

2011

## 2011 Device Advice from the FDA: Agenda

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

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**Friday, June 24, 2011**  
**12:00 pm – 4:15 pm**

**Farrell Teaching and Learning Center**  
**Connor Auditorium**

520 S. Euclid, Washington University Medical School Campus

**AGENDA:**

**12:00 pm**

**Welcome**

**Jonathan Green, MD**, Executive Chair, Human Research Protection Office

**12:10 – 1:30 pm**

**Device Advice**

**Lynn Henley, MS, MBA**, IDE and HDE Programs

Office of Device Evaluation, Center for Devices and Radiological Health, FDA

Topics to be addressed:

- How to distinguish when “standard care” use of a device is research.
- Determining if a device is “exempt” from the IDE regulations
- Who makes the first risk determination?
- Pre-IDE application: What is it? What does it encompass?
- Significant vs. non-significant risk
- Responsibilities of the investigator, sponsor and investigator-sponsor
  - Responsibilities related to disposal, storage and handling when the PI is going to handle this.
    - PI responsibilities
    - Institutional responsibilities
- What is looked for in an FDA audit of a device?
- Humanitarian Use Devices
  - Responsibilities of the IRB and investigator when there is a Premarket Approval
  - Responsibilities of the IRB and investigator when there is not a Premarket Approval
  - What is a Premarket approval?
  - FDA wants additional safety data on a HUD. What does this mean? Is this research? Responsibilities of the investigator and IRB.
- Transitional Devices – what are they?

**1:30 – 2:00 pm Billing and Compliance Issues with Devices**

**Carlos Brown, MSHA**, Compliance Director

Patient and Clinical Trials, Barnes-Jewish Hospital

**Yi Zhang, JD, RN**, Assistant Dean Clinical Studies

Center for Clinical Studies, Washington University



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**2:00 – 2:30 pm IRB Requirements in the Review of Device Studies**

**Jonathan Green, MD**, Executive Chair, Human Research Protection Office  
Washington University Human Research Protection Office

**2:30 – 2:45 pm Break**

**2:45 – 3:15 pm The Importance of Device Accountability**

**Colin Derdeyn, MD**, Professor of Radiology, Neurology and Neurological Surgery,  
Washington University School of Medicine

**3:15 – 4:15 pm Panel Discussion**

Facilitator:

**Jonathan Green, MD**, Executive Chair, Human Research Protection Office

FDA representative:

**Lynn Henley, MS, MBA**, IDE and HDE Programs

Investigators:

**Colin Derdeyn, MD**, Professor of Radiology, Neurology and Neurological Surgery

**Jin-Moo Lee, MD, PhD**, Associate Professor; Director, Cerebrovascular Disease

**Darryl Zuckerman, MD**, Assistant Professor of Radiology and Surgery

Research Administrators:

**Martha Jones, MA, CIP**, Executive Director, Human Research Protection Office

**Yi Zhang, JD, RN**, Assistant Dean Clinical Studies

Research Operations:

**Kristin Luepke, RN, MSN, CCRC**, Manager of Research Operations, Division of  
General Surgery

**4:15 pm Wrap up and Evaluations**

This event is sponsored by the Human Research Protection Office, Center for Clinical Studies,  
the Institute of Clinical and Translational Science, and Orthopedic Surgery.



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**Speakers**, in alphabetical order:

**Carlos Brown, MSHA**, Compliance Director, Patient and Clinical Trials, Barnes-Jewish Hospital

Mr. Brown has designed, directed and overseen the day to day operations for program and policies that ensure successful corporate compliance, HIPAA privacy and clinical trials operations since taking his position in 2007. Mr. Brown has helped Barnes Jewish Hospital implement “best practice standards” related to clinical trial billing compliance and research coverage analysis.

**Colin Derdeyn, MD**, Professor of Radiology, Neurology and Neurological Surgery, Washington University School of Medicine

Dr. Derdeyn has experience with medical devices and the FDA approval process for them on many levels. His clinical specialty, interventional neuroradiology, is dependent on medical devices. This specialty, also known as endovascular neurosurgery, uses x-ray guidance and catheters (tubes) guided into brain arteries to place devices to treat patients with brain aneurysms, stroke and other forms of cerebrovascular disease. New devices are frequently developed for these challenging problems. He is the immediate past president of the medical society for physicians in this specialty, the Society of NeuroInterventional Surgery. He has been a consultant to the FDA Panel for Neurological Devices for the past 8 years. He is the Neuro-Interventional Principal Investigator of the Stenting versus Aggressive Medical Management for Prevention of Recurrent Ischemic Stroke (SAMMPRIS) trial, the first NIH-funded randomized trial of an intracranial medical device (angioplasty and stent) for stroke risk reduction in patient with atherosclerotic disease of the intracranial arteries. He chairs the Data and Safety Monitoring Boards for two NIH-funded stroke treatment trials involving medical devices (MR-Rescue and Ictus-L). He is on the Scientific Advisory Board of W.L. Gore and Associates and chairs the SAB for Pulse Therapeutics, two medical device companies. Locally, Dr. Derdeyn directs the Stroke and Cerebrovascular Center at Washington University and Barnes Jewish Hospital. He has been a local site investigator for many FDA IDE trials as well.

**Jonathan Green, MD**, Executive Chair, Human Research Protection Office, Washington University

Dr. Green is Associate Professor of Medicine and he is engaged in both laboratory and clinical research. He has broad experiences in clinical research and human subjects protection having previously served as an IRB committee Vice Chair and as a member and Chair of the Barnes-Jewish Hospital Ethics Committee.



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**Lynn Henley, MS, MBA**, IDE and HDE Programs, Office of Device Evaluation, Center for Devices and Radiological Health, FDA

Ms. Henley has degrees in Biology, Biotechnology and Business. She has spoken to numerous groups at academic institutions (Stanford University, University of Pittsburgh Medical Center), conferences (Columbia University IRB Conference, MD&M West), government research facilities (National Institutes of Health, Fort Detrick) and regulatory workshops (Regulatory Affairs Professional Society, AdvaMed) concerning Investigational Device Exemptions and Humanitarian Device Exemptions. At CDRH, she serves on the Clinical Expert Review Committee, participate in the Level of Evidence Project, and represent the Office of Device Evaluation at CDISC.

**Martha Jones, MA, CIP**, Executive Director, Human Research Protection Office, Washington University

Ms. Jones is currently the Executive Director of the Human Research Protection Office (HRPO) at Washington University in St. Louis. She is also a site visitor with the Association for the Accreditation of Human Research Protection Programs (AAAHRP) and is currently an Accreditation Team Leader. Ms. Jones has served on Conflict of Interest committees, as a member of internal advisory committees and clinical trials billing task forces.

**Jin-Moo Lee, MD, PhD**, Associate Professor; Head, Cerebrovascular Disease Section, Washington University

Dr. Lee's areas of specialty are: Adult Neurology, Cerebrovascular Disease and Stroke. In particular his clinical interests are in the areas of stroke, ischemic brain injury, intracerebral hemorrhage, and stroke in young patients. He has conducted many research studies and published numerous papers within his specialty areas. Many of those have dealt with investigational devices.

**Kristin Luepke, RN, MSN, CCRC**, Manager of Research Operations, Division of General Surgery, Washington University

Ms. Luepke assists and directs administration of all aspects of multiple general surgery research trials, both drug and device studies. Ms. Luepke works with general surgery faculty and research staff in planning and conducting clinical research activities including: budgetary planning and negotiations, billing compliance, funding, accounting, contracting, financial management and oversight, regulatory documentation, IRB and FDA adherence, education and training.



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**Yi Zhang, JD, RN**, Assistant Dean Clinical Studies, Center for Clinical Studies, Washington University

As assistant dean for clinical studies, Ms. Zhang plans, directs and oversees clinical trials activities at the School of Medicine. She manages the negotiation of industry-sponsored clinical trial contracts and works with various institutional offices and stakeholders to assure compliance, including clinical trial billing compliance, with regulations, policies and laws, as well as coordinate federal clinical trials with the Grants and Contracts Office and the Research Office. Ms. Zhang leads the administrative core and manages the operations for the Center for Applied Research Sciences with its director.

**Darryl Zuckerman, MD**, Assistant Professor of Radiology and Surgery, Washington University

Dr. Zuckerman is a physician who, on occasion, treats patients with investigational devices. In this capacity, Dr. Zuckerman interfaces with nurses and other physicians as well as lay people and third party payors to facilitate such treatments. One of Dr. Zuckerman's projects has been to bring a device known as "TheraSpheres" to Washington University and BJH. These radioactive microspheres, designed for localized delivery of radiation to liver tumors, are approved by the FDA under a Humanitarian Device Exemption and as such, require local IRB oversight

**Planning Committee**, in alphabetical order:

**Sally Anderson, RN, BSN, CCRC**, CTSA Research Navigator, Washington University

**Christy Auston, MA, CIP**, Washington University

**Sarah Fowler-Dixon, PhD, CIP**, Education Specialist, Human Research Protection Office, Washington University

**Martha Jones, MA, CIP**, Executive Director, Human Research Protection Office, Washington University

**Jeanne Velders, JD, CIP**, Associate Director, Human Research Protection Office, Washington University

**Yi Zhang, JD**, Assistant Dean Clinical Studies, Center for Clinical Studies, Washington University

