

## 2019 IACRN 11<sup>th</sup> Annual Conference

### Topic Ideas for Abstracts, Workshops and Roundtables

#### Research Ethics

- Ethical dilemmas in clinical research (e.g., capacity, assent age)
- Informed consent for biologic samples, including genetic samples
- Consent
  - Varying practices
  - Readability of IC document including resources - exemplars
  - New look to IC document with Common Rule
  - E-consents/consenting
  - Vulnerable populations
  - Challenges related to guardianship for children of divorced parents
- 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)

#### Regulatory

- EU General Data Protection Regulations (GDPR):
  - Exemplars
  - Implication for US research sites
- Common Rule implementation exemplars
  - 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)
- Compassionate use protocols
- US FDA Reauthorization Act (FDARA) - Section 504, *Development of drugs and biological products for pediatric cancers*, amend current requirements for pediatric studies so that they are based on relevant molecular targets rather than cancer site of origin.
  - What is the impact for CRNs?
  - Adult nurses now caring for younger patients?
  - Collaboration with adult and pediatric investigators?
- Result reporting compliance (FDAAA Compliance): [FDAAA Tracker](#); ability to tweet lack of results posting and impact on PI/sponsor
- Big data/data sharing

#### Managing the Research Participant

- Engage patients as partners in clinical research Subject recruitment and retention (e.g., use of social media, novel approaches, rural versus urban, challenges, successful strategies)
- Cultural competency in clinical research (e.g., spirituality, community support)
- Managing participants in the genomic era/personalized health care
- Returning genetic/genomic results

## **Study Management**

- Research basics: regulations and guidelines; who oversees what
- Protocol feasibility (e.g., processes, what is involved, who is involved) and CRN role in protocol feasibility assessment and operationalization
- Protocol development
- Clinical research trial design (e.g., type of design for study results, novel designs and impact for the CRN)
- Advancements in data collection technologies
  - Use of mobile devices
  - Use of wearable device
- EMR and Documentation
- Event reporting
  - Use of CTCAE or other standard severity rating scale
  - AE assessment
  - Documentation in the medical record
- Data quality assurance
- Monitoring and auditing
- Case report form and source document development
- Informed consent document development
  - Billing & reimbursement processes
  - Developing protocol specific budgets/study contracts

## **Research Site Management**

- Assessing workload: tools, best practices
- Site performance metric tool
- Acuity tools
- Leadership for managers
- CRN ladders and other organizational strategies
- Delineation of role between CRN and non-licensed team members - how to handle issues working with unlicensed personnel
- Investigator initiated studies
  - Sponsor vs. MD initiated vs. 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

## **Professional Competency and Advancement**

- Career paths in the specialty practice
  - What are they?

- How to transition
  - Entrepreneurial opportunities for the CRN
  - Global practices
- Leadership
- Building a CRN network locally or regionally
- Use of the Scopes and Standards – exemplars
- Global dissemination of the CRN specialty practice
  - Exemplars
- Mentoring
- New CRNs in various roles
- New leaders within the specialty and organization
- Professional Development
  - Training-orientation curriculum
  - Presentation development
  - Professional portfolios
  - Poster development