2007 Device Advice from the FDA: Agenda

Human Research Protection Office, Washington University School of Medicine in St. Louis

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## Keeping Pace with Medical Device Research

### Agenda

**Farrell Teaching and Learning Center, Holden Auditorium, WUSOM**  
**March 9, 2007**

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| 1:00 – 1:10 pm | Introduction                 | **Sally Anderson**  
Director Clinical Research Services, Center for Clinical Studies, Washington University |
| 1:10 – 2:10 pm | FDA Devices                  | **Sonali Gunawardhana, Esq.**  
Regulatory Counsel  
Office of Compliance  
Division of Bioresearch Monitoring  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration |
| 2:10 – 2:20 pm | Break                        |                                                          |
| 2:20 – 2:50 pm | Contracts and Billing        | **Ann Bradley, JD**  
Assistant Vice Chancellor & Associate General Counsel, General Council, Washington University |
| 2:50 - 3:20 pm | New Device Technology        | **Melissa Walker**  
Vice President, Research Stereotaxis |
| 3:20 – 3:30 pm | Break                        |                                                          |
| 3:30 – 4:30 pm | Principal Investigators – Issues in Developing a Running Trial | **Richard Bach, MD**  
Associate Professor of Medicine, Internal Medicine-Cardiology Consultants  
Washington University  
   
**Neill Wright, MD**  
Associate Professor of Neurological Surgery  
Washington University |