**Good Clinical Practices for Pediatric Clinical Trials**

**Course Description**

Over the past few years, there have been significant developments in the review and oversight of pediatric research. Research involving children requires careful attention to additional regulatory protections designed to protect children from being enrolled in research that exceeds a level of justified risk. This program will cover key rules and regulations that govern Good Clinical Practice (GCP) and will present practical examples of incorporating GCPs into pediatric clinical trials. Emphasis will be given to recruiting, obtaining parental permission and assent, and enrolling pediatric patients. An interactive session will conclude the program by utilizing the Game Show quiz, “Is That Your Final Answer?” This Game Show has been highly successful in previous Investigator Meetings and has been a fun way to learn and retain GCP in the world of Pediatric Clinical Trials.

**Who Should Attend**

- This course is intended for Pharmaceutical Sponsors, CROs, Investigators, Study Coordinators, or other health care providers who plan to participate in pediatric clinical trials conducted under the requirements of DHHS/FDA/ICH/GCP.

**Instructor**

Jeri L. Burr, B.S., R.N.C., C.C.R.C.

**You Will Learn**

- To appreciate that we now live in a world of evidence-based medicine. Why change the culture in pediatrics?
- To define Good Clinical Practice (GCP) and learn how the International Conference on Harmonisation Guidelines (ICH) impacts and clarifies GCP with an emphasis on pediatrics.
- Basic GCP and ICH terminology used when conducting a pediatric clinical trial.
- To understand Sponsor and Monitor requirements in pediatric clinical trials.
- The basic GCP standards for protection of human subjects including current safeguards for children.
- The general responsibilities, key commitments, and obligations of clinical investigators.
- The role of critical pediatric site personnel and the importance of teambuilding skills between the PI and CRC.
- What the current compliance concerns are when conducting a pediatric clinical trial. Why do I need to know GCP?
- The amazing world of drug development for children. What have the pediatric initiatives done for children?
- To appreciate the skills required to obtain Pediatric Informed Consent including parental permission and assent of a child. What makes pediatric consents and clinical trials so unique?
- What is considered research misconduct and fraud. If something goes wrong, who complains and who gets the blame?
- The challenges of pediatric recruitment and enrollment. Learn what works, what doesn’t, and how to retain pediatric patients.

**Interactive Exercises**

- Pre- and Post-Tests • Case Studies – Review & Troubleshooting
- Simulations/Scenarios • Sample Document Templates
- Discussions • Gameshow – Is That Your Final Answer?

**Course Outline**

**Day One: 8:30 a.m. – 5:00 p.m.**

- **Introduction to Pediatric Clinical Research:** Why a culture change is needed; evidence-based medicine
- **Good Clinical Practice:** INDS 101 – what investigators should know; investigator initiated trials; sponsor and monitor requirements; human subject protection – child tragedies
- **PI Key Commitments and Responsibilities:** PI & CRC relationship – dynamic team; AE/SAE reporting; current compliance concerns
- **Drug Development for Children:** Proof is in the data; pediatric initiatives: BPCA and PREA; why are pediatric studies different?; pediatric consents and clinical trials; ethics and assignment of risk

**Day Two: 8:30 a.m. – 3:30 p.m.**

- **World of ICH:** You are making a difference; GXP – the major international GCPs; ICH GCP Guideline (E11) – Pediatrics; DHHS/FDA/ICH/GCP compliance
- **Research Misconduct and Fraud:** Misconduct scale; the blame game – who gets the blame?: who complains? – everybody! famous case study; what is FDA’s focus?
- **Pediatric Patient Recruitment Strategies:** Involving parents and pediatric staff; addressing the role of the physician; training staff to use “customer service”; effectively approaching parents; innovative parental permission and assent; appropriate compensation
- **Gameshow – Is That Your Final Answer?**

**Course Dates and Locations**

**REGISTER EARLY AND SAVE!**

<table>
<thead>
<tr>
<th>September 16-17, 2008</th>
<th>(See Page 71 for Hotel Reservation Instructions.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boston, MA</td>
<td></td>
</tr>
<tr>
<td>Hyatt Regency Boston</td>
<td></td>
</tr>
<tr>
<td>Course #: SPRB0908</td>
<td></td>
</tr>
<tr>
<td>$1,495.00 by August 8</td>
<td></td>
</tr>
<tr>
<td>$1,695 after August 8</td>
<td></td>
</tr>
</tbody>
</table>

**Registration**

- **ON-LINE:** www.barnettinternational.com
- **FAX or MAIL:** Submit Registration Form (back cover) with Payment to Barnett Customer Service

For assistance, CALL (800) 856-2556

**Accreditation:**

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 15 hours (1.5 CEU) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will mail ACPE statements within three weeks of program completion. ACPE#: 778-000-07-053-L04-P. Released: 5/08.