

Food and Drug Administration
 Pediatric Ethics Subcommittee of the Pediatric Advisory Committee
 Date: June 9-10, 2008
 Location: Holiday Inn/Gaithersburg, Gaithersburg, MD.

June 9, 2008

8:30 am (10 min)	Welcome and Introductory Remarks Introduction of PES Members	Norm Fost, MD MPH Chair, Pediatric Ethics Subcommittee of the Pediatric Advisory Committee (PAC) Carlos Peña, PhD, MS Executive Secretary, PAC Office of Science and Health Coordination, OC, FDA
8:40 am (5 min)	Meeting Agenda Overview	Robert "Skip" Nelson, MD PhD Pediatric Ethicist, Office of Pediatric Therapeutics (OPT) OC, FDA
8:45 am (20 min)	Presentation: 21 CFR 50, Subpart D	Robert "Skip" Nelson, MD PhD Pediatric Ethicist, OPT, OC, FDA
9:05 am (20 min)	Presentation of Hypothetical Case One: Enrolling Adolescents in an HIV Vaccine Clinical Study	Robert "Skip" Nelson, MD PhD Pediatric Ethicist, OPT, OC, FDA
9:25 am (65 min)	Discussion of Case One	Pediatric Ethics Subcommittee
10:30 am (15 min)	Break	
10:45 am (75 min)	Discussion of Case One (continued)	Pediatric Ethics Subcommittee
12 noon (60 min)	Lunch	
1:00 pm (30 min)	Open Public Hearing	
1:30 pm (20 min)	Presentation: Choice of Control Group	Robert "Skip" Nelson, MD PhD Pediatric Ethicist, OPT, OC, FDA
1:50 pm (20 min)	Presentation of Hypothetical Case Two: Study of ICS in Children with Mild Persistent Asthma	Robert "Skip" Nelson, MD PhD Pediatric Ethicist, OPT, OC, FDA
2:10 pm (60 min)	Discussion of Case Two	Pediatric Ethics Subcommittee
3:10 pm (15 min)	Break	
3:30 pm (120 min)	Discussion of Case Two (continued)	Pediatric Ethics Subcommittee
5:30 pm	Adjourn	Robert "Skip" Nelson, MD PhD Pediatric Ethicist, OPT, OC, FDA

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8:00 am	Welcome and Introductory Remarks Introduction of PES Members	Norm Fost, MD MPH Chair, Pediatric Ethics Subcommittee of the Pediatric Advisory Committee (PAC) Carlos Peña, PhD, MS Executive Secretary, PAC Office of Science and Health Coordination OC, FDA
8:00 am (30 min)	Open Public Hearing	
8:30 am (20 min)	Presentation: Prospect of Direct Benefit from Animal Studies	Robert "Skip" Nelson, MD PhD Pediatric Ethicist, OPT, OC, FDA
8:50 am (15 min)	Presentation of Hypothetical Case Three: Stem Cells for Neonatal Hypoxic-Ischemic Injury	Robert "Skip" Nelson, MD PhD Pediatric Ethicist, OPT, OC, FDA
9:05 am (70 min)	Discussion of Case Three	Pediatric Ethics Subcommittee
10:15 am (15 min)	Break	
10:30 am (60 min)	Discussion of Case Three (continued)	Pediatric Ethics Subcommittee
11:30 am (90 min)	General Discussion: 21 CFR 50.52	Pediatric Ethics Subcommittee
1:00 pm	Adjourn	Robert "Skip" Nelson, MD PhD Pediatric Ethicist, OPT, OC, FDA