DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary


Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for renewal of the approved information collection assigned OMB control number 0990–0382, scheduled to expire on May 31, 2015. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before May 15, 2015.

ADDRESSES: Submit your comments to OIRA_submission@omb.eop.gov or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, Information.CollectionClearance@hhs.gov or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the OMB control number 0990–0382 and document identifier HHS–OS–30D for reference.

Information Collection Request Title: Evaluation of Pregnancy Prevention Approaches—First Follow-up

Abstract: The Office of Adolescent Health (OAH), U.S. Department of Health and Human Services (HHS) is requesting an extension without change of a currently approved information collection request by OMB. The purpose of the extension is to complete the ongoing follow-up data collection for the Evaluation of Adolescent Pregnancy Prevention Approaches (PPA), a multisite random assignment evaluation of promising approaches to teen pregnancy prevention.

Likely Respondents: The 1484 youth participants who agreed to participate in the study upon sample enrollment in 5 impact study sites.

The total annual burden hours estimated for this ICR are summarized in the table below.

<table>
<thead>
<tr>
<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden per response (in hours)</th>
<th>Total burden hours</th>
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<tbody>
<tr>
<td>Oklahoma Institute for Child Advocacy (OICA)</td>
<td>294</td>
<td>2</td>
<td>42/60</td>
<td>412</td>
</tr>
<tr>
<td>Ohio Health</td>
<td>148</td>
<td>3</td>
<td>42/60</td>
<td>310</td>
</tr>
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<td>Children’s Hospital Los Angeles</td>
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<td>2</td>
<td>36/60</td>
<td>305</td>
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<tr>
<td>EngenderHealth</td>
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<td>2</td>
<td>36/60</td>
<td>288</td>
</tr>
<tr>
<td>Princeton Center for Leadership Training</td>
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<td>2</td>
<td>36/60</td>
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<tr>
<td>Total</td>
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<td>1,973</td>
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</tbody>
</table>

Terry S. Clark, Assistant Information Collection Clearance Officer.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development 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 section 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 Institute of Child Health and Human Development Special Emphasis Panel P2C_Infrastructure/Center Grants.

Date: June 29, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

List of Environmentally Responsive Human Genes Selected for Use In Screening Large Numbers of Substances Using Toxicogenomic Approaches

Request for Comments: The National Institute of Environmental Health Sciences/National Toxicology Program requests comments on a list of environmentally responsive human genes selected for use in screening large numbers of substances using toxicogenomic approaches.

SUMMARY: The National Institute of Environmental Health Sciences (NIEHS)/National Toxicology Program (NTP) requests comments on a set of approximately 1500 human genes that have been identified and prioritized as environmentally responsive. These genes will be used in toxicogenomics approaches to screen cells or tissues obtained from humans against large numbers of chemicals. The goal was to generate a set of approximately 1500 human genes to evaluate transcriptional changes in response to chemical exposures. Similar gene sets will be developed for screening cells or tissues from other species such as rats, mice, zebrafish, and Caenorhabditis elegans. The human gene set should provide maximal toxicogenomic information on effects from chemical exposures that reflect general cellular responses, independent of cell type or species, and gene expression changes that are specific by organ and/or cell type. Such a list of environmentally responsive genes may also be useful in biomarker development and basic research efforts. This list of genes, referred to as the “S1500” gene list, or gene set, is available for public comment.

DATES: The deadline for receipt of comments is May 15, 2015.

ADDRESSES: Comments on the human S1500 gene set should be submitted electronically in Microsoft Excel or Word formats to Genelist@niehs.nih.gov. Nominations for genes to be added to the S1500 must be accompanied with a strong scientific justification for inclusion.

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.

SUPPLEMENTARY INFORMATION:

Background: In 2008, 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 formalize 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.

Tox21 partner agencies collaborate to research, develop, validate, and translate innovative testing methods for characterization of toxicity pathways; identify compounds, assay, 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. The primary activity of Tox21 Phase I was the development of a quantitative high throughput screening (qHTS) approach for toxicology. The goal of Phase II was the implementation of the qHTS approach in screening a 10,000 compound library through a variety of nuclear receptor agonist/antagonist and stress response pathway assays, utilizing primarily reporter gene platforms. In Phase III, the focus is on assaying chemicals in high-content screens and mid to high throughput transcriptomic screens. High throughput gene expression changes will be the primary metric that is employed in Phase III to measure biological effects from chemical exposures.

To conduct Tox21 Phase III, Tox21 partners initiated the “S1500 Genes High Throughput Transcriptomics” project to capture information from the whole transcriptome (i.e., the entirety of all expressed RNA molecules in a cell or biological sample). This project will use a targeted subset of genes in a HTS or semi-HTS platform to gain insight into how biological systems respond to chemical exposures. Neither the actual number of genes to be utilized, nor the specific transcriptomics platform(s) needed to carry out the project, have been finalized.

In an effort to select an appropriate subset of key representative or “sentinel” genes, the NTP previously requested input from the scientific community (78 FR 45542, July 29, 2013) on the “Nomination and Prioritization of Environmentally Responsive Genes For Use in Screening Large Numbers of Substances Using Toxicogenomic Technologies.” An interagency working group composed of members of the Tox21 partnership considered the input provided in response to the Federal Register notice as they developed a consensus strategy to select appropriate genes.

The working group’s goal was to select the most relevant and biologically diverse set of sentinel genes to represent transcriptomic responses to injury. Criteria for the selection and evaluation of an appropriate gene set are: (1) Representative of highly diverse gene expression changes reported to date, (2) capable of predicting the gene expression changes observed across the transcriptome, and (3) coverage of all major biological pathways.

The current version of the human S1500 gene set can be found at http://ntp.niehs.nih.gov/go/S1500. This site will be updated as changes to the list are made. The consensus strategy for selection of an appropriate sentinel gene set can be accessed at the same site.

Comments on the human S1500 gene set should be submitted electronically in Microsoft Excel or Word format to Genelist@niehs.nih.gov.

Respondents to this request are asked to provide their name, affiliation, address, and contact information (including telephone and fax numbers, and email address). The deadline for receipt of comments is May 15, 2015.