Policy Updates Tracking Sheet
Effective 1-31-2020

Policy #	Title	Summary of updates
AUD-100	Audits and Inspections	Minor edits throughout to re-categorize Overall PI responsiiblity to PI of each site
COM-100	Clinical Research Oversight and Operations Committees	Minor edit to Responsible Personnel
CON-100	Informed Consent Process	Minor edits throughout to re-categorize Overall PI responsiiblity to PI of each site
CON-101	Obtaining Informed Consent of Non-English Speakers	Significant edits to clarify who may serve as interpreter and witness; Additional documetnation requirements added for when a remote interpreter is used
DATA-100	Data Management for Investigator-Sponsored Protocols	Minor edits throughout to remove old terminology and clarify responsibiltiies of PI at each site, sponsor-investigator and Core Site.
DOC-100	Research Subject Documentation	minor edits to remove old terminology
EDU-100	Training Requirements for Research Personnel	minor edits to remove old terminology
INV-101	Transfer of Investigational Drug	Minor edits throughout to re-categorize Overall PI responsiiblity to PI of each site
INV-102	Return of Unused Investigational Drug from Subject to the Pharmacy	Minor edits to re-categorize Overall PI responsiiblity to PI of each site
MON-101	Routine Monitoring Visits by External Sponsors	Minor edits throughout to remove old terminology and clarify responsibiltiies of PI at each site, sponsor-investigator and Core Site.
MULTI-100	Conducting DF/HCC Investigator-Sponsored Multi-Center Trials	Minor edits throughout to remove old terminology and clarify responsibiltiies of PI at each site, sponsor-investigator and Core Site.
RCL-100	Preparation for Site Close Out	Minor edits throughout to remove old terminology and clarify responsibiltiies of PI at each site, sponsor-investigator and Core Site.
RCL-101	Record Retention for Completed Research	Edits and questions throughout about Core Site PI vs PI responsibility
RCO-100	Responsibilities of the Sponsor	Edits and questions throughout about Core Site PI vs PI responsibility

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RCO-102	Responsibilities of Investigators	Significant edits throughout to remove old terminology and clarify responsibilities of the PI at each participating site and addtiional responsibilities of the PI at the Core Site
RCO-103	Confidentiality and Secondary Use of Research Information	Edits throughout to remove old terminology
RCO-203	Regulatory Documentation	Edits throughout to remove old terminology and clarify responsibilities of the PI at each participating site, significant edits to requirements of each investigator file to maintain 1572 and related documentation and delegation log for their site
RCO-204 (combined with RCO-205)	Safety and Event Reporting	Combined policies RCO-204 and RCO-205 - comprehenstive policy to address safety reporting and reporting of other protocol events (deviation, exception, violation); Edits throughout to remove old terminology and clarify responsibiltiy of each PI to report events specific to their site; For events and reporting that will require submission to the IRB, coordination with the Core Site required; Updates to require each PI to review and assess IND/IDE Safety reports when required per policy
REGIST -100	Eligibility Checklists	minor edits to remove old terminology
REGIST-101	Subject Protocol Registration	minor edits to remove old terminology
REGIST-200	Registration of Trials on Clinicaltrials.gov	minor edits to remove old terminology