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<tr>
<td>7:45 am - 8:15 am</td>
<td>Sign-In - 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, 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 |
## SESSION 2, TUESDAY, OCTOBER 13, 2015

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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 | 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 |                                                                                     |
# Fall 2015 Research Training Program Agenda

**SESSION 3, TUESDAY, OCTOBER 20, 2015**

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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**, 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 |
| 9:15 am – 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 – 10:50 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 Manager, 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  
**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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<th>Time</th>
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| 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 |                                                                             |
| 9:00 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, MPH, PhD, Associate Professor, UAB Pulmonology/Behavior Change |                                                                             |
## SESSION 5, TUESDAY, NOVEMBER 3, 2015

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| 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 |
## Fall 2015 Research Training Program Agenda

### SESSION 6, TUESDAY, NOVEMBER 10, 2015

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| 8:00 am – 8:45 am | **Closing a Study**<br>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**<br>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**<br>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**<br>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**<br>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 |
| 11:20 am-11:35 am | **ClinicalTrials.gov**<br>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**<br>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**<br>A summary of the week’s presentations and review of resources for future learning and to assist in protocol implementation. |
### Fall 2015 Research Training Program Agenda

**SESSION 6, TUESDAY, NOVEMBER 17, 2015**

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<td>7:45 am – 8:00 am</td>
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| 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 |