

CONTRACT CONCEPT REVIEW

NTP Board of Scientific Counselors Meeting

December 9-10, 2014

Concept title: Scientific Information Management and Literature-Based Evaluations for NTP

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Purpose

The purpose of this contract is to obtain scientific and technical expertise to support scientific information management and the development of literature-based assessments of environmental chemicals and other issues of concern for public health for the National Toxicology Program (NTP). This contract will service four groups within the NIEHS/DNTP in support of NTP activities:

- **Office of Health Assessment and Translation (OHAT):** Conducts literature-based assessments to identify potential noncancer health hazards, provides opinions on whether they may be of concern given human exposure levels, and organizes workshops or state-of-the-science evaluations to address other issues of importance to public health.
- **Office of Nominations and Selection (ONS):** Oversees the nomination, review, and selection of environmental substances or issues for research or testing by the NTP, and manages the development and review of comprehensive scientific documents that provide information about the breadth of data on a substance and potential toxicological data needs.
- **Office of Report on Carcinogens (ORoC):** Prepares the congressionally mandated *Report on Carcinogens*, a listing of known and reasonably anticipated human carcinogens, and organizes webinars, symposia, and workshops related to cancer hazard evaluation of environmental substances or issues.
- **Office of Liaison, Policy and Review (OLPR):** Oversees and manages activities related to scientific peer review, external advisory groups, workshops, and other programmatic meetings.

Background and Significance

To achieve its mission, the NTP carries out a broad range of toxicology research and testing activities to identify substances in our environment that are potential hazards for human health. One of the ways that the NTP identifies hazards is through conduct of literature-based health assessments. This includes preparation of documents such as the *Report on Carcinogens* and monographs on noncancer health hazards. These assessments are used broadly by others, nationally and internationally, including health regulatory and research agencies, medical and scientific communities, and the public. It is imperative that they are of the highest quality and

take advantage of current methodologies and practices. It is also important that the assessments be transparent in their conduct and decision-making.

Previously, ONS, ORoC, and OHAT, to a lesser extent, have utilized contracts to obtain scientific, technical, and administrative support for carrying out literature-based evaluations. Due to different timelines, processes and procedures, separate contracts were necessary to support the three groups' activities.

OHAT has recently published a new framework¹ for carrying out literature-based assessments that incorporates systematic review methodologies for the identification, evaluation, and integration of information, taking advantage of these and related practices that have been endorsed by committees of the National Academy of Sciences for addressing questions about environmental exposures and human health. ORoC has also incorporated new systematic approaches in preparing monographs on substances under evaluation for the *Report on Carcinogens*. NIEHS/DNTP now wants to utilize these methodologies, visualization tools, and related practices in its literature-based assessments to present information about the state of the science, scope research needs for further investigation, and/or identify potential hazards for human health. Although the assessments undertaken by OHAT, ONS, and ORoC will vary in complexity and scope, NIEHS/DNTP will benefit from having a contract that can service several groups using similar methodologies and requiring similar expertise. Likewise, OLPR will benefit from centralization of contractor support for meetings and advisory committee-related activities for the evaluations, such as peer review.

Scope and Objectives

NIEHS/DNTP seeks scientific and technical expertise and support to compile, review, and analyze scientific information and data from the published literature and other sources regarding the effects of environmental chemicals and other issues that may impact public health. The nature and complexity of the data and information requires broad professional and technical experience in environmental health sciences including, but not limited to, specialized scientific expertise in toxicology, epidemiology, chemistry, and exposure assessment. The tasks to support this endeavor will address scientific information management, literature-based health hazard assessments, and associated supporting activities for OHAT, ORoC, ONS, and OLPR. The following is a brief description of the requirements:

Environmental health literature searching and management: Expertise with and access to a variety of specialized databases and information resources is needed to develop and carry out focused and/or comprehensive literature search strategies. The outcome of these searches would be to identify and compile information and/or published articles on environmental chemicals including use, occurrence and human exposure, guidelines and regulations, and scientific literature on human, experimental animal, and in vitro/mechanistic studies.

¹ Rooney AA, Boyles AL, Wolfe MS, Bucher JR, Thayer KA. Systematic review and evidence integration for literature-based environmental health science assessments. *Environ Health Perspect*. 2014 Jul;122(7):711-8. doi: 10.1289/ehp.1307972. Epub 2014 Apr 18.

Literature screening to identify relevant scientific information: Expertise with screening of the scientific literature using state-of-the-art approaches to identify, select, and track relevant and non-relevant studies.

Scientific data extraction, management, and visualization: Scientific expertise in relevant fields to evaluate scientific literature and extract specified data using web-based forms into databases. Experience with maintaining data integrity and security and preparing graphical visualizations and tabular formats of complex scientific data and pathways.

Study quality assessment, data interpretation, and scientific evidence integration: Scientific expertise in the review, evaluation, and summarization of scientific and technical information and data. Use of scientific knowledge and independent judgment to evaluate the quality of individual studies, interpret study findings, and integrate information from multiple evidence streams including human, experimental animal, and in vitro/mechanistic studies.

Document preparation and publication: Administrative and technical expertise in the preparation, formatting, and publication of printed and electronic scientific documents, including experience with desktop publishing software and Section 508 compliance requirements.

Logistical management for meetings and events: Administrative and technical expertise in the conduct of web-based and in-person meetings, such as panels, peer reviews, symposia, workshops, focus groups, and seminars that vary in size and length, including travel, logistics, and preparation of summary reports.

Provision of scientific and technical consultants: Ability to secure and pay for consultant/experts with expertise in relevant scientific disciplines for any phase of an evaluation and/or manage subcontracts with identified experts/groups and pay for any services.