

Evidence Integration to Case Studies.” The OHAT, Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS) will host the web-based meeting and the public can register to participate at <http://ntp.niehs.nih.gov/go/41629>.

DATES:

Webinar: July 31, 2014, 12:30 p.m. to approximately 3:30 p.m. Eastern Daylight Time (EDT).

Registration for Webinar: June 17, 2014 through July 28, 2014.

ADDRESSES: *Webinar Web page:* <http://ntp.niehs.nih.gov/go/41629>.

FOR FURTHER INFORMATION CONTACT: Dr. Andrew Rooney, Deputy Director, OHAT, Division of NTP, NIEHS, P.O. Box 12233, K2-04, Research Triangle Park, NC 27709. Phone: 919-541-2999, Fax: 301-480-3299, Email:

Andrew.Rooney@nih.gov. Hand Delivery/Courier: 530 Davis Drive, Room K2154, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background: The OHAT has developed a systematic review framework, the OHAT Approach, to address environmental health questions by extending approaches developed for clinical medicine to address the greater range of data relevant to environmental health sciences (e.g., human, animal, and mechanistic studies) (available at <http://ntp.niehs.nih.gov/go/38673>). The OHAT adapted guidance from authorities on systematic review and sought advice during development of the OHAT Approach through consultation with technical experts in systematic review and human health assessment as well as scientific advisory groups and the public.

The approach includes seven steps that provide a framework for incorporating systematic review and evidence integration into NTP literature-based, non-cancer health assessments. The framework, released as the Draft OHAT Approach in February 2013 and published in April 2014 (<http://ehp.niehs.nih.gov/1307972/>), was assessed and refined through application of the procedures to case-study evaluations. The OHAT applied the approach to two case studies: (1) An evaluation of the association of bisphenol A (BPA) exposure with obesity and (2) an evaluation of the association of perfluorooctanoic acid (PFOA) or perfluorooctane sulfonate (PFOS) exposure with immunotoxicity.

The purpose of this webinar is to present lessons learned during the case-study process. The meeting will be conducted in a presentation and discussion format. The first part of the

webinar will consist of a series of topic or “lesson” focused presentations, followed by a short question-and-answer period. The second part of the webinar will be a general discussion period when the public can make brief comments on or ask questions about the application of the OHAT Approach to the case studies and lessons learned.

Webinar and Registration: The webinar is scheduled for July 31, 2014, 12:30 p.m. to 3:30 p.m. EDT and may end early if discussions are finished. Registration for the webinar is required and is open from June 17, 2014, through July 28, 2014, at <http://ntp.niehs.nih.gov/go/41629>. Registrants will receive instructions by email on accessing the webinar on or before July 28, 2014. Registrants are encouraged to access the Web site to stay abreast of current information about this event.

Public Participation: As noted above, the meeting format includes time after each lesson-presentation and during the general discussion session for the public to ask questions or make brief remarks. Individuals with disabilities who need accommodations to participate in this event should contact Dr. Andrew Rooney (See **FOR FURTHER INFORMATION CONTACT**). TTY users should contact the Federal TTY Relay Service at (800) 877-8330. Requests should be made at least 5 business days in advance of the web-based meeting.

Background Information on OHAT: The OHAT was established to serve as an environmental health resource to the public and regulatory and health agencies (<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3094430>). This office conducts evaluations to assess the evidence that environmental chemicals, physical substances, or mixtures (collectively referred to as “substances”) cause adverse health effects and provides opinions on whether these substances may be of concern given what is known about current human exposure levels. The OHAT also organizes workshops or state-of-the-science evaluations to address issues of importance in environmental health sciences. The OHAT assessments are published as NTP Monographs. Information about the OHAT is found at <http://ntp.niehs.nih.gov/go/ohat>.

Dated: June 17, 2014.

John R. Bucher,

Associate Director, National Toxicology Program.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Adverse Outcome Pathways: From Research to Regulation Workshop; Notice of Public Meeting and Registration Information**

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces a workshop on “Adverse Outcome Pathways: From Research to Regulation.” The workshop proposes to initiate stakeholder interaction and collaboration to enhance scientific development of the Adverse Outcome Pathway (AOP) concept with the goal of improving regulatory assessment of chemical toxicity. Registration is requested for attendance and required to access the webcast. Information about the meeting and registration is available at <http://ntp.niehs.nih.gov/go/41374>.

DATES:

Meeting: September 3–5, 2014, from 8:30 a.m. to approximately 5:30 p.m. Eastern Daylight Time (EDT) on September 3 and 4 and from 9:00 a.m. to approximately 4:00 p.m. EDT on September 5. A poster session will be held on September 4 from 6:30 p.m. to 8:30 p.m.

Meeting Registration: Registration is open through August 15, 2014. Registration to view the plenary sessions of the workshop via webcast is required.

ADDRESSES:

Meeting Location: William H. Natcher Conference Center, National Institutes of Health, Bethesda, Maryland 20892.

Meeting Web page: The preliminary agenda, registration, and other meeting materials are at <http://ntp.niehs.nih.gov/go/41374>.

FOR FURTHER INFORMATION CONTACT: Dr. Warren S. Casey, Director, NICEATM; email: warren.casey@nih.gov; telephone: (919) 316-4729.

SUPPLEMENTARY INFORMATION:

Background: Traditional toxicology test methods expose multiple animals to test substances and observe adverse outcomes; these methods may not efficiently serve future scientific and regulatory needs. To improve the regulatory assessment of chemical toxicity, NICEATM is evaluating the use of AOPs, a conceptual framework relating toxic exposures to illness or injury in an individual or a population through specific molecular and cellular changes.

Through plenary presentations, case studies, and breakout sessions, the

workshop will engage stakeholders in how the scientific development of AOPs could enhance regulatory assessment of chemical toxicity. The workshop steering committee is comprised of members from government and nongovernment stakeholders including the NTP, Physicians Committee for Responsible Medicine, European Union Reference Laboratory for Alternatives to Animal Testing, Consumer Product Safety Commission, Dow Chemical Company, U.S. Environmental Protection Agency, U.S. Food and Drug Administration, Health and Environmental Sciences Institute, and Proctor & Gamble.

Meeting and Registration: This meeting is open to the public, free of charge, with attendance limited only by the space available. A preliminary agenda and additional information are available at <http://ntp.niehs.nih.gov/go/41374>. The plenary sessions of the workshop will be webcast. Registration is required to view the webcast; the URL for the webcast will be provided in an email prior to the meeting. Individuals who plan to attend in person should register at <http://ntp.niehs.nih.gov/go/41374> by August 15, 2014, to facilitate planning for the workshop. Individuals interested in this workshop are encouraged to visit the Web page to stay abreast of the most current information.

Information for visitors to the William H. Natcher Conference Center is available at <http://www.orf.od.nih.gov/AboutORF/BFM/Pages/45Beth.aspx>. Individuals with disabilities who need accommodation to participate in this event should contact Dr. Elizabeth Maull at phone: (919) 316-4668 or email: maull@niehs.nih.gov. TTY users should contact the Federal TTY Relay Service at (800) 877-8339. Requests should be made at least five business days in advance of the event.

Background Information on NICEATM: NICEATM conducts data analyses, workshops, independent

validation studies, and other activities to assess new, revised, and alternative test methods and strategies. NICEATM also provides support for the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3) provides authority for ICCVAM and NICEATM in the development and implementation of alternative test methods in regulatory safety testing. Information about NICEATM and ICCVAM is found at <http://ntp.niehs.nih.gov/go/niceatm> and <http://ntp.niehs.nih.gov/go/iccvam>.

Dated: June 17, 2014.

John R. Bucher,
Associate Director, National Toxicology Program.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Project: Co-Location and Integration of HIV Prevention and Medical Care into Behavioral Health Program—NEW

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Mental Health Services, (CMHS), Center for Substance Abuse Prevention (CSAP), Center for Substance Abuse Treatment (CSAT) are

requesting approval from the Office of Management and Budget (OMB) for new data collection activities associated with their Co-location and Integration of HIV Prevention and Medical Care into Behavioral Health Program. The program is designed to support integrated behavioral health and physical health services for racial/ethnic populations at high risk for behavioral health disorders and at high risk for contracting HIV.

This information collection is needed to provide SAMHSA with objective information to document the reach and impact of the Co-location and Integration of HIV Prevention and Medical Care into Behavioral Health program. The information will be used to monitor quality assurance and quality performance outcomes for organizations funded by this grant program. The information will also be used to assess the impact of services on behavioral health and physical health services for individuals served by this program.

Collection of the information included in this request is authorized by Section 505 of the Public Health Service Act (42 U.S.C. 290aa-4)—Data Collection. Further support for the program was provided in the 2013 Senate Appropriations Report 113-71. The report urged SAMHSA to “focus its efforts on building capacity and outreach to individuals at risk or with a primary substance abuse disorder and to improve efforts to identify such individuals to prevent the spread of HIV.” Additional support for this data collection effort is provided by the 2013 National HIV/AIDS Strategy which instructed SAMHSA to “support and rigorously evaluate the development and implementation of new integrated behavioral health models to address the intersection of substance use, mental health, and HIV.”

The table below reflects the annualized hourly burden.

Instrument	Number of respondents	Number of responses per respondent	Total number of responses	Hours per response per respondent	Total burden hours
HIV/Hepatitis Testing Form	5,000	1	5,000	0.13	650
Co-Located and Integrated Care TRAC—Baseline					
Clients with HIV Receiving Integrated Medical Services	200	1	200	0.58	117
Individuals only Receiving Prevention Services	1,000	1	1,000	0.12	120
Co-Located and Integrated Care TRAC—Follow Up					
Clients with HIV Receiving Integrated Medical Services ² ..	120	1	120	0.58	69.6