

<b>AAHRPP Site Visit: University of Pittsburgh of the Commonwealth System of Higher Education</b>				
Start	End	Min	Team A	Team B
8:00 AM	8:15 AM	15	<b>Introductions</b>	
8:15 AM	8:30 AM	15	<b>Program Overview</b>	
8:30 AM	9:00 AM	30	<b>Organizational Questions</b>	
9:00 AM	9:15 AM	15	<b>Electronic Records Tutorial</b>	
9:15 AM	10:45 AM	90	<b>Records Review</b>	
10:45 AM	11:25 AM	40	<b>Researchers:</b> Goeran Fieldler; Robert Edwards (phone in); Kevin Ball	<b>Researchers:</b> David Okonkwo; Richard Beigi; Margaret Ragni
11:25 AM	11:55 AM	30	<b>Legal Counsel to the IRB - Associate General Counsel for Health Sciences, University of Pittsburgh:</b> Theresa Colecchia, Esq; <b>Senior Associate Counsel, UPMC:</b> Al Ciocca, Esq.	<b>Persons in Charge of Negotiating Contracts and Funding Agreements - Associate Vice Provost for Research Operations:</b> Jennifer Woodward, PhD; <b>Associate Director, Contract Operations:</b> Kelly Downing
11:55 AM	1:25 PM	90	<b>Records Review &amp; Lunch</b>	
1:25 PM	2:05 PM	40	<b>IRB (S) - Committee A:</b> Robert Howland, MD; Linwah Yip, MD; <b>Committee B:</b> Konasale Prasad, MD; Catherine Palmer, PhD	<b>IRB (S) - Committee C:</b> Toby Yanowitz, MD; Ariel Gildengers, MD; <b>Committee D:</b> Tracy Pasek, RN, MSN, CCNS, CCRN, CIMI, DNP; Jan Drappatz (phone-in) available til 2p
2:05 PM	2:45 PM	40	<b>COI, Committee Chair - Involved with Managing Conflict of Interest and Organizational Conflict of Interest:</b> Craig Wilcox, PhD; <b>Director, Conflict of Interest Office:</b> David Wehrle, CPA, CIA, CFE	<b>Quality Analyst:</b> Michelle Lemenager, BS, CIP
2:45 PM	2:50 PM	5	<b>Executive Session</b>	
2:50 PM	3:20 PM	30	<b>Persons who Conduct Audits of the HRPP and Post Approval-Monitoring - Director, Education and Compliance Office for Human Subject Research:</b> Kelly Dornin-Koss, MPPM, RN, CIP; <b>Director, Office of Investigator-Sponsored IND and IDE Support:</b> Cynthia Kern, RN, CIP	<b>Associate Director of Education - Conducts Education Related to the HRPP; IRB Manager:</b> Melissa Miklos, BS, CIP

3:20 PM	4:05 PM	45	<b>IRB Chair:</b> Richard Guido, MD; <b>IRB Vice-Chairs:</b> Sue Beers, PhD; Aviva Katz, MD; Judy Martin, MD	<b>Senior Coordinator, Exempt &amp; Expedited Studies:</b> Erin Holmes Graboski, BS, CIP; <b>Faculty Research Liaison; Exempt/Expedited Review:</b> Judith Navratil, BA, CIP; <b>Exempt/Expedited Research Review Coordinators:</b> Carolyn Ivanusic, MSW, CIP; Allison Gerger, MPH
4:05 PM	4:10 PM	5	<b>Executive Session</b>	
4:10 PM	4:40 PM	30	<b>IRB (S) Committee F - Representative from the Scientific Review Committee:</b> Herbert Zeh, MD;	<b>IRB Administrator for VAMC:</b> Kathy Parks (phone in)
4:40 PM	5:00 PM	20	<b>End of Day Session with Application Contact</b>	

**AAHRPP Site Visit:  
University of Pittsburgh of the Commonwealth System of Higher Education**

Start	End	Min	Team A	Team B
8:00 AM	9:15 AM	75	<b>Records Review</b>	
9:15 AM	9:55 AM	40	<b>Staff for Researchers:</b> Shannon Puhalla (Brenda Steele); Deborah McMahon (Patty Peters); Joseph Pilewski (Sandy Urban)	<b>Staff for Researchers:</b> Tim Corcoran (Liz Hartigan); Nader Shaikh (Diana Kearney); John Fowler (Cathy Naccarelli)
9:55 AM	10:35 AM	40	<b>Full Board Research Review Coordinators; Persons who Write IRB Minutes:</b> Tom Carey, MSW, CIP; Lisa DeSantes, BS, CIP; Susan Spillane, RN, CCRP	<b>Education and Compliance Staff - Medical Monitor &amp; Associate Director of the Office for Investigator Sponsorerd IND and IDE Support:</b> Mara Horwitz, MD; <b>Associate Director:</b> Nita Missig Carroll, RN, BSN, OCN, CCRC; <b>Coordinators:</b> Kelli Moffa, BS, Med, JD; Mary Ellen Carey, RN, BSN, CCRC
10:35 AM	10:40 AM	5	<b>Executive Session</b>	
10:40 AM	11:10 AM	30	<b>Associate Vice Chancellor for Technology Management and Commercialization and Director, Office of Technology Management:</b> Marc S. Malandro PhD, CLP	<b>Program Director, Office of Sponsored Programs and Research Support - Representative from the Clinical Trials Office:</b> Paula Winowich
11:10 AM	11:40 AM	30	<b>Protocol Processing Coordinator, Human Research Protection Office:</b> Kathy Hurst	<b>Director of Regulatory Affairs, Human Research Protection Office - Research Subject Advocate:</b> Jean Barone, CIP
11:40 AM	12:10 PM	30	<b>Medical Director of the Community Health Services Division, University of Pittsburgh Medical Center; Chair, Department of Family Medicine - Chair, Participant Advisory Committee:</b> Jeannette South-Paul, MD	<b>IRB Medical Director; IRB Vice-Chair:</b> Margaret Hsieh, MD, CIP
12:10 PM	2:10 PM	120	<b>Records Review &amp; Lunch</b>	
2:10 PM	2:30 PM	20	<b>Investigational Drug Service Coordinator:</b> Staci Ziobert, PharmD	<b>Regulatory Specialist:</b> Jamie Zelazny, RN, MPH, CIP
2:30 PM	2:50 PM	20	<b>Manager of Technology and Instructional Development - Conducts Education Related to the HRPP:</b> Patty Orndoff, RN, MEd, CIP	<b>Assistant Chair, Department of Psychology In Charge of Student Research Pool:</b> Anna Halechko, PhD
2:50 PM	2:55 PM	5	<b>Executive Session</b>	

2:55 PM	3:25 PM	30	<b>Senior Director of Clinical Research Services, UPCI (Representative from a Key Component):</b> Diedra Cleary, RN, BSN, CCRC <b>Senior Regulatory Supervisor, UCPI:</b> Brianna Rowles	<b>IO, UPMC (Representative from a Key Component):</b> Barbara Barnes, MD
3:25 PM	3:55 PM	30	<b>Chair, Human Use Sub Committee &amp; Radiation Safety Committee:</b> Dennis P. Swanson, MS; <b>Director, Radiation Safety Office:</b> Mike Sheetz, MS, CHP, DABMP; <b>Chair, Institutional Bio- Safety (IBC) Committee Associate Professor Microbiology and Molecular Genetics:</b> Kelly Stefano Cole, PhD; <b>Director, IBC Office:</b> Beverly Harding, MSL	<b>Executive Director, Operations Core; Director, Regulatory Knowledge and Support Core, CTSI (Representative from a Key Component):</b> Laurel Yasko, MPPM, RN, CCRC
3:55 PM	4:00 PM	5	<b>Executive Session</b>	
4:00 PM	4:40 PM	40	<b>IRB (S) - Committee G:</b> Benjamin Handen, PhD; Alexander Olawaiye, MD (phone in); <b>Committee H:</b> Jack Cornelius, MD, MPH; Richard MCGough, MD	<b>Researchers:</b> Peter Bachman; Brian Coffman; Annie Im
4:40 PM	5:00 PM	20	<b>End of Day Session with Application Contact</b>	

**AAHRPP Site Visit:  
University of Pittsburgh of the Commonwealth System of Higher Education**

Start	End	Min	Team A	Team B
8:00 AM	8:45 AM	45	<b>IRB (NS) - Committee A:</b> Robert Diltsm PhD; <b>Committee B:</b> Carylynn Jackson Graves, BS; <b>Committee C:</b> Daniel Hurst, Mdiv, MTh; Nancy Harter	<b>IRB (NS) - Committee D:</b> Connie Kumer; <b>Committee F:</b> D. Lamar Oliver; <b>Committee G:</b> Nancy Shuman, BBA; <b>Committee H:</b> Brandi Phillips, MSPPM (phone-in)
8:45 AM	9:15 AM	30	<b>Vice Provost for Research Conduct and Compliance - Organizational Official:</b> George A. Huber, JD, MSIE, MSSM	
9:15 AM	9:50 AM	35	<b>Executive Session</b>	
9:50 AM	10:05 AM	15	<b>Lead Contact Review</b>	
10:05 AM	10:50 AM	45	<b>Closeout</b>	