TITLE: Training Requirements for Research Personnel		
POLICY #: EDU-100	**Page:** 1 of 5	**Effective Date:** 2/28/17

1. POLICY STATEMENT:

Individuals who participate in research activities overseen by DF/HCC must satisfy specific training requirements in order to conduct human subject research. These training requirements apply to individuals without prior research experience and experienced individuals coming from external institutions.

2. BACKGROUND:

Individuals engaged in human subject research or responsible for overseeing human subject research must have appropriate training to assure the rights, welfare, and safety of human subjects are protected. Research personnel must be qualified by education, training, and experience to ensure the proper conduct of research.

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 Pharmacists
3.7. Biostatistician
3.8. Key Personnel Listed on an NIH grant
3.9. DFCI Institutional Official
3.10. DFHCC Clinical Trials Leadership
3.11. Research Office Managers and Directors
3.12. Office for Data Quality (ODQ) Staff
3.13. Office for Human Research Studies (OHRS) Staff
3.14. Clinical Trials Research Informatics Office (CTRIO) Staff
3.15. DFCI Institutional Review Board Members
3.16. DF/HCC Scientific Review Committee Members
3.17. Data Safety Monitoring Committee Members
3.18. Audit Committee Members
3.19. Director, Office of Research Integrity

4. DEFINITIONS:

4.1. **Research Personnel:** Individuals who participate in human subject research activities overseen by DF/HCC. These activities may include, but are not limited to, the design, conduct, coordination, research oversight, and/or the collection

and reporting of research data.

4.2. **Investigators:** Research personnel serving in the role of Overall PI, Site Responsible Investigator, or Subinvestigator.

4.3. **Interventional:** Research in which individuals are assigned by an investigator based on a protocol to receive specific interventions. Individuals may receive diagnostic, therapeutic, or other types of interventions. The assignment of the intervention may or may not be random. The individuals are then followed and biomedical and/or health outcomes are assessed.

5. POLICY:

5.1. Training Documentation

5.1.1. All instances of training must be documented. Documentation methods may vary, but training documentation must identify the date of training, the topics covered, and the names of the trainee(s).

5.1.2. Individuals are responsible for maintaining records of their training. Training documentation 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.

5.2. DF/HCC Policy Training

5.2.1. DF/HCC Policy training is required for all Research Personnel.

5.2.2. Initial Policy training is required prior to conducting research overseen by the DF/HCC. As per ADM-100, additional training may be required for new or revised DF/HCC Policies.

5.2.3. DF/HCC Policy training requirements can be satisfied by attending live Policy training sessions, viewing web-based or recorded trainings, individual Policy review, or on-the-job demonstration.

5.3. Human Subject Protection and Good Clinical Practice Training

5.3.1. Investigators and Research Personnel are required to complete comprehensive Human Subjects Protection (HSP) training and comprehensive Good Clinical Practice (GCP) training prior to conducting

research overseen by the DF/HCC.

5.3.1.1. Investigators and Research Personnel who continue to participate in research overseen by the DF/HCC must complete HSP and GCP refresher training at least once every 3 years.

5.3.1.2. Research Personnel conducting only IRB-Exempt or Not Human Subject Research are not required to complete GCP training; however, they are still required to complete the appropriate HSP training related to their area of research.

5.3.2. The HSP and GCP training requirements are met by completing the appropriate Collaborative Institutional Training Initiative (CITI) course (https://www.citiprogram.org) in the area that most closely reflects one's research practice (e.g., Biomedical, Social/Behavioral) through DFCI or another Harvard-affiliated institution.

5.3.3. Other equivalent HSP or GCP training (e.g., provided by an external sponsor or DF/HCC affiliated institution) may be accepted with approval from the ODQ Director.

5.4. **New Investigator Training**

5.4.1. New Investigator training is required for all investigators serving as the Overall PI or Site Responsible Investigator on a protocol for the first time at DF/HCC.

5.4.2. New Investigator training must be completed prior to protocol activation. Exceptions must be approved by the ODQ Director.

5.4.3. The New Investigator training requirements are met by attending an ODQ New Investigator Briefing or reviewing an equivalent online or recorded training provided by ODQ.

5.4.4. Protocols with a New Investigator may also be subject to an internal New Investigator audit by ODQ. Typically, this occurs prior to the first continuing review.

5.5. **Protocol-Specific Training**

5.5.1. The Overall PI will ensure that protocol-specific training is provided to all Research Personnel (including individuals listed on the FDA 1572, if

applicable, and the Delegation of Authority Log).

5.5.2. Initial protocol-specific training is required prior to performing any research activity under said protocol.

5.5.2.1. Training may be provided by the sponsor (e.g., at a Site Initiation Visit). Individuals not attending the sponsor training, or added to the research team at a later date, must complete separate protocol-specific training.

5.5.3. Protocol-specific training must include all information relevant to an individual's role and delegated responsibilities on the protocol.

5.5.4. Additional protocol-specific training is required for any protocol changes and/or modifications to research procedures relevant to an individual's role and delegated responsibilities on the protocol.

5.6. **Verification**

5.6.1. ODQ tracks the completion of HSP, GCP and New Investigator trainings in the OnCore CTMS. Each individual is responsible for providing HSP and GCP training certificates (initial and refresher) to ODQ.

5.6.2. The Office for Human Research Studies verifies the completion of HSP and GCP Training during IRB review. Individuals who have not complied with this policy, or have expired training, may be removed by OHRS from any active studies.

6. APPLICABLE REGULATIONS & GUIDELINES:

NIH Guide Notice OD-00-039 dated June 5, 2000
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:

Office for Human Research Studies (OHRS) Statement of Principal Investigator
DFCI IRB Policies and Procedures for the Protection of Human Subjects in Research
Guide to Human Research Activities
DF/HCC Clinical Trials Audit Manual
International Conference on Harmonisation – E6

8. RELATED FORMS & TOOLS:

DF/HCC Policy Training and Signature Record