National Institute of Environmental Health Sciences
Division of Translational Toxicology

Contract Concept Review for Toxicology Support for the Division of Translational Toxicology, NIEHS

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NTP Board of Scientific Counselors

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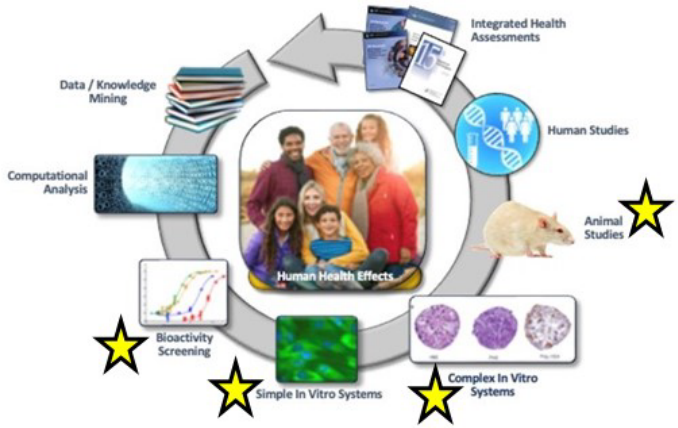
History and overview of the requirement

- Contract support for toxicology research has existed for > 40 years
- The types and use of capabilities have evolved over time
- Anticipate further alignment with the Division of Translational Toxicology strategic portfolio

Toxicology Research Areas
General Toxicology
Carcinogenicity
Development and Reproductive Toxicology
Neurobehavior and Neurotoxicity
Immunotoxicology
Molecular Toxicology

Translational Toxicology Pipeline



Overview of support

1. Implementation of in-house capabilities
2. Problem formulation
3. On-test chemistry
4. Conduct in chemico and in vitro studies
5. Conduct of in vivo animal studies

1. Implementation of in-house capabilities

– Utilize contract resources to implement and scale technologies and testing approaches developed in-house

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- Utilize contract resources to implement and scale technologies and testing approaches developed in-house
- Well established in-house workflows would be considered for implementation under contract

1. Implementation of in-house capabilities

– Utilize contract resources to implement and scale technologies and testing approaches developed in-house

- Evaluate the reliability and reproducibility, iterative refinement
- Determine the potential for routine use
- Implement as appropriate in on-going evaluations

1. Implementation of in-house capabilities

- Adoption of newer approaches within the toxicology research community
- Engage with regulatory partners

2. Problem formulation

- Utilize highly qualified, skilled, and knowledgeable contract staff
- Support the development of research questions to address broad objectives

3. On-test chemistry

Inhalation

- Bulk chemical characterization
- Develop/validate generation and monitoring systems

Non-inhalation

- Confirmation of identity and purity
- Formulation preparation and analysis

4. Conduct of in chemico or in vitro studies

- Using immortal or primary cells, cell suspensions, cells grown at the air-liquid interface, or 3D complex tissue models with multiple cell types, including microphysiological systems

5. Conduct of in vivo animal studies

- Various life stages, multiple routes of exposure
- Capacity for simultaneous conduct of multiple studies
- Wide variety of in-life and post-life assessments

Charge to the Board of Scientific Counselors

The BSC members are asked to review the concept for overall value and scientific relevance, as well as for fulling NIEHS' goal of protecting public health. Consideration should be given to:

- 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 DTT seeks approval from the BSC to continue this type of activity using a contract mechanism.

Questions?