Investigator Guide Summary of Changes Version 1/1/2020

Chapter 1
• Section 1.2 Updated the President of the University of Louisville
• Section 1.5 Updated research partners to include UofL Health
• Section 1.6 Updated Office of Sponsored Programs and Clinical Contracts Division

Chapter 2
• No significant changes

Chapter 3
• Added AAHRPP Standard III.1.B
• Section 3.7 Added Observation of Consent Process to Compliance Monitoring
• Section 3.9 Added Inspection by a Federal Agency for both sites and IRB

Chapter 4
• Section 4.2 Added AAHRPP Standard III.2.A
• Section 4.2 Added additional details about training for Principal Investigator and Key Personnel

Chapter 5
• Section 5.1 Added additional definitions for Humanitarian Device Exemption (HDE), Non-significant Risk (NSR), Significant Risk (SR) Device
• Section 5.6 Added additional definitions for Sponsor-Investigator (IND) and Sponsor-Investigator (IDE)

Chapter 6
• Section 6.1 Added additional definitions for Clinical Trials and Human Subjects approved on or after January 21, 2019.
• Section 6.2 Added a length of term for IRB Chair
• Section 6.2 Updated list of items the HSPPO IRB Analysts can approve administratively.
• Section 6.2 Ex-officio members removed Institutional Animal Care and Use Committee (IACUC) and Jefferson County Public Schools (JCPS). Added Associate Vice President for Research and Innovation (Chief of Staff) and Research Officials from Affiliated Hospital Organizations
• Section 6.6 Updated document signed by consultant to IRB.
• Section 6.9 Updated UofL Health to include the acquisition of the KentuckyOne Health facilities and to include the Veterans Affairs Medical Center (VAMC)
• Section 6.11 updated Office of Sponsored Programs Administration (OSPA) and their related offices

Chapter 7
• Added AAHRPP Standard I.1.F
• Section 7.0 Added SSMR and Department Chair signoff for exempt, expedited, and full board review.
• Section 7.2 Removed drug phases, Device Risks (see Section 9.1)
• Section 7.2 Removed Students and Employees (see Section 9.3)
• Section 7.3 explained that the IRB does not conduct “limited review” as allowed in the revised common rule.
• Section 7.3 Provided information for studies approved prior to January 21, 2019 and those approved on or after.
• Section 7.8 Removed Lapse in Continuing Review Policy (see section 3.5)
• Section 7.9 Updated Minor Changes for expedited review and Major Changes for full board review.
• Section 7.10 Added additional definitions and clarifications for events that can occur, local SAE, Unexpected adverse experience (UAE), Unanticipated adverse device effect (UADE), Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSOs)
• Section 7.10 Clarified PI responsibilities for reporting and included additional examples of events.
• Section 7.11 Clarified re-opening of studies.
• Section 7.11 removed study closure due to lapse in IRB approval (see Section 3.5)

Chapter 8
• Section 8.1 Updated Staff support of IRB Membership
• Section 8.1 Updated affiliation with UofL Health
• Section 8.2 Updated that the Chair typically abstains from voting during the meeting.
• Section 8.7 Removed Planned Emergency Research (see Section 5.11 and 12.5)
• Section 8.8 removed The Role of the Chair(s) and Vice Chair(s) and Their Voting Responsibilities (see section 8.2)

Chapter 9
• Section 9.2 Included Data Safety Monitoring Board (DSMB)/Data Monitoring Committee
• Section 9.3 Children includes information on Chair/Vice Chair reviewing pediatric studies as expedited review.
• Section 9.3 Prisoner includes full board review and expedited review procedures.
• Section 9.3 Decisionally Impaired includes information on Cognitively Impaired.
• Section 9.3 Students and Employees moved to this section

Chapter 10
• Section 10.4 Included more information on recruitment tools
• Section 10.4 included information on cold calling
• Section 10.6 updated information on community outreach
• Section 10.6 updated other UofL Research Resources and their websites

Chapter 11
• Section 11.2 changed Anonymity to Confidentiality
• Section 11.3 Updated HIPAA Regulations, Waivers or Alterations of the Authorization
• Section 11.4 Confidentiality Breach updated whom to contact if a breach is suspected.

Chapter 12
• Stated consent form includes lay language comprehensible to approximately an 8th grade level.
• Section 12.1.2 Data and Tissue Repositories updated submission process for researchers.
• Section 12.1.4 Removed Short Form Consent Process (see section 12.2.5)
• Section 12.2.3 Added guide for parent/legal guardian/foster parent consent
• Section 12.2.4 Included information on deaf, hard of hearing, and illiterate subjects.
• Section 12.2.5 Included information on translating stand-alone research authorizations
• Section 12.3 Included AAHRPP Standard III.1.F
• Section 12.4 included information of signed HIPAA research authorization
• Section 12.4 included clarification on PI as person obtaining consent.
• Section 12.4 included clarification on mail/email/fax of consent form
• Section 12.5 removed Waiver or Alteration of HIPAA Authorization (see section 11.3)
• Section 12.5 included Planned Emergency Research
• Section 12.7 Removed Observation of consent process (see section 3.7)

Chapter 13
• Section 13.1 removed definitions related to events (see section 7.10)
• Section 13.3 included information on joint review of multi-international studies.
• Section 13.3 updated information on UofL serving as IRB of Record
• Section 13.3 updated information on UofL relying on an external IRB, Investigator responsibilities, UofL responsibilities, auditing for compliance, external IRB responsibilities.

Chapter 14
• Section 14.1 Removed management of conflict of interest (see section 6.11)
• Section 14.2 Removed Sound Study Design (see section 14.4)
• Section 14.3 Removed Detection of Harm, Minimization of Risks and Mitigation (see section 9.1)
• Section 14.4 Removed Recruitment (see section 9.3, Chapter 10)
• Section 14.5 Removed Human Subjects Protection Resources (see Chapter 14)
• Section 14.6 Removed Consent Process (see Chapter 12)
• Section 14.7 Response to Participants Requests for Information and Complaints (see section 14.6)

Chapter 15- became chapter 14
• Section 15.2 Removed Qualifications of Protocol Directors and Staff (see section 4.2)
• Section 15.3 Removed Events Reportable to IRB (see section 7.10)

Chapter 16 information was merged into chapter 15

Guide 005 Definitions was deleted. Definitions are throughout the Investigator’s Guide.