestic swine herds, and ideally with other species that are susceptible to FMDV, e.g., sheep, goats, feral swine, buffalo, deer, antelope, etc.