implementation, and evaluation of tobacco-product regulations in the U.S.

Frequency of Response: Annually. *Affected Public:* Individuals or households. *Type of Respondents:* Youth (ages 12–17) and Adults (ages 18+). The annual reporting burden for the field test is presented in Table 1, and the annual reporting burden for the baseline data collection is presented in Table 2. The annualized cost to respondents for the field test is estimated at: $22,993; and the annualized cost to respondents for the baseline data collection is: $1,792,156. There are no capital, operating, or maintenance costs.

TABLE 1—PATH STUDY FIELD TEST HOUR BURDEN ESTIMATES

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Adults—Household Screener	1,295	1	17/60	367
Adults—Individual Screener	840	1	6/60	84
Adults—Extended Interview	590	1	119/60	679
Adults—Biospecimen Collection Forms	590	1	9/60	89
Adults—Tobacco Use Form	590	1	2/60	20
Adults—Followup/Tracking Participant Information Form	590	2	6/60	118
Youth—Extended Interview	100	1	35/60	58
Adult—Parent Interview	100	1	19/60	32
Adults—Followup/Tracking Participant Information Form for Youth (completed by parents)	100	2	8/60	27
Total				1,446

TABLE 2—PATH STUDY BASELINE HOUR BURDEN ESTIMATES

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Adults—Household Screener	100,983	1	17/60	28,612
Adults—Individual Screener	63,000	1	6/60	6,300
Adults—Extended Interview	42,730	1	119/60	49,140
Adults—Biospecimen Collection Forms	42,730	1	9/60	6,410
Adults—Tobacco Use Form	42,730	1	2/60	1,424
Adults—Followup/Tracking Participant Information Form	42,730	2	6/60	8,546
Youth—Extended Interview	16,857	1	35/60	9,833
Adult—Parent Interview	16,857	1	19/60	5,338
Adults—Followup/Tracking Participant Information Form for Youth (completed by parents)	16,857	2	8/60	4,495
Total				115,602

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

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: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Kevin P. Conway, Ph.D., Deputy Director, Division of Epidemiology, Services, and Prevention Research, National Institute on Drug Abuse, 6001 Executive Blvd., Room 5185; 301–443–8755; email *PATHprojectofficer@mail.nih.gov*.

Comments 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.

Dated: August 7, 2012.

Glenda J. Conroy,

Executive Officer (OM Director) NIDA.

[FR Doc. 2012–20068 Filed 8–14–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft National Toxicology Program (NTP) Monograph on Developmental Effects and Pregnancy Outcomes Associated With Cancer Chemotherapy Use During Pregnancy; Request for Comments; Peer Review Panel Meeting

AGENCY: Division of the National Toxicology Program (DNTP), National

Institute of Environmental Health Sciences (NIEHS), National Institutes of Health.

ACTION: Notice.

DATES: The peer review meeting will take place October 1, 2012, 1:00 to 5:00 p.m. Eastern Daylight Time (EDT) and October 2, 2012, from 8:30 a.m. until adjournment, approximately 5 p.m. Two days are set aside for the meeting; however, it may adjourn sooner if the panel completes its peer review of the draft monograph.

Topic: Peer review of the draft NTP Monograph on Developmental Effects and Pregnancy Outcomes Associated with Cancer Chemotherapy Use during Pregnancy (available by August 14, 2012, at *http://ntp.niehs.nih.gov/go/36639*).

Place: Rodbell Auditorium, Rall Building, NIEHS, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709. The meeting is open to the public with attendance limited only by the space available. Webcast of the meeting will be available at *http://www.niehs.nih.gov/news/video/index.cfm.*

Contact Person: Dr. Mary S. Wolfe, NTP Designated Federal Official, Office of Liaison, Policy and Review, DNTP, NIEHS, P.O. Box 12233, MD K2–03, Research Triangle Park, NC 27709, Phone: (919) 541–7539, Fax: (919) 541–0295, or *wolfe@niehs.nih.gov.* Courier address: 530 Davis Drive, Room 2142, Morrisville, NC 27560.

Request for Comments and Registration: The meeting is open to the public with time scheduled for oral public comment. The NTP also invites written comments on the draft monograph, submission deadline is September 14, 2012, and the deadline for pre-registration to attend the meeting and/or provide oral comments is September 24, 2012, online registration is available at *http://ntp.niehs.nih.gov/go/36639.* Visitor and security information is available at *http://www.niehs.nih.gov/about/visiting/index.cfm.* Public comments and any other correspondence on the draft monograph should be sent to the Contact Person. Individuals with disabilities who need accommodation to participate in this event should contact Danica Andrews at phone: (919) 541–2595 or email: *andrewsda@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.

SUPPLEMENTARY INFORMATION:

Background

The panel will peer review the Draft NTP Monograph on Developmental Effects and Pregnancy Outcomes Associated with Cancer Chemotherapy Use during Pregnancy, prepared by the Office of Health Assessment and Translation (OHAT), DNTP. Cancer diagnosed during pregnancy affects approximately 1/6000 to 1/1000 women. Treatment for cancer frequently involves chemotherapy, and nearly all chemotherapeutic agents are known developmental toxicants in laboratory animals. OHAT has prepared a comprehensive draft NTP Monograph that summarizes the effects on development and pregnancy outcomes of gestational exposure to 52 cancer chemotherapeutic agents, individually and/or in combination therapy as reported in the peer-reviewed literature. The draft monograph also provides information on seven frequently diagnosed cancers in pregnant women and on mechanism of action, placental and breast milk transport, and laboratory animal developmental toxicology for the more frequently used chemotherapeutic agents. The overall goal of the monograph is to serve as a resource for the medical communities and their patients.

Preliminary Topic and Availability of Meeting Materials

The preliminary agenda and draft monograph should be posted on the NTP Web site (*http://ntp.niehs.nih.gov/go/36639*) by August 14, 2012. Additional information, when available, will be posted on the NTP Web site or may be requested in hardcopy from the Contact Person. Following the meeting, a report of the peer review will be prepared and made available on the NTP Web site. Registered attendees are encouraged to access the meeting page to stay abreast of the most current information regarding the meeting.

Request for Comments

The NTP invites written comments on the draft monograph, which should be received by September 14, 2012, to enable review by the peer review panel and NTP staff prior to the meeting. Persons submitting written comments should include their name, affiliation, mailing address, phone, email, and sponsoring organization (if any) with the document. Written comments received in response to this notice will be posted on the NTP Web site, and the submitter will be identified by name, affiliation, and/or sponsoring organization.

Public input at this meeting is also invited, and time is set aside for the presentation of oral comments on the draft monograph. In addition to in-person oral comments at the meeting at the NIEHS, public comments can be presented by teleconference line. There will be 50 lines for this call; availability will be on a first-come, first-served basis. The available lines will be open from 1–5 p.m. EDT on October 1 and from 8:30 until adjournment on October 2, although oral comments will be received only during the formal public comment period indicated on the preliminary agenda. Each organization is allowed one time slot. At least 7 minutes will be allotted to each speaker, and if time permits, may be extended to 10 minutes at the discretion of the chair. Persons wishing to make an oral presentation are asked to register online at *http://ntp.niehs.nih.gov/go/36639* by September 24, 2012, and if possible, to send a copy of their slides and/or statement or talking points at that time. Written statements can supplement and may expand the oral presentation. Registration for oral comments will also be available at the meeting, although time allowed for presentation by on-site registrants may be less than that for pre-registered speakers and will be determined by the number of persons who register on-site.

Background Information on OHAT and NTP Peer Review Panels

The NIEHS/DNTP established OHAT to serve as an environmental health resource to the public and to regulatory and health agencies. 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. OHAT also organizes workshops or state-of-the-science evaluations to address issues of importance in environmental health sciences. OHAT assessments are published as NTP Monographs. Information about OHAT is found at *http://ntp.niehs.nih.gov/go/ohat.*

NTP panels are technical, scientific advisory bodies established on an ''as needed'' basis to provide independent scientific peer review and advise the NTP on agents of public health concern, new/revised toxicological test methods, or other issues. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human hazard, setting

research and testing priorities, and providing information to regulatory agencies about alternative methods for toxicity screening. The NTP welcomes nominations of scientific experts for upcoming panels. Scientists interested in serving on an NTP panel should provide a current *curriculum vitae* to the Contact Person. The authority for NTP panels is provided by 42 U.S.C. 217a; section 222 of the Public Health Service (PHS) Act, as amended. The panel is governed by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: August 8, 2012.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2012–20044 Filed 8–14–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, 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. 207 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.

Quick2Insight: 3D Biological Tissue Image Rendering Software

Description of Technology: Available for licensing for commercialization or internal use is software providing automatic visualization of features inside biological image volumes in 3D. The software provides a simple and interactive visualization for the exploration of biological datasets through dataset-specific transfer functions and direct volume rendering. The method employs a K–Means++ clustering algorithm to classify a two-dimensional histogram created from the input volume. The classification process utilizes spatial and data properties from the volume. Then using properties derived from the classified clusters the software automatically generates color and opacity transfer functions and presents the user with a high quality initial rendering of the volume data. User input can be incorporated through the simple yet intuitive interface for transfer function manipulation included in our framework. Our new interface helps users focus on feature space exploration instead of the usual effort intensive, low-level widget manipulation.

Potential Commercial Applications:

- Biological tissue visualization in 3D
- Research uses

Competitive Advantages:

- User friendly
- Intuitive interface

Development Stage: Prototype

Inventors: Yanling Liu, Jack Collins, Curtis Lisle (all of FCRDC/SAIC)

Publications:

1. Maciejewski R, *et al.* Structuring feature space: a non-parametric method for volumetric transfer function generation. IEEE Trans Vis Comput Graphics. 2009 Nov–Dec;15(6):1473–80. [PMID 19834223]

2. Zhou J, Takatsuka M. Automatic transfer function generation using contour tree controlled residue flow model and color harmonics. IEEE Trans Vis Comput Graphics. 2009 Nov–Dec;15(6):1481–8. [PMID 19834224]

3. Röttger S, *et al.* Spatialized Transfer Functions. In: Brodlie K, Duke DJ, and Joy KI (eds.) EuroVis05 Joint Eurographics—IEEE VGTC Symposium on Visualization 1–3 June 2005, Leeds, United Kingdom, pp. 271–278. [doi: 10.2312/VisSym/EuroVis05/271–278]

Intellectual Property: HHS Reference No. E–254–2012/0 — Software Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Michael Shmilovich; 301–435–5019; *shmilovm@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize automatic 3D visualization of biological image volumes. For collaboration opportunities, please contact John Hewes, Ph.D. at *hewesj@mail.nih.gov*.

Human Renal Epithelial Tubular Cells for Studies of Cystinosis

Description of Technology: Cystinosis is a rare lysosomal storage disease, affecting about 500 people (mostly children) in the United States and about 2000 people worldwide. It is an autosomal recessive disorder, wherein patients have a defect in the CTNS gene, which codes for the lysosomal cystine transporter. In this disorder, cystine (an amino acid) is not properly transported out of the lysosome and accumulates in the cells, forming damaging crystals. As a result, cystinosis slowly destroys various organs in the body, including kidneys, liver, muscles, eyes, and brain. Currently, the only treatment for cystinosis is cysteamine, a drug that reduces intracellular cystine levels, although this treatment requires frequent dosing.

Available from NHGRI are human renal epithelial tubular cells isolated from cystinosis patient samples. These cells may be useful for studying the biology of cystinosis, as well as the metabolic role of the lysosomal cystine transporter; they may also be useful for the development of screening assays for potential therapeutic agents for cystinosis.

Potential Commercial Applications:

- Use in studies focused on cystinosis and lysosomal metabolism
- Use in assays for high throughput screening of potential therapeutic agents

Competitive Advantages: These cell lines were derived from cystinosis patient samples, and studies performed using these cells are expected to correlate well to the initiation, progression and treatment of cystinosis in patients.

Development Stage: Early-stage

Inventor: William A. Gahl (NHGRI)

Intellectual Property: HHS Reference No. E–204–2012/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Tara L. Kirby, Ph.D.; 301–435–4426; *tarak@mail.nih.gov*.

Context Aware Mobile Device Software for Substance Abuse Interventions and Behavioral Modification

Description of Technology: Available for licensing for commercial development is software that provides personalized feedback for treating drug dependence and associated risky behaviors. The tool is designed for both healthcare providers at the point-of-care and for self-help. Many people who could benefit from treatment do not receive it because of its low availability and high cost. The available software