

## TOTAL ESTIMATED ANNUALIZED BURDEN HOURS:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total Burden hours
AENT Application including the AENT Tables and Attachments .....	236	1	236	7	1,652
Total .....	236	1	236	7	1,652

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Bahar Niakan,**

*Director, Division of Policy and Information Coordination.*

[FR Doc. 2013-18162 Filed 7-26-13; 8:45 am]

**BILLING CODE 4165-15-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****National Institute on Alcohol Abuse and Alcoholism; 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 a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism.

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.

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 grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Advisory Council on Alcohol Abuse and Alcoholism.

*Date:* September 18-19, 2013.

*Closed:* September 18, 2013.

*Time:* 5:30 p.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 5635 Fishers Lane, T508, Rockville, MD 20852.

*Open:* September 19, 2013, 8:45 a.m. to 2:00 p.m.

*Agenda:* Presentations and other business of the council.

*Place:* National Institutes of Health, 5635 Fishers Lane, T508, Rockville, MD 20852.

*Contact Person:* Abraham P. Bautista, Ph.D., Executive Secretary, National Institute on Alcohol Abuse & Alcoholism, National Institutes of Health, 5635 Fishers Lane, Rm 2085, Rockville, MD 20852, 301-443-9737, [bautista@mail.nih.gov](mailto:bautista@mail.nih.gov).

Information is also available on the Institute's/Center's home page: <http://www.niaaa.nih.gov/AboutNIAAA/AdvisoryCouncil/Pages/default.aspx> where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.273, Alcohol Research Programs, National Institutes of Health, HHS)

*Dated:* July 22, 2013.

**Carolyn A. Baum,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2013-18054 Filed 7-26-13; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****National Institute of Allergy and Infectious Diseases; Notice of Meeting**

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the AIDS Research Advisory Committee, NIAID.

The meeting will be open to the public, 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.

*Name of Committee:* AIDS Research Advisory Committee, NIAID; AIDS Vaccine Research Subcommittee.

*Date:* September 18, 2013.

*Time:* 8:30 a.m. to 12:30 p.m.

*Agenda:* Presentations by the Vaccine Research Program staff on the preclinical, translational and clinical AIDS vaccine research programs supported by the Division of AIDS for the purpose of obtaining advice and guidance from the AVRS on future vaccine efforts.

*Place:* National Institutes of Health, Natcher Building, Conference Rooms E1/E2, 45 Center Drive, Bethesda, MD 20892.

*Contact Person:* James A. Bradac, Ph.D., Chief, Preclinical Research and Development Branch, Division of AIDS, Room 5134, National Institutes of Health/NIAID, 6700B Rockledge Drive, Bethesda, MD 20892-7628, 301-435-3754, [jbradac@mail.nih.gov](mailto:jbradac@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

*Dated:* July 22, 2013.

**David Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2013-18055 Filed 7-26-13; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****Center for Scientific Review ;Notice of Closed 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 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 grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; OppNet RFA: Culture, Health and Wellbeing.

*Date:* August 1, 2013.

*Time:* 4:00 p.m. to 5:00 p.m.  
*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Karin F Helmers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3144, MSC 7770, Bethesda, MD 20892, (301) 254-9975, [helmersk@csr.nih.gov](mailto:helmersk@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(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: July 23, 2013.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2013-18053 Filed 7-26-13; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Request for Information: The National Institute of Environmental Health Sciences/National Toxicology Program Requests the Nomination and Prioritization of Environmentally Responsive Genes for Use in Screening Large Numbers of Substances Using Toxicogenomic Technologies**

**SUMMARY:** The National Institute of Environmental Health Sciences (NIEHS)/National Toxicology Program (NTP) is interested in the identification and prioritization of a comprehensive list of environmentally responsive genes that might be targets for screening cells or tissues obtained from humans, rats, mice, zebrafish, and *Caenorhabditis elegans* against large numbers of substances. The goal is to generate a minimum list of 1000 genes for each species that would provide the maximal toxicogenomic information on (1) effects that reflect general cellular responses, independent of cell type or species, and (2) gene expression changes that are specific by organ and/or cell type. The NIEHS/NTP also seeks recommendations on criteria to use for prioritizing the genes in order to identify those potentially most useful in a screening paradigm. Such a list of environmentally responsive genes may be useful also in biomarker development and basic research efforts.

**DATES:** The deadline for receipt of information is August 23, 2013.

**ADDRESSES:** Nominated genes and/or recommendations on prioritization criteria should be submitted electronically in Microsoft Excel or Word formats to [Genelist@niehs.nih.gov](mailto:Genelist@niehs.nih.gov).

**FOR FURTHER INFORMATION CONTACT:** Dr. Elizabeth Maull, NIEHS, P. O. Box 12233 (MD K2-17), Research Triangle Park, NC 27709; email: [maull@niehs.nih.gov](mailto:maull@niehs.nih.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **Background:**

In 2008, the NIEHS/NTP, the U.S. Environmental Protection Agency's (EPA) National Center for Computational Toxicology (NCCT), and the National Human Genome Research Institute (NHGRI)/NIH Chemical Genomics Center (NCGC) (now located within the National Center for Advancing Translational Sciences (NCATS)) entered into a formal agreement to develop a vision and devise an implementation strategy to shift the assessment of chemical hazards from traditional, experimental animal, toxicology studies to target-specific, mechanism-based, biological observations largely obtained using *in vitro* assays. In mid-2010, the U.S. Food and Drug Administration (FDA) joined the collaboration that is known informally as Tox21.

In Tox21, the agencies collaborate to research, develop, validate, and translate innovative testing methods for characterization of toxicity pathways; identify compounds, assays, informatic analyses, and targeted testing needed to support the development of new methods; identify patterns of compound-induced biological response(s) in order to characterize toxicity pathways; facilitate cross-species and low-dose extrapolation; prioritize compounds for more extensive toxicological evaluation; and develop predictive models for biological response in humans. Currently, the primary Tox21 activity is the screening of a 10,000 compound library in a number of nuclear receptor agonist/antagonist and stress response pathway assays primarily using reporter gene platforms. In the next phase, the focus will be on assaying large numbers of chemicals in high content screens and mid to high throughput, targeted gene expression platforms.

To conduct the next phase, the NIEHS/NTP in collaboration with its Tox21 partners seeks to identify a prioritized set of at least 1000 genes that would provide comprehensive toxicogenomic information on (1) gene

induction or repression reflecting general cellular responses that are largely independent of cell type or species, and (2) gene expression changes that are organ and/or cell type specific. Examples of processes likely to be cell-type independent include genes involved in stress-response pathways (e.g., DNA repair, hypoxia, heat shock), chromatin remodeling, and those that regulate cell division and death. Examples of processes more likely to be cell-type specific include induction or repression of expression of enzymes that modify or activate chemical toxicants, regulation of the hypothalamic-pituitary-adrenal axis, and inflammatory responses. In keeping with the Tox21 goal of facilitating cross-species extrapolation, the NIEHS/NTP is especially interested in the nomination of genes or gene sets specifically relevant for comparisons between humans, rats, mice, zebrafish, and *C. elegans* and especially those for which complementary functional pathways exist. Such a list of environmentally responsive genes may be useful also in biomarker development and basic research efforts. To facilitate identification of the most useful genes to include in a screening paradigm, the NIEHS/NTP also requests recommendations on criteria to use for their prioritization.

##### **Request for Information**

The NIEHS/NTP seeks to establish a prioritized list of environmentally responsive genes to screen cells/tissues from humans, rats, mice, zebrafish, and *C. elegans* for agent-induced alterations using mid to high throughput, targeted transcriptomics platforms. The goal is to screen a large number of compounds and obtain information useful for understanding the potential for adverse health outcomes. To that end, the NIEHS/NTP requests that respondents provide information for either or both of the following:

- Nominations of specific genes or gene sets. Nominated genes should be identified using Entrez and/or Ensembl gene IDs. Desirable supporting information for the nominated gene(s) would include the associated pathway(s) or biological process(s), the cellular context(s) where demonstrated, and the technology used to measure expression of the nominated gene. If available, please include relevant citations as a part of the supporting information.
- Criteria for prioritization of the genes or gene sets. The NIEHS/NTP is interested in criteria that could be used to develop a prioritized list of genes that would provide the greatest level of