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National Toxicology Program

NTP Testing Program: Nominations and Research Concepts

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NTP Board of Scientific Counselors Meeting
July 23-24, 2009

Development of NTP Research Projects

- Toxicological research programs are developed in response to external and NIEHS/NTP nominations
- Multiple levels of review to determine merit and priority for study
- Selection for study primarily on the basis of:
  - Use and production levels
  - Known or anticipated human exposure
  - Suspicion of toxicity based on chemical structure or existing health effects data
  - Availability of adequate toxicological data
  - Extent of public concern
  - Utility of additional studies for public health decision-making
- Iterative, tiered approach to study design and conduct

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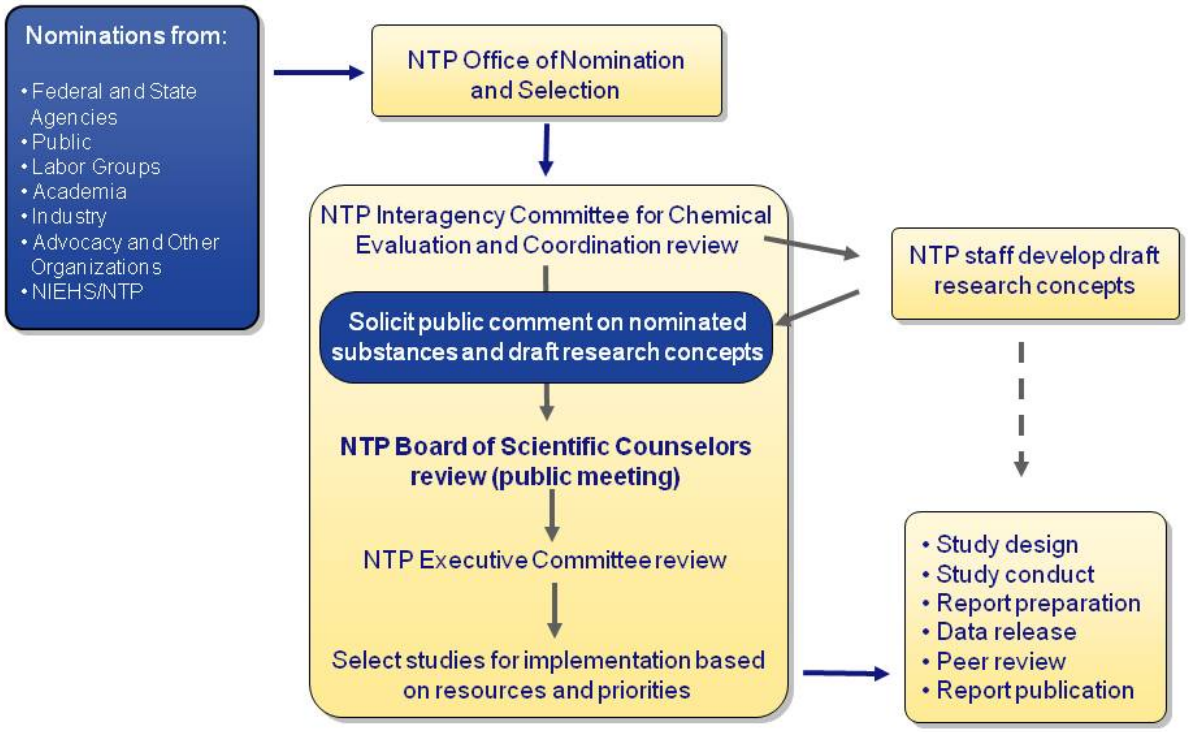
NTP Study Nomination Review Process



New Research Projects for BSC Review

- NTP staff have prepared draft research concepts for 6 new nominations
  - Proposed approach to address toxicological data needs for each substance or issue, not experimental study design
    - Outline data gaps, key issues, hypotheses and/or specific aims
- Proposed research projects
  - Alkylanilines (Dr. Scott Auerbach)
  - Deoxynivalenol (Dr. Dori Germolec)
  - Dong quai (Dr. Michael Wyde)
  - Indium tin oxide (Dr. Patrick Kirby)
  - *p*-Chlorobenzotrifluoride (Dr. Matt Stout)
  - Tris(4-chlorophenyl)methane and Tris(4-chlorophenyl)methanol (Dr. Po Chan)

BSC Review of Proposed Research Projects: Charge

- To review and comment on draft research concepts and determine whether the proposed research projects are an appropriate use of NTP testing program resources. *A research concept is a brief document outlining the nomination or study rationale, and the significance, study approach, and expected outcome of a proposed research program.*

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BSC Review of Proposed Research Projects: Specific Comments

- Comment on the clarity and validity of the rationale for the proposed research program as articulated in the NTP research concept document.
- Comment on the merit of the proposed research program relative to the mission and goals of the NTP. *The NTP's stated goals are to: Provide information on potentially hazardous substances to all stakeholders; Develop and validate improved test methods; Strengthen the science base in toxicology; Coordinate toxicology testing programs across DHHS.*
- Based on your evaluation of rationale and merit, rate the overall significance and public health impact of this research program as low, moderate, or high. *NTP management will use this rating in assessing the relative priority of projects in the NTP's testing program.*
- Comment on the scope of the proposed program relative to your evaluation of significance and public health impact. Is the scope too broad or too limited relative to the public health importance of the substance or issue under consideration? If so, what modifications do you recommend?
- Provide any other comments you feel NTP staff should consider in developing this research program.

Today's Session

- Introduction to testing program project reviews
- Presentation of research concepts by NTP project leaders
- Public comments
- Comments from assigned Board reviewers
  - Response to charge
- Board discussion

Questions and Comments