Policy Manual

Protocol and Protocol Specific Procedure Training

Approval Date: 01SEP2022

1. PRIOR to any staff or contractors working on a study protocol training will occur. If they are performing a specific procedure for the study then procedure training will also occur. This training will be done either by the PI, the lead CRC, or a Sponsor/CRO designated program.
2. DOCUMENTATION of this training will be completed and signed (or a certificate given if completed though a Sponsor/CRO designated program).
3. Documentation will be FILED in the regulatory binder for retrieval by Sponsor, CRO, or regulatory authority.
4. In the event of a PROTOCOL AMENDMENT or PROCEDURE CHANGE, the applicable staff and/or contractors will complete steps 1-3 above.
5. This training will occur regardless of a person being listed on the DELEGATION OF AUTHORITY LOG or the FDA FORM 1572.

Policy Manual

CARE
CARDIO RENAL INSTITUTE