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
IBC	Institutional Biosafety Committee
HIPAA	Health Insurance Portability and Accountability Act of 1996
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IDE	Investigational Device Exemption
IDMC	Independent Data Monitoring Committee
IEC	Independent Ethics Committee
IND	Investigational New Drug
IRB	Institutional Review Board
IVD	In Vitro Diagnostic
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
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	IRB Policy & Standard Operating Procedure