Fall 2018
Research Training Program
Agenda

SESSION 1, Tuesday, September 11, 2018	
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.* **Meredith Fitz-Gerald, BSN/MSN,** Director, Clinical Research Support Program, UAB Center for Clinical and Translational Science
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.* **Meredith Fitz-Gerald, BSN/MSN,** Director, Clinical Research Support Program, UAB Center for Clinical and Translational Science
9:15 am – 9:30 am	**BREAK** - *Refreshments provided.*
9:30 am - 10:30 am	**Drug Accountability** *Objective 2– Overview of the drug accountability process.* **Brenda Denson*, PharmD,*** Investigational Studies Pharmacist / Pharmacy Educator, Children's of Alabama
10:30 am - 11:30 am	**The IRB Process** *Objective 3 - IRB submission errors, documenting the consent process, enrolling children and obtaining signatures.* **Cari Oliver**, Assistant Director, OIRB, Office of Institutional Review Board for Human Use

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SESSION 2, Tuesday, September 18, 2018	
7:45 am – 8:00 am	**Sign-In** – *Refreshments provided.*
8:00 am - 9:00 am	**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.* **Rhonda Corvalan, RN, MSN, Nurse Manager,** Clinical Research Support Program, UAB Center for Clinical and Translational Science
9:00 am – 10:00 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.* **Cynthia Joiner, , PhD, MPH, RN,** Assistant Vice Chair for Research, Assistant Professor, Department of Medicine
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 Coordinator, Department of Neurology, Division of Movement Disorder
11:15 am-12:00pm	**Health Behavior Research** *Objective 4 - Basic understanding of the study of the determinants and outcomes of actions that affect health.* **Kathy Harrington, PhD, MPH,** Associate Professor, UAB Pulmonology/Behavior Change

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SESSION 3, TUESDAY, September 25, 2018	
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,** Associate University Compliance Officer, 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 Unit
9:15am-10:00 am	**Overview of Office of Sponsored Programs (OSP) Processes** *Objective 3 - Review and negotiation of industry agreements.* **Richard McGuire, JD,** Grants and Contracts Officer, UAB Office of Sponsored Programs
10:00 am – 10:10 am	**BREAK** - *Refreshments provided*
10:10 am-10:50am	**Creating Budgets – The Basics** *Objective 4 - The basics of creating a site specific study budget: what you should know.* **Tina Ayer, BS, CCRP,** Program Director, 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* **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** *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 2, 2018	
7:45 am – 8:00 am	**Sign-In** – *Refreshments provided.*
8:00 am - 9:00 am	**The Informed Consent** *Objective 2 - Overview of the informed consent purpose, development and implementation.* **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** *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	**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 5, Tuesday, October 9, 2018	
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 - 9:50 am	**Serious Adverse Event Reporting (Includes Hands-on Exercises)** *Objective 2 - Familiarization of the importance of SAEs and general principles of reporting SAEs.* **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** *Objective 3 - Differentiate between pharmacological* studies *and device studies.* **Thomas Patrick Frazier, RN,** Research Nurse Manager, UAB Cardiology
11:00 am – 12:00 pm	**Breakout Session** *Objective 4 – Understanding how to work better together as a team.* **Anthony Hood, PhD** Assistant Professor, Management, Informatics Systems, and Quantitative Methods, UAB School of Business

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SESSION ,Tuesday, October 16, 2018	
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.* **Ilet Dale RN, BSN, MScM, CCRP**
8:45 am – 9:30 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,** Director of Clinical Studies, VISTAR, Inc., Research Service, Birmingham VA Medical Center
9:30 am – 9:45 am	**Specimen Management** *Objective 3 – Overview of specimen management.* **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** *Objective 4 – Brief Overview of Human Specimen Handling and OSHA* **Judith McBride, CIH,** Director of Laboratory Health and Safety, Department of 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, BSN/MSN,** Director, Clinical Research Support Program, UAB Center for Clinical and Translational Science
11:20am-11:35 am	**ClinicalTrials.gov** *Objective 6– Overview of clinical trial registration* **Denise McKenzie, RN, BSN,** Clinical Research Support Program, UAB Center for Clinical and Translational Science
11:35 am – 11:50 am	**Post Test** *A brief posttest 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 program and review of resources for future learning and to assist in protocol implementation.***