

LIST OF ABBREVIATIONS

ADE	Adverse Drug Event/Experience
AE	Adverse Event
CAP	College of American Pathologists
CFR	Code of Federal Regulations
CGMP	Current Good Manufacturing Practice
CIOMS	Council for International Organizations of Medical Science
CLIA	Clinical Laboratory Improvement Act
CSO	Consumer Safety Officer (FDA)
CRA	Clinical Research Associate
CRC	Clinical Research Coordinator
CRF	Case Report Form
CRO	Contract Research Organizations
DHHS	Department of Health and Human Services (or HHS)
DSMB	Data Safety and Monitoring Board
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HDE	Humanitarian Device Exemption
HIPAA	Health Insurance Portability and Accountability Act of 1996
HUD	Humanitarian Use Devices
IBC	Institutional Biosafety Committee
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IDE	Investigational Device Exemption
IDMC	Independent Data Monitoring Committee
IEC	Independent Ethics Committee
IND	Investigational New Drug
IO	Institutional Official
IRB	Institutional Review Board
IRRC	Institutional Research Review Committee (Sparrow Health System's IRB)
IVD	In Vitro Diagnostic
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
NDA	New Drug Application
NIH	National Institutes of Health
OBA	Office of Biotechnology Activities (NIH)
OCR	Office for Civil Rights
OHRP	Office for Human Research Protections (former OPRR)
OPRR	Office for Protection from Research Risks
OROC	Office of Research Oversight and Compliance for Sparrow Health System
PHI	Protected Health Information
PI	Principal Investigator
PMA	Premarket Approval (Application)
QA	Quality Assurance
QC	Quality Control
RAC	Recombinant DNA Advisory Committee (NIH)
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SHS	Sparrow Health System