ACRP Association of Clinical Research Professionals

ACRP-CP Association of Clinical Research Professionals – Certified Professional

AE Adverse Event

ADR Adverse Drug Reaction

ALCOA-C Accurate, Legible, Contemporaneous, Original, Attributable, and Complete

ALT Alanine Transaminase (liver enzyme)

AMA American Medical Association

AST Aspartate Transaminase (liver enzyme)

BID Twice Daily

BIND Biological IND

BMI Body Mass Index

BP Blood Pressure

BUN Blood Urea Nitrogen (kidney function test)

C Celsius

CAP College of American Pathologists

CAPA Corrective and Prevention Action

CBER Center for Biologics Evaluation and Research (FDA)

CCRA Certified Clinical Research Associate (ACRP)

CCRC Certified Clinical Research Coordinator (ACRP)

CCRP Certified Clinical Research Professional (SoCRA)

CDA Confidentiality Disclosure Agreement

CDC Center for Disease Control

CDER Center for Drug Evaluation and Research (FDA)

CDRH Center for Devices and Radiological Health (FDA)

CFR Code of Federal Regulations

CIOMS Council for International Organizations of Medical Sciences

CK Creatine Kinase (muscle enzyme)

CLIA Clinical Laboratory Improvement Amendments

CME Continuing Medical Education

COI Conflict of Interest

CRA Clinical Research Associate

CRC Clinical Research Coordinator

CRF Case Report Form

CRM Clinical Research Manager

CRO Contract Research Organization

CT Clinical Trial

CTA Clinical Trial Agreement

CS Clinically Significant

CSA Clinical Service Agreement

CTMS Clinical Trial Management System

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

DSMB Data and Safety Monitoring Board

ECG Electrocardiogram

eCRF Electronic Case Report Form

EDC Electronic Data Capture

EHR Electronic Health Record

EKG Electrocardiogram

EMR Electronic Medical Record

ePRO Electronic Patient Reported Outcomes

eTMF Electronic Trial Master File

F Fahrenheit

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

FEV1 Forced Expiratory Volume in 1 Second

GCP Good Clinical Practices

GDA Global Disclosure Agreement

GI Gastrointestinal

GLP Good Laboratory Practices

GMP Good Manufacturing Practices

hCG Human Chorionic Gonadotrophin (hormone produced during pregnancy)

HIPAA Health Insurance Portability and Accountability Act

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

IDMC Independent Data Monitoring Committee

IDS Investigational Drug Service (pharmacy)

IEC Independent Ethics Committee

IND Investigational New Drug

IVRS Interactive Voice Response System

IWRS Interactive Web Response System

IRB Institutional Review Board

JCAHO Joint Commission of Accreditation of Health Care Organizations

LAR Legally Authorized Representative

LOA Letter of Agreement

Mcg Microgram

MDR Medical Device Reporting

mmHg Millimeters of mercury

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

NSAID Non-Steroidal Anti Inflammatory Drug

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

PM Project Manager

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

PO By Mouth

PPE Personal Protective Equipment

PPI Patient Package Inserts

PRN As Needed

PRO Patient Reported Outcomes

QA Quality Assurance

QC Quality Control

QD Every day

QID Four Times a Day

QOL Quality of Life

QTc ECG/EKG QT interval corrected for heart rate

R&D Research and Development

RBC Red Blood Cells

RBM Risk Based Monitoring

RDE Remote Data Entry

RL Regulatory Letter (post-FDA audit letter)

SAE Serious Adverse Event

SC Study Coordinator

SD Source Document

SDV Source Document Verification

SMO Site Management Organization

SoCRA Society of Clinical Research Associates

SOP Standard Operating Procedure

Sub-I Sub-Investigator

SUSAR Suspected Unexpected Serious Adverse Reaction

TID Three Times a Day

TMF Trial Master File

UNK Unknown

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

VS Vital Signs

WBC White Blood Cells (or leukocytes)

WHO World Health Organization

WL Warning Letter (FDA)