

**Draft Agenda for FDA Workshop –
Ischemia Reperfusion Injury and Downstream Effects of Long Term Outcomes in
Kidney Transplantation**

Day 1: September 8, 2011

9:00am to 6:00pm

9:00am	Welcome and Introductions
5 minutes	Session 1: Pathophysiology and Contributing Factors of Ischemia Reperfusion Injury (IRI) and DGF in Kidney Transplantation Moderators: Christopher Lu (Speaker) and Ergun Velidedeoglu (FDA) 5 minute brief overview to introduce the subject.
15 min	Topic #1: Cellular and Molecular Mechanisms of IRI Speaker #1: Christopher Lu
15 min	Topic #2: Role of Immune Cells and Complement System in IRI (Innate and Adaptive Immunity) Speaker #2: Peter Lobo
15 min	Topic #3: Donor Factors Influencing IRI/DGF Speaker #3: Sandy Feng
15 min	Topic #4: Effect of Recipient Factors in IRI/DGF Speaker #4: Mona D. Doshi
45 minutes	<i>Question and Answer Period (Panel and Audience) /Public Comment Discussion of Suggested Questions --Question(s) will be introduced by the moderator(s).</i>
10:50am	Break

11:05 am	Session 2: Downstream Measures of Response to IRI in Kidney Transplantation
5 minutes	Moderators: Marc Lorber (Steering Committee) and Patrick Archdeacon (FDA) (5 minute brief overview to introduce the subject)
15 min	Topic #1: The Utility of Biomarkers for Early Identification of IRI and their Correlation with Long-term Outcomes Speaker #1: Chirag Parikh
15 min	Topic #2: Early and Late Histopathologic Findings Associated with IRI Speaker #2: Lorraine Racussen
15 min	Topic #3: Role of the Transcriptome – extra renal compartments Speaker #3:
15 min	Topic #4: Role of the Transcriptome – in the kidney Speaker #4: Phil Halloran
15 min	Topic #5: Early and Late Clinical Findings Associated with IRI Speaker #5: Art Matas Evolution of DGF and other downstream consequences in relation to pathophysiology of I/RI
45 minutes	<i>Question and Answer Period (Panel and Audience) /Public Comment Discussion of Suggested Questions --Question(s) will be introduced by</i>

	<i>the moderator(s).</i>
1:10 pm – 2:10 pm	LUNCH Break

2:10 pm 5 minutes	Session 3 (4): Current Management Strategies and Outcomes Moderators: Michael Abecassis (Steering Committee) and Joette Meyer (FDA) (5 minute brief overview to introduce the subject) establish the baseline of what we would expect to see as care in the control arm
15 min	Topic #1: Treatment of the Donor, including ischemic preconditioning Speaker #1: Michael Abecassis
15 min	Topic #2: Natural History, Management and Clinical Outcomes of DGF in the Early Post-Transplantation Period Speaker #2: Jimmy Light
15 min	Topic #3: Review of Previously Studied Therapeutic Agents (including immunosuppressant and non-immunosuppressant drugs/biologics which have been studied in randomized, controlled trials in patients) Speaker #3: Marcello Cantarovich
30 minutes	<i>Question and Answer Period (Panel and Audience) /Public Comment Discussion of Suggested Questions --Question(s) will be introduced by the moderator(s).</i>
3:45 pm	Break as needed

4:00pm	Session 4: Industry Perspective and Public Comment
	Device Industry
10 min	Industry Perspective #1: Organ Recovery Systems, Inc (LifePort™) Or Waters Instruments, Inc. (RM3 Renal Preservation System)
10 min	Industry Perspective #2 Washington Regional Transplant Consortium
	Drug Industry
10 min	Industry Perspective #1 Astellas
10 min	Industry Perspective #2 Harry Cook Vice President, Clinical Operations, Eleos: Challenges of Endpoints in Clinical Trials
	Public Session
10 min	Patient Perspective Donna Cryer, JD CEO of CryerHealth
4:50 PM	Summary Day 1, overview Day 2
5:00 pm	Adjourn Day 1

Day 2: September 9, 2011**8:00am to 3:00pm**

	Welcome
8:00am 5 minutes	Session 5 (3): Animal Models of IRI and DGF/SGF Moderators: Stefan Tullius (Steering Committee) and Shukal Bala (FDA) (5 minute brief overview to introduce the subject)
15 min	Topic #1: Models of Brain Death Speaker #1: Stefan Tullius
15 min.	Topic #2: Models of Cold and Warm Ischemia Injury Speaker #2: Joseph Bonventre
15 min	Topic #3: Experience with carbon monoxide - from animals to humans Speaker #3: Douglas Hanto
15 min	Topic #4 : Activated Protein C (aPC) in IRI in kidney transplant, Speaker #4: John H Griffin
15 min	Topic #5: Strengths and Limitations of Current Animals Models Speaker #5: Hamid Rabb
35 minutes	<i>Question and Answer Period (Panel and Audience) /Public Comment Discussion of Suggested Questions --Question(s) will be introduced by the moderator(s).</i>
9:55 am	Break as needed

10:10am 5 minutes	Session 6 (5): Device Issues in IRI/DGF Moderators: Jimmy Light (Steering Committee), and Arturo Hernandez (FDA) (5 minute brief overview to introduce the subject)
10 min.	Topic #1: The Approval Process for Devices in Kidney Preservation. Speaker: Carolyn Y. Neuland, CDRH
10 min	Topic #2: 510K and PMA Applications Speaker: Gema Gonzalez, CDRH
10 min	Topic #3: Preservation Solutions and Pumps for Organ Preservation Speaker: Arturo Hernandez, CDRH
20 min	Topic #4: Long Term Outcomes with Cold Storage Solutions Speaker: Dorry Segev
20 min	Topic #5: Cold Machine Perfusion versus Static Cold Storage for SCD, ECD, and DCD Kidneys. Speaker: William Irish
20 min	Topic #6: Innovative Methods of Kidney Preservation Speaker: Sarah A Hosgood
35 minutes	<i>Question and Answer Period (Panel and Audience) /Public Comment Discussion of Suggested Questions --Question(s) will be introduced by the moderator(s).</i>
12:30pm	Working LUNCH ?

1:00 pm	
5 minutes	Session 7 (6): Clinical Trials Issues Related to the Recipient Moderators: Marcelo Cantarovich (Steering Committee), Mary Beth Harler (Steering Committee) and Marc Cavaillé-Coll (FDA) 5 minute brief overview to introduce the subject.
15 minutes	Topic #1: Indications (prevention/treatment) and Populations (inclusion/exclusion) Speaker #1: Dorry Segev *
15 minutes	Topic#2: Clinical Pharmacology Issues (PK/PD, Phase 2b and getting the dose right) Speaker #2: Rita Alloway *
15 minutes	Topic #3: Statistical Issues (including blinding, enrichment and adaptive design, etc) Speaker #3: Hongling Zhou *
15 minutes	Topic #4: Clinical trial design issues Speaker #4: Steve Woodle *
15 minutes	Topic #5: Endpoints: Short term and Long-term (graft survival) Speaker #5: Bruce Kaplan *
30 minutes	<i>Question and Answer Period (Panel and Audience) /Public Comment Discussion of Suggested Questions --Question(s) will be introduced by the moderator(s).</i>
2:50 pm	Summary
3:00 pm	Adjourn