



**Annual ACTG Network Meeting
June 26-30, 2016**

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PLENARY SESSION I

Monday, June 27, 2016, 3:00 p.m. – 6:00 p.m.

Chair: Daniel Kuritzkes, MD
ACTG Network Chair

Vice Chairs: Judith Currier, MD, MSc
ACTG Network Vice Chair

Ian Sanne, MBBCH, FTP (SA)
ACTG Network International Vice Chair

3:00	Welcome	Daniel Kuritzkes, MD
	NIAID: State of the Institute and Priorities in HIV/AIDS Research	Anthony Fauci, MD
4:00	State of the ACTG	Daniel Kuritzkes, MD
4:25	Recognition of ACTG Service	Daniel Kuritzkes, MD Judith Currier, MD, MSc Ian Sanne, MBBCH, FTP
4:45	Presentation of 2016 ACTG Awards (6 minutes each)	
	a. Minority HIV Investigator Mentoring Program	Daniel Kuritzkes, MD
	b. John Carey Young Investigator Award	Judith Currier, MD, MSc
	c. Constance B. Wofsy Women's Health Investigator Award	Cynthia Firnhaber, MD, MS
	d. Donna Davis Community Award	Morénike Giwa Onaiwu and Lionel Hillard
5:10	Community Updates	
	a. Community Scientific Agenda	Flavia Miiro and Larry Lyle
	b. CAB Draft and Community Input	Angel Luis Hernandez and Royce Hardin
	c. Engaging the ACTG Community	Morénike Giwa Onaiwu and Lionel Hillard
5:30	A5300/I2003: PHOENix Preparatory Study of MDR TB Cases and Household Contacts	Sarita Shah, MD, MPH

PLENARY SESSION II

Tuesday, June 28, 2016, 8:00 a.m. – 10:00 a.m.

Moderator: Judith Currier, MD, MSc
ACTG Network Vice Chair

Clinical Trials Data Management System

8:00 Medidata Update Marlene Cooper, MS

HIV Reservoirs and Viral Eradication Transformative Science Group

8:15 A5326: Safety, Immunologic and Virologic Activity of Anti-PD-L1 (BMS-936559) in HIV-1 Participants on ART (Phase 1, Double-Blind, Placebo-Controlled, Ascending Single Dose Study) Joseph Eron, MD

8:33 A5321: Effect of Long-Term Antiretroviral Therapy on HIV Reservoir Decay, Immune Activation and Inflammation Rajesh Gandhi, MD

8:51 NWCS 380: Viral and Immune Characteristics of HIV Post-Treatment Controllers in ACTG Studies Jonathan Li, MD, MMS

Neurology Collaborative Science Group

9:10 DACS 319: Stroke Incidence Highest in Women and Black HIV-Infected Participants in ALLRT Cohort Felicia Chow, MD

9:25 A5303: MVC and TDF Reduce Neurocognitive Impairment in Initial ART Kevin Robertson, PhD

Antiretroviral Therapy Strategies Subcommittee

9:40 A5340 (Phase I Study of VRC01 During ATI) Pablo Tebas, MD

PLENARY SESSION III

Wednesday, June 29, 2016, 8:00 a.m. – 10:00 a.m.

Moderator: Ian Sanne, MBBCH, FTP (SA)
ACTG Network International Vice Chair

Hepatitis Transformative Science Group

8:00 A5327: Relationship of RBV to Treatment Outcome, Tenofovir Pharmacokinetics Jennifer Kiser, PharmD

Women's Health Inter-network Scientific Committee

8:20 DACS 325 (Evaluation of ACTG Protocol Screening and Enrollment by Sex) Laura Smeaton, MS

Co-Infections and Malignancies Working Group

8:30 A5298 (HPV Test-and-Treat Study) Timothy Wilkin, MD, MPH

Tuberculosis Transformative Science Group

8:50 A5307 (Essentiality of INH) William Bishai, MD, PhD

End-Organ Disease/Inflammation Transformative Science Group

9:10 Overview of the State of Inflammation Research Peter Hunt, MD

9:20 A5331 (Immune Modulation by Aspirin) Meagan O'Brien, MD

9:35 A5318 (Effects of ART on Bone Mineral Density: LEACH) Todd Brown, MD, PhD

9:50 A5260s (Metabolic Substudy of A5257) Structural Equation Modeling Approach to Understanding the Cardiovascular Effects of Antiretroviral Therapy (ART) Initiation: Results from a Phase III Clinical Trial Carlee Moser, PhD

SYMPOSIUM I

JOINT ANTIRETROVIRAL THERAPY STRATEGIES SUBCOMMITTEE (ARTS SC) AND HIV RESERVIORS AND VIRAL ERADICATION TRANSFORMATIVE SCIENCE GROUP (CURE TSG)

Tuesday, June 28, 2016, 4:00 p.m. – 6:00 p.m.

Session Co-Chairs: Babafemi Taiwo, MD
ARTS SC Chair
Northwestern University CRS

Raphael Landovitz, MD
ARTS SC Vice Chair
University of California, Los Angeles CARE Center CRS

Joseph Eron MD
Cure TSG Chair
University of North Carolina Global HIV Prevention and
Treatment CTU

Rajesh Gandhi, MD
Cure TSG Vice Chair
Massachusetts General Hospital CRS

4:00	Introductions	Joseph Eron, MD Babafemi Taiwo, MBBS
4:05	Overview of Broadly neutralizing Antibodies (bnAbs) and Clinical Data to Date	Marina Caskey, MD
4:35	Antibody Susceptibility, Escape and Other Challenges to Trials Design	Katharine Bar, MD
5:05	Optimizing Effector Function of bnAbs	John Corbin, PhD
5:35	Bispecific Antibodies to Reduce Viral Reservoirs	Richard Koup, MD

SYMPOSIUM II

TUBERCULOSIS (TB) TRANSFORMATIVE SCIENCE GROUP

Wednesday, June 29, 2016, 11:00 a.m. – 1:00 p.m.

Chair: Richard Chaisson, MD
Johns Hopkins University CRS

Co-Vice Chairs: Gavin Churchyard, MBBCh, MMed, FCP, PhD
The Aurum Institute

Diane Havlir, MD
San Francisco Bay CTU

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|-------|---|---------------------------------|
| 11:00 | Integration of TB Screening, Prevention and Treatment | Moderator: Richard Chaisson, MD |
| | a. Efficacy of 6-month IPT to Reduce Mortality in HIV-infected Adults with High CD4 Counts: Long term Follow-up of the Temprano Trial | Anani Badje, MD, MPH |
| | b. Screening for TB in Various Populations and Opportunities for IPT | Neil Martinson, MBBCh, MPH |
| | c. TB Screening, Treatment and Prevention in HPTN071 (PopART) | Helen Ayles, MBBS, DTM&H, PhD |
| 12:00 | Treatment and Prevention of Multidrug-Resistant TB (MDR TB) | Moderator: Richard Chaisson, MD |
| | a. The South African Bedaquiline Journey - from RCT to Program | Ian Sanne, MBBCh |
| | b. endTB Clinical Trial: Response-Adaptive Randomized Evaluation of All-Oral, Shortened MDR-TB Regimens Containing New and Repurposed Drugs | Carole Mitnick, ScD |

SYMPOSIUM III

END-ORGAN DISEASE AND INFLAMMATION TRANSFORMATIVE SCIENCE GROUP (ITSG) AND HEPATITIS TRANSFORMATIVE SCIENCE GROUP (HEP TSG)

Wednesday, June 29, 2016, 1:30 p.m. – 3:30 p.m.

Session Co-Chairs: Peter Hunt, MD
ITSG Chair
University of California, San Francisco HIV/AIDS CRS

Raymond Chung, MD
Hep TSG Vice Chair
Massachusetts General Hospital CRS

Session Co-Vice-Chairs: Turner Overton, MD
ITSG Vice Chair
Alabama CRS

Mark Sulkowski, MD
Hep TSG Vice Chair
Johns Hopkins University CRS

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|---|--|
| 1. Welcome and Updates | Raymond Chung, MD
Peter Hunt, MD |
| 2. Clinical Features and Natural History of Non-Alcoholic Fatty Liver Disease (NAFLD) | Kathleen Corey, MD, MPH, MMSc |
| 3. Pathological Dimensions of NAFLD | David Kleiner, MD, PhD |
| 4. Noninvasive Assessment and Biomarkers for NAFLD | Zobair Younossi MD, MPH, FACG,
AGAF, FAASLD |
| 5. Metabolic Consequences of Fatty Liver | Fred Sattler, MD |
| 6. Roundtable Discussion | All Members |

**END-ORGAN DISEASE AND INFLAMMATION
TRANSFORMATIVE SCIENCE GROUP THINK TANK**

Wednesday, June 29, 2016, 4:00 p.m. – 6:00 p.m.

Chair: Peter Hunt, MD
University of California, San Francisco HIV/AIDS CRS

Vice Chair: Turner Overton, MD
Alabama CRS

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|---|--------------------------------------|
| 1. Welcome and Introductions | Peter Hunt, MD
Turner Overton, MD |
| 2. The Impact of Early vs Delayed Therapy (When to Start) | |
| a. Overview and Clinical Context | Peter Hunt, MD |
| b. Initiation of Antiretroviral Therapy (ART) in Acute HIV-
infection Reduces but does not Abrogate Chronic Residual
Inflammation | Netanya Utay, MD |
| c. The Impact of Early ART on Cellular Markers | Sonya Heath, MD |
| d. Coagulation Defects and The Impact of Early vs. Delayed
ART | Irini Sereti, MD |
| 3. Physical Function and Frailty in HIV | Kristine Erlandson, MD |

HEPATITIS TRANSFORMATIVE SCIENCE GROUP (HEP TSG) THINK TANK

Thursday, June 30, 2016, 9:00 a.m. – 11:00 a.m.

Chair: Raymond Chung, MD
Massachusetts General Hospital CRS

Vice Chair: Mark Sulkowski, MD
Johns Hopkins University CRS

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| 1. Welcome and Update on the HEP TSG Scientific Agenda | Raymond Chung, MD
Mark Sulkowski, MD |
| 2. HIV and NAFLD/NASH Pathogenesis | Colleen Hadigan, MD, MPH |
| 3. Clinical Trials, Surrogates, and Endpoints | Caryn Morse, MD, MPH |
| 4. The Microbiome and its Contribution on NASH | Alan Landay, PhD |
| 5. Roundtable Discussion | HEP TSG Members |
| 6. Protocols and Hepatitis B Vaccine Working Group Updates | Protocol Team Leadership |

HIV RESERVOIRS AND VIRAL ERADICATION TRANSFORMATIVE SCIENCE GROUP THINK TANK

Tuesday, June 28, 2016, 1:00 p.m.-3:30 p.m.

Chair: Joseph Eron, MD
University of North Carolina Global HIV Prevention and Treatment CTU

Vice Chair: Rajesh Gandhi, MD
Massachusetts General Hospital CRS

1:00 Introduction to Think Tank Goals Joseph Eron, MD

Presentations (10-minute presentation and 5-minute discussion each)

1:10 HIV-1 Antigen Expanded Specific T-Cell Therapy Work Julia Sung, MD
1:25 T-cell Enhancement in HIV Conrad Russell Cruz, MD, PhD
1:40 Chimeric Antigen Receptor T-cell Study Pablo Tebas, MD
1:55 Total Virus Recovery Assay Joseph Hesselgesser, PhD

Concept Proposal Presentation (20-minute presentation and 10-minute discussion)

2:10 Combination Broadly Neutralizing Antibodies for Reservoir Reduction Concept Proposal Sharon Riddler, MD
Christine Durand, MD

Potential New Horizons/Future Directions: Updates to Include Data from Macaques or New Clinical Studies Beginning (2 to 5-minute presentations)

2:40 Latency Reversing Agents Mathias Lichtenfeld, MD
a. What is Being Studied Now?
b. Next Generation Histone Deacetylase Inhibitors (HdACi)
2:45 Toll-like Receptors-7 and -9 Open Discussion
2:50 Update on Current Status of Checkpoint Inhibitors Joseph Eron, MD
Cynthia Gay, MD
2:55 Therapeutic Vaccines Alan Landay, MD
3:00 Zinc-finger Nucleases and Various Host Modification Strategies in Clinical Trials Pablo Tebas, MD
3:05 Open Discussion on What Combination of Agents Makes the Most Sense to Study? All Attendees

TUBERCULOSIS (TB) TRANSFORMATIVE SCIENCE GROUP THINK TANK

Tuesday, June 28, 2016, 1:30 p.m. – 3:30 p.m.

Chair: Richard Chaisson, MD
Johns Hopkins University CRS

Co-Vice Chairs: Gavin Churchyard, MBChB, MMed, FCP, PhD
The Aurum Institute

Diane Havlir, MD
San Francisco Bay CTU

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|---|-------------------------|
| 1. Welcome | Richard Chaisson, MD |
| 2. Update on Implementation of A5349 (TBTC S31) and Discussion of any Issues | Susan Swindells, MBBS |
| 3. Update on A5344 (STAND) | Richard Chaisson, MD |
| 4. Study Updates | |
| a. A5289 (Phase II Study of Sutezolid vs. Ethambutol in DS TB) | Annie Luetkemeyer, MD |
| b. A5300B (PHOENIx MDR TB Household Prevention) | Gavin Churchyard, MBChB |
| c. A5343 (Bedaquiline Delamanid Study) | Kelly Dooley, MD, PhD |
| d. A5356 (MDR TB Linezolid Delamanid Study) | Constance Benson, MD |
| e. A5362 (Clofazimine for Treatment Shortening in DS TB) | Kimberly Scarsi, PharmD |
| 5. Update on PR 726 (Trial of Two Ultra-Short Course Isoniazid/Rifapentine Strategies to Prevent Active Tuberculosis in HIV-infected Individuals Living in Medium and High-TB Endemic Settings) | PR 726 Proposing Team |

**ANTIRETROVIRAL THERAPY STRATEGIES SUBCOMMITTEE (ARTS SC)
BUSINESS SESSION**

Tuesday, June 28, 2016, 10:30 a.m. – 12:30 p.m.

Chair: Babafemi Taiwo, MD
Northwestern University CRS

Vice Chair: Raphael Landovitz, MD
University of California, Los Angeles CARE Center CRS

1. Welcome and Introductions ARTS SC Chairs

Hard to Reach Populations Working Group Think Tank

2. The Scope of the Problem: Out-Of-Care and Non-Adherent Populations as a Population-Level “Reservoir” of HIV Carlos del Rio, MD

3. The State of the Science: Evidence-Based Interventions to Support Engagement, Retention and Adherence Jane Simoni, PhD

Measuring Adherence Biomarkers

4. Using Hair Antiretroviral Therapy (ART) Levels as a Surrogate of Adherence in Therapeutic Settings Monica Gandhi, MD, MPH

5. Intraerythrocytic ARV Metabolites in Dried Blood Spots Jose Castillo-Mancilla, MD

How Can the ACTG Participate in this Agenda?

6. Panel Discussion
Jose Castillo-Mancilla, MD
Carlos Del Rio, MD
Aadia Rana, MD
Steve Shoptaw, PhD
Jane Simoni, PhD
Michael Stirratt, PhD

ARTS SC Business Session

7. Protocol Updates: Protocol Chairs

a. A5353 (Dolutegravir plus Lamivudine in Treatment Naïve HIV-1 Participants)

b. A5357 (CAB LA+VRC01LS for HIV Suppression)

c. A5359 (LA for Non-adherent)

NEUROLOGY COLLABORATIVE SCIENCE GROUP (NEURO CSG) SESSION

Tuesday, June 28, 2016, 11:30 a.m. – 1:30 p.m.

Chair: Serena Spudich, MD
Weill Cornell Chelsea CRS
Yale University School of Medicine

Vice Chair: Scott Letendre, MD
University of California, San Diego AntiViral Research Center CRS

Part I: Business Session

11:30	Welcome and Introductions	Neuro CSG Chairs
11:35	Working Group Updates	Neuro CSG members
11:45	A5324 (ART intensification for HAND)/InMIND and SPIRIT Neuroimaging Study Updates	Kevin Robertson, PhD

Part II: Think Tank

12:00	Approach to Biomarkers of Central Nervous System (CNS) HIV Infection and Active Injury	Richard Price, MD
12:30	HIV Reservoirs in the CNS: Potential Challenges to HIV Eradication	Avindra Nath, MD
1:00	Discussion of Ideas for New Works Concept Sheets, Data Analysis Concept Sheets, and Concept Proposals	Group Discussion

WOMEN'S HEALTH INTER-NETWORK SCIENTIFIC COMMITTEE THINK TANK

Wednesday, June 29, 2016, 10:30 a.m. – 12:30 p.m.

Chair: Cynthia Firnhaber, MD, MS, DTM&H
University of Witwatersrand Helen Joseph CRS

Vice Chair: Elizabeth Connick, MD
University of Arizona

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| 1. Welcome | Cindy Firnhaber, MD |
| 2. Think Tank with HIV Reservoir and Viral Eradication
Transformative Science Group Leadership - Barriers to
Cure Research for Women and Approaches to Overcome
the Barriers | Joseph Eron, MD
Rajesh Gandhi, MD |
| 3. DACS 283 (Differences by Age among Women in the
Response to Initial HAART) | Cynthia Firnhaber, MD,
MS, DTM&H |
| 4. Women's Health Assessment Checklist and Forms | Karin Klingman, MD
Laura Smeaton, MS |
| 5. Update on Relevant IMPAACT Studies | Adriana Weinberg, MD |
| 6. Women's Outreach Worker (WOW) Project Video | Susan Cohn, MD, MPH |

CO-INFECTIONS AND MALIGNANCIES WORKING GROUP BUSINESS SESSION

Tuesday, June 28, 2016, 4:00 p.m. – 5:00 p.m.

Chair: Timothy Wilkin, MD, MPH
Weill Cornell Chelsea CRS

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| 1. Where Are We Now? Brief Summary of Ongoing Projects | Timothy Wilkin, MD, MPH |
| 2. A5263 (Advanced KS Chemo) | A5263 Team Leadership |
| a. Letter of Amendment #4 and the upcoming Amendment | |
| b. How to Increase Accrual while going through the Approval Process | |
| 3. A5264 (Limited KS Study) - Closeout Procedures | A5264 Team Leadership |

**DATA MANAGEMENT COMMITTEE
BUSINESS SESSION**

Wednesday, June 29, 2016, 10:00 a.m. – 11:00 a.m.

Co-Chairs: Robert Murphy, MD
Chicago CTU

Doug Kitch, MS
ACTG Statistical and Data Analysis Center

Lu (Summer) Zhang, PhD
ACTG Statistical and Data Analysis Center

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| 1. Welcome and Introductions | Robert Murphy, MD |
| 2. Demonstration of E-Screens | Kristine Coughlin, BA |
| 3. Interactive/Searchable Appendix 100 | Chad Achenbach, MD |
| 4. Open Discussion | All Members |

FIELD REPRESENTATIVES WORKING GROUP BUSINESS SESSION

Tuesday, June 28, 2016, 2:30 p.m. – 4:00 p.m.

Co-Chairs: Kathy Watson, RN
Ohio State University CRS

Susan Pedersen, RN BSN
Chapel Hill CRS

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| 1. Introductions | Kathy Watson, RN
Susan Pedersen, RN, BSN |
| 2. The Field Representative Newsletter Reveal | Kathy Watson, RN
Susan Pedersen, RN, BSN |
| 3. Effective Communication and Collaboration between
Community Scientific Subcommittee Representatives
and Field Representatives | All Members |

**OUTREACH, RECRUITMENT AND RETENTION (ORR)
WORKING GROUP BUSINESS SESSION**

Tuesday, June 28, 2016, 3:30 p.m. – 5:00 p.m.

Chair: Bob Bucklew, JD
Case CRS

Vice Chair: Janice Fritsche, MS, APRN, PMHNP-BC
Rush University CRS

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|--|---|
| 1. Welcome and Introductions | Bob Bucklew, JD
Janice Fritsche, MS, APRN,
PMHNP-BC |
| 2. ORR Potential Roles in Protocol Development Process | All Members |
| 3. ORR Best Practices: Sharing CRS Innovation and Experiences | All Members |
| 4. Ongoing Projects: Participant Appreciation Day; Flyers and Other Study Specific Support | All Members |

PHARMACY WORKING GROUP BUSINESS SESSION

Tuesday, June 28, 2016, 1:30 p.m. – 3:00 p.m.

Co-Chairs: Grady Douglas, RPh
Houston AIDS Research Team CRS

Michael Royal, RPh
Washington University Therapeutics CRS

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| 1. Introductions | Grady Douglas, RPh |
| 2. "Participant Counselling Based on Education Level" | Marlize Smuts, MPharm
Grady Douglas, RPh |
| 3. Review of Pharmacy Working Group Role in the Protocol Development and Implementation Subcommittee and the Community | All Members |
| 4. Future Projects | All Attendees |
| 5. Open Discussion | All Attendees |

**SITE MANAGEMENT AND CLINICAL CARE COMMITTEE
BUSINESS SESSION**

Tuesday, June 28, 2016, 11:30 a.m. – 12:30 p.m.

Chair: David Currin, RN, ACRN, CCRC
University of North Carolina Chapel Hill CRS

Co-Vice Chairs: Ilene Wiggins, RN
Johns Hopkins University CRS

Smita Nimkar, MSc
Byramjee Jeejeebhoy Government Medical
College CRS

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| 1. Welcome and Introductions | David Currin, RN, ACRN, CCRC |
| 2. Updates from Subcommittee | Subcommittee Leaders |
| 3. Feedback on New Subcommittees Structure | All Participants |

**UNDERREPRESENTED POPULATIONS COMMITTEE
BUSINESS SESSION**

Wednesday, June 29, 2016, 7:00 a.m. – 8:00 a.m.

Chair: Michelle Cespedes, MD, MS
Columbia Physicians & Surgeons CRS

Vice Chair: Jose Castillo-Mancilla, MD
University of Colorado Hospital CRS

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| 1. Welcome and Introductions | Michelle Cespedes, MD, MS |
| 2. Minority HIV Investigator Mentoring Program | |
| a. Introduction of the 2016 – 2017 awardees | Michelle Cespedes, MD, MS |
| b. Presentation by Current Award Recipients | Carlos Malvestutto, MD
Jose Serpa-Alvarez, MD |
| 3. Overview of A5359 (Long-Acting Antiretroviral Therapy in Non-Adherent HIV Infected Individuals) | Jose Castillo-Mancilla, MD
Aadia Rana, MD |
| 4. Minority Recruitment Open Forum | All Members |

COMMUNITY SCIENTIFIC SUBCOMMITTEE SESSION I

Tuesday, June 28, 2016, 11:30 a.m. – 1:30 p.m.

Co-Chairs: Angel Hernandez
Puerto Rico AIDS Clinical Trials Unit CRS

Royce Hardin
Chapel Hill CRS

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|------------------------------------|---|
| 1. Welcome and Introductions | Angel Hernandez
Royce Hardin |
| 2. Roles and Responsibilities | Flavia Miiro
Angel Hernandez
Royce Hardin |
| 3. Field Representative Discussion | Kathy Watson, RN
Ilene Wiggins, RN
Derrick Mapp |
| 4. CAB Draft Feedback | Timothy Wilkin, MD, MPH
Shobha Swaminathan, MD |

COMMUNITY SCIENTIFIC SUBCOMMITTEE SESSION II

Wednesday, June 29, 2016, 11:30 a.m. – 1:30 p.m.

Co-Chairs: Angel Hernandez
Puerto Rico AIDS Clinical Trials Unit CRS

Royce Hardin
Chapel Hill CRS

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| 1. CSS Bylaws | Flavia Miiro
Angel Hernandez
Royce Hardin |
| 2. Role of the Clinical Trials Specialist (12:45 – 1:15) | Linda Naini, MPH, CCRP |
| 3. Thank You to Departing Members | All |

GLOBAL COMMUNITY ADVISORY BOARD (GCAB) SESSION I

Sunday, June 26 2016, 9:00 a.m. – 12:00 p.m.

GCAB Morenike Giwa Onaiwu
Co-Chairs: Houston AIDS Research Team CRS

Lionel Hillard
Trinity Health & Wellness Center CRS

CSS Co- Chairs: Angel Hernandez
Puerto Rico AIDS Clinical Trials Unit CRS

Royce Hardin
Chapel Hill CRS

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|--|---|
| 1. Welcome and Introductions; Review of Agenda | Morenike Giwa Onaiwu
Lionel Hillard |
| 2. CAB Presentations | George Kukhala - Blantyre
Daniel O'Neill - Puerto Rico
Angel Hernandez - Puerto Rico
Andy Kaytes - San Diego
Larry Lyle - San Diego |
| 3. Contributions of HIV Research | Peter Kim, MD
DAIDS Therapeutics Research
Program |

GLOBAL COMMUNITY ADVISORY BOARD (GCAB) SESSION II

Sunday, June 26 2016, 1:00 p.m. – 5:00 p.m.

GCAB Morenike Giwa Onaiwu
Co-Chairs: Houston AIDS Research Team CRS

Lionel Hillard
Trinity Health & Wellness Center CRS

CSS Co- Chairs: Angel Hernandez
Puerto Rico AIDS Clinical Trials Unit CRS

Royce Hardin
Chapel Hill CRS

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| 1. Women Hold Up Half the Sky: Opportunities and Challenges for Women in HIV Research and Leadership | Danielle Campbell
Kate Borloglou
Liz Barr
Morénike Giwa Onaiwu
Representatives from the GCAB |
| 2. Staff and Community Interactive; Reaching Outside the Clinic | Robert Bucklew Jr., JD
Carl Bruton |
| 3. Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP) Misconceptions | Michael Royal, RPh
Grady Douglas, BS, RPh |
| 4. Tuberculosis Update | Vidya Mave MD, TM, MPH |

GLOBAL COMMUNITY ADVISORY BOARD SESSION III

Monday, June 27 2016, 9:00 a.m. – 12:00 p.m.

GCAB Morenike Giwa Onaiwu
Co-Chairs: Houston AIDS Research Team CRS

Lionel Hillard
Trinity Health & Wellness Center CRS

CSS Co- Chairs: Angel Hernandez
Puerto Rico AIDS Clinical Trials Unit CRS

Royce Hardin
Chapel Hill CRS

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| 1. Monoclonal Antibodies and their Use in Treating HIV Infections | Stephen Bartlett, RPh, MSPH |
| 2. Cardiovascular Update/ REPRIEVE (A5332) Video | Sara Looby, PhD
Markella Zanni, MD |
| 3. A5359 (Long-acting Antiretroviral Therapy in Non-adherent HIV Infected Individuals) | Jose Castillo-Mancilla, MD
Raphael Landovitz, MD
Karen Tashima, MD |
| 4. A5321 [ACTG HIV Reservoirs Cohort (AHRC)]/A5341s (Anatomic Sampling Subbstudy of A5321) | Deborah McMahon, MD |

GLOBAL COMMUNITY ADVISORY BOARD SESSION IV

Monday, June 27 2016, 12:45 p.m. – 2:30 p.m.

GCAB Morenike Giwa Onaiwu
Co-Chairs: Houston AIDS Research Team CRS

Lionel Hillard
Trinity Health & Wellness Center CRS

CSS Co- Chairs: Angel Hernandez
Puerto Rico AIDS Clinical Trials Unit CRS

Royce Hardin
Chapel Hill CRS

1. Long-acting Antiretrovirals: Promise and Pitfalls
Amesika Nyaku, MD
Babafemi Taiwo, MD
2. Gender and Racial Differences in Outcomes
Michelle Cespedes, MD, MS

GLOBAL COMMUNITY ADVISORY BOARD SESSION V

Thursday, June 30 2016, 11:00 a.m. – 3:00 p.m.

GCAB Morenike Giwa Onaiwu
Co-Chairs: Houston AIDS Research Team CRS

Lionel Hillard
Trinity Health & Wellness Center CRS

CSS Co- Chairs: Angel Hernandez
Puerto Rico AIDS Clinical Trials Unit CRS

Royce Hardin
Chapel Hill CRS

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| 1. Hair Measures in ACTG Trials | Monica Gandhi M.D., M.P.H. |
| 2. Informed Consent and Ethics in Clinical Research | Rona Siskind, MHS
Rick Ferrer |
| 2. Community Reports | Morenike Giwa Onaiwu
Lionel Hillard |
| 3. Standard of Care International Ethics | Liza Dawson, PhD |
| 4. Community Recognition, Bridget Murtagh, and Sharon Maxwell Awards | Morenike Giwa Onaiwu
Lionel Hillard |

**A5349/TBTC STUDY 31 (RIFAPENTINE-CONTAINING TUBERCULOSIS
TREATMENT SHORTENING REGIMENS) LABORATORY TRAINING SESSION**

Monday, June 27, 2016, 9:30 a.m. – 10:30 a.m.

	Introduction and Welcome	Anita Gillis, MPH
9:30	A5349/TBTC Study 31 Laboratory Testing Review: Basics and Highlights	Anne Purfield, PhD
9:40	Completing the Microbiology (MB) Form	Anne Purfield, PhD
10:00	Questions and Answers with A5349/TBTC Study 31 Laboratory Panel	Christopher Lane Anne Purfield, PhD Anita Gillis, MPH

ABBOTT DRIED BLOOD SPOT (DBS) SESSION

Sunday, June 26, 2016, 1:30 p.m. – 2:30 p.m.

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| 1:30 | Introduction and Welcome | Anita Gillis, MPH |
| 1:35 | RealTime HIV-1 Viral Load w/ DBS Specimen Claim | Carrie Palmer |
| 2:15 | Questions and Answers/Closing | |

**DATA MANAGEMENT CENTER (DMC) PORTAL WEBSITE
TOOLS FOR LABORATORIES DEMO ROOM**

Tuesday, June 28, 2016, 10:30 a.m. – 11:30 a.m.

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| 10:30 | Introduction and Welcome | Angela Johnson, BS |
| 10:40 | Review of the DMC Website | Heather Sprenger, MS |
| | a. Laboratory Data Management System Resources | |
| | b. Submit Contact Changes | |
| | c. Data Submission System | |
| | d. Biological Sequencing System | |
| | e. Clinical Pharmacology Tutorial | |
| | f. Specimen Inventory Report | |
| | g. DMC Contacts | |
| | h. Email Address Lookup | |
| 11:00 | Reviewing the New Query System | |
| 11:20 | Questions and Answers/Closing | |

**FUTURE DIRECTIONS AND PROGRESS OF THE
ACTG NETWORK LABORATORY CENTER**

Sunday, June 26, 2016, 9:00 a.m. – 11:00 a.m.

Chair: Robert Coombs, MD, PhD
University of Washington AIDS Clinical Trials Unit CRS

9:00	Introduction and Welcome	Robert Coombs, MD, PhD
9:05	Update on the Network Laboratory Center	Robert Coombs, MD, PhD
9:25	Update on Line Probe Assay (LPA)	Lesley Scott, PhD
9:40	Introduction to the TB Infectious Control Checklist (TB ICC)	Catherine Godfrey, MD
9:55	Leukapheresis Quality Assurance Program	Joan Dragavon, MLM
10:10	Virology Quality Assurance (VQA) Update	Cheryl Jennings, BS James Bremer, PhD
10:25	Summary of Performance Evaluation Committee Laboratory Metrics	Robert Coombs, MD, PhD
10:40	Summary of Laboratory Business and Training Sessions	Robert Coombs, MD, PhD
10:50	Questions and Answers/Closing	

**IMMUNOLOGY SPECIALTY LABORATORIES (ISL)
BREAKOUT SESSION**

Monday, June 27, 2016, 12:00 p.m. – 1:30 p.m.

Chair: Michael Lederman, MD
Case Western Reserve University School of Medicine
Immunology Specialty Laboratory

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|-------|---|------------------------|
| 12:00 | Introduction and Welcome | Michael Lederman, MD |
| 12:02 | Case ISL: More Conspiracy Theories; CD8 T Cells and Monocytes Scheme to Drive CV Risk | Michael Lederman, MD |
| 12:24 | Rush ISL: "T Cell ImmunoMetabolism in HIV; How Sweet is It" | Alan Landay, PhD |
| 12:46 | Pittsburgh ISL: Myeloid-Derived Suppressor Cells in Treated HIV Infection | Bernard Macatangay, MD |
| 1:08 | South African Tuberculosis Vaccine Initiative: Building a Strong Quality Foundation - Implementation of an Inter-Lab Comparison Scheme to fulfil Whole Blood-ICS EQA Requirements | Simbarashe Mabwe |
| 1:30 | Questions and Answers/Closing | |

**INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA) SHIPPING TRAINING -
WITH SPECIAL TOPICS**

Sunday, June 26, 2016, 1:30 p.m. – 5:00 p.m.

Co-Chairs: David L. Shugarts, MA
University of Colorado Hospital CRS

Christopher Lane, AAS
University of Rochester Adult HIV
Therapeutic Strategies Network CRS

- 1:30 Introduction to IACO/IATA, US Department of Transportation David Shugarts, M.A.
Dangerous Goods Shipping Christopher Lane, AAS
- Category A Infectious Substances Shipping
- Category B Infectious Substance Shipping
- Liquid Nitrogen Dry Shipper Demonstration
- Certification Test
- SOP ACTG-144: Shipment of Clinical Specimens to the
ACTG Specimen Repository and any Additional Shipping
Resources
- 4:55 Closing

**INTERNATIONAL TUBERCULOSIS SPECIALTY LABORATORIES
BREAKOUT SESSION**

Monday, June 29, 2016, 12:00 p.m. – 1:30 p.m.

Chair: Andreas Diacon, MD, PhD
TASK Applied Science CRS

12:00	Introduction/Welcome	Marinus Barnard, PhD
12:05	Update from ACTG/IMPAACT/HVTN International TB Specialty Laboratory Centre for Clinical Tuberculosis Research (CTTR) University of Cape Town (UCT) and Stellenbosch University (SU) Consortium	Marinus Barnard, PhD
12:20	Updates from the Regional TB Specialty Laboratories	TBD
1:10	Future Projects	Marinus Barnard, PhD
1:25	Questions and Answers/Closing	

LABORATORY TECHNOLOGIST COMMITTEE TRAINING SESSION

Sunday, June 26, 2016, 5:00 p.m. – 6:00 p.m.

Chair: Cheryl Jennings, BS
Rush University CRS

Co-Vice Chairs: Christopher Lane, AAS
University of Rochester Adult HIV Therapeutic Strategies Network CRS

David Shugarts, MA
University of Colorado Hospital CRS

5:00	Introduction and Welcome	Cheryl Jennings, BS
5:05	Tuberculosis Laboratory Processing and Testing	David Shugarts, MA Christopher Lane, AAS Peter Meewes
5:25	Cold Chain Custody	Joan Dragavon, MS Francoise Giguel
5:55	Questions and Answers/Closing	

LDMS-LABORATORY TECHNOLOGIST COMMITTEE INTERACTIVE SESSION

Monday, June 27, 2016, 8:00 a.m. – 9:30 a.m.

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| 8:00 | Introduction and Welcome | Morgan Gapara, MPH |
| 8:10 | LDMS Version 11 and 12
Web Version of LDMS | Howard Gutzman, BS |
| 8:45 | Data Management Center Plans to Transition
Laboratories from the Current (Windows)
Version to the Web Platform | |
| 9:15 | Questions and Answers/Closing | |

**PHARMACOLOGY SPECIALTY LABORATORIES (PSL)/
CLINICAL PHARMACOLOGY ADVISORY GROUP
BREAKOUT SESSION**

Wednesday, June 29, 2016, 10:00 a.m. – 12:00 p.m.

Chair: Gene D. Morse, PharmD
State University of New York at Buffalo PSL
University of Rochester Adult Therapeutic Strategies Network CRS

10:30	Introduction and Welcome	Gene D. Morse, PharmD
10:35	Alabama PSL Update	Chantelle Hood, PhD
10:45	University of California, San Francisco PSL Update	Florence Marzan
10:55	University of Nebraska Medical Center PSL Update	Anthony Podany, PharmD Kim Scarsi, PharmD, MS, BCPS
11:05	State University of New York at Buffalo PSL	Charles Venuto, PharmD Qing Ma, PhD
11:15	Harare Developmental International PSL Update	Charles Maponga, PharmD
11:25	University of Cape Town, ACTG International HIV/AIDS PSL Update	Jennifer Norman, MSc
11:35	CPQA Update	Robin DiFrancesco, MT, (ASCP), MBA
11:45	Hair Pharmacology in ACTG Protocols	Monica Gandhi, MD, MPH
11:55	Questions and Answers/Closing	Gene D. Morse, PharmD

SPECIALTY LABORATORY DIRECTOR'S BUSINESS SESSION

Monday, June 27, 2016, 10:30 a.m. – 11:45 a.m.

Chair: Robert Coombs, MD, PhD
University of Washington AIDS Clinical Trials Unit CRS

10:30	Introduction and Welcome	Robert Coombs, MD, PhD
10:35	Preparation for the 2016 Progress Report	Robert Coombs, MD, PhD
10:45	Biomedical Research Institute (BRI) FOA Update	Robert Coombs, MD, PhD
10:55	Summary of Performance Evaluation Committee (PEC) Laboratory Metrics	Robert Coombs, MD, PhD
11:05	Laboratory Technologists Committee Update	Cheryl Jennings, BS
11:25	End of Study Analysis from an Immunologist Perspective	Michael Lederman, MD
11:35	Questions and Answers/Closing	

**UPDATE ON THE PROGRESS OF TUBERCULOSIS (TB)
IN LABORATORY SCIENCE**

Sunday, June 26, 2016, 11:00 a.m. – 12:30 a.m.

	Introduction and Welcome	Morgan Gapara, MPH
11:00	TB Quality Indicators	Peggy Coulter
11:15	Mycobacterium Microbank Validation Update	Peter Meewes
11:30	CO ₂ Impact on TB Cultures	Marinus Barnard, PhD
11:45	OMNIgene®•SPUTUM	Marinus Barnard, PhD Lesley Scott, PhD
12:00	Line Probe Assay (LPA) EQA	Marinus Barnard, PhD Lesley Scott, PhD
12:15	Abbott <i>m2000</i> Validation Data on the TB Platform	Carole Wallis, PhD Lesley Scott, PhD
12:30	Questions and Answers/Closing	

VIROLOGY AND IMMUNOLOGY ASSAY INTERACTIVE SESSION

Wednesday, June 29, 2016, 10:00 a.m. – 11:30 a.m.

Co-Chairs: Robert Coombs, MD, PhD
University of Washington AIDS Clinical Trials Unit CRS

Alan Landay, PhD
Rush University CRS

10:00	Introduction and Welcome	Robert Coombs, MD, PhD
10:05	What IL-15 Does to You	Michael Lederman, MD
10:15	Priming CTL to Kill HIV-Infected T Cells as an Immunotherapy	Charles Rinaldo Jr, PhD
10:25	HIV and the Microbiome	Alan Landay, PhD
10:35	Should We Quality Assure Plasma Stored in the BRI Repository?	Robert Coombs, MD, PhD
10:45	Simplified Virus Recovery Assay	John Mellors, MD
10:55	The External Quality Assurance Program Oversight Laboratory (EQAPOL)	Thomas Denny, MSc
11:15	Discussion	

**VIROLOGY SPECIALTY LABORATORIES, GENOTYPING, GENOMICS, AND
STATISTICAL AND DATA ANALYSIS CENTER (SDAC) BREAKOUT SESSION**

Wednesday, June 29, 2016, 11:30 a.m. – 1:30 p.m.

Chair: John Mellors, MD
Pitt-Ohio State CTU

	Introduction and Welcome	John Mellors, MD
11:30	New Scientific Updates: Vanderbilt DNA Resources Core	David Haas, MD
11:45	New Scientific Updates: SDAC and DACS 330	Ronald Bosch, PhD Steven Hart, PhD
12:15	New Scientific Updates: University of Pittsburgh ACTG Virology Specialty Laboratory	John Mellors, MD
12:30	New Scientific Updates: University of Washington ACTG Virology Specialty Laboratory	Robert Coombs, MD, PhD
12:45	New Scientific Updates: Harvard University ACTG Virology Specialty Laboratory	Jonathan Li, MD
12:00	International Genotyping Laboratories Update	Carole Wallis, MSc, MED, PhD
1:00	Virology Quality Assurance (VQA) Update on Virology Specialty Assays EQA Efforts	Cheryl Jennings, BS
1:25	Questions and Answers/Closing	

**INTRODUCTION TO THE ACTG:
A WORKSHOP FOR NEW INVESTIGATORS**

Monday, June 27, 2016, 11:00 a.m. – 12:30 p.m.

Chair: Judith S. Currier, MD, MSc
ACTG Vice Chair

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|----|---|----------------------------------|
| 1. | Introduction and ACTG Structure | Judith Currier, MD, MSc |
| 2. | Scientific Committee Directions:
Opportunities for New Investigators | |
| | a. Antiretroviral Therapy Strategies
Subcommittee | Babafemi Taiwo, , MD |
| | b. HIV Reservoir and Viral Eradication
Transformative Science Group
(TSG) | Joseph J. Eron, MD |
| | c. Hepatitis TSG | TBC |
| | d. End-Organ and Inflammation TSG | Edgar (Turner) Overton, MD |
| | e. Neurology Collaborative Science
Group | Serena Spudich, MD |
| | f. Tuberculosis TSG | Richard Chaisson, MD |
| | g. Women’s Health Inter-Network
Scientific Committee | Cynthia Firnhaber, MD, MS, DTM&H |
| 3. | Community Priorities in Clinical
Research | Larry Lyle, DO, MS |
| 4. | Introduction to the Statistical and Data
Analysis Center | Janet Andersen, ScD |
| 5. | Protocol Team Involvement and
Opportunities | Joseph Eron, MD |
| 6. | Protocol Writing Projects | Ian Sanne |
| | a. A5273 (2nd line ART in RLS) | |
| | b. A5274 (Empiric TB Tx) | |
| | c. A5282 (HPV Test-and-Treat) | |
| | d. A5288 (3rd-Line ART in RLS) | |
| 7. | Wrap-up | Judith Currier, MD, MSc |

**A5273 (2ND LINE ART IN RLS) NEW INVESTIGATOR WORKSHOP FOLLOW-UP
AND PROTOCOL WRITING TEAM SESSION**

Tuesday, June 28, 2016, 12:40 p.m. – 2:00 p.m.

Co-Chairs: Ann Collier, MD
University of Washington AIDS Clinical Trials Unit CRS

Alberto La Rosa, MD
Barranco and San Miguel CRSs

Co-Vice Chairs: John W. Mellors, MD
Pitt-Ohio State CTU

Babafemi Taiwo, MBBS
Northwestern University CRS

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| 1. Welcome and Introductions | Ann Collier, MD
Alberto La Rosa, MD |
| 2. Ongoing Secondary Analyses | |
| a. Follow-up on the Analysis of Replication Capacity
and Susceptibility to Lopinavir | Carole L. Wallis, MSc MED,
PhD |
| b. Follow-up on Quality of Life | Thiago Torres, RPh, PhD |
| 3. Invitation to Collaborate with SECONDLINE | Ann Collier, MD |
| 4. Potential New Secondary Analyses | A5273 Writing Team |
| a. Refined Adherence Analysis | |
| b. Analysis of Predictors of Toxicity | |
| 5. Review of Protocol Secondary Objectives | A5273 Team Leadership |
| 6. Open Discussion | All |

**A5282 (HPV TEST-AND-TREAT) NEW INVESTIGATOR WORKSHOP
FOLLOW-UP AND PROTOCOL WRITING TEAM SESSION**

Wednesday, June 29, 2016, 2:00 p.m. – 3:00 p.m.

Chair: Timothy Wilkin, MD, MPH
Weill Cornell Chelsea CRS

Co-Vice Chairs: Cynthia Firnhaber, MD, MS, DTM&H
University of the Witwatersrand Helen Joseph CRS

Vikrant Sahasrabuddhe MBBS, MPH, DrPH
National Cancer Institute, NIH

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| 1. Welcome and Introductions | Timothy Wilkin, MD, MPH |
| 2. Study Status Update | Timothy Wilkin, MD, MPH |
| 3. Manuscript Plans and Timelines | Timothy Wilkin, MD, MPH
All Members |

PROTOCOL-SPECIFIC TRAINING

A5322 (AGING, HIV INFECTION, & INFLAMMATION) SITE TRAINING AND FRAILTY RECERTIFICATION

Tuesday, June 28, 2016, 10:30 a.m. – 12:30 p.m.

Co-Chairs: Katherine Tassiopoulos, DSc, MPH
ACTG Statistical and Data Analysis Center

Frank Palella, Jr., MD
Northwestern University CRS

Co-Vice Chairs: Susan Koletar, MD
Pitt-Ohio State University CTU

Babafemi Taiwo, MD
Northwestern University CRS

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| 1. Frailty Assessment Introduction | Kristine Erlandson, MD |
| 2. Frailty Assessment Training and Recertification | Kristine Erlandson, MD
Joan Gottesman, RN, CCRP
M. Graham Ray, RN, MSN
Kathy Watson, RN |

PROTOCOL-SPECIFIC TRAINING

A5349/TBTC STUDY 31 (RIFAPENTINE-CONTAINING TUBERCULOSIS TREATMENT SHORTENING REGIMENS) PROTOCOL-SPECIFIC TRAINING SESSIONS

ACTG Chairs: Sue Swindells, MBBS
University of Nebraska Medical Center
University of Colorado Hospital CRS

Wadzanai P. Samaneka, MBChb, MSc
Parienyatwa CRS, Zimbabwe

TBTC Chairs: Payam Nahid, MD, MPH
University of California, San Francisco

Susan Dorman, MD
John Hopkins University

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| 1. | Introduction to the TBTC Web Application and Data Entry
Day & Time: Sunday, 06/26, 1:00 p.m. – 3:30 p.m. | Erin Sizemore, MPH |
| 2. | A5349 Laboratory Training Session
Day & Time: Monday, 06/27, 9:30 a.m. – 10:30 a.m. | Anne Purfield, PhD
Christopher Lane, AAS
Anita Gills, MPH |
| 3. | Protocol Team/Site Meeting
Day & Time: Wednesday, 06/29, 3:30 p.m. – 4:30 p.m. | Sue Swindells, MD
Susan Dorman, MD
Stefan Goldberg, MD |
| 4. | Management of Drug Supply and Directly Observed Therapy (DOT)
Day & Time: Thursday, 06/30, 9:00 a.m. – 10:00 a.m. | Stefan Goldberg, MD
Erin Sizemore, MPH |
| 5. | Possible Poor Treatment Response Procedures
Day & Time: Thursday, 06/30, 10:00 a.m. – 11:00 a.m. | Stefan Goldberg, MD
Susan Dorman, MD |
| 6. | Pharmacokinetic Training
Date & Time: Thursday, 06/30, 11:30 a.m. – 12:30 p.m. | Erin Sizemore, MPH |

PROTOCOL-SPECIFIC TRAINING

A5354 (EARLIER) TEAM AND SITES TRAINING SESSION

Wednesday, June 29, 2016, 10:30 a.m. – 11:30 a.m.

Co-Chairs: Jintanat Ananworanich, MD, PhD
Kenya Medical Research Institute/Walter Reed Project Clinical Research
Center CRS

Eric Daar, MD
Harbor University of California Los Angeles Center CRS

Co-Vice Chairs: Trevor Crowell, MD, PhD
Kenya Medical Research Institute/Walter Reed Project Clinical Research
Center CRS

Javier Lama, MD, MPH
IMPACTA Peru CTU

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| 1. Welcome and Introductions | Trevor Crowell, MD, PhD
Javier Lama, MD, MPH |
| 2. Eligible and Participating Sites | Trevor Crowell, MD, PhD
Javier Lama, MD, MPH |
| 3. General Overview of Protocol | Trevor Crowell, MD, PhD |
| 4. Overview of Clinical and Laboratory Evaluations | Valery Hughes, FNP
Dimas Kliemann, MD |
| 5. Laboratory Considerations | LuAnn Borowski, MSc |
| 6. Pharmacy Considerations | Oladapo Alli, PharmD |
| 7. Site Questions and Comments | All Sites |
| 8. Concluding Remarks | Trevor Crowell, MD, PhD
Javier Lama, MD, MPH |

PROTOCOL-SPECIFIC TRAINING

NEUROPSYCHOLOGICAL BATTERY, NEUROLOGICAL EXAMINATION, AND LUMBAR PUNCTURE TRAINING FOR A5324 (ART INTENSIFICATION FOR HAND), A5322 (AGING, HIV INFECTION AND INFLAMMATION), AND A5341S (A5321 SAMPLING SUBSTUDY)

Monday, June 27, 2016, 10:00 a.m. – 12:00 p.m.

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| 1. Welcome and Overview | Kevin Robertson, PhD |
| 2. Neuropsychological Examination | Kevin Robertson, PhD |
| a. Video | |
| b. Hands-on activity | |
| 3. Neurological Examination | Serena Spudich, MD |
| 4. Lumbar Puncture | Serena Spudich, MD |

SITE STAFF TRAINING
COFFEE, COLLEAGUES AND COLLABORATION

Monday, June 26, 2016, 8:00 a.m. – 9:00 a.m.

Facilitator: David Currin, RN, ACRN, CCRC
Chapel Hill CRS

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| 1. Introduction | David Currin, RN, ACRN, CCRC |
| 2. Overview of the Protocol Development and Implementation Subcommittee and Site Operations Subcommittee | Suzanne Fiorillo, MSPH
Michael Royal, RPh |
| 3. Overview of the Role of the Field Representative and Available Training | Kathy Watson, RN |
| 4. Identifying Site Staff Roles and Networking | David Currin, RN, ACRN, CCRC |

SITE STAFF TRAINING

DATA MANAGER/CLINICIAN INTERACTIVE: MEDIDATA

Sunday, June 26, 2016, 9:00 a.m. – 10:30 a.m.

Facilitator: Sara Mattiucci, RN, CCRP
University of Pittsburgh CRS

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| 1. Welcome and Introductions | Sara Mattiucci, RN CCRP |
| 2. Medidata Interactive – Data Management Center and site staff will discuss the transition to direct data entry | Laura Smith, MPH - DMC
James Gavel - University of Pittsburgh CRS
Catherine Kronk - Chapel Hill CRS
Sara Mattiucci, RN, CCRP |
| 3. Questions and Answers | All |

SITE STAFF TRAINING

DIVISION OF AIDS ADVERSE EVENT REPORTING SYSTEM (DAERS) TRAINING

Sunday, June 26, 2016, 10:30 a.m. – 12:00 p.m.

Facilitator: Carl Bruton
Chapel Hill CRS

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| 1. Welcome and Introductions | Carl Bruton |
| 2. DAERS Training | Archita Chatterjee
Lauren Miller |
| 3. Questions and Answers | All |

SITE STAFF TRAINING
STANDARD OPERATING PROCEDURE DEVELOPMENT

Sunday, June 26, 2016, 1:00 p.m. – 2:00 p.m.

Facilitator: Suzanne Fiorillo, MSPH
University of Colorado Hospital CRS

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| 1. Welcome and Introductions | Suzanne Fiorillo, MSPH |
| 2. Standard Operating Procedure Development | Lysa Triantafillou |
| 3. Questions and Answers | All |

SITE STAFF TRAINING

COMMUNITY/STAFF INTERACTIVE - CAB STRATEGIES FOR REACHING POPULATIONS OUTSIDE OF THE HEALTHCARE SYSTEM

Sunday, June 26, 2016, 2:00 p.m. – 3:00 p.m.

Facilitator: Fanny Rosas, RN
Barranco CRS

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| 1. Welcome and Introductions | Fanny Rosas, RN |
| 2. Interactive Discussion | Carl Bruton
Robert Bucklew, JD
CRS Staff
Community Members |
| 3. Questions and Answers | All |

SITE STAFF TRAINING

CONSENTING

Sunday, June 26, 2016, 3:00 p.m. – 4:00 p.m.

Facilitator: Kathy Watson, RN
Ohio State University CRS

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| 1. Welcome and Introductions | Kathy Watson, RN |
| 2. Consenting Presentation | Eva Whitehead, RN, BSN |
| 3. Questions and Answers | All |

SITE STAFF TRAINING

ACUTE HIV INFECTION

Sunday, June 26, 2016, 4:00 p.m. – 5:00 p.m.

Facilitator: Sara Mattiucci, RN, CCRP
University of Pittsburgh CRS

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| 1. Welcome and Introductions | Sara Mattiucci, RN, CCRP |
| 2. Acute HIV Presentation | Trevor Crowell, MD, PhD |
| 3. Questions and Answers | All |

SITE STAFF TRAINING

INTERNATIONAL ROUNDTABLE: LESSONS LEARNED

Monday, June 27, 2016, 8:00 a.m. – 9:00 a.m.

Facilitator: Fanny Rosas, RN
Barranco CRS

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| 1. Welcome and Introductions | Fanny Rosas, RN |
| 2. International Roundtable Discussion | Isabel Guerra, MPH
Akbar Shahkolahi, PhD |
| 3. Questions and Answers | All |

SITE STAFF TRAINING

QUALITY ASSURANCE/CLINICAL QUALITY MANAGEMENT PLANS (QA/CQMP)

Monday, June 27, 2016, 10:00 a.m. – 11:00 a.m.

Facilitator: Suzanne Fiorillo, MSPH
University of Colorado Hospitals CRS

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| 1. Welcome and Introductions | Suzanne Fiorillo, MSPH |
| 2. QA/CQMP Presentation | Bariatu Smith, RN, MS, CRA
Mary Jane (MJ) Humphries, RN, NP, CCRP |
| 3. Questions and Answers | All |

SITE STAFF TRAINING
COMMUNICATING WITH THE MEDIA

Monday, June 27, 2016, 11:00 a.m. – 12:00 p.m.

Facilitator: Carl Bruton
Chapel Hill CRS

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| 1. Welcome and Introductions | Carl Bruton |
| 2. Communications Presentation | Patrick Bayhulle, MA |
| 3. Questions and Answers | All |

**A5274 (EMPIRIC TB Tx)
ANALYSES AND MANUSCRIPT PREPARATION**

Tuesday, June 28, 2016, 11:30 a.m. – 12:30 p.m.

Co-Chairs: Mina Hosseinipour, MD
University of North Carolina (Lilongwe)

Johnstone Kumwenda, FCRP
Blantyre Clinical Research Site

Co-Vice Chairs: Gregory Bisson, MD
University of Pennsylvania

Amita Gupta, MD
Johns Hopkins University

Andrew Zolopa, MD
Stanford University

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| 1. Welcome | Mina Hosseinipour, MD |
| 2. Overview of Planned Secondary Analyses | Mina Hosseinipour, MD,
Sachiko Miyahara, PhD |
| 3. Manuscript Preparation (Plans and Timelines) | Amita Gupta, MD,
Sachiko Miyahara, PhD
Mina Hosseinipour, MD |

**A5288 (3RD-LINE ART IN RLS)
TEAM AND SITES MEETING**

Wednesday, June 29, 2016, 10:30 a.m. – 12:00 p.m.

Co-Chairs: Beatriz Grinsztejn, MD, PhD
Instituto de Pesquisa Clinica Evandro Chagas CRS

Peter Mugenyi, MB, ChB, FRCP, DSc
Joint Clinical Research Center/Kampala CRS

Co-Vice Chairs: Ann Collier, MD
University of Washington AIDS Clinical Trials Unit CRS

Robert Salata, MD
Case CRS

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| 1. Welcome | Ann Collier, MD
Robert Salata, MD |
| 2. Update on Study Status | Ann Collier, MD |
| 3. Overview of Pre-Step 2 Procedures | Linda Wieclaw, BS
Ann Collier, MD |
| 4. End of Steps 1 and 2 | Ann Collier, MD
Robert Salata, MD |
| 5. Step 3 Timeline and CRFs | Ann Collier, MD
Linda Wieclaw, BS |
| 6. Upcoming Plans for Analyses | Ann Collier, MD
Robert Salata, MD
Justin Ritz, MS |
| 7. Site Questions | |

A5300/I2003/PHOENIX FEASIBILITY STUDY SITES SESSION

Tuesday, June 28, 2016, 4:30 p.m. – 6:00 p.m.

Co-Chairs: Gavin Churchyard, MBBCh, MMed, FCP(SA), PhD (ACTG)
The Aurum Institute

Amita Gupta, MD, MHS (IMPAACT)
Johns Hopkins Medical Institutions

Anneke Hesselning, MD, PhD (IMPAACT)
Desmond Tutu TB Centre

Susan Swindells, MBBS (ACTG)
University of Colorado Hospital CRS

Vice Chair: Sarita Shah, MD, MPH
Center for Disease Control and Prevention (CDC)

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| 1. Welcome and Introductions | Gavin Churchyard, MBBCh, MMed, FCP
PhD |
| 2. Small Groups | |
| a. Laboratory Issues | Site Staff
Patricia Anthony, BS, CLS
Christopher Lane, AAS |
| b. Case Report Forms | Site Staff
Lynne Jones BS, MT(ASCP) |
| c. Home Visits/Infection Control | Site Staff
Amita Gupta, MD, MHS
Susan Swindells, MBBS |
| d. Local Partnerships and Community Engagement | Site Staff
Sarita Shah, MD, MPH |
| 3. Next Steps/Lessons Learned (Five Minute
Presentations by Each Group) | Appointed Leader for Each Group |
| 4. Closing Remarks | Gavin Churchyard, MBBCh, MMed, FCP
PhD |

**A5315 (ROMIDEPSIN TO AWAKEN HIV)
TEAM AND SITES MEETING**

Tuesday, June 28, 2016, 10:30 a.m. – 11:00 a.m.

Co-Chairs: Deb McMahon, MD
University of Pittsburgh CRS

John Mellors, MD
Pitt-Ohio State CTU

Co-Vice Chairs: Raj Gandhi, MD
Massachusetts General Hospital CRS

Mike Para, MD
The Ohio State University CRS

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| 1. Welcome | Deb McMahon, MD |
| 2. Brief Update on Study Progress | Deb McMahon, MD |
| 3. Amending to Add Cohort 4 | Deb McMahon, MD |
| 4. Site Questions | |

**A5321 [ACTG HIV RESERVOIR COHORT (AHRC)]/
A5341s (INTENSIVE RESERVOIR SAMPLING SUBSTUDY)
SITES AND TEAM MEETING**

Tuesday, June 28, 2016, 7:00 a.m. – 8:00 a.m.

Co-Chairs: Raj Gandhi, MD
Massachusetts General Hospital CRS

Deb McMahon, MD
University of Pittsburgh CRS

Co-Vice Chairs: Joe Eron, MD
University of North Carolina Global HIV Prevention and Treatment CTU

John Mellors, MD
Pitt-Ohio State CTU

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| 1. Welcome | Raj Gandhi, MD
Deb McMahon, MD |
| 2. Brief Review of A5321 Progress | Raj Gandhi, MD,
Deb McMahon, MD |
| 3. Focus on A5341s | Raj Gandhi, MD
Deb McMahon, MD |
| 4. Study Implementation Issues | Susan Pedersen, RN, BSN |
| 5. Lumbar Punctures | Serena Spudich, MD |
| 6. Outreach Activities and Materials | Ann Collier, MD |
| 7. Site Questions | |

**A5324 (ART INTENSIFICATION FOR HAND)
TEAM AND SITES MEETING**

Monday, June 27, 2016, 6:00 p.m. – 7:00 p.m.

Co-Chairs: Kevin Robertson, PhD
University of North Carolina

Serena Spudich, MD
Yale University School of Medicine

Vice Chair: Scott Letendre, MD
University of California, San Diego AntiViral Research Center

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| 1. Welcome and Introduction of Team Members | Kevin Robertson, PhD |
| 2. Brief Review of A5324 Progress | Kevin Robertson, PhD |
| 3. Barriers to Recruitment and Enrollment | Team and Sites Discussion |

A5338 (DMPA IN HIV/TB) TEAM AND SITES MEETING

Tuesday, June 28, 2016, 6:00 p.m. – 6:30 p.m.

Chair: Rosie Mngqibisa, MBChB
Durban Adult HIV CRS

Co-Vice Chairs: Susan E. Cohn, MD, MPH
Northwestern University CRS

Jennifer Robinson, MD, MPH
Johns Hopkins University CRS

1. Welcome Rosie Mngqibisa, MBChB
2. Protocol-Specific Challenges Team and Sites Discussion
 - a. Regulatory Approval
 - b. Protocol Registration and/or Activation
 - c. Recruitment and Enrollment

**REPRIEVE (A5332) REPRISE AND REVEAL:
PROGRESS TO DATE AND FUTURE DIRECTIONS**

Monday, June 27, 2016, 9:00 a.m. – 10:00 a.m.

Principal Investigators: Steven Grinspoon, MD
Harvard Medical School/Massachusetts General Hospital

Pamela Douglas, MD
Duke Clinical Research Institute

Udo Hoffmann, MD, MPH
Massachusetts General Hospital

Heather Ribaud, PhD
ACTG Statistical and Data Analysis Center

ACTG Investigators: Turner Overton, MD
Alabama CRS

Carl Fichtenbaum, MD
University of Cincinnati CRS

Judith Aberg, MD
Mt. Sinai CRS

Markella Zanni, MD
Massachusetts General Hospital CRS

9:00	Welcome	Steven Grinspoon, MD
9:05	Progress to Date/ REPRIEVE Study Population	Steven Grinspoon, MD
9:15	A5333s (Mechanistic Substudy) Progress	Steven Grinspoon, MD
9:20	REPRIEVE Champion Feedback	Markella Zanni, MD
9:30	Site Selection and Performance Committee Assessment and Evaluation	Carl Fichtenbaum, MD
9:40	Discussion of Proposed Protocol Modifications	Turner Overton, MD
9:45	A5361s (PREPARE) Substudy	Todd Brown, MD
9:50	Questions and Answers	Team

**A5345 (HIV REBOUND AND CONTROL BIOMARKERS) AND
A5347s (SAMPLING SUBSTUDY OF A5345)
SITES AND TEAM MEETING**

Wednesday, June 29, 2016, 2:30 p.m. – 3:30 p.m.

Co-Chairs: Jonathan Li, MD, MMS
Brigham and Women's Hospital Therapeutics CRS

Davey Smith, MD, MAS
University of California, San Diego Antiretroviral Research Center crs

Bernard Macatangay, MD
University of Pittsburgh CRS

Co-Vice Chairs: Steven Deeks, MD
University of California, San Francisco HIV/AIDS CRS

Raj Gandhi, MD
Massachusetts General Hospital CRS

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| 1. Welcome | Jon Li, MD, MMS |
| 2. Overview of A5345 | Jon Li, MD, MMS
Davey Smith, MD |
| 3. Overview of A5347s | Jon Li, MD
Bernard Macatangay, MD |
| 4. Site Questions | |