

Abbreviation	Meaning
ACRP	Association of Clinical Research Professionals
ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
AE	Adverse Event
AERS	Adverse Event Reporting System (NCI specific)
AI	Associate Investigator
ANPRM	Advanced Notice of Proposed Rulemaking
ASCO	American Society of Clinical Oncology
AUC	Area Under the Curve
BLA	Biologic License Application
CAEPR	Complete Adverse Events and Potential Risks (NCI specific)
CAP	Corrective Action Plan
CAPA	Corrective and Preventative Action
CBER	Center for Biologics Evaluation and Research-FDA
CC	Clinical Research Center-NIH
CDE	Common Data Elements
CDER	Center for Drug Evaluation and Research - FDA
CDM	Clinical Data Manager
CDMS	Clinical Data Management System
CDUS	Clinical Data Update System (NCI specific)
CFR	Code of Federal Regulations
CIB	Clinical Investigations Branch (NCI CTEP specific)
CIRB	Central Institutional Review Board
COG	Children's Oncology Group
CRA	Clinical research associate
CRADA	Cooperative Research and Development Agreement
CRC	Clinical Research Coordinator
CRF	Case Report Form
CRO	Contract Research Organization
CTA	Clinical Trials Agreement (U.S). Clinical Trials Authorisation
CTC	Common Toxicity Criteria (replaced with CTCAE in June 2003)
CTCAE	Common Terminology Criteria for Adverse Events
CTD	Common Technical Document
CTEP	Cancer Therapy Evaluation Program (NCI specific)
CTMS	Clinical Trial Management System Clinical Trial Monitoring Service (For CTEP- sponsored studies)
CTO	Clinical Trials Office
CTSU	Cancer Trials Support Unit (NCI specific)
DAR	Drug Accountability Record
DARF	Drug Accountability Record Forms-Investigational Agents
DCB	Division of Cancer Biology (NCI specific)

DCCPS	Division of Cancer Control and Population Sciences (NCI specific)
DCEG	Division of Cancer Epidemiology and Genetics (NCI specific)
DCP	Division of Cancer Prevention (NCI specific)
DCTD	Division of Cancer Treatment and Diagnosis (NCI specific)
DEA	Division of Extramural Activities
DHHS	Department of Health and Human Services
DM	Data Manager
DMC	Data Monitoring Committee
DOD	Department of Defense
DOT	Department of Transportation
DSMB/DSMC	Data Safety Monitoring Board/Committee
EC	Ethics Committee
ECOG	Eastern Cooperative Oncology Group
e-CRF	Electronic Case Report Form
EDC	Electric Data Capture
ELSI	Ethics, Legal, and Social Implications
EME	European Medicines Agency
EMMES Coporation	Contract Research Organization
EMR	Electronic Medical Record
EONS	European Oncology Nursing Society
EORTC	European Organization for the Research and Treatment of Cancer
EU	European Union
FAQ	Frequently Asked Questions
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendment Act
FWA	Federal Wide Assurance
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HHS	Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HRSA	Health Resources and Services Administration
IACRN	International Association of Research Nurses
IATA	International Air Transport Association
IB	Investigator's Brochure
IBC	Institutional Biosafety Committee
IC	Informed Consent
ICD	Informed Consent Document
ICH	International Conference on Harmonization
ICMJE	International Committee of Medical Journal Editors

IDB	Investigator Drug Brochure Investigational Drug Branch (NCI CTEP specific)
IDE	Investigational Device Exemption
IND	Investigational New Drug
IOM	Institute of Medicine
IRB	Institutional Review Board
ISNCC	International Society of Nurses in Cancer Care
LOI	Letter of Intent
LOINC®	Logical Observation Identifiers Names and Codes
MedDRA	Medical Dictionary for Regulatory Activities
NCCN	National Comprehensive Cancer Network
NCI	National Cancer Institute
NCIC-CTG	NCI of Canada Clinical Trials Group
NCI-FCRDC	NCI Frederick Cancer Research and Development Center
NCMHD	National Center on Minority Health and Health Disparities
NCORP	NCI Community Oncology Research Program
NCRR	National Center for Research Resources
NCTN	National Clinical Trials Network
NDA	New Drug Application
NEI	National Eye Institute
NExT	NCI Experimental Therapeutics (NCI specific)
NHGRI	National Human Genome Research Institute
NHLBI	National Heart, Lung, and Blood Institute
NIA	National Institute on Aging
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIAID	National Institute of Allergy and Infectious Disease
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases
NIBIB	National Institute of Biomedical Imaging and Bioengineering
NICHD	National Institute of Child Health and Human Development
NIDA	National Institute on Drug Abuse
NIDCD	National Institute of Deafness and Other Communication Disorders
NIDCR	National Institute of Dental and Craniofacial Research
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIEHS	National Institute of Environmental Health Sciences
NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
NIH	National Institutes of Health
NIMH	National Institutes of Mental Health
NINDS	National Institute of Neurological Disorders and Strokes
NINR	National Institute of Nursing Research
NLM	National Library of Medicine
NPRM	Notice of Proposed Rulemaking
OAI	Official Action Indicated

OBA	Office for Biotechnology Activities (NIH specific)
OHRP	Office for Human Research Protection
PAP	Preventative Action Plan
PHI	Protected Health Information
PHS	Public Health Service
PI	Principal Investigator
PIO	Protocol and Information Office (NCI CTEP specific)
PK	Pharmacokinetics
PMB	Pharmaceutical Management Branch (NCI CTEP specific)
PRC	Protocol Review Committee (NCI CTEP specific)
PRO	Patient Reported Outcomes
PSU	Protocol Status Update (NCI CTEP specific form)
PSW	Protocol Submission Worksheet (NCI CTEP specific form)
QA	Quality Assurance
QC	Quality Control
QI	Quality Improvement
QOL	Quality of Life
RA	Research Associate
RAB	Regulatory Affairs Branch (NCI CTEP specific)
RAC	Recombinant DNA Advisory Committee
RDC	Remote Data Capture
RDE	Remote Data Entry
REC	Research Ethics Committees
RECIST	Response Evaluation Criteria in Solid Tumors
RFP	Request for Proposals
RSC	Radiation Safety Committee
RSS	Regulatory Support System
SACHRP	Secretary's Advisory Committee on Human Research Protections
SAE	Serious Adverse Event
SAS®	Statistical Analysis System®
SDV	Source Document Verification
SMO	Site Management Organization
SoCRA	Society of Clinical Research Associates
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction
SWOG	Southwest Oncology Group
Theradex®	Contract Research Organization
TRC	Treatment Referral Center (NCI CTEP specific)
VAI	Voluntary Action Indicated
WHO	World Health Organization
WMA	World Medical Association