# National Cancer Institute 11th Meeting of the CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE Bethesda Marriott Hotel Grand Ballroom Salon Rooms C, D, E 5151 Pooks Hill Road Bethesda, Maryland Tuesday, September 21, 2010 - OPEN <u>8:00 a.m. – 8:10 a.m.</u>

	I.	Call to Order and Opening Remarks	Dr. Doroshow
		<ul> <li>Introduction of Ad Hoc Members</li> </ul>	
		<ul> <li>Consideration of March 10, 2010 Meeting Summary</li> </ul>	
		<ul> <li>Confirmed Future Meeting Dates:</li> </ul>	
		December 15, 2010 Wednesday	
		March 3, 2011 Thursday	
		July 13, 2011 Wednesday	
		November 9, 2011 Wednesday	
<u>8:10 a</u>	<u>ı.m. –</u>	<u>8:45 a.m.</u>	
	II.	NCI Director's Update	Dr. Varmus
<u>8:45 a</u>	<u>ı.m. –</u>	<u>9:00 a.m.</u>	
	III.	Legislative Update	Ms. Erickson
<u>9:00 a</u>	<u>ı.m. –</u>	<u>9:45 a.m.</u>	
	IV.	Process to Accelerate Translational Science (PATS) Working Group Update	Dr. Matrisian Dr. Cowan

#### <u>9:45 a.m. – 10:00 a.m.</u>

COFFEE BREAK

# <u>10:00 a.m. – 10:30 a.m.</u>

V. The Clinical Assay Development Program: Available Services And How to Access Them	Dr. Conley
<u>10:30 a.m. – 11:15 a.m.</u>	
VI. Cost-Effectiveness Analysis Working Group Report	Dr. Ramsey
<u>11:15 a.m. – 11:45 a.m.</u>	
VII. A National Cancer Clinical Trials System for the 21 <sup>st</sup> Century: Reinvigorating the NCI Cooperative Group Program [Institute of Medicine (IOM) Report]	Dr. Nass
<u>11:45 a.m. – 12:45 p.m.</u>	
LUNCH BREAK	
<u>12:45 p.m. – 1:45 p.m.</u>	
VIII. Financial, Organizational, and Management Analysis of the Cooperative Groups	Dr. Hautala
<u>1:45 p.m. – 2:15 p.m.</u>	
IX. Coordination of Data Management and Biostatistics of NCCTG, ACOSOG, and CALGB	Dr. Bertagnolli Dr. Sargent Dr. Buckner Dr. Nelson
<u>2:15 p.m. – 2:45 p.m.</u>	
X. Changing the NCI's Clinical Trials System to Meet the Needs of the 21 <sup>st</sup> Century: Implementation of the Clinical Trials Working Group (CTWG) and Institute Of Medicine (IOM) Recommendations	Dr. Doroshow
<u>2:45 p.m. – 3:15 p.m.</u>	
XI. Discussion of the Approach to the Implementation of the IOM Report	Dr. Doroshow (Facilitator)

## COFFEE BREAK

### <u>3:30 p.m. – 4:00 p.m.</u>

XII. Central Institutional Review Board (CIRB) Update	Ms. Goldberg

### <u>4:00 p.m. – 4:30 p.m.</u>

XIII. Guidelines Harmonization Working Group Report Implementation	Dr. Abbruzzese
Update	Dr. Prindiville
	Dr. Hecht
	Dr. Mooney
	Dr. Weiss

Dr. Doroshow

<u>4:30 p.m. – 4:45 p.m.</u>

XIV. New Business

<u>4:45 p.m.</u>

ADJOURNMENT