

**DANA-FARBER / HARVARD CANCER CENTER  
STANDARD OPERATING PROCEDURES FOR HUMAN SUBJECT RESEARCH**

<b>TITLE:</b> Protocol Specific Training Requirements		
<b>SOP #:</b> EDU-100 ( <i>formerly ET-203</i> )	<b>Page:</b> 1 of 3	<b>Effective Date:</b> 10/01/2014

**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 must be completed prior to that individual performing any research procedure.

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- 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. It is not necessary to document training of research study staff for protocol amendments that are administrative in nature only. For example: amendments to correct typographical errors or clarifications do not require documented re-training of all team members.
- 5.6. 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

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**RELATED REFERENCES:**

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

**7. RELATED FORMS & TOOLS:**

None

<b>Version:</b> 4
<b>Effective Date:</b> 10/01/2014
<b>Last Reviewed Date:</b> 10/01/2014