CCTST
Accelerating and Improving Clinical and Translational Research

Center for Clinical and Translational Science and Training
University of Cincinnati Academic Health Center
Acute Care Research Council
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Acute Care Research *Special Interest* Competencies for Clinical Research Professionals

Communication & Teamwork

1. Understands each acute audience as its own vulnerable population and is considerate and ***empathetic**** of the diverse perspectives and feelings of Participants.
2. Utilizes regular checkpoints in concise presentations to ensure common understanding and relatability; assesses appropriate audience comprehension and engagement, making no assumptions with Participants nor ACR Team.
3. Anticipates needs from each enrollment presentation and adapts in response to the Participants' questions and feedback; proactively offers to gather disease related questions to partner with MD/PI.
4. Builds teamwork and trust with open and collaborative exchange of information among ACR Team and key stakeholders *(e.g. IRB, RNs)*.

***empathetic** – Top recommendation from discussion of desire of "super coordinator" @CCHMC's Research Participant Advisory Council.

Clinical Trials Operations (GCPs)*

5. Models how to conduct oneself in an ethical manner, complying with acute care regulations, rules and policies for the involved division(s), institution(s) and ICH-GCPs.
6. Utilizes open, patient and constructive communication in emergency settings to breed a welcoming atmosphere of information updates to policies and procedures for the involved division(s) and institution(s).
7. Examines and adjusts, when appropriate, the strengths and weaknesses, costs and benefits, and short- and long-term consequences of multiple approaches and standards of care. *(e.g. ACR Directors, Managers and Coordinators review cases together and with PIs in addition to other key partners.)*

***GCPs** – *Good Clinical Practices (e.g. Ethics and Human Protections, CITI training, etc.)*

Data Management and Informatics

8. Designs data collection techniques in collaboration with the ACR Team that are user-friendly, succinct and can be quickly executed correctly in the fast-paced acute setting; flexes ability to use basic math and problem solving skills at any time.
9. Examines data in detail-oriented and accurate manner to ensure important gaps in existing information are eliminated; assures the integrity of the research data; streamlines processes per ICH FDA CFR Part II.
10. Models efficiency, using tools to maximize amount of automated data entry, minimizing duplication and error as time is of the essence; *if data is incomplete (when later reviewed again for study)* ***there is not a way to "go back."…data will remain incomplete.***

Ethical & Participant Safety Considerations

11. Demonstrates empathy and a high level of understanding of this vulnerable patient population, in order to protect Participants rights, as participation in acute care research is voluntary.
12. Determines Participants capacity and ability to consent, recognizing ***when to best approach**** for ACR studies to maximize enrollment while minimizing stress and maintaining Participants' autonomy in research decisions.
13. Employs positive relationship building skills, using clarifying and confirming communication in presenting key information, halting in the face of uncertainty and being adaptable in the emergency setting.
14. Takes responsibility for one's actions, admitting mistakes and treating them as learning experiences to ensure highest level of safety standards for acute (all) Participants.

***When to (best) approach** – refers to process of actively recruiting patients as participants of clinical acute care research.*

Leadership & Professionalism

15. Demonstrates ownership and confidence in the protocol, takes every opportunity to lead and mentor, and acts with integrity and patience in emergency situations.
16. Adapts well, flexible and receptive to feedback and information.
17. Gathers alternatives to various difficult issues, troubleshooting, problem solving and determining judgment calls; sharing learnings will improve the creativity and collaboration within ACR Team.
18. Proactive about career development opportunities to advance education and anticipation of research partner' needs *(e.g. clinician test, blood draw, regulatory document)*; taking lead to author research protocol(s) and paper(s).

Scientific Concepts & Research Design

19. Exhibits intellectual curiosity for medical and research knowledge, even striving to be Principal (or Co/Sub) Investigator and/or co-author of research paper(s).
20. Fosters teamwork with acute care PIs and key ACR team partners to build an ***innovative ACR team science environment.***
21. Creates professional development opportunities that broaden knowledge and skills to facilitate innovation in acute care research.

Study and Site Management

22. Envisions the work process from start to finish, meticulously ensuring eligibility criteria and study protocol adherence, including 24/7 timeframes and serious events reporting plan. *(e.g. blood draws every 3 hours or by 7am and 7pm).*
23. Exemplifies onsite preparedness at all times, ***in real time***, ensuring proficiency on enrollment procedures and operation of various equipment in order to deliver excellent study task performance. *(To achieve, must also have the support of tools and efficiencies in place.)*
24. Cultivates relationships with key ACR stakeholders and decision makers who have the ability to provide needed hospital access, resources, information and/or expertise. *(e.g. ACR-CRP access during/for overnight surgeries.)*

Regulations and Medicines Development

25. Demonstrates expertise and continuous pursuit of knowledge around new regulations impacting acute care research, proactively sharing knowledge with ACR Team.
26. Prioritizes multiple studies appropriately, managing the IRB/FDA/Hospital policies and procedures, in tandem and in a timely manner, for acute regulatory responsibilities.
27. Utilizes the ***Exception from Informed Consent (EFIC)*** for emergency research interventions under carefully controlled circumstances, ensuring required follow-up necessary once the intervention has begun.
28. Develops and monitors study protocol guidance for consenting vulnerable populations, specifically the requirements of a waiver of informed consent for a minimal risk study versus a study with greater than minimal risk, where a waiver cannot apply.