

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Health Assessment and Translation Evaluation of the State of the Science for Transgenerational Inheritance of Health Effects; Request for Information

SUMMARY: The Office of Health Assessment and Translation (OHAT) of the Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS), is initiating one or more systematic reviews to examine the state of the science for transgenerational inheritance of health effects. The specific scope of the evaluation will be determined following a phase of exploratory screening of the literature and consideration of responses to this request for information (RFI). OHAT requests information on the proposed approach for conducting the exploratory screening of the literature and the identification of scientists with knowledge or expertise relevant to this topic.

DATES: The deadline for receipt of information is June 28, 2013.

ADDRESSES: Information should be submitted at <http://ntp.niehs.nih.gov/go/38656>.

FOR FURTHER INFORMATION CONTACT:

Vickie R. Walker, Health Scientist, OHAT, DNTP, NIEHS, P.O. Box 12233, MD K2-04, Research Triangle Park, NC 27709; telephone (919) 541-4514; FAX: (301) 480-3337; vickie.walker@nih.gov. Courier Address: NIEHS, Room 2163, 530 Davis Drive, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background: There is a large body of evidence indicating that early life exposures can lead to disease outcomes later in life. The effects of these exposures are thought to be limited to the exposed generation, such that subsequent generations are unaffected by the exposure history of their parents and grandparents. However, recent reports have suggested that this may not be the case, and that adverse outcomes may be carried over to multiple unexposed generations. This phenomenon is known as "transgenerational inheritance." If the effects of exposure can indeed be transmitted to subsequent generations, this would have major public health implications. It is critical to determine how widespread and robust this phenomenon is, the factors that influence it, the mechanism by which it occurs, and the range of possible phenotypic outcomes (see <http://>

grants.nih.gov/grants/guide/rfa-files/RFA-ES-12-006.html). To assist with this effort, OHAT is initiating one or more evaluations using systematic review methodology to examine the state of the science for transgenerational inheritance of health effects associated with exposure to a wide range of stressors (e.g., environmental chemicals, drugs of abuse, nutrition and diet, pharmaceuticals, infectious agents, or stress).

The specific scope of the evaluation will be determined following a phase of exploratory screening of the literature and consideration of responses to this RFI.

Request for Information: A document outlining the proposed approach to conduct the exploratory screening is available at <http://ntp.niehs.nih.gov/go/38656>. OHAT requests information on the proposed approach for conducting the exploratory screening of the literature and the identification of scientists with knowledge or expertise relevant to this topic. Specifically, this information will help to (1) refine the proposed literature search strategy and criteria used to conduct the exploratory screening; (2) identify potential areas of focus for the systematic review(s); (3) identify unpublished, ongoing, or planned studies related to transgenerational inheritance; and (4) identify scientists with expertise or knowledge relative to this topic.

Responses are requested from all interested parties, such as the research community, health professionals, educators, policy makers, industry, and the public. Responses to this RFI are voluntary. OHAT does not intend to publish a summary of responses received or any other information provided, except very broad characterizations. Despite this, proprietary, classified, or confidential information should not be included in the response. This RFI is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to it. Please note that the U.S. Government will not pay for the preparation of any information submitted or for its use of that information. The U.S. Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted.

Future updates on this project, will be posted at <http://ntp.niehs.nih.gov/go/38159>. Individuals interested in receiving updates on this and other NTP projects are encouraged to register to the

NTP Listserv (<http://ntp.niehs.nih.gov/go/getnews>).

Background Information on the NTP and OHAT: The NTP is an interagency program, established in 1978 (43 FR 53060) and headquartered at the NIEHS, whose mission is to evaluate agents of public health concern by developing and applying tools of modern toxicology and molecular biology. The NTP carries out literature analysis activities in OHAT and the Office of the Reports on Carcinogens within the DNTP. The NTP also designs and conducts laboratory studies and testing programs and analyzes its findings to assess potential hazards to human health from exposure to environmental substances (see <http://ntp.niehs.nih.gov/>).

OHAT was established 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>.

Dated: April 26, 2013.

John R. Bucher,

Associate Director, National Toxicology Program.

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Prospective Grant of Start-Up Exclusive License: 1. Catalytic Domains of Beta (1,4)-Galactosyltransferase I Having Altered Donor and Acceptor Specificities Domains, That Promote in Vitro Protein Folding and Methods for Their Use; 2. Targeted Delivery System for Bioactive Agents

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National