

**Advisory Committee on
Blood Safety and Availability
Department of Health and Human Services**

Forty-First Meeting, December 5 & 6, 2011

NIH Conference Room
5635 Fisher's Lane, Terrace Level
Rockville, MD

Monday, December 5, 2011

08:00	Doors Open	Open to the Public
09:00	Call to Order	Chairman
09:05	Roll Call	James Berger Executive Secretary

Committee Updates

09:10	HRSA Update <ul style="list-style-type: none">• ACOT Update	Mark Barr, MD Chair, Advisory Committee on Organ Transplantation
09:25	FDA Update <ul style="list-style-type: none">• Quarantine-Release Errors Workshop • Hemoglobin Workshop	Orieji Illoh, MD Medical Officer Division of Blood Applications OBRR/CBER/FDA Richard Davey, MD Director Division of Blood Applications
09:50	CDC Update <ul style="list-style-type: none">• Draft 2011 Public Health Service (PHS) Guideline for Reducing Transmission of HIV, HBV, and HCV through Solid Organ Transplantation	Matthew Kuehnert, MD Office of Blood, Organ and Other Tissue Safety, CDC

Committee Business

10:00	New Members Welcome and Oath	Howard K. Koh, MD, MPH Assistant Secretary for Health
10:05	Recognition of Outgoing Members	
10:15	Assistant Secretary for Health's Charge to the Committee	
10:30	Break	

Committee Topic: Informed Consent of Recipients of Blood, Organs and Tissues

Session 1: Overview of Informed Consent: Content and Efficacy

10:45	Overview of the Informed Consent Process	Elisa J Gordon, PhD, MPH Northwestern University Feinberg School of Medicine
11:15	CMS Requirements Related to Informed Consent	Daniel Schwartz, MD Chief Medical Officer Karen Tritz, MD Transplant Team Lead Survey and Certification Group Centers for Medicare and Medicaid Services
11:45	Patient Perspective on Informed Consent	Benjamin Moulton Foundation for Informed Medical Decision Making
12:15	Lunch	
1:00	Risk Communication: How to Best Present Medical Information	Gavin Huntley-Fenner, PhD Huntley-Fenner Advisors, Inc.
1:30	Panel Discussion for Committee Questions	Session Speakers/Committee

Session 2: Current Clinical Consent Practices in Transfusion and Transplantation

2:00	Patient Blood Management	Jonathan Waters, MD University of Pittsburgh School of Medicine
2:30	Noninfectious Risk in Blood Transfusion	Mark Yazer, MD Institute for Transfusion Medicine Department of Pathology, University of Pittsburgh
3:00	Panel Discussion for Committee Questions	Session Speakers/Committee
3:10	Break	
3:25	Consent Practices in Heart Valve Transplantation	Kelly Stutes, MBA, BSBA, CTBS AlloAdvantage
3:45	Consent Practices in Ocular Tissue Transplantation	David Glasser, MD Chair, Medical Advisory Board Eye Bank Association of America Assistant Professor of Ophthalmology Johns Hopkins University School of Medicine

4:10	General Consent Considerations in Organ Transplantation	Richard Freeman, Jr., MD Dartmouth-Hitchcock Medical Center
4:40	Panel Discussion for Committee Questions	Session Speakers/Committee
5:00	Adjournment	Committee Chair

Tuesday December 6, 2011

08:00	Doors Open	Open to the Public
08:30	Call to Order	Committee Chair
08:30	Roll Call	James Berger Executive Secretary

Session 2: Current Clinical Consent Practices in Transfusion and Transplantation (Session Continued)

08:40	Clinical Aspects of Consenting Adult Patients for Blood Transfusion	Ann Zimrin, MD University of Maryland Medical Center
09:00	Consent Practices in Orthopedic Surgery Utilizing Human Allograft Tissue	Michael Joyce, MD Cleveland Clinic
09:30	Special Consent Considerations in Organ Transplantation: Noninfectious Risks and Blood Utilization	Jeffrey Punch, MD University of Michigan Health Systems
10:00	Panel Discussion for Committee Questions	Session Speakers/Committee
10:30	Break	

Session 3: Data Provision for Adequate Informed Consent: Sources and Research Opportunities

10:45	Incorporating Data into the Consent Process: Where Are We Now?	Emily Blumberg, MD Chair, Disease Transmission Advisory Committee Hospital of the University of Pennsylvania
11:05	Research Opportunities in Improving the Consenting Process for Transfusion	Kathleen Sazama, MD, JD Life South Community Blood Centers
11:25	Risk Data Consolidation Efforts in Transplantation: Project Notify	D. Michael Strong, PhD WHO Secretariat for Project Notify

11:55	Lunch	
12:40	Opportunities: Unmet Data Needs for Improved Informed Consent in Organ and Tissue Transplantation	Jay Fishman, MD Massachusetts General Hospital
1:10	Panel Discussion	Session Speakers/Committee
1:40	Open Public Hearing	
2:20	Committee Discussion	Committee
5:00	Adjournment	Committee Chair