

Pediatric Ethics Subcommittee of the Pediatric Advisory Committee

Location: The Legacy Hotel & Meeting Centre
1775 Rockville Pike, Rockville, MD 20852.

“Children’s Oncology Group Protocol ASCT0631: A Phase III Randomized Trial of Granulocyte Colony Stimulating Factor (G–CSF) Stimulated Bone Marrow vs. Conventional Bone Marrow as a Stem Cell Source in Matched Sibling Donor Transplantation.”

Agenda for Tuesday, December 9, 2008
9:00 a.m. to 3:00 p.m.

9:00 a.m.	Call to Order, Introductions	Jeffrey Botkin, MD, MPH Chair (Acting), Pediatric Ethics Subcommittee
	Meeting Statement	Carlos Peña, PhD, MS Executive Secretary
9:10 a.m.	Welcome from OHRP	Jerry Menikoff, MD, JD Director, Office for Human Research Protections, HHS
9:15 a.m.	Overview of Expert Panel Process, Subpart D, and Questions for Panel	Robert M. Nelson, MD, PhD Pediatric Ethicist, Office of Pediatric Therapeutics, FDA
9:40 a.m.	Introduction to Presentations	Jeffrey Botkin, MD, MPH
9:45 a.m.	Background and Overview on the Use of G-CSF in Stem Cell Transplantation	Victor Santana, MD Consultant, Pediatric Ethics Subcommittee
10:05 a.m.	Background and Overview on Protocol ASCT0631	Stephan A. Grupp, MD, PhD ASCT0631 Study Chair
10:25 a.m.	Referring IRB Presentation	Tim Wysocki, PhD, ABPP, CIP Chair, Nemours Oncology IRB
10:45 a.m.	Break	
11:00 a.m.	Summary of Submitted Public Comments	Jeffrey Botkin, MD, MPH
11:05 a.m.	Open Public Hearing	
12 noon	Lunch	
1:00 p.m.	Panel Discussion	Pediatric Ethics Subcommittee Members
2:45 p.m.	Summary of PES Deliberations and Recommendations	Jeffrey Botkin, MD, MPH
3:00 p.m.	Close	