

**The Fundamentals of International Clinical Research Workshop
Vitória, Brazil
January 23-28, 2011**

	Start Time	Session - Presenter	Tab
Sunday 23 January	7:00 PM	Welcoming Dinner and Opening Remarks – Polly Sager and Kenneth Schulz	
Monday	8:30 AM	Opening Orientation - Kenneth Schulz	
24 January	9:10 AM	Workshop Introduction - Polly Sager	
	9:20 AM	What is the ICSSC? – Mario Chen	1
	9:35 AM	Introduction to Epidemiology – Kenneth Schulz	2
	10:05 AM	Break	
	10:35 AM	The Role of the Biostatistics – Mario Chen	3
	11:20 AM	ICH GCP – Deborah Hilgenberg	4
	11:40 AM	Break-out Session: ICH	
	12:10 PM	Lunch	
	1:10 PM	Primary Research Question and Definition of Endpoints – Mario Chen	5
	2:00 PM	Writing a Protocol – Deborah Hilgenberg	6
	2:40 PM	Break	
	3:10 PM	Break-out Session: Writing a Protocol and Selecting Endpoints	
	4:10 PM	Understanding Adverse Events – Deborah Hilgenberg	7
	4:25 PM	Safety Oversight Guidelines – Mario Chen	8
	4:45 PM	Per Diem and Reimbursement – Laura Phillips	
	4:55 PM	Q & A - Faculty	
	5:05 PM	Session Adjourns	
Tuesday	8:30 AM	Q & A from Day 1 – Faculty	
25 January	8:45 AM	Source Documents and Essential Documents – Deborah Hilgenberg	9
	9:20 AM	Break-out Session : Source Documents and Essential Documents	
	9:30 AM	Clinical Site Monitoring – Deborah Hilgenberg	10
	9:50 AM	Break-out Session : Monitoring	
	10:20 AM	Break	
	10:50 AM	Quality Control / Quality Assurance – Deborah Hilgenberg	11
	11:10 AM	GCP Requirements for IRBs – Deborah Hilgenberg	12
	11:30 AM	Break-out Session: IRBs	
	12:10 PM	Lunch	
	1:10 PM	GCP Requirements for Informed Consents (ICs) – Deborah Hilgenberg	13
	1:35 PM	Break-out Session: ICs	
	2:10 PM	Practical Considerations for Fielding a Research Study – Deborah Hilgenberg	14
	2:40 PM	Break	
	3:10 PM	Break-out Session: Fielding a Research Study	
	4:10 PM	Lab Samples and Tracking – Erik Jolles	15
	4:40 PM	Discussion: Lab Samples and Tracking	
	4:55 PM	Q & A - Faculty	
	5:10 PM	Session Adjourns	

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	Start Time	Session - Presenter	Tab
Wednesday	8:30 AM	Q & A from Day 2 – Faculty	
26 January	8:45 AM	Analytic Study Design – Kenneth Schulz	16
	9:45 AM	Break-out Session: Study Design	
	10:45 AM	Break	
	11:15 AM	Sample Size Determination – Mario Chen	17
	12:05 PM	Group Activity: Sample Size Determination	
	12:35 PM	Q & A – Faculty	
	12:45 PM	Group Photo – Afternoon Free	
Thursday	8:30 AM	Q & A from Day 3 – Faculty	
27 January	8:45 AM	Critical Elements of Randomized Trials – Kenneth Schulz	18
	9:30 AM	Development of Analysis Plans – Mario Chen	19
	10:15 AM	Data Management Plans – Erik Jolles	20
	10:45 AM	Break	
	11:15 AM	Break-out Session: Flow Charts	
	12:30 PM	Lunch	
	1:30 PM	Protecting Human Participants in Research: Historical and Ethical Perspectives – Jeremy Sugarman	21
	2:15 PM	Retention in Prospective Studies – Kenneth Schulz	22
	2:45 PM	SOPs, WIs and Forms – Erik Jolles	23
	3:15 PM	Break	
	3:45 PM	Break-out Session: SOPs	
	4:30 PM	The Informed Consent Process – Jeremy Sugarman	24
	5:15 PM	Q & A – Faculty	
	5:30 PM	Session Adjourns	
Friday	8:30 AM	Q & A from Day 4 - Faculty	
28 January	8:45 AM	Ethics in the Design of Clinical Research – Jeremy Sugarman	25
	9:45 AM	Case Report Form (CRF) Design – Erik Jolles	26
	10:45 AM	Break	
	11:15 AM	Break-out Session: CRF Design	
	12:00 PM	Assessing Risks and Benefits – Jeremy Sugarman	27
	12:30 PM	Lunch	
	1:30 PM	Role of Institutional Review Boards (IRBs) – Jeremy Sugarman	28
	2:00 PM	Break-out Session: Mock IRB Meeting	
	3:15 PM	Break	
	3:45 PM	Publishing is Important: Science and Game – Kenneth Schulz	29
	4:15 PM	NIAID Oversight of Clinical Research & Funding Opportunities – NIH – Polly Sager	
	4:45 PM	Workshop Evaluation – Laura Phillips	
	4:55 PM	Closing Remarks – Polly Sager and Kenneth Schulz	
	5:00 PM	Meeting Adjourns	