

Dated: January 24, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences (NIEHS); Request for Information (NOT-ES-11-006): Interagency Breast Cancer and Environmental Research Coordinating Committee

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

ACTION: Request for information.

SUMMARY: The Interagency Breast Cancer and Environmental Research Coordinating Committee is a congressionally mandated body established by the National Institute of Environmental Health Sciences (NIEHS), in collaboration with the National Cancer Institute (NCI). This Committee is comprised of 19 voting members, including representatives of Federal agencies; non-federal scientists, physicians, and other health professionals from clinical, basic, and public health sciences; and advocates for individuals with breast cancer.

The IBCERCC is charged with reviewing all research efforts within the U.S. Department of Health and Human Services (HHS) concerning the environmental and genomic factors related to the etiology of breast cancer, and developing a comprehensive summary of advances and recommendations regarding research gaps and needs for the Secretary of HHS.

This Request for Information (RFI) is directed toward addressing questions relevant to the Committee's mandate. The RFI was announced in the NIH Guide on January 13, 2011, and is available at <http://grants.nih.gov/grants/guide/notice-files/NOT-ES-11-006.html>.

DATES: A response is requested by February 16, 2011. Responses received after February 16, 2011 will be considered to the extent possible.

Responses: Please send responses to the IBCERCC (ibcercc@niehs.nih.gov) by February 16, 2011. The following are acceptable ways to submit your responses:

1. Copy and paste the questions into the body of an e-mail message and send

your responses to ibcercc@niehs.nih.gov; or

2. Mail or fax your responses in a letter to the attention of the contact person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

FOR FURTHER INFORMATION CONTACT:

Jennifer B. Collins, Division of Extramural Research and Training, NIEHS, P.O. Box 12233, MD K3-12, RTP, NC 27709; Telephone: 919-541-0117, FAX: 919-541-2860, E-mail: collins6@niehs.nih.gov.

SUPPLEMENTARY INFORMATION:

Background

The Committee's primary mission is to facilitate the efficient and effective exchange of information on breast cancer research activities among the member agencies, and to advise the NIH and other Federal agencies in the solicitation of proposals for collaborative, multidisciplinary research, including proposals to further evaluate environmental and genomic factors that may be related to the etiology of breast cancer. The Committee serves as a forum and assists in increasing public understanding of the member agencies' activities, programs, policies, and research, and in bringing important matters of interest forward for discussion.

Definition of Environment: For the purpose of this RFI, "environment" is broadly defined as any factors that are non-genetic in nature. This can include environmental chemicals, radiation, biological agents, pharmaceuticals, nutritional factors, and psychosocial and behavioral stressors.

Definition of Systems Biology: For the purpose of this RFI, "systems biology" refers to a holistic approach to the study of breast cancer etiology with the objective of simultaneously monitoring all biological processes and environmental exposures operating as an integrated system.

Information Requested

Input is invited on the items listed below and will be used as a resource by the IBCERCC members during the development of the comprehensive summary of advances and recommendations regarding research gaps and needs for the Secretary of HHS. Comment on each item is optional.

(1) How susceptibility to the effects of environmental exposures in sub-groups of the population (resulting from factors such as genetic or epigenetic variability, or timing of exposure during

development or other stages) impacts breast cancer risk.

(2) Differences in the type and extent of environmental exposures which help explain the differential distribution of breast cancer subtypes in the U.S. population.

(3) How windows of susceptibility during the life-course can be integrated into a complex systems biology approach to better understand the role of the environment and breast cancer.

(4) How additional insight into normal mammary gland development through research using cell lines and animal models can enhance our understanding of environmental exposures and mammary carcinogenesis.

(5) The technologies and analytic capacity needed to accurately measure environmental exposures (including biological dose) and to develop markers of early damage relevant to breast cancer risk.

(6) The translation of research findings to the public about the environment and breast cancer risk considering the timing, and the strength of evidence, and the roles of community and advocacy groups.

(7) Engagement of advocacy organizations to ensure that environmental exposures of greatest interest and concern are studied and the role of media, data access, and publication access in this process.

(8) Approaches and effective models for coordination and collaboration among research agencies of the Federal Government to identify emerging opportunities in and programs to study environmental causes of breast cancer, such as in peer review, collaborative program development, and models for supporting cross-agency opportunities.

This Request for Information (RFI) is for information and planning purposes only and should not be construed as a solicitation or as an obligation on the part of the Federal Government, the National Institutes of Health (NIH), National Institute of Environmental Health Sciences (NIEHS) and or the National Cancer Institute (NCI). The NIH does not intend to award a grant or contract to pay for the preparation of any information submitted or for the NIH's use of such information. Respondents will not be notified of the NIH evaluation of the information received. No basis for claims against the NIH shall arise as a result of a response to this request for information or the NIH's use of such information as either part of our evaluation process or in developing specifications for any subsequent announcement. Responses

will be held confidential. Proprietary information should not be sent.

Dated: January 19, 2011.

Linda S. Birnbaum,

Director, National Institute of Environmental Health Sciences and National Toxicology Program.

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DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2010-0084]

National Protection and Programs Directorate; Agency Information Collection Activities; Office of Infrastructure Protection; Infrastructure Protection Stakeholder Input Project—Generic Clearance

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: 30-day notice and request for comments; New Information Collection Request: 1670-NEW.

SUMMARY: The Department of Homeland Security (DHS), National Protection and Programs Directorate (NPPD), Office of Infrastructure Protection (IP), will submit the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chapter 35). IP is soliciting comments concerning this New Information Collection Request, Infrastructure Protection Stakeholder Input Project—Generic Clearance. DHS previously published this information collection request (ICR) in the **Federal Register** on November 4, 2010, at 75 FR 67989, for a 60-day public comment period. No comments were received by DHS. The purpose of this notice is to allow additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until February 28, 2011. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. Comments should be addressed to the OMB Desk Officer, Department of Homeland Security, Office of Civil Rights and Civil Liberties. Comments must be identified by DHS-2010-0084 and may be submitted by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>.

- **E-mail:**

aira_submission@omb.eop.gov. Include the docket number in the subject line of the message.

- **Fax:** (202) 395-5806.

Instructions: All submissions received must include the words “Department of Homeland Security” and the docket number for this action. Comments received will be posted without alteration at <http://www.regulations.gov>, including any personal information provided.

OMB is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate 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. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

FOR FURTHER INFORMATION CONTACT: If additional information is required, contact DHS/NPPD/IP, Michael Beland, (703) 235-3696, Michael.Beland@hq.dhs.gov.

SUPPLEMENTARY INFORMATION: The Homeland Security Act of 2002 and Homeland Security Presidential Directive 7 (HSPD-7) call for DHS to coordinate the overall effort to enhance the protection of the Nation’s critical infrastructure and key resources. Specifically, HSPD-7 states that DHS “shall establish appropriate systems, mechanisms, and procedures to share homeland security information relevant to threats and vulnerabilities in national critical infrastructure and key resources with other Federal departments and agencies, State and local governments, and the private sector in a timely manner.” DHS designated IP to lead these efforts.

Given that the vast majority of the Nation’s critical infrastructure and key resources in most sectors are privately owned or controlled, IP’s success in achieving the homeland security mission for critical infrastructure protection and resilience is dependent

upon how well critical infrastructure owners and operators and members of the general public understand the key concepts, are aware of their contribution to achieve a shared national goal, participate in public-private partnerships, and are motivated to take action. However, IP has never conducted a comprehensive feedback assessment with the full range of its stakeholders to identify, measure, and improve the effectiveness of its efforts. IP desires to collect information from its stakeholders in order to:

- Provide a baseline for the effectiveness of efforts to improve the security of the nation’s infrastructure;
- Assist in validating and achieving IP’s strategic and mission area objectives;
- Obtain a better understanding of the evolving infrastructure protection and resiliency requirements of IP’s stakeholders;
- Increase the visibility and awareness of the critical infrastructure protection and resilience mission;
- Initiate the coordination and uniformity of outreach efforts by IP, sector-specific agencies, and other partners engaged in the infrastructure protection mission; and
- Collect feedback regarding event, threat or service-specific activities in a timely fashion.

Analysis

Agency: Department of Homeland Security, National Protection and Programs Directorate.

Title: Infrastructure Protection Stakeholder Input Project—Generic Clearance.

OMB Number: 1670-NEW.

IP Stakeholder Input Project—Surveys

Frequency: On occasion.

Affected Public: Private sector and non-Federal infrastructure protection community.

Number of Respondents: 5,980.

Estimated Time per Respondent: 40 minutes.

Total Burden Hours: 3,056 annual burden hours.

Total Burden Cost (capital/startup): \$0.

Total Burden Cost (operating/maintaining): \$0.

IP Stakeholder Input Project—Focus Groups

Frequency: On occasion.

Affected Public: Private sector and non-Federal infrastructure protection community.

Number of Respondents: 260.

Estimated Time per Respondent: 2 hours.