National Cancer Institute 2nd Meeting of the

CLINICAL TRIALS ADVISORY COMMITTEE

Building 31, C Wing, Conference Room 10 9000 Rockville Pike Bethesda, Maryland

Wednesday, 11 July 2007 - 8:30 a.m. – 4:00 p.m. - Open to the Public

8:30 a.m. – 8:40 a.m.

I. Call to Order and Opening Remarks

Dr. Niederhuber

- Consideration of 10 January 2007 Minutes
- Confirmed Future Meeting Dates

November 14, 2007 Wednesday February 4, 2008 Monday June 25, 2008 Wednesday December 8, 2008 Monday March 4, 2009 Wednesday

8:40 a.m. – 9:15 a.m.

II. Director's Update

Dr. Niederhuber

9:15 a.m. – 9:45 a.m.

III. CTWG Implementation Update

Dr. Prindiville

9:45 a.m. – 10:15 a.m.

IV. Investigational Drug Steering Committee: Career Development Letter of Intent Dr. Zwiebel

10:15 a.m. – 10:30 a.m.

COFFEE BREAK

10:30 a.m. – 12:00 p.m.

V. Mini-Symposium: Biological Studies in Association with Clinical Trials

IntroductionDr. Doroshow

in Patients with Advanced Non-Small Cell Lung Cancer Dr. Adjei Dr. Hirsch • Evaluation and Prioritization of Biological Studies in Dr. Taube **Association with Clinical Trials** 12:00 p.m. – 12:30 p.m. LUNCH 12:30 p.m. – 1:15 p.m. VI. Update: Institutional Barriers to Clinical Trials Dr. Dilts Dr. Sandler 1:15 p.m. – 1:45 p.m. VII. NCI Central IRB Evaluation Ms. Goldberg 1:45 p.m. - 2:30 p.m.VIII. CTWG Informatics Initiatives Update Dr. Buetow 2:30 p.m. – 2:45 p.m. **COFFEE BREAK** 2:45 p.m. – 3:45 p.m. IX. Translational Research Working Group (TRWG) Report Dr. Hawk 3:45 p.m. – 4:00 p.m. X. New Business Dr. Niederhuber Subcommittees Future Agenda Items 4:00 p.m.

Adjournment

Phase III Biomarker Validation Study of Second-Line Therapy

Dr. Dancey