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| 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. |
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