TITLE: Protocol Specific Training Requirements		
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1. POLICY STATEMENT:

The Overall Principal Investigator (PI) will ensure that protocol specific training is provided to the entire research team and each incident of initial and continuing training is documented.

2. BACKGROUND:

A commitment made by the Overall PI when the investigator agreement is signed is that he/she will keep the research team fully informed about the protocol and their respective duties and functions.

3. RESPONSIBLE PERSONNEL:

3.1. Sponsor
3.2. Overall Principal Investigator (PI)
3.3. Site Responsible Investigator
3.4. Subinvestigator
3.5. Research Nurse
3.6. Study Coordinator
3.7. Research Pharmacy Personnel

4. DEFINITIONS:

4.1. None

5. PROCEDURE:

5.1. The entire research team receives protocol specific initial and continuing training.

5.2. Initial protocol specific training is typically conducted by the sponsor or a sponsor representative at a Site Initiation Visit (SIV). The research team is informed of the purpose of the research and the protocol design; attributes of the investigational product needed to perform their assigned tasks; regulatory requirements and acceptable standards for the conduct of research and the protection of human subjects.

5.2.1. Individuals not attending the SIV or added to the research team after the SIV are trained by the sponsor, a sponsor representative, the Overall PI, or another trained research team member. Training is completed prior to that individual performing any research procedure.

5.3. Continuing protocol specific training is typically delivered during routine protocol meetings at each institution. The research team is informed of the progress of the research, protocol changes and/or modifications to research procedures, serious adverse events (SAEs), and issues of non-compliance (i.e., protocol deviations/violations or subject non-compliance).

5.3.1. Individuals not attending a protocol meeting receive and review materials describing the updates.

5.4. All incidents of training are documented. The method to document protocol specific training will vary according to the mechanism provided by the sponsor. Regardless of whether the sponsor provides a mechanism to capture protocol specific training, the Overall PI must ensure that training is documented. Training documentation must identify the date of training, the topics covered, and the trainee(s). A copy of the training material is retained as part of the site's essential regulatory documents along with the training record/attendance sheet.

5.5. As applicable to their research role, there must be evidence of protocol specific training for each individual listed on the Form FDA 1572 (if applicable) and the Delegation of Authority Log. Training must be available for review by the sponsor, QACT Clinical Research Auditors and to any representative of the Food and Drug Administration (FDA) or other regulatory entity.

6. APPLICABLE REGULATIONS & GUIDELINES:

21 CFR 50 – Protection of Human Research Subjects
21 CFR 54 – Financial Disclosure by Clinical Investigators
21 CFR 56 – Institutional Review Boards
21 CFR 312 - Investigational New Drugs – Drugs for Human Use
21 CFR 812 – Investigational Device Exemptions
45 CFR 46 – Protection of Human Subjects
FDA Industry Guidelines and Information Sheets
FDA Compliance Policy Guidance Programs: 7348.809, 7348.810, and 7348.811
Form FDA 1572

7. RELATED REFERENCES:

International Conference on Harmonisation – E6
Office for Human Research Studies (OHRS) Statement of Principal Investigator

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8. RELATED FORMS & TOOLS:

None

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