Breakout Group 1

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Objective

Solicit comment on a process for selection of appropriate nominated substances to undergo cancer hazard evaluation in genetically modified or "transgenic" models

Proposed Revision to Current Process

Agents or substances nominated to the NTP for cancer studies undergo several levels of review before studies are designed and implemented (Attachment 1). The NTP invites comment about how best to ensure adequate stakeholder input regarding the potential use of genetically modified models for studying nominated agents or substances. The NTP proposes that it would follow its current process and at each level of review would specifically ask for input about whether studies in genetically modified animal models might provide data sufficient to address information needs concerning potential cancer hazards. The NTP would not ask for recommendations about specific models at any level of review. Model selection would generally be left to the discretion of the NTP study scientists and study design team that are responsible for designing the research program for a specific substance.

Current Nomination, Review, and Selection Process

- The NTP welcomes the nomination of agents or substances for study from all interested groups including the public. At the first level, NIEHS Nominations Faculty reviews nominations received by the NTP, evaluates potential data needs, and makes a recommendation regarding whether individual nominations should be considered. Nominations originating from NTP member agencies, such as NCI, FDA, and NIOSH, are reviewed initially by their respective chemical selection working groups prior to submission to the NTP.

- Recommendations on the nominations from the NIEHS Nominations Faculty are forwarded to the Interagency Committee for Chemical Evaluation and Coordination (ICCEC), the second level of review. The ICCEC is a federal interagency committee that provides multiagency comment on the data needs for each nominated substance and helps set priorities for studies. As part of this process, the ICCEC would be asked to determine whether assessments in genetically modified animal models would provide sufficient information for anticipated regulatory or health guidance activities that might stem from such studies.

- The NTP next publicizes the nominations and ICCEC recommendations through the Federal Register, NTP list-serve, as well as other means, and invites public comment. The public can submit written comments now or at any time. The public is also notified of the opportunity to make oral presentations at meetings of the NTP Board of Scientific Counselors, the program's external scientific advisory group who typically meets once or twice a year in open session. The Board reviews the written comments, receives oral comments, and provides input to the NTP on the study nominations. The NTP would invite input from the Board regarding the use of genetically modified animal models in the study of these nominations.

- At the final step, the NTP Executive Committee, comprised of the heads of the major Federal health research and regulatory agencies, reviews and evaluates the public comments and study recommendations for each nomination and makes a recommendation to test, to not test at this time, or to defer testing until additional information is received and considered. This committee's recommendation for testing would consider the suitability of including studies using genetically altered models.

- The Executive Committee's recommendation of a nomination for study does not automatically commit the NTP to its evaluation. The NTP initiates studies as time and resources permit. The NTP designates an NIEHS study scientist and study design team to develop the research program for each agent being studied. If study using genetically modified animal models were appropriate, this group would select the best model and plan the study.

Question

Is the proposed process adequate to ensure that all stakeholders have a sufficient opportunity to provide comment on substances selected for study in genetically modified models?

Note: It is anticipated that Breakout Group 1 will conclude discussion of this question in time to also address some or all of the questions directed to Breakout Group 2.