

## **NTP BSC Reproductive and Developmental Criteria Working Group (RDCWG)**

The NTP developed two sets of draft criteria, criteria for reproductive toxicology studies and criteria for developmental toxicology studies, loosely based on those used to evaluate NTP carcinogenicity studies. The NTP convened a working group in September 2008 to evaluate the draft criteria for each type of study. The RDCWG was given the following charges:

*To evaluate the suitability and utility of proposed criteria for describing the results from individual NTP reproductive toxicology studies to indicate the strength of the evidence for their conclusions.*

*To evaluate the suitability and utility of proposed criteria for describing the results from individual NTP developmental toxicology studies to indicate the strength of the evidence for their conclusions.*

The RDCWG addressed each set of draft NTP criteria separately. First, the RDCWG reviewed and discussed the draft NTP criteria for reproductive toxicology studies, tested their utility by applying them to case studies, and reached consensus about changes needed in the draft criteria to facilitate their use. The RDCWG repeated these steps for the draft criteria for developmental toxicology studies. Each RDCWG report outlines the meeting and presents the group's recommendations for revised criteria.

### **Process**

Dr. Edward Carney, RDCWG chair, will first present the draft report on the reproductive toxicology criteria followed by BSC discussion and action. Next, Dr. Carney will present the draft report on the developmental toxicology criteria followed by BSC discussion and action.

### **Action**

The BSC will vote on acceptance of each RDCWG report. The BSC can vote to (1) accept the report as written, (2) accept with revision (assuming identifiable edits are needed), or (3) not accept. Please note: the BSC can have additional discussion about the draft criteria that will be captured in the minutes for this meeting and still accept the report.

### **Lead Discussants**

Jon Mirsalis and Michael Pino

### **Discussion Questions**

- Do you have any comments on the RDCWG reports?
- Do you have any comments on the proposed revised criteria?
- Do you have any comments on the other key factors that NTP should consider in applying the criteria to the study results?

### **Materials**

- Criteria for NTP Reproductive Toxicology Studies. Report from the Reproductive and Developmental Criteria Working Group (RDCWG) of the NTP Board of Scientific Counselors
- Criteria for NTP Developmental Toxicology Studies. Report from the Reproductive and Developmental Criteria Working Group (RDCWG) of the NTP Board of Scientific Counselors