To Each Investigator Whose Proposal for Clinical Investigation Involves Possible Human Experimentation: SWOG 7624, ADR Vs. ADR + CACP In Transitional Cell Bladder Carcinoma

In order that the Wilford Hall Human Experimentation Committee may judge fairly your proposal, please answer clearly and succinctly the questions below. These answers will be appended to your investigative proposal before it is referred to the Human Experimentation Committee. Please respond on this sheet (you may use supplemental copy if necessary).

1. Is this research necessary?
   Yes

2. What are the direct advantages to the test subjects?
   Advanced treatment of patients with disseminated transitional cell bladder carcinoma.

3. What are the indirect benefits to the test subject (or to society)?
   Improved treatment.

4. What risks are there to the test subjects (and how serious)?
   Mild to moderate nausea and vomiting will occur. Nephrotoxicity as manifested by an elevation of BUN or serum creatinine, and those listed under protocol para 3.22, page 5.

5. Are there practical alternatives to this research or its mode of conduct?
   none

6. What manipulations of test subjects are required in this investigation that otherwise would not be done?

   none

7. Are there any direct, or indirect, penalties to the test subject if he does not participate?

   none

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Atch 2