Appendix C

Title **Master Protocol Working Group**

Purpose **Develop master protocol to be used for all trials:**

- define inclusion/exclusion/deferral criteria
- select diagnostic and follow-up procedures
- decide whether to do biopsy
- generate generic case report forms
- generate master protocol document
- will draw heavily from ICDB

Title **Treatment And Study Design Working Group**

Purpose **Choose treatment regimens and both overall and individual study designs:**

- overall plans for multiple simultaneous clinical trials
- treatments to be evaluated (e.g. systemic, intravesical)
- subsets of patients to be targeted towards specific therapies (e.g. men, "de novo" patients, treatment failures)

Title **Outcomes Working Group**

Purpose **Identify primary outcome measures to be used for all trials:**

- identify types of outcomes to be measured
- choose scales/methods for measurement
- define “response” and follow-up requirements
- define clinically significant differences
- utilize ICDB to explore options

Title **Novel Therapy Working Group**

Purpose **Choose treatment regimens for additional Randomized Clinical Trials:**

- develop strategies for selecting novel therapy protocols
- overall plans for RCT #2
- treatments to be evaluated (e.g. systemic, intravesical)