TITLE: Standard Operating Procedure (SOP) Training Requirements		
SOP #: EDU-101 *(formerly ET-201)*	**Page:** 1 of 3	**Effective Date:** 1/14/2016

1. POLICY STATEMENT:

Initial and continuing SOP training is required for all individuals involved in the implementation and coordination of research, including the Overall Principal Investigator (PI) and all research team members.

2. BACKGROUND:

Study personnel must be qualified by means of background, education, training and experience to perform their assigned duties. Training should encompass acceptable standards for the conduct of research, regulatory requirements and Standard Operating Procedures (SOPs).

3. RESPONSIBLE PERSONNEL:

3.1. Overall Principal Investigator (PI)
3.2. Site Responsible Investigator
3.3. Subinvestigator
3.4. Research Nurse
3.5. Study Coordinator
3.6. Research Pharmacy Personnel
3.7. ODQ Clinical Trials Education Coordinator
3.8. Office of Data Quality (ODQ) Clinical Research Auditor

4. DEFINITIONS:

4.1. None

5. PROCEDURE:

5.1. All members of the research team are responsible for complying with the DF/HCC SOPs.

5.2. The Clinical Trials Education Coordinator will identify SOP training requirements and develop or purchase training programs to provide this training.

5.3. Individuals will complete training on the DF/HCC SOPs where their role is listed as “Responsible Personnel”. Refer to the *Role Matrix for Responsible Personnel.*

5.4. Training may be conducted in many manners including, but not limited to: lecture, computer module or web-based, reading, or on-the-job demonstration.

5.5. The DF/HCC SOPs cover the following topics and elements as needed:
- 5.5.1. Adverse Events
- 5.5.2. Case Report Forms (CRFs)
- 5.5.3. ClinicalTrials.gov Requirements
- 5.5.4. Delegation of Authority
- 5.5.5. Informed Consent
- 5.5.6. Investigational Drug/Device
- 5.5.7. Monitoring Visits
- 5.5.8. Protocol Compliance
- 5.5.9. Protocol Training
- 5.5.10. Roles and Responsibilities
- 5.5.11. Source Documentation
- 5.5.12. 21 Code of Federal Regulation (CFR) Parts 50, 54, 56, 312, and 812
- 5.5.13. 45 CFR Part 46
- 5.5.14. International Conference on Harmonisation Guidelines – E6

5.6. Individuals will complete the initial SOP training within the timeframe set by their institutional clinical trials office and within 2 months of revisions or newly released SOPs, unless otherwise specified by DF/HCC leadership.

5.7. All SOP training will be documented and may be maintained either electronically or in hard copy. Regardless of the method used, documentation of SOP training must be available for review by the sponsor, ODQ Clinical Research Auditors and to any representative of the Food and Drug Administration (FDA) or other regulatory entity.

5.8. Completion certificates or other documents confirming SOP training will be kept by each individual. Copies of SOP training should be forwarded to the institutional clinical trials office as applicable.

5.9. If required by a sponsor, copies of SOP training documents should also be retained with study records for the duration of the study.

5.10. The ODQ Clinical Research Auditors will audit SOP training documentation per the requirements of this policy during scheduled audit visits.

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

7. RELATED REFERENCES:

International Conference on Harmonisation – E6

8. RELATED FORMS & TOOLS:

Role Matrix for Responsible Personnel