

**Title:**

A New Role for Chinese Nurses: The Clinical Research Nurse in Clinical Trials

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**Session Title:**

Role Delineation Through Leadership

**Slot:**

LC 04: Friday, September 26, 2014: 3:30 PM-4:45 PM

**Scheduled Time:**

3:30 PM

**Keywords:**

Clinical Trials, Global Education and Nursing

**References:**

1. Yoshida Y, Zhang y, Yoshida Y, Ma D, and Wang P. Current situation of clinical trials in Beijing, China. *Contemporary Clinical Trials* 2012;33:583-588 2. Zhang J, Zhang H, Yu C, Li J, Jiang Y. The attitudes of oncology physicians and nurses toward phase I, II, and III cancer clinical trials. *Contemporary Clinical Trials* 2011;32:649-653 3. Hastings CE, Fisher CA, McCabe MA. Clinical research nursing: a critical resources in the national research enterprise. *Nurs Outlook* 2012;60(3):149-156

**Learning Activity:**

LEARNING OBJECTIVES	EXPANDED CONTENT OUTLINE	TIME ALLOTTED	FACULTY/SPEAKER	TEACHING/LEARNING METHOD	EVALUATION/FEEDBACK
<b>Example</b>  Critique selected definition of the term, "curriculum"	<b>Example</b>  Definitions of "curriculum"  Course of study Arrangements of	<b>Example</b>  20 minutes	<b>Example</b>  Name, Credentials	<b>Example</b>  Lecture PowerPoint presentation Participant feedback	<b>Example</b>  Group discussion: What does cultural training mean to you?

	<p>instructional materials</p> <p>The subject matter that is taught</p> <p>Cultural "training"</p> <p>Planned engagement of learners</p>				
Describe the current status and Nurse involvement of Clinical Trials in China.	Provide current status of Clinical Trials in China. Describe required training of Chinese physicians and nurses in Clinical Trials and identify gaps in the existing education.	5 minutes	Shaunagh Browning RN, FNP- BC and Xiaokun Liang, PhD	Lecture Power Point Presentation	Open group discussion
Describe the specialty of Clinical Research Nursing	Define a Clinical Research Nurse (CRN) and their domains	5 minutes	Shaunagh Browning RN, FNP-BC	Lecture with Power Point Presentation	Open group discussion.

	of practice Describe the impact CRNs have on clinical trials				
Discuss the Core Curriculum presented to the Nurses in China.	Explore the gaps in current GCP training of nurses in China. Describe how the introduction to the role of the Clinical Research Nursing will enhance the education and the Clinical Trials. Provide examples and elicit discussion and questions.	10 minutes	Shaunagh Browning RN, FNP-BC	Lecture with Power Point and case examples from training completed.	Open Group discussion on case examples.

**Abstract Text:**

**Purpose:**

Over recent years China has been working to build a Clinical Trials Infrastructure to ensure new therapies are available to patients in China. (1) Basic Good Clinical Practice (GCP) education is the minimum requirement for physicians and nurses to participate in clinical trials in China. A recent survey of physician

working in 7 hospitals in Beijing showed that only 47% of respondents (n=145) had participated in an annual GCP education. There is no data available that demonstrates how many nurses in China have received the minimal training on GCP; however, literature suggests that it is far less than that of the physicians. (1,2) The International Association of Clinical Research Nurses (IACRN) was founded in 2008 to advance the specialty of Clinical Research Nursing. "Its purpose is to define, validate and advance clinical research nursing as a specialty practice and to support the professional development of registered nurses who directly or indirectly impact the care of clinical research participants." (IACRN 2012) Since its first annual conference in 2009 IACRN has held annual high quality educational conferences in the United States to address the professional development of clinical research nurses internationally. These conferences however, are not accessible to the number of Chinese nurses that need high quality education in clinical trials and the material presented are often advanced in nature. In 2012 a contingent of 6 nurses from China supported by the non-profit organization, Global MD attended the annual IACRN conference in Houston Texas. These nurses also visited several research centers throughout the US to gain further insight into the role and competencies of CRNs. It was clear from discussions with these nursing attending the conference education around the role of the CRN in Clinical Trials was of value. In 2014 IACRN and Global MD began work together to provide Basic Level Clinical Research Nursing Core Curriculum to Chinese nurses in China participating or considering participation in clinical trials.

### **Methods:**

Education that focuses beyond the tasks associated with the clinical trials management and empowers CRNs globally to lead the clinical trial process is essential. The specialty practice of Clinical Research Nursing "incorporates human subject protection; care coordination and continuity; contribution to clinical science; clinical practice; and study management". (3) Clinical research nurses are asked to balance the needs of the participant and that of the clinical trial. IACRN integrated into the GCP training the introduction of the unique role that nurses play in clinical research. The curriculum was presented as a 2 day course to approximately 150 nurses in Beijing China April 26 and 27, 2014. The course provided basic GCP content with case studies and examples demonstrating the impact that clinical research nurses have throughout the domains of practice: human subject protections, care coordination and continuity, contribution to clinical science, clinical practice and study management. Time was allotted for discussion on the topics presented and examination of cultural difference between US practice and those in China.

### **Results:**

Plans are in place to provide this training annual throughout different providences of China and empowering Chinese Clinical Research Nurses to lead this course in the future. In addition, a mentorship program is being established for the prospective nurse leaders in China to come to the United States for a 3-6 month internship working in various settings and institutions with Clinical Research Nurses.

### **Conclusion:**

By introducing the nurses in China to the unique role of the Clinical Research Nurse, IACRN and Global MD are ensuring that the armamentarium of the nurse is utilized to improve the quality of the clinical trial data while ensuring the safety of the clinical trial participant in China. New therapies and knowledge gained from the clinical trials that nurses will lead as a result of this education, ultimately make available new and important treatments that would otherwise not be available to the Chinese community.