

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3130, MSC 7850, Bethesda, MD 20892, 301-435-3009, [elliottro@csr.nih.gov](mailto:elliottro@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR Panel: FIRCA and GRIP Review.

*Date:* May 31–June 1, 2012.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hotel Monaco Washington DC, 700 F Street NW., Washington, DC 20004.

*Contact Person:* Hilary D Sigmon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5222, MSC 7852, Bethesda, MD 20892, (301) 594-6377, [sigmonh@csr.nih.gov](mailto:sigmonh@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Obesity-Clinical Research.

*Date:* June 1, 2012.

*Time:* 10:00 a.m. to 3:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Krish Krishnan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, (301) 435-1041, [krishnak@csr.nih.gov](mailto:krishnak@csr.nih.gov).

*Name of Committee:* Healthcare Delivery and Methodologies Integrated Review Group; Societal and Ethical Issues in Research Study Section.

*Date:* June 4, 2012.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Karin F Helmers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, MSC 7770, Bethesda, MD 20892, 301-254-9975, [helmersk@csr.nih.gov](mailto:helmersk@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

*Dated:* May 1, 2012.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2012-10969 Filed 5-4-12; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; 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 the meeting of the NCI-Frederick Advisory Committee.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

A portion of the meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(9)(B), Title 5 U.S.C., as amended. The premature disclosure of information to be discussed during the meeting would significantly frustrate implementation of a proposed agency action.

*Name of Committee:* NCI-Frederick Advisory Committee.

*Open:* May 30, 2012, 9:00 a.m. to 11:00 a.m.

*Agenda:* Ongoing and New Business and Scientific Presentations.

*Place:* National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

*Closed:* May 30, 2012, 11:00 a.m. to 3:00 p.m.

*Agenda:* Discussion of Proposed Frederick National Laboratory Strategic Plan.

*Place:* National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

*Contact Person:* Thomas M. Vollberg, Sr., Ph.D., Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 7th Floor, Room 7142, Bethesda, MD 20892-8327, (301) 694-9582.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: <http://>

[deainfo.nci.nih.gov/advisory/fac/fac.htm](http://deainfo.nci.nih.gov/advisory/fac/fac.htm), where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

*Dated:* April 27, 2012.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2012-10964 Filed 5-4-12; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of Exclusive License: Ocular Therapeutics Agent Delivery Devices and Methods for Making and Using Such Devices

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in Patent Applications USSN 09/808,149, filed Mar 15, 2001, issued Mar 30, 2004; PCT/US02/07836, filed Mar 14, 2002, designated EP, 02723446,7 and US 10/471,468, issued Feb 9, 2010; USSN 11/739,540, filed Apr 29, 2007; and USSN 12/647,980, filed Dec 28, 2009; entitled "Ocular Therapeutic Agent Delivery Devices and Methods For Making and Using Such Devices", by Michael R. Robinson *et al* (NEI, CC, and NIBIB) (E-241-1999/0), to ODIN Biotech having a place of business in 4000 Hanover Street, Dallas, TX. The patent rights in this invention have been assigned to the United States of America. The exclusive patent license is one which qualifies under the Start-up Exclusive Patent License Agreement program, which is in place from October 1, 2011 through September 30, 2012.

**DATES:** Only written comments and/or application for a license that are received by the NIH Office of Technology Transfer on or before May 22, 2012 will be considered.

**FOR FURTHER INFORMATION CONTACT:**

Requests for a copy of the patent application, inquiries, and comments relating to the contemplated license should be directed to: Susan Ano, Ph.D., Branch Chief, IDME, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Email: [anos@mail.nih.gov](mailto:anos@mail.nih.gov); Telephone: 301-435-5515; Facsimile: 301-402-0220.

**SUPPLEMENTARY INFORMATION:**

The invention relates to a drug delivery system, compositions of, methods of making the drug delivery system, and methods of use as a drug delivery platform. Ocular therapeutics that require repeated intravitreal injections are associated with eye infections, retinal detachment, hemorrhaging, endophthalmitis, and/or cataracts, while topical solutions that require daily application are associated with patient non-compliance. This technology describes a drug delivery platform that can be designed to deliver therapeutics to the eye over months to years. Therefore, this technology can be used to design a therapeutic implant that reduces or eliminates patient non-compliance and/or improve patient safety. The therapeutic implant has the following advantages: (a) It is bioerodible which makes it more noninvasive than repeated intravitreal injections and non-bioerodible implants; (b) has a dual release system that allows the release of two distinct therapeutics or a single therapeutic at different rates; (c) prolongs the therapeutic dose of an agent across the surface of the eye compared to topical solutions; (d) reduces the risk of additional eye damage compared to repeated intravitreal injections; (e) dispenses a therapeutic agent over a long period of time resulting in increase patient compliance and patient health; and (f) is associated with reduced systemic drug side-effects compared to drugs applied systemically. Data are available for rodents, rabbits, dogs, and horses.

The field of use may be limited to "Episcleral Therapeutic Implant for Ophthalmic Diseases".

The prospective worldwide exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within fifteen (15) days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent

with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response 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 1, 2012.

**Richard U. Rodriguez,**

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

[FR Doc. 2012-10836 Filed 5-4-12; 8:45 am]

**BILLING CODE 4140-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Substance Abuse and Mental Health Services Administration**

#### **Agency Information Collection Activities: Proposed Collection; Comment Request**

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

#### **Proposed Project: Healthy Transitions Initiative Cross-Site Evaluation—NEW**

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center of Mental Health Services is responsible for the cross-site evaluation of the Cooperative

Agreements for State/Community Partnerships to Integrate Services and Supports for Youth and Young Adults 16–25 with Serious Emotional Disturbances (SED) or Serious Mental Illness (SMI), and Their Families (Healthy Transitions Initiative—HTI) that will collect data on program implementation and youth and young adult outcomes in the areas of education, employment, housing, mental health and co-occurring disorders, and involvement with the juvenile and criminal justice systems. This cross-site evaluation design includes a process and an outcome evaluation and data will be collected over a 3-year period from 7 grantee sites.

The cross-site evaluation is designed to address the following questions.

#### *Process Evaluation Questions*

1. How closely does implementation match the plan proposed in the grant?
2. What types of deviation from the plan occur?
3. What effect do the deviations have on the planned intervention and performance assessment?
4. What facilitates a successful transition between youth and adult systems?
5. Is there a change from a "youth-guided" model to a "youth and young adult consumer-driven" model?
6. What is the extent of interagency coordination and collaboration?
7. How are state and local-level systems changing in response to the HTI implementation? How does state and local-level policy change affect the implementation of the Initiative?
8. Who provides services (i.e., program staff, agency site)?
9. What services are being provided (i.e., modality, type, intensity, duration)?
10. Is there a viable cultural and linguistic competence plan?
11. What are the individual characteristics of the youth and young adults (i.e., who is being served)?
12. In what settings (i.e., system, community) are they being served?

#### *Outcome Evaluation Questions*

1. What is the effect of the HTI intervention on the participants?
2. What is the effect of the HTI intervention, compared to a sample of similar young adults not participating in the HTI intervention?
3. What program factors are associated with the observed outcomes?
4. What individual factors are associated with the observed outcomes?
5. How durable are the effects over 24 months?