

Dated: August 17, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-20643 Filed 8-20-15; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission for OMB Review; 30-Day Comment Request; Web-Based Resource for Youth About Clinical Research**

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on 3/12/2015 pages 13013-13014, and allowed 60-days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

*Direct Comments to OMB:* Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office

of Management and Budget, Office of Regulatory Affairs, *OIRA\_submission@omb.eop.gov* or by fax to 202-395-6974, Attention: NIH Desk Officer.

*Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. Victoria Pemberton, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Dr., Room 8102, MSC 7940, Bethesda, MD 20892-7940, or call non-toll-free number 301-435-0510, or Email your request, including your address to *pembertonv@nhlbi.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

*Proposed Collection:* Web-based Resource for Youth about Clinical Research (NHLBI), 0925-New, National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH).

*Need and Use of Information Collection:* The purpose and use of the information collection for this project is to develop a comprehensive web-based resource for youth with chronic illnesses or diseases that will attempt to increase knowledge, self-efficacy, and positive attitudes towards participation in various clinical trials and research. As a result of the proposed web-based resource, the knowledge gained from developing and testing this web-based resource will ultimately help equip youth to make informed decisions about clinical research and increase motivation to participate in that

research. In addition, the knowledge gained will be invaluable to the field of clinical research given the need for more clinical trials with youth. Specifically, the proposed web-based resource will be an interactive, multimedia, developmentally appropriate resource for youth to be educated about pediatric clinical trials. The resource will be developed for youth aged 8 to 14 years. The theme of “investigative cyber-reporting” will be used throughout and will include youth making a series of decisions about different aspects of participating in clinical research studies. Youth will be tasked with the responsibility of learning all they can about clinical research trials in order to facilitate their knowledge and decision-making processes. Language typically used in journalism and design elements reminiscent of journalism will be incorporated into the content, design, and layout of the resource. There are three main components that will comprise the web-based resource. These include an interactive leaning module, full length video testimonials, and an electronic comic book. The benefits and necessities for this particular research on pediatric clinical trials are congruent with NHLBI’s research goals and mission statement: Attempting to assist in the enhancement of the health of individuals so that they can live longer and more fulfilling lives. The current lack of knowledge surrounding pediatric clinical trials can be dangerous and unhealthy towards the lives of youth, becoming a large public health need.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 172.

**ESTIMATES OF HOUR BURDEN**

Form name	Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Individual Interview Parent Permission Form .....	parents .....	9	1	5/60	1
One-to-One Evaluation Study Parent Permission Form .....	parents .....	5	1	5/60	0.42
Pre-Post Feedback Study Parent Permission .....	parents .....	34	1	5/60	3
Individual Interview Child Assent Form .....	youth .....	9	1	5/60	1
One-to-One Evaluation Study Child Assent Form .....	youth .....	5	1	5/60	0.42
Pre-Post Feedback Study Child Assent Form .....	youth .....	34	1	5/60	3
Individual Interview Questions (Feature Stories) .....	youth .....	3	1	2	6
Individual Interview Questions (Family Spotlights) .....	youth .....	3	1	2	6
Individual Interview Questions (Comic Book) .....	youth .....	3	1	2	6
One-to-One Evaluation Study Questionnaire .....	youth .....	5	1	2	10
Pre-Post Feedback Study Questionnaire .....	youth .....	34	1	4	136

Dated: July 30, 2015.

**Valery Gheen,**

*NHLBI Project Clearance Liaison, National Institutes of Health.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Cancer Institute; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2); notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The purpose of this meeting is to evaluate requests for preclinical development resources for potential new therapeutics for the treatment of cancer. The outcome of the evaluation will provide information to internal NCI committees that will decide whether NCI should support requests and make available contract resources for development of the potential therapeutic to improve the treatment of various forms of cancer. The research proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposed research projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Jun2015 Cycle 20 NExT SEP Committee Meeting.

*Date:* September 22, 2015.

*Time:* 8:30 a.m. to 4:30 p.m.

*Agenda:* To evaluate the NCI Experimental Therapeutics Program Portfolio.

*Place:* National Institutes of Health, 9000 Rockville Pike, Campus Building 31, Conference Room 6C6, Bethesda, MD 20892.

*Contact Person:* Barbara Mroczkowski, Ph.D., Executive Secretary, Discovery Experimental Therapeutics Program, National Cancer Institute, NIH, 31 Center Drive, Room 3A44, Bethesda, MD 20817, (301) 496-4291, [mroczkoskib@mail.nih.gov](mailto:mroczkoskib@mail.nih.gov).

Toby Hecht, Ph.D., Executive Secretary, Development Experimental Therapeutics Program, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 3W110, Rockville, MD 20850, (240) 276-5683, [toby.hecht2@nih.gov](mailto:toby.hecht2@nih.gov). (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)

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Government-Owned Inventions; Availability for Licensing**

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

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**FOR FURTHER INFORMATION CONTACT:**

Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301-496-7057; fax: 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

**SUPPLEMENTARY INFORMATION:** Technology descriptions follow.

**Novel Benztrapine Analogs for Treatment of Cocaine Abuse and Other Mental Disorders**

*Description of Technology:* Dopamine is a neurotransmitter that exerts important effects on locomotor activity, motivation and reward, and cognition. The dopamine transporter (DAT) is expressed on the plasma membrane of dopamine synthesizing neurons, and is responsible for clearing dopamine released into the extra-cellular space, thereby regulating neurotransmission. The dopamine transporter plays a

significant role in neurotoxicity and human diseases, such as Parkinson's disease, drug abuse (especially cocaine addiction), Attention Deficit Disorder/Attention Deficit Hyperactivity Disorder (ADD/ADHD), and a number of other CNS disorders. Therefore, the dopamine transporter is a strong target for research and the discovery of potential therapeutics for the treatment of these indications.

This invention discloses novel benztrapine analogs and methods of using these analogs for treatment of mental and conduct disorders such as cocaine abuse, narcolepsy, ADHD, obesity and nicotine abuse. The disclosed analogs are highly selective and potent inhibitors of DAT, but without an apparent cocaine-like behavioral profile. In addition to their use as a treatment for cocaine abuse, these compounds have also shown efficacy in animal models of ADHD and nicotine abuse, and have also been shown to reduce food intake in animals. They may also be useful medications for other indications where dopamine-related behavior is compromised, such as alcohol addiction, tobacco addiction, and Parkinson's disease.

*Potential Commercial Applications:*

- Drug leads for treatment of cocaine abuse, ADHD, nicotine abuse, obesity, and other dopamine-related disorders
- Imaging probes for dopamine transporter binding sites

*Development Stage:* Early-stage; In vitro data available

*Inventors:* Amy H. Newman, Mu-fa Zou, Jonathan L. Katz (all of NIDA)

*Intellectual Property:* HHS Reference No. E-234-2005/1—US Patent No. 8,383,817 issued February 26, 2013

*Licensing Contact:* Betty B. Tong, Ph.D.; 301-594-6565; [tongb@mail.nih.gov](mailto:tongb@mail.nih.gov)

*Collaborative Research Opportunity:*

The National Institute on Drug Abuse, Medicinal Chemistry and Psychobiology Sections, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize medications to treat cocaine abuse and addiction. For collaboration opportunities please contact John D. Hewes, Ph.D. at [john.hewes@nih.gov](mailto:john.hewes@nih.gov).

**Novel Dopamine Receptor Ligands as Therapeutics for Central Nervous System Disorders**

*Description of Technology:* The dopamine D3 receptor subtype is a member of the dopamine D2 subclass of receptors. These receptors have been implicated in a number of CNS disorders, including psychostimulant