DF/HCC Policies and Operations

SOP Conversion Guide and Master Policy and Operation List

SOP	Title	New Document Type	Operation Number and Title (if applicable)
ADM-100	Creation and Maintenance of DF/HCC Policies and Operations	Policy	
ADM-101	Use of the DF/HCC Research Listserv	Operation	**ADM-OP-1: Maintenance and Use of the DF/HCC Research Listserv** (click to view tracked changes)
ADM-102	Maintenance of the OncPro Priority List	Operation	**COM-OP-1: Maintenance of the OncPro Priority List** (click to view tracked changes)
ADM-103	Maintenance of the AAHRPP Accreditation	Operation	**ADM-OP-2: Maintenance of the AAHRPP Accreditation** (click to view tracked changes)
AUD-100	Internal Auditing of Clinical Research	Policy	
AUD-101	Audit Preparation and Response	Operation (combined)	**AUD-OP-2: FDA and Other Regulatory Inspections** (click to view tracked changes)
AUD-102	External Audits of DF/HCC Clinical Research		
COM-100	Responsibilities of the Clinical Research Operations Committee (CLINOPS)	Policy	
COM-101	Responsibilities of the Audit Committee	Policy	
COM-102	Accrual and Scientific Progress by the Scientific Review Committee (SRC)	Policy	
COM-103	Responsibilities of the Clinical Investigations Leadership Committee (CLC)	Policy	
CON-100	Informed Consent Process	Policy	
CON-101	Obtaining Informed Consent of Non-English Speakers	Policy	
CON-103	Enrolling Subjects onto Secondary Studies Evaluating Research	Policy	
DATA-100	Data Management of PI-Initiated Protocols	Policy	
DATA-101	Case Report Form Design for PI-Initiated Protocols	Policy	
DATA-103	CRF Submission Compliance for PI-Initiated Protocols	Policy	
DATA-104	Data and Safety Monitoring Committee Data Submission Compliance	Operation	**DATA-OP-2: DSMC Review** (click to view tracked changes)
DOC-100	Subject Research Charts	Policy	
DOC-101	Source Documentation Requirements	Policy	
DOC-102	Note to File	Policy	
EDU-100	Training Requirements for Research Personnel	Policy	
INV-100	Research Pharmacy Standard Procedures	Policy	
INV-101	Transfer of Investigational Drug	Policy	

SOP	Title	New Document Type	Operation Number and Title (if applicable)
INV-102	Return of Unused Investigational Drug from Subject to the Pharmacy	Policy	
INV-103	Protocol Mandated Drug Taken at Home	Policy	
MON-100	Monitoring Phase I Dose Escalation for PI-Initiated Protocols	Operation	**REGIST-OP-2: Dose Escalation for Investigator-Sponsored Protocols** (click to view tracked changes)
MON-101	Routine Monitoring Visits by External Sponsors	Policy	
MULTI-100	Conducting DF/HCC Investigator-Sponsored Multi-Center Trials	Policy	
RCL-100	Preparation for Site Close Out	Policy	
RCL-101	Record Retention for Completed Research	Policy	
RCO-100	Responsibilities of the Sponsor Conducting Research Involving a Drug	Policy	
RCO-101	Responsibilities of the Sponsor Conducting Research Involving a Device	Policy	
RCO-102	Responsibilities of Investigators	Policy	
RCO-103	Confidentiality of Research Information	Policy	
RCO-200	Documenting Delegation of Authority	Policy	
RCO-201	Completion of Form FDA 1572	Policy	
RCO-202	Research Personnel CVs and Licenses	Policy	
RCO-203	Managing Essential Regulatory Documents	Policy	
RCO-204	Reporting Adverse Events	Policy	
RCO-205	Reporting of Protocol Deviations, Exceptions and Violations	Policy	
RCO-206	Overall PI or Site Responsible Investigator Leave of Absence	Policy	
RCO-207	Performance of Protocol Specified Procedures at Non-DF/HCC sites	Policy	
REGIST -100	Internal Eligibility Checklist	Policy	
REGIST-101A	Centralized Subject Protocol Registration	Policy	
REGIST-101B	De-Centralized Subject Protocol Registration	Policy	
REGIST-102	Subject Removal from a Protocol	Operation (combined)	**REGIST-OP-1: Subject Registration Procedures** (click to view tracked changes)
REGIST-103	Transfer of Subjects Between Institutions		
REGIST-104	Using the Eligibility Checklist	Policy	
REGIST-200	Registration of Trials on Clinicaltrials.gov	Policy	
REGIST-202	National Cancer Institute Clinical Trials Reporting Program (CTRP)	Policy	

DF/HCC Policies (post-conversion)	
Policy Number	**Policy Title**
ADM-100	Creation and Maintenance of DF/HCC Policies and Operations
AUD-100	Internal Auditing of Clinical Research
COM-100	Responsibilities of the Clinical Research Operations Committee (CLINOPS)
COM-101	Responsibilities of the Audit Committee
COM-102	Accrual and Scientific Progress by the Scientific Review Committee
COM-103	Responsibilities of the Clinical Investigator Leadership Committee (CLC)
CON-100	Informed Consent Process
CON-101	Obtaining Informed Consent of Non-English Speakers
CON-103	Enrolling Subjects onto Secondary Studies Evaluating Research
DATA-100	Data Management of PI-Initiated Protocols
DATA-101	Case Report Form Development
DATA-103	CRF Submission Compliance for PI-Initiated Protocols
DOC-100	Subject Research Charts
DOC-101	Source Documentation Requirements
DOC-102	Note to File
EDU-100	Training Requirements for Research Personnel
INV-100	Research Pharmacy Standard Procedures
INV-101	Transfer of Investigational Drug
INV-102	Return of Unused Investigational Drug from Subject to the Pharmacy
INV-103	Protocol Mandated Drug Taken at Home
MULTI-100	Conducting DF/HCC Investigator-Sponsored Multi-Center Trials
RCL-100	Preparation for Site Close Out
RCL-101	Record Retention for Completed Research

DF/HCC Policies (post-conversion)	
Policy Number	**Policy Title**
RCO-100	Responsibilities of the Sponsor Conducting Research Involving a Drug
RCO-101	Responsibilities of the Sponsor Conducting Research Involving a Device
RCO-102	Responsibilities of Investigators
RCO-103	Confidentiality of Research Information
RCO-200	Documenting Delegation of Authority
RCO-201	Completion of Form FDA 1572
RCO-202	Research Personnel CVs and Licenses
RCO-203	Managing Essential Regulatory Documents
RCO-204	Reporting Adverse Events
RCO-205	Reporting of Protocol Deviations, Exceptions and Violations
RCO-206	Overall PI or Site Responsible Investigator Leave of Absence
RCO-207	Performance of Protocol Specified Procedures at Non-DF/HCC sites
REGIST - 100	Internal Eligibility Checklist
REGIST-101A	Centralized Subject Protocol Registration
REGIST-101B	De-Centralized Subject Protocol Registration
REGIST-104	Using the Eligibility Checklist
REGIST-202	National Cancer Institute Clinical Trials Reporting Program (CTRP)

DF/HCC Operations (post-conversion)	
Associated SOP or Guidance	**Operation Title**
ADM-101 (replace and retire)	ADM-OP-1: Use of the DF/HCC Research Listserv
ADM-103 (replace and retire)	ADM-OP-2: Maintenance of the AAHRPP Accreditation
Converted from previously posted **DF/HCC Audit Manual**	AUD-OP-1: Internal Auditing of Clinical Research
AUD-101 (replace and retire)	AUD-OP-2: FDA and other Regulatory Inspections (merged AUD-101 and 102)
AUD-102 (replace and retire)	
ADM-102 (replace and retire)	COM-OP-1: Maintenance of the OncPro Priority List
Previously Posted (supports **CON-100)**	CON-OP-1: Reconsent / Patient Notification Guide
NEW (supports **DATA-100**)	DATA-OP-1: Data Requests
DATA-104 (replace and retire)	DATA-OP-2: DSMC Review
Previously Posted (supports **INV-100**)	INV-OP-1: Mandatory Research Pharmacy Standard Procedures
Previously Posted (supports **MULTI-100**)	MULTI-OP-1: Review and Approval Process for Investigator-Sponsored Multi-Center Trials
REGIST-102 (replace and retire)	REGIST-OP-1: Subject Registration Procedures (merged REGIST-102 and 103)
REGIST-103 (replace and retire)	
MON-100 (replace and retire)	REGIST-OP-2: Dose Escalation in Investigator-Sponsored Protocols
NEW (supports **RCL-100**)	RCL-OP-1: Procedures for Study Completion
Previously Posted (supports **RCO-200**)	RCO-OP-1: Documenting Delegation of Authority