COMMONLY-USED ABBREVIATIONS AND ACRONYMS IN RESEARCH

Blue text indicates abbreviations/acronyms that are specific to the University of Rochester

AAHRPP	Association for the Accreditation of Human Research Protection Programs
AARC	Administrative Research Review Committee (Highland Hospital)
ACRP	Association of Clinical Research Professionals
ADE	Adverse Drug Event Adverse Drug Experience
ADME	Absorption, Distribution, Metabolism, and Elimination
ADR	Adverse Drug Reaction
AE	Adverse Event
ALCOAC	Accurate, Legible, Contemporaneous, Original, Attributable, and Complete
ARO	Academic Research Organization
BAA	Business Associates Agreement
BA/BE	Bioavailability/Bioequivalence
BIMO	Bioresearch Monitoring Program (FDA)
BLA	Biological Licensing Application
CABIN	Center for Advanced Brain Imaging & Neurophysiology (formerly Rochester Center for Brain Imaging)
CAPA	Corrective and Preventative Action
CART	Center for Advanced Research Technologies
CBER	Center for Biologics Evaluation and Research (FDA)
CC	Coordinating Center
CCC	Clinical Coordinating Center
CCEA	Complete, Consistent, Enduring, Available
CCRA	Certified Clinical Research Associate
CCRC	Certified Clinical Research Coordinator
CCRP	Certified Clinical Research Professional
CDA	Confidential Disclosure Agreement
CDER	Center for Drug Evaluation and Research (FDA)
CDP	Clinical Development Plan
CDS	Clinical Data System
CEL	Center for Experiential Learning
CFR	Code of Federal Regulations
Chet	Center for Health and Technology

CIDUR*	Clinical Imaging Data for UR Researchers
CISCRP	Center for Information and Study on Clinical Research Participation
CIOMS	Council for International Organizations of Medical Sciences
cIRB	Central Institutional Review Board
CITI	Collaborative Institutional Training Initiative
CLIA	Clinical Laboratory Improvement Amendments
CME	Continuing Medical Education
CMSU	Clinical Materials Service Unit
CoC	Certificate of Confidentiality
COI	Conflict of Interest
CPI	Certified Principal Investigator
CR	Continuing Review (Click IRB)
CRA	Clinical Research Associate
CRC	Clinical Research Center (CTSI) Clinical Research Coordinator
CRF	Case Report Form
CRO	Clinical Research Organization
CSR	Clinical Study Report
CT	Clinical Trial
CTA	Clinical Trial Agreement
CTCC	Clinical Trials Coordination Center
CTM	Clinical Trail Material
CTMS	Clinical Trial Management System
CTO	Clinical Trial Office (Cancer Center)
CTPL	Clinical Trials Processing Laboratory
CTSA	Clinical & Translational Science Aware
CTSI	Clinical & Translational Science Institute
CTTI	Clinical Trials Transformation Initiative
CV	Curriculum Vitae
DB	Double Blind
DCC	Data Coordinating Center
DCF	Data Correction Form Data Clarification Form

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DHHS (HHS)	Department of Health & Human Services
DM	Data Manager
DMC	Data Monitoring Committee
DMP	Data Management Plan
DROIPR	Department of Radiation Oncology Protocol Review Committee
DSMB	Data and Safety Monitoring Board
DSME	Data and Safety Monitoring Entity
DSMP	Data and Safety Monitoring Plan
DUA	Data Use Agreement
EAC	Endpoint Adjudication Committee
EC	Ethics Committee European Commission
ECI	Event of Clinical Interest
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
EDRA	Emergency Department Research Associate
EHR	Electronic Health Record
EIR	Establishment Inspection Report
EMR	Electronic Medical Record
EMRC	Emergency Medicine Research Committee
ePRO	Electronic Patient Reported Outcomes
eTMF	Electronic Trial Master File
fCOI	Financial Conflict of Interest
FDA	Food and Drug Administration
FERPA	Family Educational Rights and Privacy Act
FWA	Federalwide Assurance
GCP	Good Clinical Practice
GDP	Good Documentation Practice
GDPR	General Data Protection Regulations (European Union)
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HIPAA	Health Insurance Portability & Accountability Act
HRPP	Human Research Protection Program
HSP	Human Subject Protection

HUD	Humanitarian Use Device
HURC	Human Use of Radiation Committee
IB	Investigator's Brochure
IBC	Institutional Biosafety Committee
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IDE	Investigational Device Exemption
IDMC	Independent Data Monitoring Committee
IDS	Investigational Drug Service
IEC	Independent Ethics Committee
IIT	Investigator-Initiated Trial
IND	Investigational New Drug
INDSR	Investigational New Drug Safety Report
IO	Institutional Official
IORA	Integrated Online Research Administration
IP	Investigational Product
IRB	Institutional Review Board
IRBC	Institutional Review Board Coordinator
IRBD	Institutional Review Board Director
ISO	International Standards Organization
ITT	Intent to Treat
IVRS	Interactive Voice Response System
IWRS	Interactive Web Response System
JIT	Just-in-Time
LAR	Legally Authorized Representative
LDS	Limited Data Set
LOI	Letter of Intent
LTFU	Long Term Follow Up
MAC	Medicare Administrative Contractor
MCA	Medicare Coverage Analysis
MOD	Modification (Click IRB)
MOD/CR	Modification & Continuing Review (Click IRB)
MOO	Manual of Operations
MOP	Manual of Procedures
MRCT	Multi-Regional Clinical Trials Center

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MSS	Multi-Site Study
MTA	Material Transfer Agreement
NAF	Notice of Adverse Findings
NAI	No Action Indicated
NCD	National Coverage Determination
NCTG	Neonatal Clinical Trials Group
NDA	New Drug Application
NIH	National Institutes of Health
NOA	Notice of Award
NOFO	Notice of Funding Opportunity
NTF	Note to File
OAI	Official Action Indicated
OCR	Office of Civil Rights Office of Clinical Research (CTSI)
OHRP	Office for Human Research Protections
OHSP	Office for Human Subject Protection
OIG	Office of the Inspector General
ORACS	Office of Research Accounting and Costing Standards
ORC	Obstetrical Research Committee
ORPA	Office of Research & Project Administration
ORS	Office of Regulatory Support (CTSI)
OSMB	Observational Study Monitoring Board
OVPR	Office of the Vice President for Research
PAC	Post-Approval Consultation
PD	Pharmacodynamic
PHI	Protected Health Information
PHS	Public Health Service
PI	Principal Investigator
PIPL	Personal Information Protection Law (China)
PK/PD	Pharmacokinetic/Pharmacodynamic
PM	Project Manager
PMA	Premarket Approval
PPRA	Protection of Pupil Rights Amendment
PRIM&R	Public Responsibility in Medicine and Research
PRO	Patient Reported Outcomes
PROMIS	Patient Reported Outcomes Measurement Information System
pSite	Participating Site
QA	Quality Assurance
QC	Quality Control
QCT	Qualifying Clinical Trial
QI	Quality Improvement
QMP	Quality Management Plan
RBM	Risk Based Monitoring
RCR	Responsible Conduct of Research
RCT	Randomized Controlled Trial
RDE	Remote Data Entry
REB	Research Ethics Board
RESIN	Rochester Early-Stage Investigator Network
RHIO	Rochester Regional Health Information Organization
RMF	Research Methods Forum
RNI	Reportable New Information (Click IRB)
ROPI	Report of Prior Investigations
RSA	Research Subject Advocate
RSRB	Research Subjects Review Board
SADE	Serious Adverse Drug Experience
SAE	Serious Adverse Event
SC	Safety Cohort Study Coordinator Subcutaneous
SCORE	Study Coordinators Organization for Research & Education
SCRS	Society for Clinical Research Sites
SDV	Source Document Verification
SI	Sponsor-Investigator
sIRB	Single Institutional Review Board
SIV	Site Initiation Visit
SMO	Site Management Organization
SO	Safety Officer
SOC	Standard of Care

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SOCRA	Society of Clinical Research Associates
SOE	Schedule of Events
SOP	Standard Operating Procedure
SRO	Scientific Review Officer
SUSAR	Suspected Unexpected Serious Adverse Reaction
TIN	Trial Innovation Network
TMF	Trial Master File
TMO	Trial Management Organization
UADE	Unanticipated Adverse Device Effect
UADR	Unexpected Adverse Drug Reaction
UAP	Unanticipated Problem
UPIRTSO	Unanticipated Problem Involving Risk to Subjects or Others
VAI	Voluntary Action Indicated
WCG	WIRB Copernicus Group
WCI PRMC	Wilmot Cancer Institute Protocol Review and Monitoring Committee
WIRB	Western Institutional Review Board