DAY ONE:

8:00-8:30 - Registration and Continental Breakfast (Provided)

8:30-9:00 - Introduction to Emergency Research Conference
*Silas Bussmann, MPH, MBA Lecturer III, Clinical Research, UNM Department of Emergency Medicine*
Mr. Bussmann will provide an introduction and overview to the Emergency Research Conference. During this time there will be discussion to assist the faculty in getting to know our attendees and their learning objectives.

9:00-10:00 - Management of a U.S. Multi-center Emergency Department Study Network – EMERGEncy ID NET
*Anusha Krishnadasan, PhD, Project Director of Research, Olive View-UCLA Education and Research Institute*
Dr. Krishnadasan will be presenting a brief history of EMERGEncy ID NET and its successful research conducted over the last 25 years. She will present the operations and logistics of managing the network’s set up, collaborations, and study activities on a limited federal budget.

10:00 – 10:15 - Break - Opportunity for networking

10:15-11:45 - Program Management in Emergency Medicine
*Silas Bussmann MPH, MBA, Lecturer III, Clinical Research, UNM Department of Emergency Medicine*
Mr. Bussmann will share site-level structures and strategies used for managing and administering a sustainable research enterprise. This session will include both lecture and exercises for skill development. While this may be most relevant to those working at or in collaboration with academic medical centers, the basic management tenants are transferable or adaptable to a variety of team-based research settings.

11:45 – 12:30 - Lunch (Provided)

12:30-1:30 - Emergency Research Regulations
*Elizabeth Mendelsohn, CIP, Research Compliance Analyst, University of California*
Ms. Mendelsohn will review current regulations related to emergency research.

1:30 – 2:30 - Consent? But it’s an emergency! The world of EFIC research
*Jenny Cook, BA, GCPH, Research Associate, Oregon Health and Science University*
Ms. Cook will guide us on a dive into the world of Exception from Informed Consent (EFIC) Research. She will cover the rules and guidelines that govern EFIC approved studies, the wide world of community consultation and public disclosure, and best practices from real world scenarios.

2:30 – 2:45 - Break - Opportunity for networking

2:45 – 4:00 - Managing Clinical Research Trials that Enroll Pediatric Participants in Emergency Settings
*Brenda Barton, RN, BSN, CCRP Nurse Project Manager, Boston Children’s Hospital
Ashley Kuniholm, Regulatory Affairs Specialist, Boston Children’s Hospital*
Ms. Barton and Ms. Kuniholm will present lessons learned to aid research staff involved in coordinating trials in an emergency setting that enroll pediatric participants or who are interested in learning key elements involved for enrolling this vulnerable population in clinical research trials. This session will review regulatory considerations to be addressed prior to initiation of clinical trial and the need for precise planning to ensure that study safety and study integrity is maintained while in the emergency setting.
**DAY TWO:**

8:30 - 9:00 - Continental Breakfast (Provided)

9:00 - 10:30 - Developing Study Budgets for Emergency Research  
*Lisa Benson, BS, CRCP, Vice President Clinical Research Operations, Quality and Education Institute for Advanced Clinical Trials for Children*  
Ms. Benson will provide information on how to develop a study budget for emergency research including contracting and payment terms while addressing differences impacting budgets compared to routine clinical trials.

10:30 - 10:45 - Break - Opportunity for networking

10:45 - 12:15 - Emergency Research Problems and Solutions – Round Tables  
*Silas Bussmann MPH, MBA, Lecturer III Clinical Research, UNM Department of Emergency Medicine*  
*Susan Devine, CCRP, Research Consultant*  
Mr. Bussmann and Ms. Devine will facilitate round table discussion between faculty and participants on important issues they are facing in emergency research. Solutions will be reported back to the group as a whole.

12:15 – 1:00 - Lunch (Provided)

1:00 - 2:00  
**Sponsor and CRO perspectives in Emergency Care Research**  
Sites often struggle to prepare for the collaborative endeavor of working with industry sponsors and contract research organizations (CROs). This session will highlight experiences and recommendations for sites to improve collaboration with sponsors and CROs.

2:00 - 2:45 - Operating a Research Associate Program in Emergency Medicine  
*Silas Bussmann MPH, MBA, Lecturer III, Clinical Research, UNM Department of Emergency Medicine*  
Opportunities for students, even in clinical education tracks, to gain exposure to hospital-based research are very limited. Mr. Bussmann will present the structure and function of a Course-Based Undergraduate Research Experience (CURE) in Emergency Medicine, discuss needs and strategies for program start-up and why the emergency department is an ideal setting for learners new to clinical research.

2:45 - 3:00- Break – Opportunity for networking

3:00 – 4:00 - Compassionate Use and Emergency Use Drugs in Emergency Research  
*April Lehman, MSPPM, Regulatory Specialist, University of Pittsburgh*  
Ms. Lehman provide an overview of the FDA Expanded Access Program related to investigational drugs. Detailed information will be presented on the process for submitting an Emergency Use Request to the FDA for expanded access to an investigational drug.

4:00 - 4:30 - Close - Group Discussion - Q & A