ACRP Association of Clinical Research Professionals AE Adverse Event

ADR Adverse Drug Reaction

AMA American Medical Association

BID Twice Daily

BIND Biological IND

CAP College of American Pathologists

CBER Center for Biologics Evaluation and Research (FDA) CCRA Certified Clinical Research Associate (ACRP)

CCRC Certified Clinical Research Coordinator (ACRP) CCRC Clinical Research Center

CCRP Certified Clinical Research Professional (SoCRA) CDA Confidential Disclosure Agreement

CDC Center for Disease Control

CDER Center for Drug Evaluation and Research (FDA) CDRH Center for Devices and Radiological Health (FDA) CF Consent Form

CFR Code of Federal Regulations

CLIA Clinical Laboratory Improvement Amendments CME Continuing Medical Education

CP Compliance Program (FDA)

COI Conflict of Interest

CRA Clinical Research Associate

CRC Clinical Research Coordinator

CRF Case Report Form

CRM Clinical Research manager

CRO Clinical Research Organization

CT Clinical Trial

CTA Clinical Trial Agreement

CS Clinically Significant

CSA Clinical Service Agreement

CTSC Clinical and Translational Science Center CV Curriculum Vitae

DCF Data Correction Form / Data Clarification Form

DEA Drug Enforcement Agency (law enforcement division of FDA) DHHS Department of Health & Human Services

DOS Description of Study

EAB Ethical Advisory Board (similar to IRB, used by other nations) EDC Electronic Data Capture

FDA Food and Drug Administration FDA-482 Notice of Inspection

FDA-483 Notice of Adverse Findings in an Inspection FDA-1571 FDA Form for New Drug Application

FDA-1572 FDA Form for Statement of Investigator FDA-SRS Spontaneous Reporting System of the FDA FDCA Food, Drug, and Cosmetic Act

FOIA Freedom of Information Act

FDA Food and Drug Administration

GCP Good Clinical Practice

GDA Global Disclosure Agreement

GLP Good Laboratory Practice

GMP Good Manufacturing Practice

HIPAA Health Insurance Portability and

HHS Health and Human Services (Department of) HMO Health Maintenance Organization

IACUC Institutional Animal Care and Use Committee (IRB for animal use) IB Investigator’s Brochure

ICF Informed Consent Form

ICH International Conference on Harmonisation

IDB Investigational Drug Brochure

IDE Investigational Device Exemption

IDS Investigational Drug Service (pharmacy)

IND Investigational New Drug

IRB Institutional Review Board

JCAHO Joint Commission of Accreditation of Health Care Organizations LOA Letter of Agreement

MDR Medical Device Reporting

MOU Memoranda of Understanding

MRA Medical Research Associate

NAI No Action Indication (most favorable post-FDA inspection classification) NCS Not Clinically Significant

NDA New Drug Application

NHLBI National Heart, Lung, and Blood Institute

NIAID National Institute of Allergy and Infectious Diseases NIH National Institutes of Health

NIMH National Institute of Mental Health NKA No Known Allergies

OAI Official Action Indicated (serious post-FDA inspection classification) OHRP Office for Human Research Protection

OSHA Occupational Safety and Health Administration OTC Over-the-counter (non-prescription drugs)

PD Pharmacodynamics

PE Physical Examination

PHI Protected Health Information

PI Package Insert

PI Principal Investigator

PK Pharmacokinetics

PMA Pre-Market Approval (when seeking commercialization of a device) PO By Mouth

PPE Personal Protective Equipment

PPI Patient Package Inserts

PRN As Needed

QA Quality Assurance

QC Quality Control

QD Every day

QID Four Times a Day

QOL Quality of Life

R&D Research and Development

RDE Remote Data Entry

RL Regulatory Letter (post-FDA audit letter)

SAE Serious Adverse Event

SC Study Coordinator

SD Source Document

SMO Site Management Organization

SoCRA Society of Clinical Research Associates SOM School of Medicine

SOP Standard Operating Procedure

TID Three Times a Day

UNK Unknown

USP U.S. Pharmacopeia

VAI Voluntary Action Indicated (post-FDA audit inspection classification) VS Vital Signs

WHO World Health Organization

WL Warning Letter (FDA)