DAY ONE:

8:00 – 8:30 - Registration and Continental Breakfast (provided)

8:30 – 9:00 - Introduction to Pediatric Clinical Research
Susan Devine, Research Consultant
Ms. Devine will provide an introduction and overview to the Pediatric 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 - Opening Plenary Session
Ronald Portman, MD, FAAP, FASN, Executive Director, Pediatric Development, Science and Innovation, Novartis Pharmaceutical Company

10:00 – 10:15 - Break and opportunity for discussion

10:15 – 11:15 - Regulatory and Ethical Considerations in Pediatric Research
Amanda Galster, MPH, CCRP, Director, Clinical Research Program, University of Minnesota Department of Pediatrics
Ms. Galster will review the regulatory considerations and ethical principles in the context of pediatric research. She will review regulatory requirements, the consent process and discuss therapeutic misconceptions.

11:15 – 12:15 - Project Planning and Management
Susan Devine, Research Consultant
Ms. Devine will discuss project planning and management of pediatric research trials based on a project management approach. Helpful templates geared to enhance efficiency will be shared.

12:15 – 1:00 - Lunch (Provided)

1:00 – 2:00 - Monitoring, Auditing and Compliance
Lisa Benson, BS, CRCP, Senior Vice President, Clinical Research Operations, Quality and Education, Institute for Advanced Clinical Trials for Children
This session will consider monitoring and auditing issues specific to pediatric research. Ms. Benson will highlight FDA inspections and financial compliance. The concept of minimizing risk through good clinical practice will also be explored.

2:00 – 3:00 - Round Table Discussions
Susan Devine, Research Consultant
Lisa Benson, BS, CRCP, Vice President, Clinical Research Operations, Quality and Education, Institute for Advanced Clinical Trials for Children
Through a series of directed questions, participants will engage in discussion related to pediatric research in their specific research areas.

3:00 – 3:15 - Break and Opportunity for Discussion

3:15 – 4:15 - Pediatric Rare Diseases Clinical Research
Grace Wentzel, CCRP CHRC, Director, Clinical Research, Nationwide Children’s Hospital
Ms. Wentzel will discuss the administrative and financial challenges of conducting pediatric rare disease research. Additionally she will discuss these trials from the site and patient perspective.

4:15 – 4:30 - Day One Round Up / Questions and Answers All Faculty
DAY TWO:

8:00 – 8:30 - Continental Breakfast (provided)

8:30 – 10:00 - Budgeting and Contracting for Pediatric Trials
*Lisa Benson, BS, CRCP, Senior Vice President, Clinical Research Operations, Quality and Education, Institute for Advanced Clinical Trials for Children*
Ms. Benson will discuss special considerations for developing pediatric research study budgets including a review of “hidden costs”. Ms. Benson will present best practices for contract negotiation and payment collection.

10:00 – 10:15 - Break and Opportunity for Discussion

10:15 – 11:15 - Consenting in the Pediatric Population
*Kandice Roush, RN, BSN, CCRC, Clinical Team Leader, Clinical Research Services, Nationwide Children’s Hospital*
Ms. Roush will discuss the informed consent process in the pediatric population; techniques for assessing developmental age to gauge assent requirements; helpful tips for explaining complicated medical terms and procedures in language children and their families can understand. Ms. Roush will also discuss ways to manage updates and protocol changes.

11:15 – 12:15 - Sponsor Perspective
*Roxzana Kelly, MS, Senior Clinical Study Manager, Cardiovascular/Respiratory, Novartis*
Dr. Kelly will describe what sponsor companies look for when selecting sites. She will also explore challenges in study management and timelines from the Sponsors perspective.

12:15 – 1:00 - Lunch (Provided)

1:00 – 2:00 - Trials and Tribulations of Device Research
*Michael Mapel, CCRP, Pediatrics Clinical Research Lead, UCLA*
Mr. Mapel will discuss conducting pediatric device research essential to advancing the field and ensuring state-of-the-art care for patients. He will describe the distinct rules and regulations for device research which are necessary to successfully conduct these studies.

2:00 – 2:15 - Break and Opportunity for Discussion

2:15 – 4:15 - Challenges in Pediatric Research
*Janelle Allen, MS, BS, CCRP, Director, Clinical Research Operations, Quality & Education, Institute for Advanced Clinical Trials for Children*
Ms. Allen will discuss the challenges faced in recruitment, enrollment and retention of participants in pediatric trials. Specific strategies and approaches to bolster recruitment and retention will be discussed. This presentation will also include managing the transition from childhood to young adulthood by study participants.

4:15 – 4:30 - Close Group Discussion/ Q & A Day 2 Sessions