

Solid Organ Transplantation in HIV: Multi-Site Study Investigator Meeting

**Embassy Suites Dulles Airport
13341 Woodland Park Road
Herndon, VA 20171
703-464-0200**

Monday, September 22 (Remington Boardroom) Steering Committee Meeting

1:00 – 4:00 PM: Steering Committee Meeting

Agenda:

- a) Overview of Key Players (45 minutes)
- b) Roles and Members (40 minutes)
- c) Operations Committee (20 minutes)
- d) Publications and Media Policy (75 minutes)
- e) Protocol Discussion

5:30 – 7:30 PM: Informal Reception (Hotel Lounge and Restaurant)

Tuesday, September 23 (Remington Ballroom) Investigator Meeting

Complimentary cooked to order breakfast will be served for persons staying at the hotel will be served in the Embassy Suites Restaurant beginning at 6:30am. If you will be having breakfast and are not staying in the hotel, be sure to tell your waiter that the Solid Organ Transplantation in HIV: Multi-Site study will be paying for your breakfast and they will not bill you.

8:00 – 8:10 a.m. Introductions and Opening Remarks (Nancy Bridges, Peter Stock, Michelle Roland)

8:10 – 8:20 a.m. Review of Meeting Objectives (Michelle Roland: 10 minutes)

8:20 – 8:30 p.m. Budget and Regulatory issues (Michelle Roland: 10 minutes)

8:30 – 10:00 a.m. GCP Training (Barbara Pennington: 1.5 hours)

10:00 – 10:15 a.m. Break (15 minutes)

10:15 – 10:25 a.m. Study Aims (Peter Stock: 10 minutes)

10:25 – 10:40 a.m. Committees (Michelle Roland: 15 minutes)

10:40 – 10:55 a.m. Study Stopping Rules and the Statistics behind Them (Don Stablein: 15 minutes)

Protocol Review:

Inclusion Criteria and Schedule of Events

10:55 – 11:10 a.m.	Inclusion/Exclusion Criteria (Michelle Roland: 15 minutes)
11:10 – 11:25 a.m.	Schedule of Events and Clusters/Sub-studies (Michelle Roland: 15 minutes)
11:25 – 11:45 a.m.	Questions and answers (20 minutes)
11:45 – 12:30 p.m.	Buffet Lunch (45 minutes)

Medication Regimens

12:30 – 12:45 p.m.	Immunosuppressives (Peter Stock: 15 minutes)
12:45 – 1:00 p.m.	Antiretrovirals and Resistance (Michelle Roland: 15 minutes)
1:00 – 1:15 p.m.	Prophylaxis (Michelle Roland: 15 minutes)
1:15 – 1:30 p.m.	Anticipated Drug Interactions and Dosing (Laurie Carlson: 15 minutes)
1:30 – 1:45 p.m.	Questions and answers (15 minutes)
1:45 – 2:00 p.m.	Break (15 minutes)

Clinical Issues

2:00 – 2:20 p.m.	HCV (Peter Stock: 20 minutes)
2:20 – 2:30 p.m.	HBV (Peter Stock: 10 minutes)
2:30 – 2:45 p.m.	Rejection (Peter Stock: 15 minutes)
2:45 – 3:10 p.m.	Questions and answers (25 minutes)
3:10 – 3:25 p.m.	Adverse Event reporting (Natasha Tomilin: 15 minutes)
3:25 – 3:45 p.m.	Data Management and database/website demonstration (Craig Lazar: 20 minutes)

Other:

3:45 – 3:55 p.m.	Publication and Media Policy (PPSC Chair: 10 minutes)
3:55 – 4:10 p.m.	Reimbursement Considerations (Peter Stock: 15 minutes)
4:10 – 4:20 p.m.	National CAB (Michelle Roland: 10 minutes)
4:20 – 5:00 p.m.	Open Discussion of outstanding issues

Wednesday, September 24 (Remington Boardroom) Study Coordinator Meeting

Complimentary cooked to order breakfast will be served for persons staying at the hotel will be served in the Embassy Suites Restaurant beginning at 6:30am. If you will be having breakfast and are not staying in the hotel, be sure to tell your waiter that the Solid Organ Transplantation in HIV: Multi-Site study will be paying for your breakfast and they will not bill you.

Study Coordinators Only:

8:00 – 10:00 a.m.	Good Clinical Practices Training (NIH: 2 hours)
10:00 – 10:15 a.m.	Break
10:15 – 11:15 a.m.	Specimen Issues (Rodney Rogers, Kathi Shea: 60 minutes)
11:15 – 11:35 p.m.	Obtaining HPV Anal Swab (Michelle Roland: 20 minutes)
11:35 – 12:15 a.m.	Lunch (40 minutes)
12:15 – 2:15 a.m.	Data Entry (EMMES: 2 hours)