

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 An, 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; 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?

Process Evaluation

The process evaluation is designed to assess the fidelity of grantees to implement their proposed program model, and consists of young person focus groups, young person surveys, youth mentor focus groups, transitional program personnel interviews and surveys, and local and state administrator interviews. Process evaluation data will be collected in two waves during FY 2012 and during FY 2014 and, with the exception of the state administrator interviews, participants are not expected to participate more than one time during the 2 waves of data collection.

Outcome Evaluation

The outcome evaluation is designed to assess outcomes of youth and young adults in regards to education, employment, housing, mental health and co-occurring disorders, and involvement with the juvenile and

criminal justice systems. The outcome evaluation will utilize both an enhanced and standard data collection and a longitudinal cohort design, and will include a comparative study to assess the effectiveness of HTI relative to a similar sample of young persons who did not receive HTI services. In the standard data collection protocol, outcome data will be collected for each HTI young adult participant, at a minimum of, at baseline at least every 6 months for up to 24 months for as long as the participant remains in HTI services. Enhanced outcome data will be collected on a subsample of young adults at 6 month intervals. The enhanced protocol will continue even after the young person from the subsample has left or has been discharged from HTI services, for up to 24 months. The baseline and follow up outcome instruments include the following key indicators: Demographic information, service use, education,

employment/vocational training, housing and living situation, clinical outcomes, behavioral and other health, trauma-related experiences, life skills, parenting skills and supports, involvement with juvenile or criminal justice systems, and social and peer relationships. While participants are enrolled in HTI services, these data collected by the HTI grantees as specified in the RFA.

The HTI Data Center (HTI DC) will be developed for data collection and management. The HTI DC will be a secure Web site that allows uploading of data, real-time access to data by grantees, and production of automated reports for the sites. It is flexible for local use and simplifies the management, monitoring, and reporting of data.

The summary burden reflects the distinct number of respondents, total annual burden, and total hourly cost of the study.

SUMMARY BURDEN TABLE

	Number of distinct respondents	Average annual number responses/respondent	Total annual number of responses	Average 3-year burden per response (hours)	Total annual burden (hours)	Hourly wage cost	Total hourly cost*
Young Persons	320	1.10	796	1.55	547	^a \$7.25	\$3966
Youth Mentors	84	0.33	28	1.25	35	^b 10.74	376
Transitional Program Personnel	49	0.33	23	1.41	23	^c 15.24	351
Local Administrators	21	0.67	14	1.50	21	^d 22.69	476
State Administrators	7	0.67	9	0.54	3	^e 23.54	220
Total Summary	481	3	871	629	5,389

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 8-1099, One Choke Cherry Road, Rockville, MD 20857 or email a copy to summer.king@samhsa.hhs.gov. Written comments must be received before 60 days after the date of the publication in the **Federal Register**.

Summer King,
Statistician.

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DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2012-0021]

Homeland Security Advisory Council

AGENCY: The Office of Policy, DHS.

ACTION: Notice of partially closed federal advisory committee meeting.

SUMMARY: The Homeland Security Advisory Council (HSAC) will meet in

person and members of the public may participate by conference call on May 24, 2012. The meeting will be partially closed to the public.

DATES: The HSAC will meet on Thursday, May 24, 2012, from 9:00 a.m. to 3:00 p.m. EDT. The portion of the meeting from 9:00 a.m. to 12:45 p.m. will be closed to the public. The meeting will be open to the public from 1:00 p.m. to 3:00 p.m.

ADDRESSES: Written comments must be submitted and received by May 22, 2012. Comments must be identified by Docket No. DHS-2012-0021 and may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *E-mail:* HSAC@dhs.gov. Include docket number in the subject line of the message.
- *Fax:* (202) 282-9207.
- *Mail:* Homeland Security Advisory Council, Department of Homeland

Security, Mailstop 0450, 245 Murray Lane SW., Washington, DC 20528.

Instructions: All submissions received must include the words "Department of Homeland Security" and DHS-2012-0021, the docket number for this action. Comments received will be posted without alteration at <http://www.regulations.gov>, including any personal information provided.

Docket: For access to the docket to read background documents or comments received by the DHS Homeland Security Advisory Council, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: HSAC Staff at hsac@dhs.gov or 202-447-3135.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App.

The HSAC provides organizationally independent, strategic, timely, specific and actionable advice and recommendations for the consideration of the Secretary of the Department of