



Spring 2018 Research Training Program Agenda

SESSION 1, WEDNESDAY, MAY 2, 2018	
7:45 am – 8:15 am	Sign-In - Refreshments provided, course materials distributed
8:15 am - 8:25 am	Introduction <i>Welcome and overview of the six session course.</i>
8:25 am - 8:45 am	Pretest <i>A brief pre-test will be given to assist with evaluation of the program and the ability for the training program objectives.</i>
8:45 am - 9:00 am	Housekeeping <i>General overview and explanation of notebook/binder.</i> Penelope Jester, BSN, MPH, CCRC, Program Director III, UAB Pediatric Infectious Disease
9:00 am - 9:15 am	Good Clinical Practices: An Overview <i>Objective 1 - GCPs and federal regulations - what GCPs are and how they are used in research.</i> Penelope Jester, BSN, MPH, CCRC, Program Director III, UAB Pediatric Infectious Disease
9:15 am – 9:30 am	BREAK - Refreshments provided.
9:30 am - 10:30 am	History and Ethics of Research <i>Objective 2 - Summary of current regulations that impact the implementation of clinical research including the role of IRBs.</i> Sheila Moore, BS, Director of Clinical Studies, VISTAR, Inc., Research Service, Birmingham VA Medical Center
10:30 am - 11:30 am	The IRB Process <i>Objective 3 - IRB submission errors, documenting the consent process, enrolling children and obtaining signatures.</i> V. Leslie Cooper, CIP, Director, UAB Institutional Review Board

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SESSION 2, MONDAY, MAY 7, 2018	
7:45 am – 8:00 am	Sign-In – Refreshments provided.
8:00 am - 9:00 am	Understanding the Protocol <i>Objective 1 - How to use the protocol as a resource; how the protocol can provide guidance to implement a study; and understanding the relationship of the Manual of Procedures to the protocol; and the requirement for adherence to the protocol.</i> Penelope Jester, BSN, MPH, CCRC, Program Director III, UAB Pediatric Infectious Disease
9:00 am – 10:00 am	Managing a Study <i>Objective 1 - Key elements in preparing for a new study, basic principles of managing a study and discussion on study roles.</i> Bari Cotton, RN, BS, MA, Research Nurse Coordinator, UAB Pediatric Infectious Disease
10:00 am – 10:15 am	BREAK - Refreshments provided
10:15 am - 11:15 am	Recruitment and Retention <i>Objective 3 - Basic elements needed for successful recruitment and retention of study subjects.</i> Joseph H. Richardson, RN, CCRC, Research Nurse Coordinator, Department of Neurology, Division of Movement Disorder
11:15 am – 12:00 pm	Health Behavior Research <i>Objective 4 - Basic understanding of the study of the determinants and outcomes of actions that affect health.</i> Kathy Harrington, PhD, MPH, Associate Professor, UAB Pulmonology/Behavior Change



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SESSION 3, TUESDAY, MAY 15, 2018

7:45 am – 8:00 am	Sign-In – Refreshments provided.
8:00 am - 8:45 am	UAB Enterprise Code of Conduct <i>Objective 1 - Recognize standards of behavior required of UAB employees, especially as related to the conduct of clinical research, and discuss resources available to support compliance.</i> Katie Crenshaw, JD, MEd, Associate University Compliance Officer, University Compliance Office
8:45 am – 9:15 am	UAB Clinical Trials Office (CTO) Clinical Billing Review <i>Objective 2 - Mission and objectives of the CBR, FAP/SiteMinder implementation update.</i> Dawn Bryant Matthews, BS, CCRC, CPC, Clinical Trials Billing Officer, UAB Clinical Billing Review Unit
9:15 am - 10:00 am	Overview of Office of Sponsored Programs (OSP) Processes <i>Objective 3 - Review and negotiation of industry agreements.</i> Richard McGuire, JD, Grants and Contracts Officer, UAB Office of Sponsored Programs
10:00 am – 10:10 am	BREAK - Refreshments provided
10:10 am - 10:50 am	Creating Budgets – The Basics <i>Objective 4 - The basics of creating a site specific study budget: what you should know.</i> Tina Ayer, BS, CCRP, Program Director, UAB Nephrology Transplant Clinical Research
10:50 am - 11:20 am	Integrated Research Administration Portal (IRAP) Overview <i>Objective 5 – Using IRAP to help manage clinical trials</i> Molly Moran Lerew, Manager, Research Administration Systems, Office of the Vice President for Research and Economic Development
11:20 am - 11:50 am	Conflict of Interest <i>Objective 6 - Basic understanding of the importance and concepts behind conflict of interest.</i> Brenda Cox, MBA, Associate Director, UAB Office Conflict of Interest Review Board



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SESSION 4, MONDAY, MAY 21, 2018

7:45 am – 8:00 am	Sign-In – <i>Refreshments provided.</i>
8:00 am - 9:00 am	The Informed Consent <i>Objective 2 - Overview of the informed consent purpose, development and implementation.</i> Tiffany Grimes, RN, BSN, Program Director II, UAB Comprehensive Diabetes Center
9:00 am - 10:00 am	Quality Control / Quality Assurance and Management of CRFs and Source Documents <i>Objective 2 - Overview on understanding and preparing for internal compliance and internal monitoring and understanding of source documents and CRF completion.</i> Karen Savage, BSN, CCRC, Program Director III, UAB Infectious Disease
10:00 am – 10:15 am	BREAK - <i>Refreshments provided</i>
10:15 am – 11:00 am	Understanding HIPAA <i>Objective 3 - Basic understanding of HIPAA.</i> Terri Alexander, Legal Counsel, UAB Office of Counsel
11:00 am-12:00pm	Regulatory Document Management <i>Objective 4- Overview of essential documents required to conduct a clinical trial and introduction to the sources requiring regulatory documents.</i> Susan Branscum, CCRP, Regulatory Administrator, UAB Pediatric Infectious Disease



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SESSION 5, MONDAY, JUNE 4, 2018

7:45 am – 8:00 am	Sign-In – Refreshments provided
8:00 am - 9:00 am	The Key to Data Management <i>Objective 1 - An explanation of statistical measures and the importance of recruiting the correct sample of research subjects.</i> David Redden, PhD, Professor, UAB Biostatistics
9:00am - 9:50 am	Serious Adverse Event Reporting (Includes Hands-on Exercises) <i>Objective 2 - Familiarization of the importance of SAEs and general principles of reporting SAEs.</i> Leigh Powell, MSN, BSN, RN, CCRC, Clinical Trials Manager, Cardiovascular Clinical Trial Unit
9:50 am - 10:00 am	BREAK - Refreshments provided
10:00 am – 11:00 am	Device Studies <i>Objective 3 - Differentiate between pharmacological studies and device studies.</i> Thomas Patrick Frazier, RN, Research Nurse Manager, UAB Cardiology
11:00 am – 12:00 pm	Breakout Session <i>Objective 4 – Understanding how to work better together as a team.</i> Anthony Hood, PhD Assistant Professor, Management, Informatics Systems, and Quantitative Methods, UAB School of Business

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SESSION 6, FRIDAY, JUNE 8, 2018	
7:45 am – 8:00 am	Sign-In – Refreshments provided
8:00 am – 8:45 am	Closing a Study <i>Objective 1 - Reasons for study closure and the key elements of study closure.</i> TBD
8:45 am – 9:30 am	Drug Accountability <i>Objective 2- Overview of the drug accountability process.</i> Brenda Denson, PharmD , Investigational Studies Pharmacist / Pharmacy Educator, Children's of Alabama
9:30 am – 9:45 am	Specimen Management <i>Objective 3 – Overview of specimen management.</i> Maitlyn Mullen , Research Assistant, UAB Center for Clinical and Translational Science, Processing Lab
9:45 am-10:00 am	BREAK - Refreshments provided
10:00 am – 10:20 am	Specimen Handling <i>Objective 4 – Brief Overview of Human Specimen Handling and OSHA</i> Judith McBride, CIH , Director of Laboratory Health and Safety, Department of Occupational Health and Safety
10:20am – 11:20 am	Monitoring Visits and Audits <i>Objective 5 - Overview on understanding and preparing for a monitor visit and audit.</i> Meredith Fitz-Gerald, BSN/MSN , Director, Clinical Research Support Program, UAB Center for Clinical and Translational Science
11:20am-11:35 am	ClinicalTrials.gov <i>Objective 6– Overview of clinical trial registration</i> Denise McKenzie, RN , Research Nurse Coordinator, Clinical Research Support Program, UAB Center for Clinical and Translational Science
11:35 am – 11:50 am	Post Test <i>A brief post test will be given to assist with evaluation of the program and the ability for the training program objectives.</i>
11:50 am – 12:00pm	Closing Remarks <i>A summary of the program and review of resources for future learning and to assist in protocol implementation.</i>



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