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Fall 2015
Research Training Program
Agenda

SESSION 1, TUESDAY, OCTOBER 6, 2015	
7:45 am – 8:15 am	Sign-In - *Refreshments provided, course materials distributed*
8:15 am - 8:25 am	Introduction *Welcome and overview of the six session course.*
8:25 am - 8:45 am	Pretest *A brief pre-test will be given to assist with evaluation of the program and the ability for the training program objectives.*
8:45 am - 9:00 am	Housekeeping *General overview and explanation of notebook/binder.* Penelope Jester, BSN, MPH, CCRC, Program Director III, UAB Pediatric Infectious Disease
9:00 am - 9:15 am	Good Clinical Practices: An Overview *Objective 1 - GCPs and federal regulations - what GCPs are and how they are used in research.* 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 *Objective 2 - Summary of current regulations that impact the implementation of clinical research including the role of IRBs.* Sheila Moore, BS, VISTAR, Inc. and Research Service, Birmingham VA Medical Center
10:30 am - 11:30 am	The IRB Process *Objective 3 - IRB submission errors, documenting the consent process, enrolling children and obtaining signatures.* Nancy Stansfield, RN, MSN, CCRC, CIP, Assistant Director, UAB Institutional Review Board

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SESSION 2, TUESDAY, OCTOBER 13, 2015	
7:45 am – 8:00 am	Sign-In – *Refreshments provided.*
8:00 am - 9:00 am	Understanding the Protocol *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.* Penelope Jester, BSN, MPH, CCRC, Program Director III, UAB Pediatric Infectious Disease
9:00 am – 10:00 am	The Informed Consent *Objective 2 - Overview of the informed consent purpose, development and implementation.* Tiffany Grimes, RN, Research Nurse Coordinator, UAB Center for Clinical and Translational Science
10:00 am – 10:15 am	BREAK - *Refreshments provided*
10:15 am - 11:15 am	Recruitment and Retention *Objective 3 - Basic elements needed for successful recruitment and retention of study subjects.* Joseph H. Richardson, RN, CCRC, Research Nurse Supervisor, UAB Surgical Oncology
11:15 am-12:00pm	Regulatory Document Management *Objective 4- Overview of essential documents required to conduct a clinical trial and introduction to the sources requiring regulatory documents.* Susan Branscum, CCRP, Regulatory Administrator, UAB Pediatric Infectious Disease

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SESSION 3, TUESDAY, OCTOBER 20, 2015	
7:45 am – 8:00 am	Sign-In – *Refreshments provided.*
8:00am-8:45 am	UAB Enterprise Code of Conduct *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.* Katie Crenshaw, JD, MSEd, University Compliance Coordinator, University Compliance Office
8:45 am – 9:15 am	UAB Clinical Trials Office (CTO) Clinical Billing Review *Objective 2 - Mission and objectives of the CBR, FAP/SiteMinder implementation update.* Dawn Bryant Matthews, BS, CCRC, CPC, Clinical Trials Billing Officer, UAB Clinical Billing Review
9:15am-10:00 am	Overview of Office of Sponsored Programs Processes *Objective 3 - Review and negotiation of industry agreements.* Bonita Stokes, UAB Office of Sponsored Programs
10:00 am – 10:10 am	BREAK - *Refreshments provided*
10:10 am-10:50am	Creating Budgets – The Basics *Objective 4 - The basics of creating a site specific study budget: what you should know.* Tina Ayer, BS, CCRP, Program Manager, UAB Nephrology Transplant Clinical Research
10:50 am-11: 20am	Integrated Research Administration Portal (IRAP) Overview *Objective 5 – Using IRAP to help manage clinical trials* Carolyn P. Whitmire, MBA, CHRC, Director, Research Implementation Program, Office of VP Research and Economic Development
11:20 am - 11:50 am	Conflict of Interest *Objective 6 - Basic understanding of the importance and concepts behind conflict of interest.* Brenda Cox, MBA, Associate Director, UAB Office Conflict of Interest Review Board

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SESSION 4, TUESDAY, OCTOBER 27, 2015	
7:45 am – 8:00 am	Sign-In – *Refreshments provided.*
8:00 am - 9:00 am	Managing a Study *Objective 1 - Key elements in preparing for a new study, basic principles of managing a study and discussion on study roles.* Bari Cotton, RN, BS, MA, Research Nurse Coordinator, UAB Pediatric Infectious Disease
9:00am - 10:00 am	Quality Control / Quality Assurance and Management of CRFs and Source Documents *Objective 2 - Overview on understanding and preparing for internal compliance and internal monitoring and understanding of source documents and CRF completion.* Karen Savage, BSN, CCRC, Program Director III, UAB Infectious Disease
10:00 am – 10:15 am	BREAK - *Refreshments provided*
10:15 am – 11: 00 am	Understanding HIPAA *Objective 3 - Basic understanding of HIPAA.* Terri Alexander, Legal Counsel, UAB Office of Counsel
11:00 am – 12:00 pm	Health Behavior Research *Objective 4 - Basic understanding of the study of the determinants and outcomes of actions that affect health.* Kathy Harrington, MPH, PhD, Associate Professor, UAB Pulmonology/Behavior Change

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SESSION 5, TUESDAY, NOVEMBER 3, 2015	
7:45 am – 8:00 am	Sign-In – *Refreshments provided*
8:00 am - 9:00 am	The Key to Data Management *Objective 1 - An explanation of statistical measures and the importance of recruiting the correct sample of research subjects.* David Redden, PhD, Professor, UAB Biostatistics
9:00am - 10:30 am	Serious Adverse Event Reporting (Includes Hands-on Exercises) *Objective 2 - Familiarization of the importance of SAEs and general principles of reporting SAEs.* Cynthia Joiner, PhD, MPH, MSN, RN, Instructor, UAB Cardiovascular Disease
10:30 am - 10:45 am	BREAK - *Refreshments provided*
10:45 am – 11:45 am	Device Studies *Objective 3 - Differentiate between pharmacological* studies *and device studies.* Cynthia Joiner, PhD, MPH, MSN, RN, Instructor, UAB Cardiovascular Disease

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SESSION 6, TUESDAY, NOVEMBER 10, 2015	
7:45 am – 8:00 am	Sign-In – *Refreshments provided*
8:00 am – 8:45 am	Closing a Study *Objective 1 - Reasons for study closure and the key elements of study closure.* Jolene Lewis, RN, Nurse Manager, Medical Nursing
8:45 am – 9:30 am	Drug Accountability *Objective 2– Overview of the drug accountability process.* Brenda Denson, *PharmD,* Investigational Studies Pharmacist / Pharmacy Educator, Children's of Alabama
9:30 am – 9:45 am	Specimen Management *Objective 3 – Overview of specimen management.* Lauren Tarpley, Research Specialist, UAB CCTS Clinical Research Unit (CRU)
9:45 am-10:00 am	BREAK - *Refreshments provided*
10:00 am – 10:20 am	Specimen Handling *Objective 4 – Brief Overview of Human Specimen Handling and OSHA* Donna Williamson, Research Safety Committee, Office of the Assistant Vice President for Occupational Health and Safety
10:20am – 11:20 am	Monitoring Visits and Audits *Objective 5 - Overview on understanding and preparing for a monitor visit and audit.* Meredith Fitz-Gerald, MSN, RN, BSN, Nurse Research Manager, UAB Center for Clinical and Translational Science
11:20am-11:35 am	ClinicalTrials.gov *Objective 6– Overview of clinical trial registration* Penelope Jester, BSN, MPH, CCRC, Program Director III, Pediatric Infectious Disease
11:35 am – 11:50 am	Post Test *A brief post test will be given to assist with evaluation of the program and the ability for the training program objectives.*
11:50 am – 12:00pm	Closing Remarks *A summary of the week's presentations and review of resources for future learning and to assist in protocol implementation.*

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SESSION 6, TUESDAY, NOVEMBER 17, 2015	
7:45 am – 8:00 am	Sign-In – *Refreshments provided*
8:00 am – 9:00 am	Breakout Session *Objective 1 – Understanding how to work better together as a team.* Anthony Patterson, PhD Assistant Professor, Department of Management, Informatics Systems, and Quantitative Methods, Collat School of Business
9:00 am-9:15 am	BREAK - *Refreshments provided*
9:15 am – 10:15 am	Final Remarks Penelope Jester, BSN, MPH, CCRC, Program Director III, Pediatric Infectious Disease