

Contract Concept Review: Predictive Toxicology and Evidence Integration for the Division of Translational Toxicology, NIEHS

Kelly Shipkowski, Ph.D., DABT

Health Science Evaluator, Office of Program Operations

NTP Board of Scientific Counselors Meeting

July 11, 2023



Agenda

- Introduction
 - Contract concepts
 - DTT contract support
- Concept review: Predictive toxicology and evidence integration



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 - **DTT contract support**
- Concept review: Predictive toxicology and evidence integration



What is Reviewed by the BSC?

- Research and development (R&D) contracts require external peer review of the corresponding contract concept:
 - New
 - Recompétitions with changes in the statements of work
 - Ongoing for five or more years since last review



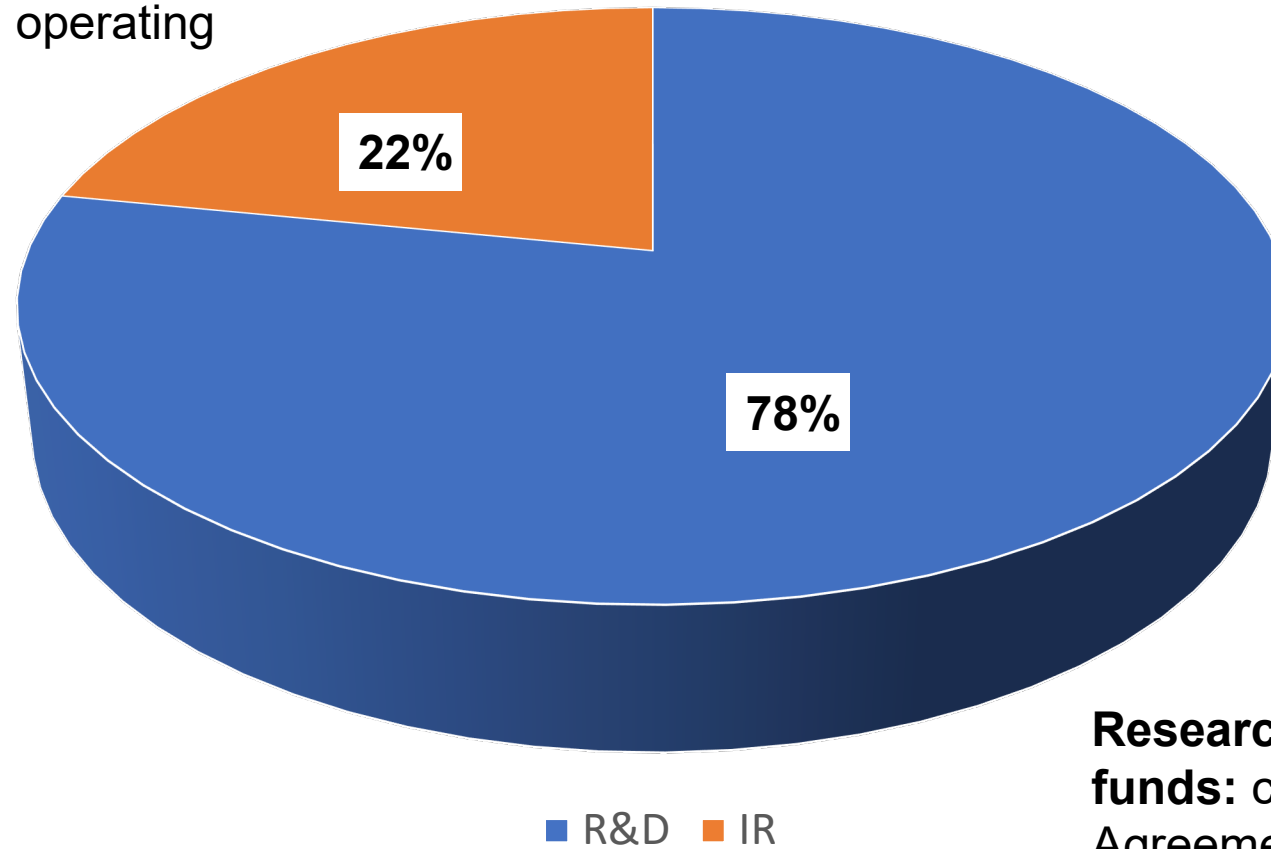
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 - **Recompetitions with changes in the statements of work**
 - **Ongoing for five or more years since last review**
- Required prior to requesting proposals (i.e., Requests for Proposals [RFPs])
- A single contract concept may encompass multiple statements of work, solicitations, and/or contracts
- Resulting contract(s) will be with NIEHS, but may support NTP projects

Intramural (IR) funds:
salaries/fringe benefits, operating
expenses, and travel



**Research & development (R&D)
funds:** contracts and Interagency
Agreements (IAAs)

Role of a Contracting Officer's Representative 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 DTT budget and contract acquisition/management, as well as scientific and project management expertise



Numerous Areas of Support Across the Division

- Archives and repository
- Bioinformatics
- Chemistry
- Genetic toxicity testing
- In-life data collection and management
- In vitro developmental neurotoxicity assays
- NextGen sequencing projects
- Pathology
- Predictive toxicology and evidence integration
- Program and project management software
- Research data management and reporting
- Statistics
- Tissue chip consortium membership
- Toxicology

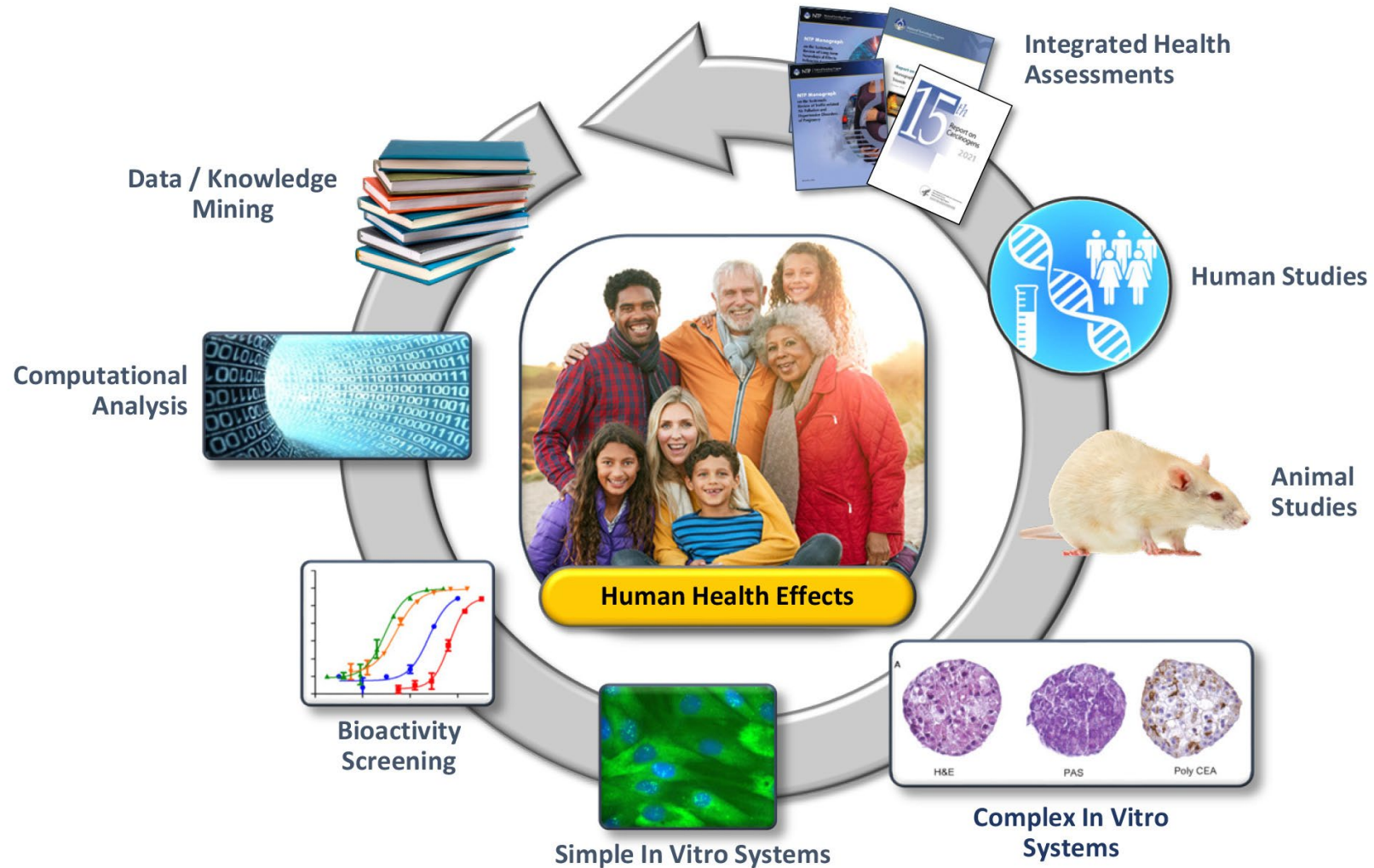
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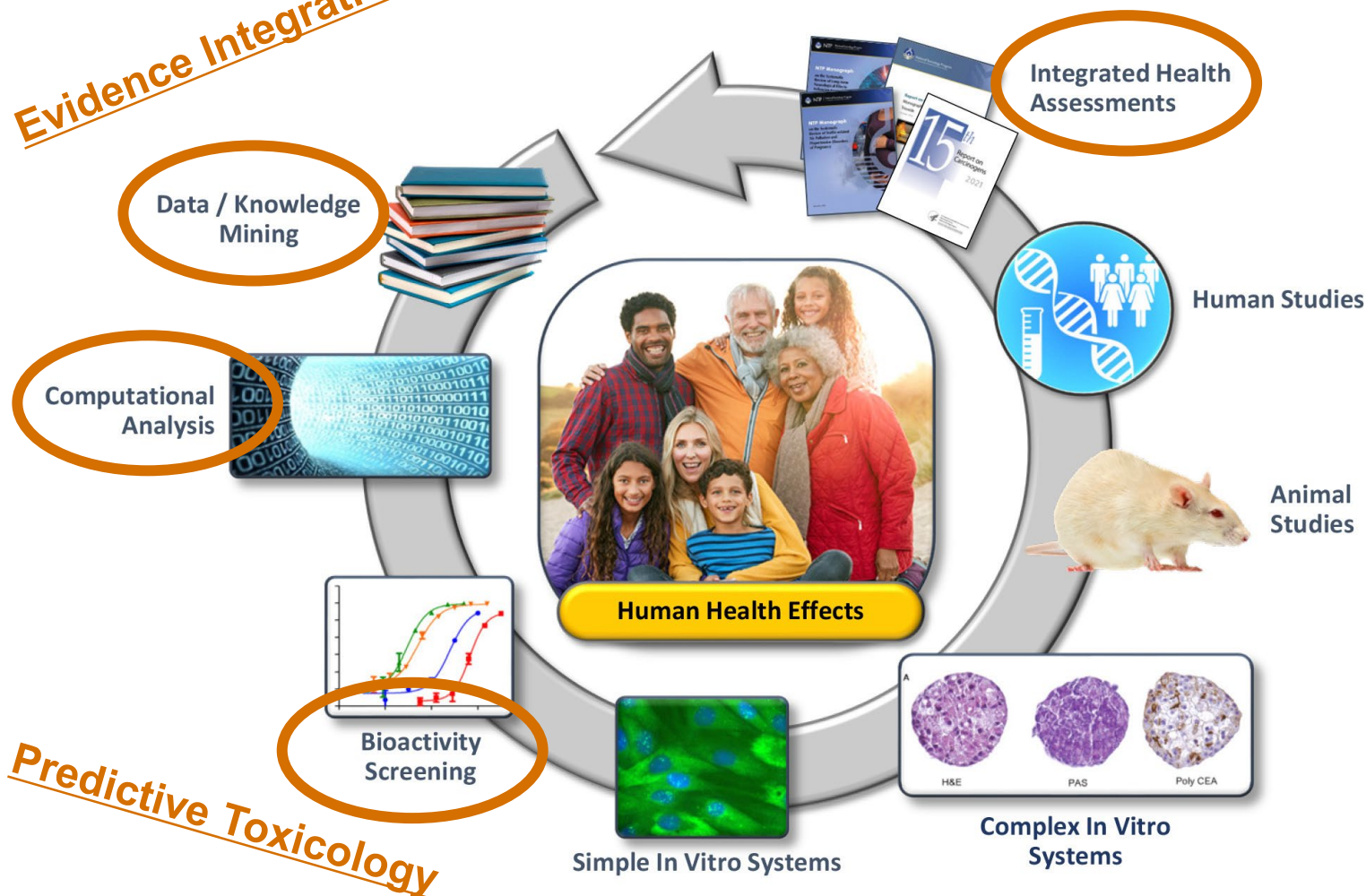
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Translational Toxicology Pipeline



Evidence Integration



- Predictive toxicology and evidence integration support contracts represent a variety of DTT capabilities
- Interconnectivity between these and other DTT contracts
- Relationships among capabilities are such that outputs of one contract may become inputs for another

Predictive Toxicology

Other Mechanisms for Collaboration and Support

- NIEHS Office of Technology Transfer
 - Examples: Materials Transfer Agreement (MTA), Cooperative Research & Development Agreements (CRADA), Research Collaborative Agreement (RCA)
 - Government not able to add funding to these agreements
 - DTT utilizes these for collaborations
- NIEHS Division of Extramural Research and Training
 - Grants, cooperative agreements (U-mechanism)
 - Requires grant authority and funding
 - DTT scientists may serve as subject matter experts on cooperative agreements

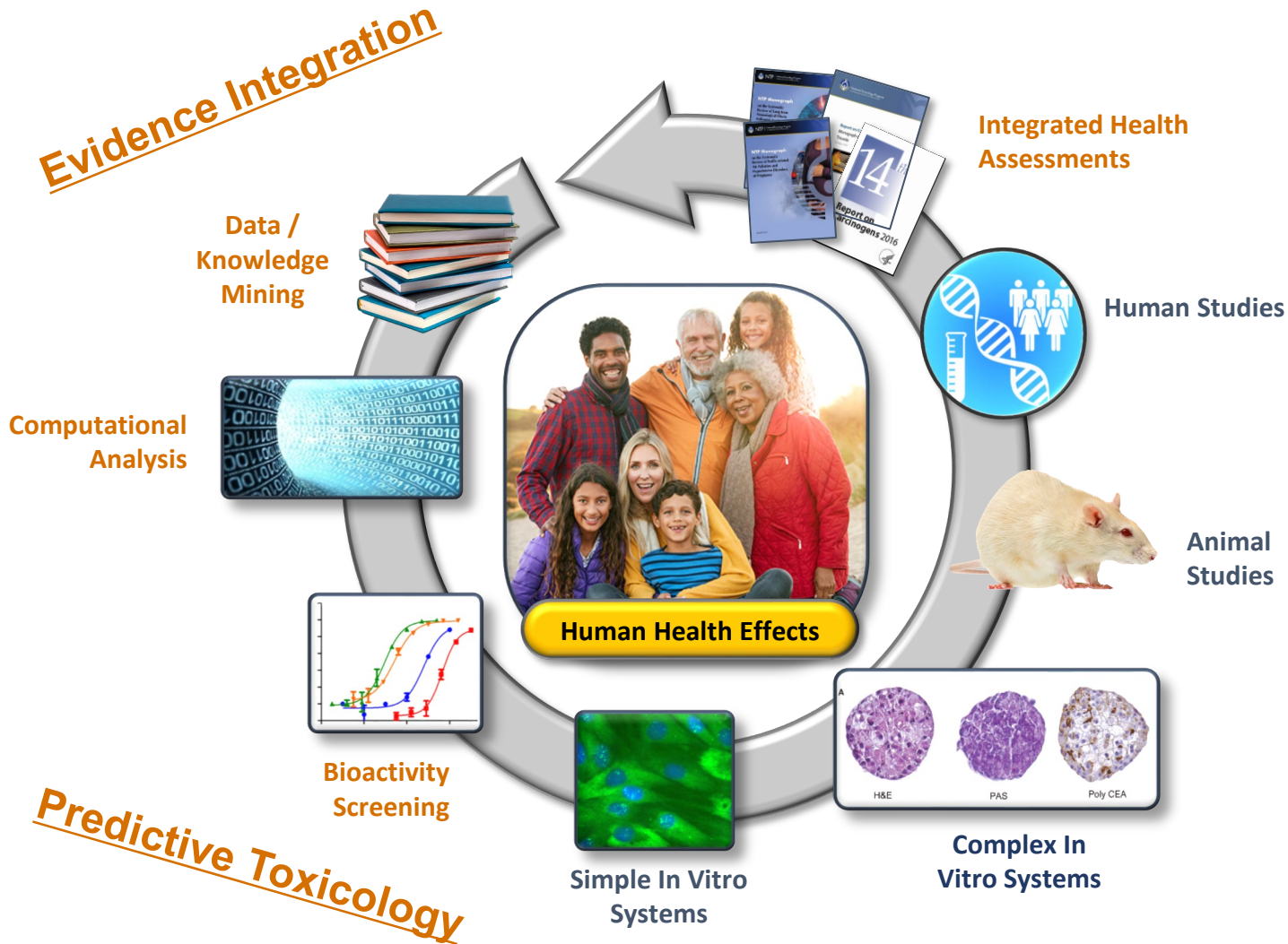


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- **Concept review: Predictive toxicology and evidence integration**

History and Overview of the Requirement

- Support for predictive toxicology and evidence integration is essential for Division of Translational Toxicology (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
 - Anticipate further alignment with the DTT strategic portfolio



- Predictive toxicology and evidence integration support contracts represent a variety of DTT capabilities
- **Nine key capability areas**

Predictive Toxicology and Evidence Integration Support

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

Predictive Toxicology and Evidence Integration Support

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

Predictive Toxicology and Evidence Integration Support

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

Concept Discussions

- Meeting open to the public – discussions are limited to review of the general project purposes, scopes, goals, and various optional approaches to pursue the overall objectives
- *Meeting will be closed to the public if discussions turn into the development or selection of details for the projects or Requests for Proposals (RFPs)*
 - Specific technical approaches, protocols, statements of work, data formats, specifications
 - Intended to protect the free exchange of the advisory group members' opinions while avoiding premature release of details on proposed contract projects or RFPs

Charge to the Board of Scientific Counselors

- 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 are asked to *review the contract concept and vote on whether a contract mechanism is the appropriate mechanism to support the proposed activities*

Questions?



Comments?