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| Definition: Tool: | A Non-Credentialed Person may be a licensed or a non-licensed person who is not credentialed by the affiliate institution to perform specific research procedures or tasks. CTRC Training of Non-Credentialed Personnel conducting research.  |
| Purpose: | To provide a Generic Standard Operating Procedure for the CTRC Network with guidelines for training non-credentialed personnel for clinical research procedures.* Each CTRC Site will be responsible for creating competency SOPs for training needs at their site.

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| Audience/User: | Principal Investigators (PIs), Study Coordinators, CTRC Staff, other site Research Staff, Clinical Monitors.  |
| Description: Approval:Applicable ProtocolsTiming: | This SOP should provide a comprehensive guideline to the CTRC Network, Principal Investigators and Research Teams regarding the training of non-credentialed personnel. The Training and Competency SOPs that are developed by each CTRC must be approved by the applicable Institution, the CTRC Medical Director for that site, and the CTRC Network Director prior to implementation. The verification of the specific competency must be completed prior to the trainee performing the specific research procedure or task. The protocol must be an active CTRC Protocol. The task or research procedure may only be performed within CTRC Facility Space.  The verification of the non-credentialed personnel’s training must be documented prior to performing the research procedure or task with Research Participants. Once training is complete and demonstration of competency has occurred, the trainee will be allowed to conduct that specific activity within that CTRC location only. If the procedure is to be performed at other CTRC sites, additional site-specific competencies and verifications must be performed at each site.   |
| Best Practice Recommendations: | * Each CTRC site may offer training to non-licensed personnel who assist the Research Team with the implementation of Research Protocols. Adequate records for training and competencies should be maintained, with follow-up training and documentation of competencies as necessary.
* Each CTRC site will determine which personnel are required to be trained according to their appropriate scope of practice and the requirements for competency for each individual procedure.
* Each CTRC site will develop training requirements to demonstrate competencies for each individual procedure and the approach to assess competency. The training should be consistent with the site’s institutional policies and procedures, as well as current best practices.
* The Study Physician for the Protocol is directly responsible for the non-credentialed personnel who are performing the designated tasks for his/her study.
* Each non-credentialed personnel must be deemed “Competent” to perform each designated task per CTRC competencies.
* The Training and Competency SOPs that are developed by each CTRC will require sign off by the CTRC Medical Director for that site in addition to the CTRC Network Director.
* The Training and Competency SOPs that are developed will also require approval from their Institution.
* Once training and demonstration of competency is completed, the non-credentialed personnel may independently implement the research procedure on the CTRC, however,
1. The research procedure may only be performed as part of an active research protocol on the CTRC
2. The research procedure may only be conducted within the CTRC Facility Space.
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