

Topic Ideas For IACRN 2021 Conference

- **Research Ethics & Protection of Research Participants**
 - Ethical dilemmas: Research vs clinical care
 - Health disparities in clinical research
 - Single IRB review and challenges for compliance monitoring
 - Ethical considerations/impact on subjects:
 - Computer-based trials
 - Artificial Intelligence
- **Informed Consent**
 - Health literacy and impact on informed consent process
 - Decisional capacity assessment and implications for the CRN
 - Consent and e-consent development and implementation (e.g., remote signatures, e-consents, e-signatures)
- **Protocol Development, Review and Approval**
 - Impact of diversity and inclusivity on eligibility criteria
 - Mobile health/Advancements in data collection technologies
 - Use of mobile devices
 - Use of wearable device
- **Financial: Study Feasibility and Billing Compliance**
 - Developing budgets/contracts for clinical research/clinical trials
 - Research billing compliance: concerns and traps/pitfalls to avoid
 - Budget negotiation: achieving adequate returns for the work that is put into a study.
- **Recruitment and Retention**
 - Cultural competency during recruitment
 - Subject recruitment and retention strategies
 - Effective measures to promote the recruitment of minorities
 - Gender equality
- **Drug and Device Development**
 - Drug development process: similarities and difference between US and other regions
 - Investigator held INDs
 - Vaccine development
 - Overview of the device development process
- **Roles and Responsibilities of the Clinical Research Nurse and Research Team**
 - Direct care CRN challenges/opportunities
 - Delineation of role between CRN and licensed practical/vocation nurse and non-licensed team members
 - Reflections on things learned during the pandemic
 - Collaborative role of nurse navigator and CRN
- **Study Conduct and Participant Care**
 - Managing telehealth visits
 - Screening vs prescreening

- Standard Operating Procedures (SOP) development
- Tips for success in conducting clinical research in a community or home setting
- Challenges and strategies for operationalizing a study
- **Data and Safety Monitoring and Reportable Events**
 - Adverse event definition, assessment, and documentation
 - Quality management activities for research sites
 - Remote monitoring visits
 - Development Corrective and Preventive Action (CAPA) plans at research sites
 - FDA inspection preparation
- **Research Site Management**
 - Protocol acuity tools
 - Managing a remote workforce
 - Staffing models
 - Managing a team of coordinators with and without medical backgrounds
- **Professional Development**
 - Leadership role of the CRN
 - Leadership strategies
 - Working with challenging PIs and other team members
 - Improving relationship and collaboration between the study team, non-clinical research staff, non-clinical research nursing staff and clinical research nursing staff.
 - Professional Practice
 - Ways to advance in the field of clinical research close to home in our own community
 - Scope of practice, how to function to the highest level with a nursing license in research
 - CRN scope of practice and tips on role independence
 - Career paths including member of pharmaceutical sponsors for a research nurse
 - CRN Training/Education
 - How to create or curate education and training materials for RN's new to clinical research
 - Details on how to orient CRNs, not just a big picture. Specifics examples of what has worked and what hasn't worked
 - Developing a professional portfolio
 - Exemplars using the Scopes and Standards of Practice
 - Career paths in the specialty practice
 - What are they?
 - How to transition
 - Entrepreneurial opportunities for the CRN
 - Global practices