## SESSION 1, MONDAY, SEPTEMBER 25, 2017

<table>
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<tr>
<th>Time</th>
<th>Session</th>
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<tr>
<td>7:45 am – 8:15 am</td>
<td><strong>Sign-In</strong> - Refreshments provided, course materials distributed</td>
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| 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, Director of Clinical Studies, VISTAR, Inc., 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.  
V. Leslie Cooper, CIP, Director, UAB Institutional Review Board |
### FALL 2017
### RESEARCH TRAINING PROGRAM
### AGENDA

#### SESSION 2, WEDNESDAY, OCTOBER 11, 2017

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<td>7:45 am – 8:00 am</td>
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| 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 | 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 |
| 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 | 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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| 8:00 am – 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 |
| 9:15 am – 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 – 10:50 am | **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 – 11:20 am | **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 |
## Fall 2017 Research Training Program Agenda

### SESSION 4, TUESDAY, OCTOBER 24, 2017

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| 8:00 am - 9:00 am | The Informed Consent  
Objective 2 - Overview of the informed consent purpose, development and implementation.  
Tiffany Grimes, RN, Program Manager II, Med – Endocrinology, Diabetes & Metabolism |
| 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 | 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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<td>8:00 am - 9:00 am</td>
<td><strong>The Key to Data Management</strong> &lt;br&gt;Objective 1 - An explanation of statistical measures and the importance of recruiting the correct sample of research subjects. &lt;br&gt;David Redden, PhD, Professor, UAB Biostatistics</td>
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<td>9:00am - 10:00 am</td>
<td><strong>Serious Adverse Event Reporting (Includes Hands-on Exercises)</strong> &lt;br&gt;Objective 2 - Familiarization of the importance of SAEs and general principles of reporting SAEs. &lt;br&gt;Leigh Powell, MSN, BSN, RN, CCRC, Clinical Trials Manager, Cardiovascular Clinical Trial Unit</td>
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<td>10:00 am - 10:15 am</td>
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<td>10:15 am – 11:15 am</td>
<td><strong>Device Studies</strong> &lt;br&gt;Objective 3 - Differentiate between pharmacological studies and device studies. &lt;br&gt;Thomas Patrick Frazier, RN, Research Nurse Manager, UAB Cardiology</td>
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| 8:00 am - 8:45 am | **Closing a Study**  
**Objective 1 - Reasons for study closure and the key elements of study closure.**  
Jolene Lewis, MSN, RN, Nurse Manager, Clinical Research Unit, UAB Hospital |
| 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.**  
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, 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 – 12:00 pm | **Closing Remarks**  
A summary of the week’s presentations and review of resources for future learning and to assist in protocol implementation. |
## Fall 2017 Research Training Program

**Agenda**

### SESSION 7, WEDNESDAY, NOVEMBER 15, 2017

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| **8:00 am – 9:00 am** | **Breakout Session**  
**Objective 1 – Understanding how to work better together as a team.** 
**Anthony Hood, PhD**  
Assistant Professor, Management, Informatics Systems, and Quantitative Methods, UAB 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 |