DF/HCC

DANA-FARBER / HARVARD CANCER CENTER

DF/HCC Policy Training and Signature Record

Instructions: Complete this form to document that you have received or completed training on DF/HCC Policies and to provide a record of your signature and initials for use with the DF/HCC Delegation of Authority Log template. An X indicates that training is required; however, individuals are responsible for reviewing any additional Policies ***relevant to their specific role and research activities.*** Please contact ODQEducation@dfci.harvard.edu with any questions.

	Required for Review				
	Research Personnel	Research Personnel Working on High Risk Interventional Trials[A]	~~Overall PI and Site-Responsible Investigator~~Principal Invesitgator	Research Pharmacy Personnel	**Indicate Completion**
ADM-100: Creation and Maintenance of DF/HCC Policies and Operations					☐
AUD-100: Audits and Inspections	X	X	X	X	☐
COM-100: Human Research Oversight and Operations Committees			X		☐
CON-100: Informed Consent Process	X	X	X		☐
CON-101: Obtaining Informed Consent from Non-English Speakers	X	X	X		☐
DATA-100: Data Management of Investigator-Sponsored Therapeutic Protocols[B]			X		☐
DATA-101: Case Report Form (CRF) Development			X		☐
DOC-100: Research Subject Documentation	X	X	X		☐
EDU-100: Training Requirements for Research Personnel	X	X	X	X	☐
INV-100: Research Pharmacy Standard Policy				X	☐
INV-101: Transfer of Investigational Drug				X	☐
INV-102: Return of Unused Investigational Drug from Subject to Pharmacy		X		X	☐
INV-103: Protocol Mandated Drug Taken at Home		X		X	☐
MON-101: Research Conduct Oversight by External Sponsors					☐
MULTI-100: DF/HCC Investigator-Sponsored Multi-Center Research[B]			X		☐
RCL-100: Preparation for Site Close Out			X		☐
RCL-101: Record Retention for Completed Research			X		☐
RCO-100: Investigator-Sponsored Research		X			☐
RCO-102: Responsibilities of Investigators			X		☐
RCO-103: Confidentiality and Secondary Use of Research Information	X	X	X	X	☐
RCO-203: Regulatory Documentation	X	X	X	X	☐

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	Research Personnel	Research Personnel Working on High Risk Interventional Trials[A]	~~Overall PI and Site-Responsible Investigator~~Principal Invesitgator	Research Pharmacy Personnel	**Indicate Completion**
RCO-204: Reporting Adverse Events	X	X	X	X	☐
~~RCO-205: Reporting of Protocol Deviations, Exceptions, and Violations~~	~~X~~	~~X~~	~~X~~	~~X~~	☐
REGIST-100: Eligibility Checklists	X	X	X		☐
REGIST-101: Subject Protocol Registration	X	X	X		☐
REGIST-200: Registration of Clinical Trials on ClinicalTrials.gov			X		☐

[A] Interventional research involving a drug, device, biologic, radiation or surgery.
[B] Only required for Sponsor-Investigator

By signing below, I attest that I have reviewed the DF/HCC Policies indicated. My signature and initials below are consistent with how they will appear on other documentation related to human subject research at the DF/HCC.

Printed/Typed Name	Signature	Initials	Date