National Toxicology Program

Board of Scientific Counselors

July 11, 2023

National Institute of Environmental Health Sciences
Research Triangle Park, NC

Summary Minutes

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1. Location of Background Materials and Presentations

Background materials and presentations for the Board of Scientific Counselors meeting on July 11, 2023, are available on the National Toxicology Program (NTP) Past BSC Meetings page (https://ntp.niehs.nih.gov/go/meeting)

2. Abbreviations and Acronyms

BSC	Board of Scientific Counselors
COR	Contracting Officer's Representative
DTT	Division of Translational Toxicology
FACA	Federal Advisory Committee Act
NTP	National Toxicology Program
OA	Office of Acquisitions
R&D	Research and Development

3. Attendees[1]

Board of Scientific Counselors

Chair: Pamela Lein, PhD, University of California, Davis

Eric Blomme, DVM, PhD, DACVP, AbbVie

Kathleen Gray, PhD, University of North Carolina, Chapel Hill

Erin Haynes, DrPH, University of Kentucky

K. Sean Kimbro, PhD, Morehouse School of Medicine

Matthew Martin, PhD, Pfizer

John Meeker, ScD, University of Michigan

Mark Russi, MD, Yale University

Veena Singla, PhD, Natural Resources Defense Council

Janet Yang, PhD, University of Buffalo

National Institute of Environmental Health Sciences/Division of Translational Toxicology (NIEHS/DTT) Staff

Milene Brownlow, PhD

Robbin Guy

Erica Kitzmiller

[1]The meeting was webcast with the listed individuals attending by Zoom. NIEHS/NTP staff are limited to those with a role in the meeting. Public attendees are not listed.

Kelly Shipkowski, PhD

Robert Sills, PhD

Mary Wolfe, PHD

Rick Woychik, PhD

Other Federal Agency Staff

Gonçalo Gamboa da Costa, PhD, U.S. Food and Drug Administration (BSC liaison)

Christina Lawson, PhD, National Institute for Occupational Safety and Health (BSC liaison)

Contract Support Staff

Ernie Hood, Bridport Services

Oral Public Commenter

Randolph Ashton, PhD, Neurosetta LLC

4. Introductions and Welcome

The National Toxicology Program (NTP) Board of Scientific Counselors (BSC) convened on July 11, 2023, via Zoom for identified attendees noted above and by webcast for public attendees. Dr. Pamela Lein served as chair. Dr. Milene Brownlow served as the Designated Federal Officer.

Dr. Lein called the meeting to order at 11:00 a.m., welcomed everyone to the meeting, and asked all attendees to introduce themselves. BSC member Dr. Payne-Sturges was unable to attend.

Dr. Sills provided introductory remarks in his first BSC meeting as Interim Scientific Director of the Division of Translational Toxicology (DTT). He thanked everyone involved in preparing for the Contract Concept Review meeting. He said he had two goals when he started his current position. First, to engage with staff and support everyone, given the many changes in DTT over the past several years. His second goal was to build on the division's scientific strengths. He noted that there are currently three candidates for the permanent DTT Scientific Director position, who would be interviewed in the near future.

Dr. Woychik thanked Dr. Sills for his willingness to step into this very important role during this interim period.

Dr. Brownlow read the conflict-of-interest policy statement and briefed the attendees on meeting logistics.

5. Instructions for Concept Review

Erica Kitzmiller, a Contracting Officer from the NIEHS Office of Acquisitions (OA) provided background information about NIEHS contract concepts. The BSC is asked to review biomedical research and development (R&D) contracts requiring external peer review. **The concept review is required prior to the issuance of a contract solicitation.** Part of the concept review involves a high-level discussion of the project to identify the basic purpose, scope, and overall objectives

of the work. BSC members are reminded that the discussion is not to include specifics such as technical approaches, protocols, product specifications, or details of the acquisition approach.

BSC members are asked to review the contract concept for overall value and scientific relevance of the project as well as whether it supports the DTT goal of protecting public health. Specific areas should include:

- The significance of the goals of the proposed research activity
- The availability of technology and other resources necessary to achieve those goals
- The extent to which there are practical scientific or clinical uses for the expected results
- The adequacy of the proposed methodology
- The appropriateness of the use of a contract mechanism to support the activity

6. Contract Concept Review: Predictive Toxicology and Evidence Integration for the DTT, NIEHS

Dr. Kelly Shipkowski, the Contracting Officer's Representative (COR), briefed the board on the contract concept for Predictive Toxicology and Evidence Integration. She provided a high-level introduction to contract concepts and DTT contract support.

R&D contracts require external peer review of the corresponding contract concept if they are new, recompetitions with changes in the statement of work, or have been ongoing for five or more years since the last review. A review is required prior to requesting any proposals. A single contract concept may encompass multiple statements of work, solicitations, and/or contracts. Resulting contracts will be with NIEHS, but may support NTP projects.

Dr. Shipkowski noted that 78% of DTT funding involves R&D funds, which cover contracts and interagency agreements. She described the role of a COR in contract award and management and delineated the many areas of DTT contract support across the division, including the current area of contract concept review, Predictive Toxicology and Evidence Integration. She discussed how that area fits into the overall Translational Toxicology Pipeline, by supporting contracts that represent a variety of DTT capabilities. They are often interconnected with other DTT contracts, with the relationships among capabilities often leading to outputs of one contract becoming inputs for another.

She began the contract concept review itself by providing a history and overview of the requirement.

- Support for predictive toxicology and evidence integration is essential for DTT research program activities.
- The scope and breadth of the required support exceeds the internal staff resources available at NIEHS.
- Support for these activities has been obtained via contract resources for over 40 years.
- The type of support required has evolved over the years to align with changing division needs.

- Further alignment with the DTT strategic portfolio is anticipated.

The predictive toxicology and evidence integration support contracts represent nine key DTT capability areas:

1. Developing, evaluating, and implementing computational tools and methodologies
2. Developing, validating, and implementing alternative approaches for toxicity testing
3. Searching, screening, evaluating, and synthesizing information from environmental health literature
4. Compiling and preparing reports for publication, editing documents, and providing technical review for completeness, accuracy, and readability
5. Managing logistics for external peer reviews, including identifying and maintaining a directory of scientific experts, conducting conflict of interest screening, and preparing documents for peer review
6. Managing logistics for remote and in-person events, including Federal Advisory Committee Act (FACA) meetings, interagency engagements, and public workshops
7. Assessing the quality (accuracy, consistency, and completeness) of products, including toxicology study reports, literature evaluation reports, manuscripts, and data pipelines by comparing their content to original records and documentation
8. Identifying knowledge gaps and formulating discrete research questions
9. Tracking contract project spending, milestones, and deliverables, and managing personnel with efficient coordination of schedules to meet project needs

Dr. Shipkowski read the charge to the BSC:

- NIEHS proposes to obtain support for these activities via contract mechanism due to the scope of the required capabilities and availability of personnel with relevant experience to perform these activities exceeding the internal resources available.
- Consideration should be given to:
  - The significance of the goals of the proposed research activity
  - The availability of the technology and other resources necessary to achieve those goals
  - The extent to which there are practical scientific or clinical uses for the expected results
  - The adequacy of the proposed methodology
- The BSC members were asked to *review the contract concept and vote on <u>whether a contract mechanism is the appropriate mechanism to support the proposed activities</u>*.

Clarifying Questions

Dr. Blomme noted that the project would generate a high volume of data, and asked Dr. Shipkowski whether data storage capabilities are included in the scope or are completely separate. She answered that many of the data storage requirements are supported by other contracts.

Dr. Martin asked about the computing needs beyond storage and whether those capabilities are built in either through contractors or as a general service to all of NTP. Dr. Shipkowski said that those needs are certainly worth thinking about in terms of the contract concept, particularly since NIH has guidelines regarding data sharing and storage. Those needs are definitely considered, she added.

6.1 Oral Public Comment

Dr. Randolph Ashton, an associate professor of biomedical engineering at the University of Wisconsin-Madison and co-founder of Neurosetta LLC, addressed the BSC about the company's technology, a human stem cell-derived platform for quantitative high-throughput modeling of early human brain and spinal cord development. The RosetteArray™ platform is designed for developmental neurotoxicity screening. It represents an *in vitro*, bioengineered neural organoid morphogenesis model to allow neurotoxicity screening in a system where *in vivo* screening is not possible.

6.2 BSC Discussion

Dr. Lein reminded BSC members that their role is to vote on whether a contract mechanism is the appropriate mechanism to support the proposed activities that Dr. Shipkowski had reviewed. She asked the BSC members if anyone had any questions or comments to start the discussion. There were none. Dr. Lein, as chair, commented that the activity the board was being asked to consider seemed very straightforward, and that the contract mechanism, which had been used successfully in the past, remained appropriate.

6.3 BSC Action

Dr. Lein called for a motion on whether a contract mechanism is the appropriate mechanism to support the proposed activities. Dr. Martin so moved; Dr. Haynes seconded the motion.

The Board voted unanimously in favor of the motion to approve the contract concept.

7. Adjournment

Dr. Lein thanked the BSC members for their engagement during the meeting, and the NTP staff for arranging a clear presentation and charge, which made the board's decisions relatively straightforward.

Dr. Sills thanked everyone for their involvement in the meeting. Dr. Woychik added his thanks to all, and to Dr. Lein for chairing the proceedings.

Dr. Brownlow thanked everyone who handled the meeting's logistics and planning.

Dr. Lein adjourned the meeting at 11:52 a.m., July 11, 2023.

8. Approval of the Summary Minutes by the NTP BSC Chair

These summary minutes for the NTP Board of Scientific Counselors meeting on July 11, 2023, have been read and approved by the chair.

Signed

Pamela J. Lein, PhD

Professor and Chair, University of California, Davis

NTP BSC Chair