

LIST OF ABBREVIATIONS

AE	Adverse Event (same as Adverse Drug Experience, Adverse Experience, Adverse Drug Reaction, Adverse Reaction)
CFR	Code of Federal Regulations
CMC	Chemistry, Manufacturing and Control
CRA	Clinical Research Associate
CRF	Case Report Form
CRO	Contract Research Organization
CSO	Consumer Safety Officer (FDA)
DMC	Data Monitoring Committee
EC	Ethics Committee (see IRB)
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HIPAA	Health Insurance Portability and Accountability Act of 1996
IB	Investigator's Brochure
IBC	Institutional Biosafety Committee
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IND	Investigational New Drug
IRB	Institutional Review Board
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
PHI	Protected Health Information
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
RAC	Recombinant DNA Advisory Committee (NIH)
RMF	Regulatory Master File
SOP	Standard Operating Procedure