Potential Topics for IACRN Conference
Gap Analysis 2018

- Research Ethics
  - Ethical dilemmas in clinical research (e.g., capacity, assent age)
  - Informed consent for biologic samples, including genetic samples
  - Consent – varying practices and roles
  - Clinical care consent versus clinical protocol/research consent
  - Informed consent process and the role of the CRN (e.g., delegation, education to perform delegated activity)
- Subject Management
  - Subject recruitment and retention (e.g., novel approaches, rural versus urban, challenges, successful strategies)
  - Cultural competency in clinical research (e.g., spirituality, community support)
  - Health disparities in clinical research
  - Managing participants in the genomic era/personalized health care
  - Returning genetic/genomic results
- Regulatory
  - Single IRB for multi-site research – site exemplars
  - Impact of state laws on clinical research (e.g., PA Supreme Court ruling for informed consent by physician)
  - Common Rule update
  - Impact of legislation and payer policies on finances of clinical trials (e.g., state level, CMS, ACA, VA)
- Study Management
  - Protocol review (e.g., what is involved, who is involved)
  - Protocol feasibility (e.g., processes, what is involved, who is involved)
  - Protocol development
  - Clinical research trial design (e.g., type of design for study results, novel designs and impact for the CRN)
  - Data quality assurance
  - Standard of Practice (SOP) development
  - Reportable event monitoring and reporting
  - EMR and Documentation
  - Research sample documentation
  - Research sample collection, processing, and storage
  - Monitoring and auditing
  - Case report form and source document development
  - Informed consent document development
  - Billing & reimbursement processes
  - Acuity tools
  - Developing protocol specific budgets/study contracts
- Site Management
  - Assessing workload: tools, best practices
  - Site performance metric tool
  - Delineation of role between CRN and non-licensed team members - how to handle issues working with unlicensed personnel
  - Investigator initiated studies
    - Sponsor v MD initiated v federal funded (e.g., what is the difference)
    - Sponsor – drug/device and/or fiscal
    - Investigator-sponsor
  - Managing discrepancies with institutional policy and research protocol
    - Example, how to handle this
    - How to use protocol feasibility for this
    - Using company/sponsor supplied equipment
    - Case study with CAPA plan

Potential Topics for IACRN Conference
Gap Analysis 2018

- Professional Advancement
    - Leadership
    - Use of CRN Scopes and Standards
        - Exemplars
    - Advocacy roles of the CRN
        - Policy
            - Apply for license and CRN not included – Candi had added to OK Board of Nursing – share this process – promoting the CRN specialty
        - Patient/Participant
        - Protocol
            - CRN role in protocol feasibility assessment and operationalization
        - Professional Development
            - Delegation – what to do if you don't know how to do something you are delegated
            - Training-orientation curriculum
            - Presentation development
            - Professional portfolios
            - Poster development