University Hospitals

Short List of Commonly Used Acronyms in Clinical Research

ACRP	Association of Clinical Research Professionals
AE	Adverse Event
ADR	Adverse Drug Reaction
AMA	American Medical Association
BAA	Business Associate Agreement
BIND	Biological IND
CA	Coverage Analysis
CAP	College of American Pathologists
CBCTN	Community Based Clinical Trials Network
CCRA	Certified Clinical Research Associate (ACRP)
CCRC	Certified Clinical Research Coordinator (ACRP)
CCRT	Center for Clinical Research & Technology
CCRP	Certified Clinical Research Professional (SoCRA)
CDA	Confidential Disclosure Agreement
CDC	Center for Disease Control
CFR	Code of Federal Regulations
CIRBI	Center for IRB Intelligence
CITI	Collaborative Institutional Training Initiative
CLIA	Clinical Laboratory Improvement Amendments
CME	Continuing Medical Education
CMS	Central Management System
COI	Conflict of Interest
CRA	Clinical Research Associate
CRC	Clinical Research Coordinator
CREC	Continuing Research Education Credit
CRF	Case Report Form
CRO	Clinical Research Organization
CTA	Clinical Trial Agreement
CTSC	Clinical & Translational Science Collaborative
CV	Curriculum Vitae
DCF	Data Correction Form / Data Clarification Form
DEA	Drug Enforcement Agency (law enforcement division of FDA)
DHHS	Department of Health and Human Services
DOS	Date of Service
DSMB or DSMP/C	Data and Safety Monitoring Board (Plan or Committee)
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
FDCA	Food, Drug, and Cosmetic Act
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
HIPAA	Health Insurance Portability and Accountability Act
HHS	(Department of) Health and Human Services
HITECH	Health Information Technology for Economic and Clinical Health Act
HSP	Human Subjects Protections
IACUC	Institutional Animal Care and Use Committee (IRB for animal use)
IB	Investigator's Brochure

ICD-9	International Classification of Disease Codes, 9th revision
ICD-9-CM	International Classification of Disease Codes, 9th revision-Clinical Modification
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IDB	Investigational Drug Brochure
IDE	Investigational Device Exemption
IDS	Investigational Drug Services (pharmacy)
IND	Investigational New Drug
IRB	Institutional Review Board
iRIS	Integrated Medical Research
JCAHO	Joint Commission of Accreditation of Health Care Organizations
LOA	Letter of Agreement Informational Systems
MCTA	Master Clinical Trial Agreement
MDR	Medical Device Reporting
MOP	Manual of Operation
MOU	Memoranda of Understanding
MTA	Material Transfer Agreement
NAI	No Action Indication (most favorable post-FDA inspection classification)
NCI	National Cancer Institute
NCS	Not Clinically Significant
NDA	New Drug Application
NIH	National Institutes of Health
OAI	Official Action Indicated (serious post-FDA inspection classification)
OCR	Office of Civil Rights
OHRP	Office for Human Research Protection
ORI	Office of Research Integrity
PDQ	Physician's Data Query (NCI sponsored cancer trial registry)
PDR	Physician's Desk Reference
PHI	Protected Health Information
PI	Package Insert
PI	Principal Investigator
PK	Pharmacokinetics
PLA	Product License Application (when seeking commercialization of a biologic)
PMA	Pre-Market Approval (when seeking commercialization of a device)
PPI	Patient Package Inserts
PTAEO	Project, Task, Award, Expenditure
QA	Quality Assurance
QC	Quality Control
QI	Quality Improvement
R&D	Research and Development
RBNF	Research Billing Notification Form
RDE	Remote Data Entry
RFS	Research Finance Specialist
RL	Regulatory Letter (post-FDA audit letter)
SAE	Serious Adverse Event
SC	Study Coordinator
SD	Source Document
SoCRA	Society of Clinical Research Associates
SOM	School of Medicine
SOP	Standard Operating Procedure
VA	United States Department of Veterans Affairs
VAI	Voluntary Action Indicated (post-FDA audit inspection classification)
WHO	World Health Organization
WL	Warning Letter (most serious of post-FDA audit letter, demands immediate action within 15 days)