

CONTRACT CONCEPT REVIEW

NTP Board of Scientific Counselors Meeting
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Title: Chemistry Support Contract Services for the Division of Translational Toxicology (DTT), National Institute of Environmental Health Sciences (NIEHS)

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Background and Significance:

The Division of Translational Toxicology (DTT) at the National Institute of Environmental Health Sciences (NIEHS) has a long history (> 40 years) of performing chemistry activities via contract mechanisms. DTT conducts a wide array of research utilizing in vitro assays and in vivo animal models to assess potential environmental contributors to human health effects. Chemistry support is a critical element of many of these projects. Research initiatives of the DTT can be found at <https://www.niehs.nih.gov/research/atniehs/dntp/index.cfm>.

Justification for Use of Contract Mechanism:

DTT requires chemistry support, using robust and accurate analytical methods and state-of-the-art techniques. Test articles may include chemical or physical agents. Support is typically provided by the contractor on a per-test article basis to provide key pieces of information at each step of the toxicological evaluation process. Because many of the DTT research programs study the same test articles, this approach allows chemistry support to be applied to multiple studies conducted at different times and research facilities. In addition, the scope of the required capabilities and the facilities, equipment, and personnel with relevant experience to perform these activities, exceed the resources available at the NIEHS; therefore, we request approval to obtain this support through a contract mechanism.

Capabilities:

Chemistry Support falls under nine key functional areas, which are *drafted* in the DTT Chemistry Specifications (https://ntp.niehs.nih.gov/go/SS_chemistryspecs).

The activities under these functional areas are well-aligned with the DTT mission and the support provided will be tailored to the requirements of a given research area. Briefly, the functional areas are:

- **Logistics and Handling:** Activities related to test article procurement, handling, and shipping.

- **Characterization:** Activities related to establishing the identity and determining the purity of a test article.
- **Formulation:** Activities related to preparation and analysis of formulations containing a single or multiple test article(s) in a vehicle.
- **Biosample Analysis:** Activities related to determination of the concentration of a test article, a metabolite of a test article, or a reaction product of the test article and/or a metabolite with cellular molecules (e.g., glutathione, protein or DNA adduct), in a biological matrix.
- **Animal Studies:** Studies include determination of palatability, absorption, distribution, metabolism, excretion, and toxicokinetic parameters.
- **Special Studies:** Activities that are within the overall scope of the contract and may or may not be contained within a single functional activity or that represent only a portion of a single functional activity (e.g., enzyme activity measurements, annual water analysis).
- **Omics:** Activities include those related to exposomics, metabolomics, proteomics analyses.
- **In Vitro Assays:** Activities include those related to determining in vitro absorption, distribution, metabolism, excretion, and bioaccumulation of a test article typically in rodent and human models.
- **Medium to High Throughput Screening (MHTS) activities:** Activities including procurement of small quantities of test articles, determination of identity and purity, preparation of solutions for testing, and inventory management for the DTT MHTS activities in in vitro or small animal models.

Most assignments under these contracts are conducted in a manner consistent with Good Laboratory Practice for Nonclinical laboratory Studies (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=58>). The proposed requirements encompass the current capabilities of the existing chemistry support contracts, with expanded capabilities in the areas of omics and in vitro assays to better address current program needs and directions.