



NTP
National Toxicology Program

NTP Testing Program: Proposed Research Projects

Dr. Scott Masten

NTP Board of Scientific Counselors Meeting

June 12, 2008

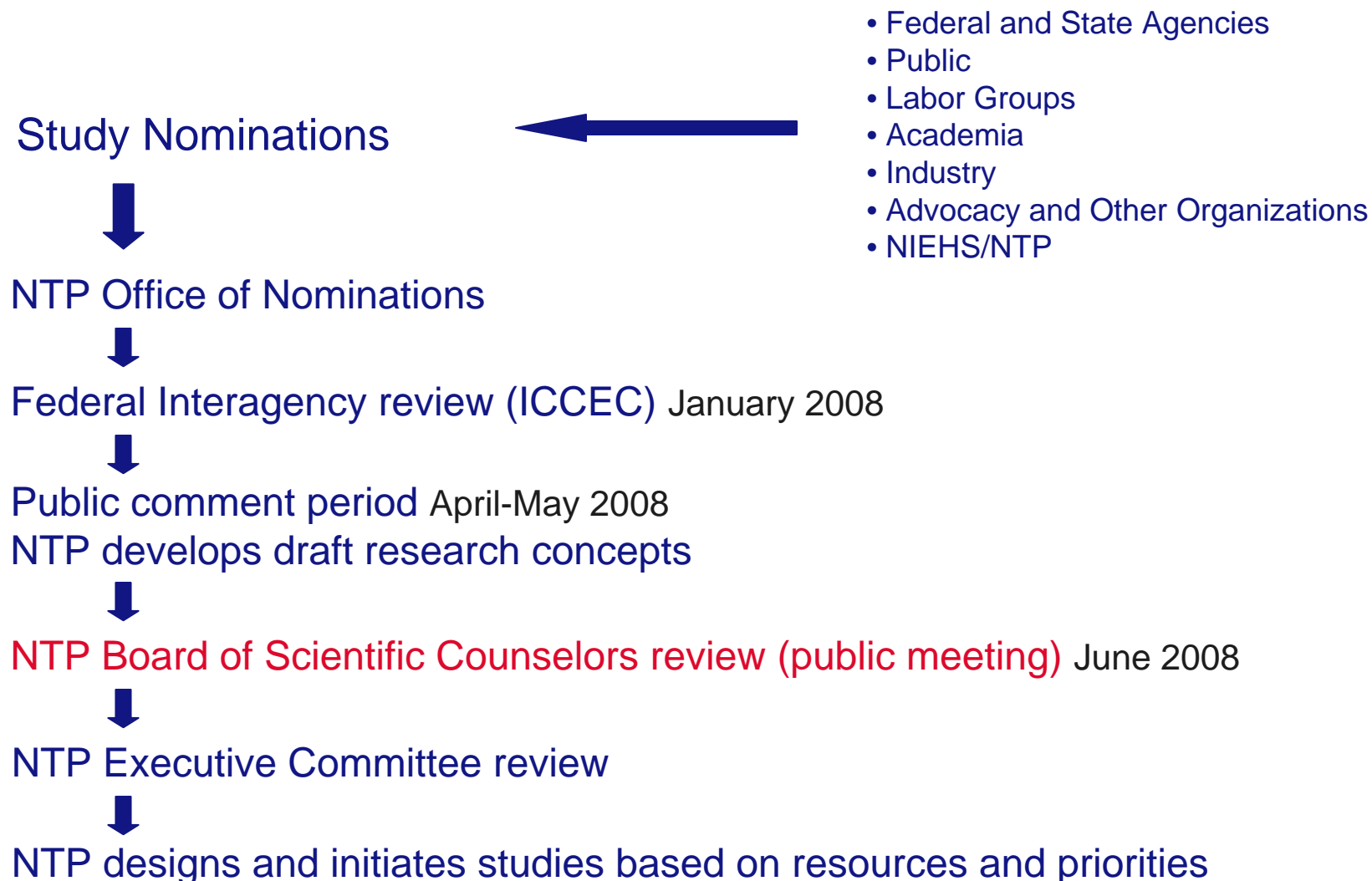


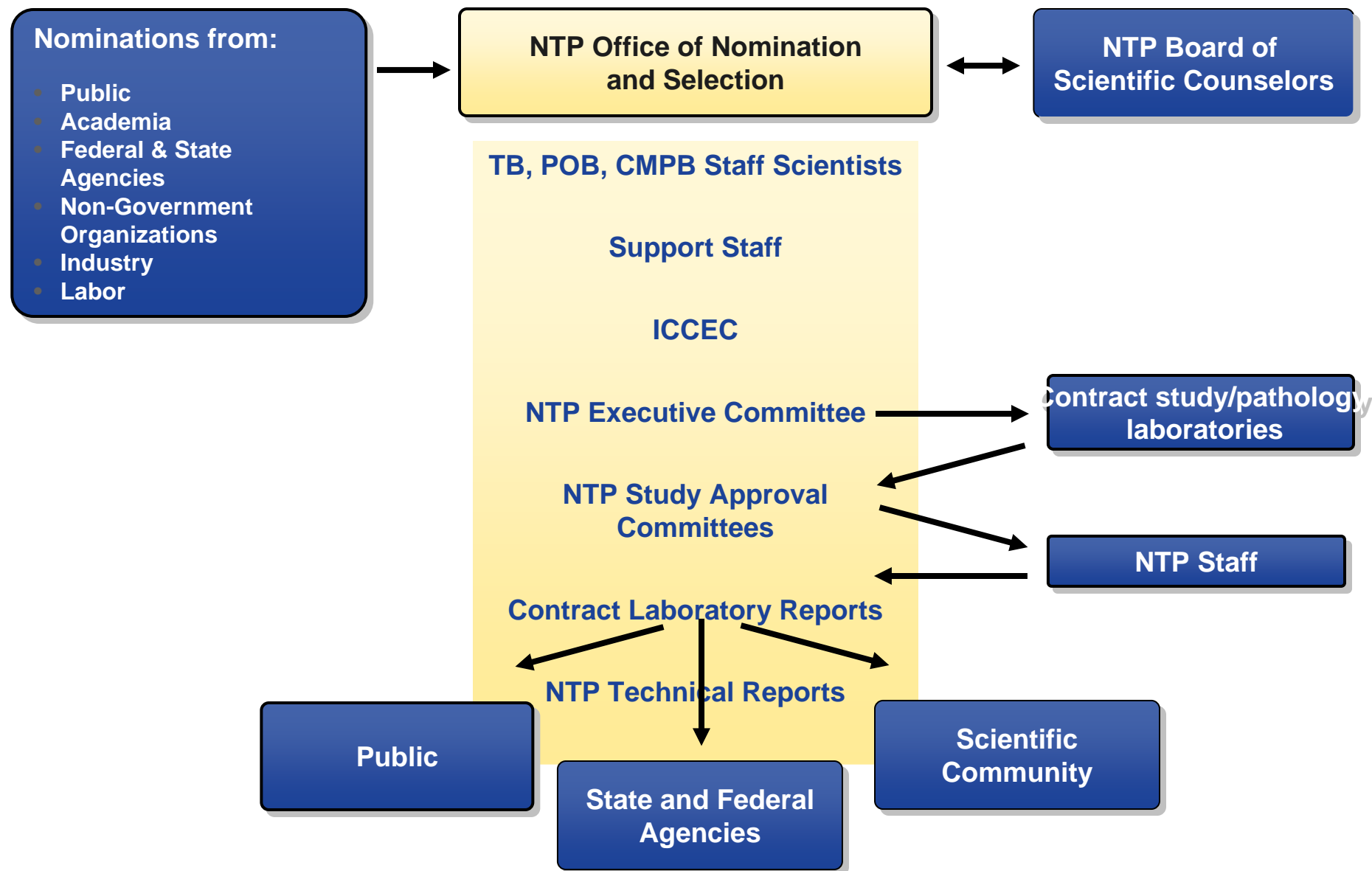
Initiation of Research Projects in the NTP Testing Program

- Toxicological research programs are developed by NTP staff internally and in response to external nominations
- Substances considered appropriate for study generally fall into two broad yet overlapping categories:
 - Substances judged to have high concern as a possible public health hazard based on the extent of human exposure and/or suspicion of toxicity
 - Substances for which toxicological data gaps exist and additional studies would aid in assessing potential human health risks, e.g. by facilitating cross-species extrapolation or evaluating dose-response relationships
- Substances are selected for study primarily on the basis of known or anticipated human exposure, production levels, suspicion of toxicity based on chemical structure or existing health effects data, availability of toxicological data, and extent of public concern
- Multiple levels of review to determine merit and priority for study



NTP Study Nomination Review Process







New Research Projects for BSC Review

- NTP staff have prepared draft research concepts for 5 substances
 - Proposed approach to address toxicological data needs for each substance or issue, not experimental study design
 - Outline key issues, data gaps, hypotheses and/or specific aims
- Proposed projects for new study nominations
 - Dimorpholinodiethyl ether (Dr. Rick Irwin)
 - 2-Ethylhexyl *p*-methoxycinnamate (Dr. Michael Wyde)
 - Tetravalent and pentavalent vanadium compounds (Dr. Michelle Hooth)
 - 4,7,10-Trioxatridecane-1,13-diamine (Dr. Scott Masten)
 - Limited scope of proposed studies
- Proposed projects for previously evaluated substances
 - Furan (Dr. Daniel Doerge)
 - Melamine and cyanuric acid (Dr. Goncala Gamboa da Costa)



BSC Review of Proposed Research Projects

Charge: To determine whether sufficient justification is provided for the use of NTP testing program resources to carry out proposed research projects as outlined in the draft research concept documents.

Action: The NTP BSC will review and comment on draft NTP research concepts with respect to the specific charge questions. 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.



Charge Questions for BSC Review of Proposed Research Projects

- Please comment on the clarity and validity of the rationale for the proposed research program as articulated in the NTP research concept document.
- Please comment on the merit of the proposed research program relative to the goals of the NTP. *The NTP's purpose is to: Provide information on potentially hazardous substances; Develop and validate improved test methods; Strengthen the science base in toxicology; Coordinate toxicology testing programs across DHHS.*
- Please comment on the scope of the proposed program and its appropriateness, relative to the public health importance of the issue or substance being proposed for study. Are there additional studies that should be considered as part of this research program? Should some of the proposed studies be considered lower priority?
- What priority (low, moderate, or high) should NTP give to the proposed research program given the rationale, merit and scope?



Today's Session

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



Questions and Comments



New Study Nominations

- 4 new study nominations reviewed by the ICCEC, January 2008
- Preliminary study recommendations developed for each nomination
- NTP staff developed draft research concepts
- Public comment period, April-May 2008
- Review by the BSC, June 2008