



National Institute of
Environmental Health Sciences
Division of Translational Toxicology

NIEHS Contract Concept Introduction

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NTP Board of Scientific Counselors Meeting

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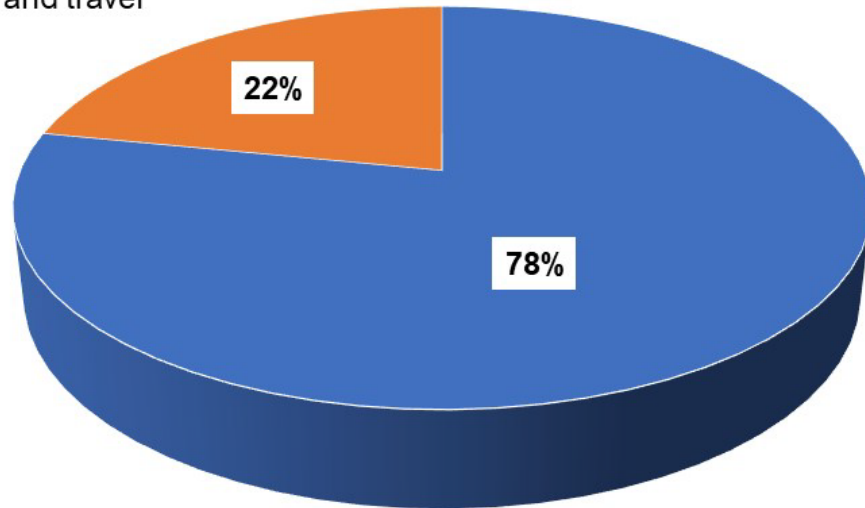


What is reviewed by BSC?

- Research and Development Contracts requiring external peer review:
 - New
 - **Recompetitions with changes in the statements of work**
 - **Ongoing for five or more years since last review**
- Required prior to issuance of a Request for Proposal (RFP)
- A single contract concept may encompass multiple statements of work, solicitations and/or contracts
- Resulting contracts will be with NIEHS
 - May support NTP projects



IR funding - salaries/fringe benefits,
operating expenses, and travel



■ R&D ■ IR

R&D funds - contracts
and Interagency Agreements (IAAs)

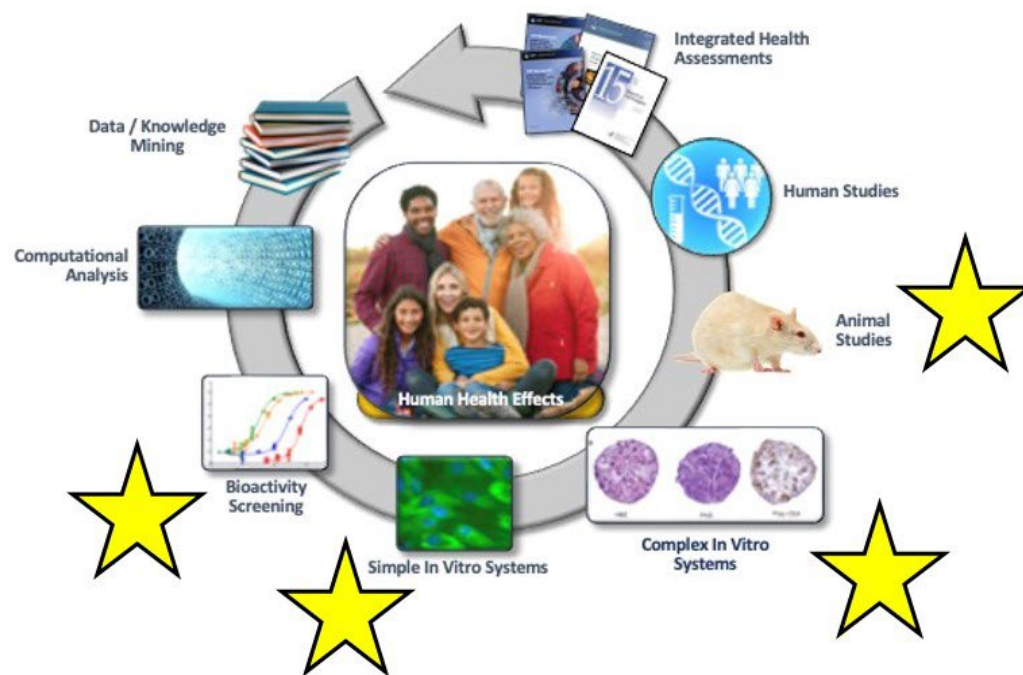


- **Chemistry**
- **Toxicology**
- **Pathology**
- Scientific information management & literature-based evaluations
- Evaluation of alternative toxicological methods
- Quality assessment
- Bioinformatics
- Genetic Toxicity Testing
- In life data collection and management (Provantis)
- Statistics
- Archives and repository
- Research data management and reporting
- Program and project management software
- NextGen sequencing projects
- Tissue chip consortium membership
- Conduct of in vitro developmental neurotoxicity assays



Translational Toxicology Pipeline

- Chemistry support, toxicology support, and pathology support contracts represent DTTs primary "wet-lab" capabilities
- Interconnectivities among DTT contracts and relationships among capabilities such that outputs of one contract may become inputs for another





Oral chronic study with in-life endpoints, internal concentration determination and histopathology

Chemistry Support

Test article procurement
& comprehensive characterization

Formulation and analysis method
development

Shipment of the test article to the
toxicology support contractor

Biosample analysis method
development and analysis for
internal concentrations

Chemical storage

Preparation of lab reports



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Toxicology Support

Receive test article; confirmation of
identity and purity; formulation
preparation and analysis

Study protocol, dosing, in-life
endpoints

Collect and send internal
concentration specimens

Return remaining test article

Gross and histopathology;
submission of pathology data and
specimens to NTP Archives

Preparation of lab report including
final histopathology data



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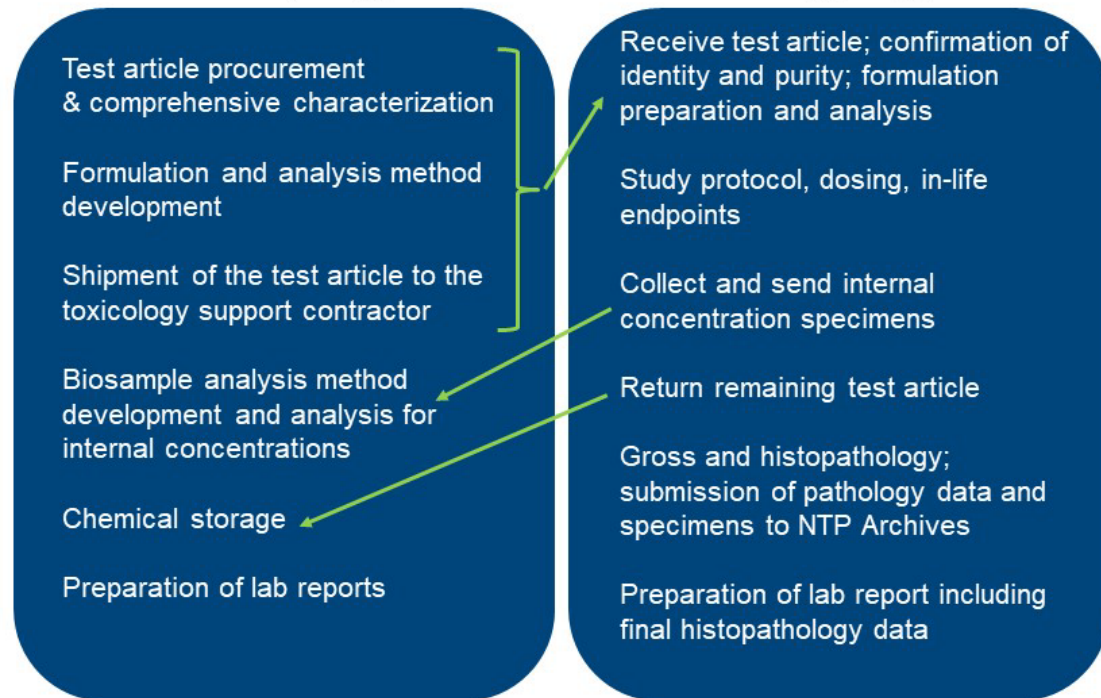
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Preparation of lab report including final histopathology data

Pathology Support

Receive pathology specimens from NTP Archives

Pathology data review

Audit of pathology specimens

Pathology quality assessment

Pathology working group

Finalization of histopathology data and preparation of lab reports



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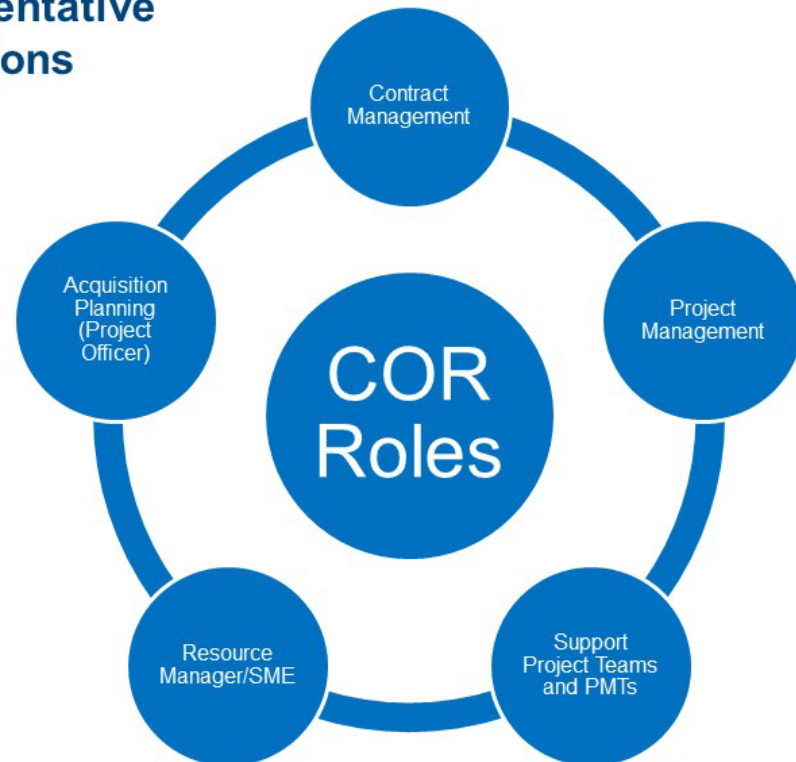
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Role of a Contracting Officer's Representative and the DTT Office of Program Operations in contract award and management

- Contracting Officer's Representative (COR) – authorized to perform specific technical and administrative functions under a contract
- Certification: COR I → COR II → COR III
 - Experience (2 years on federal projects for COR III)
 - Formal training
 - Transcript – competencies
 - Approval by NIH and HHS
- Most CORs at DTT reside in the Office of Program Operations (OPO)
 - OPO provides centralized oversight of budget and contract acquisition/management to DTT, as well as scientific and project management expertise





Other Mechanisms

- NIEHS Office of Technology Transfer
 - E.g., Materials transfer agreement (MTA), Cooperative Research & Development Agreements (CRADA), Research collaborative agreement (RCA)
 - Government not able to add funding to these agreements
 - DTT utilizes for collaborations
- NIEHS Division of Extramural Research and Training
 - Grants, Cooperative Agreements (U-mechanism)
 - Requires grant funding - not part of DTT allocation
 - DTT scientists frequently asked to serve as subject matter experts on cooperative agreements



Concept Discussions

- Meeting open to public - discussions are limited to review of the general project purposes, scopes, goals, and various optional approaches to pursue the overall objectives
- *Meeting closed to public - if discussion turns to the development or selection of details of the projects or RFPs*
 - e.g., specific technical approaches, protocols, statements of work, data formats, specifications
 - Intended to protect the free exchange of the advisory group members' opinions and avoid premature release of details of proposed contract projects or RFPs



Concept Discussions

- The BSC members are asked to review the contract project concepts for overall value and scientific relevance as well as for fulfilling the program goal of protecting public health. Specific areas should include:
 - The significance from a scientific or technical standpoint of the goals of the proposed research or development activity;
 - The availability of the technology and other resources necessary to achieve those goals;
 - The extent to which there are identified, practical use for the anticipated results of the activity;
 - Where the review includes the project approach, the adequacy of the methodology to be utilized in carrying out the activity



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Questions?



Comments?