#### **National Cancer Institute**

#### 9th Meeting of the

#### CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE

# Building 31, C Wing, $6^{\text{th}}$ Floor, Conference Room 10

#### 9000 Rockville Pike

#### Bethesda, Maryland

#### Wednesday, November 4, 2009 - OPEN

#### 8:00 a.m. – 8:10 a.m.

I. Call to Order and Opening Remarks

Dr. Niederhuber

- Consideration of July 15, 2009 Meeting Summary
- Confirmed Future Meeting Dates:

March 10, 2010 Wednesday
July 14, 2010 Wednesday
November 17, 2010 Wednesday
March 3, 2011 Thursday
July 13, 2011 Wednesday
November 9, 2011 Wednesday

#### 8:10 a.m. – 9:00 a.m.

II. Director's Update

Dr. Niederhuber

#### 9:00 a.m. – 9:15 a.m.

III. Legislative Update

Ms. Erickson

### 9:15 a.m. – 10:00 a.m.

IV. Operational Efficiency Working Group (OEWG) Update

Dr. Doroshow

#### <u>10:00 a.m. – 10:15 a.m.</u>

COFFEE BREAK

#### 10:15 a.m. – 10:45 a.m.

V. Update on Cooperative Group Clinical Trial Complexity Funding

Dr. Mooney

### 10:45 a.m. – 11:30 a.m.

VI. Biomarker, Imaging and Quality of Life Studies Funding Program (BIQSFP): 2010 Program Changes

Dr. Petryshyn

A Randomized Phase III Double-Blind Trial Evaluating

Dr. Dansky Ullmann

Selective COX-2 Inhibition in COX-2 Expressing Advanced

Non-Small Cell Lung Cancer

#### 11:30 a.m. – 12:00 p.m.

VII. Central Institutional Review Board (CIRB): Revised Procedures, Accreditation Update and Cost-Benefit Analysis Ms. Goldberg

Dr. Mooney

Dr. Wagner

#### <u>12:00 p.m. – 1:00 p.m.</u>

#### LUNCH BREAK

#### 1:00 p.m. – 1:45 p.m.

VIII. Issues Related to the Revision of the Intellectual Property Option in DCTD Sponsored Clinical Trials

Dr. Abrams

Dr. Cristofaro

## 1:45 p.m. – 2:15 p.m.

IX. NCI's Experimental Therapeutics Program (NExT)

Dr. Doroshow

#### 2:15 p.m. – 2:45 p.m.

X. Update on the Translational Research Acceleration Initiative

Dr. Matrisian

#### 2:45 p.m. – 3:45 p.m.

XI. Immune Response Modifiers (IRM) Prioritization Working Group Report Dr. Cheever

## 3:45 p.m. – 4:00 p.m.

XII. New Business and Announcements

Dr. Prindiville

## 4:00 p.m.

ADJOURNMENT