COMMONLY USED ABBREVIATIONS AND ACRONYMS IN RESEARCH
in the NIH Intramural Research Program (IRP)

AAHRPP	Association for the Accreditation of Human Research Protection Programs
ACAT	Ability to Consent Assessment Team (at the Clinical Center)
ADE	Adverse Drug Experience
ADR	Adverse Drug Reaction
AE	Adverse Event
AI	Associate Investigator, or Accountable Investigator
AIRIO	Agency Intramural Research Integrity Officer
ALCOAC	Accurate, Legible, Contemporaneous, Original, Attributable, and Complete
BIMO	Bioresearch Monitoring Program (FDA)
BTRIS	(NIH IRP) Biomedical Translational Information System
C&T	(OHSRP office of) Compliance and Training
CAPA	Corrective and Preventative Action
CBER	Center for Biologics Evaluation and Research (FDA)
CC	(NIH) Clinical Center, or Coordinating Center
CCRA	Certified Clinical Research Associate
CCRC	Certified Clinical Research Coordinator
CCRP	Certified Clinical Research Professional
CD	(Institute/Center) Clinical Director
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research (FDA)
CFR	Code of Federal Regulations
CIOMS	Council for International Organizations of Medical Sciences
CITI	Collaborative Institutional Training Initiative
CLIA	Clinical Laboratory Improvement Amendments
CMP	Clinical Monitoring Plan
CoC	Certificate of Confidentiality
COI	Conflict of Interest

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CONSORT	Consolidated Standards of Reporting Trials
CPI	Certified Principal Investigator
CR	Continuing Review or Common Rule
CRA	Clinical Research Associate
CRADA	Cooperative Research and Development Agreement
CRC	Clinical Research Coordinator
CRF	Case Report Form
CRIS	Clinical Research Information System
CRO	Clinical Research Organization
CSR	Clinical Study Report
CT	Clinical Trial
CTA	Clinical Trial Agreement
CTM	Clinical Trial Material
CTMS	Clinical Trial Management System
CV	Curriculum Vitae
DB	Double Blind
DCC	Data Coordinating Center
DCF	Data Correction Form or Data Clarification Form
DEC	Deputy Ethics Counselor
DHHS (HHS)	Department of Health & Human Services
DMC	Data Monitoring Committee
DMP	Data Management Plan
DPA	Durable Power of Attorney
DSMC	Data Safety Monitoring Committee
DSME	Data Safety Monitoring Entity
DSMB	Data and Safety Monitoring Board
DSMP	Data and Safety Monitoring Plan
DUA	Data Use Agreement
EC	Ethics Committee or European Commission

COMMONLY USED ABBREVIATIONS AND ACRONYMS IN RESEARCH
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DURC	Dual Use Research of Concern
ECI	Event of Clinical Interest
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
EHR	Electronic Health Record
EIR	Establishment Inspection Report
EMR	Electronic Medical Record
ePRO	Electronic Patient Reported Outcomes
eTMF	Electronic Trial Master File
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
FTE	Full-time employee
FWA	Federalwide Assurance
GCP	Good Clinical Practice
GDS	Genomic Data Sharing
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GTC	Gene Therapy Center
GWAS	Genome-Wide Association Studies
HDE	Humanitarian Device Exemption
HIPAA	Health Insurance Portability & Accountability Act
HRPP	Human Research Protection Program
HUD	Humanitarian Use Device
HSP	Human Subject Protection
HSPU	(Clinical Center) Human Subjects Protection Unit
IB	Investigator's Brochure
IBC	Institutional Biosafety Committee
IC	(NIH) Institutes and Centers
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IDE	Investigational Device Exemption
IDMC	Independent Data Monitoring Committee

COMMONLY USED ABBREVIATIONS AND ACRONYMS IN RESEARCH
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IEC	Independent Ethics Committee
IIA	Individual or Institutional Investigator Agreement
IND	Investigational New Drug
IHS	Indian Health Service
INDSR	Investigational New Drug Safety Report
IO	Institutional Official
IP	Investigational Product
IR	Initial Review (by the IRB)
IRB	Institutional Review Board
IRBO	(NIH) Office of IRB Operations
iRIS	Integrated Research Information System
IRP	(NIH) Intramural Research Program
IRT	Incident Response Team
ISI	Identifiable Sensitive Information
ISM	Independent Safety Monitor
ITT	Intention to Treat
IVRS	Interactive Voice Response System
IWRS	Interactive Web Response System
LAI	Lead Associate Investigator
LAR	Legally Authorized Representative
LDS	Limited Data Set
LOA	Letter of Authorization
MAI	Medical Advisory Investigator
MAS	Medical Administrative Series
MEC	Medical Executive Committee (Clinical Center)
MOO	Manual of Operations
MOP	Manual of Procedures
MOU	Memorandum of Understanding
MTA	Material Transfer Agreement
NAF	Notice of Adverse Findings
NAI	No Action Indicated
NSR	Non-Significant Risk (Device)

COMMONLY USED ABBREVIATIONS AND ACRONYMS IN RESEARCH
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OCR	Office of Civil Rights
OHRP	(HHS) Office for Human Research Protections
OHSRP	(NIH) Office of Human Subjects Research Protections
OIG	Office of the Inspector General
ORSC	(CC) Office of Research Support and Compliance
OSMB	Observational Study Monitoring Board
OSOP	(NIH) Office of the Senior Official for Privacy
OPS	Office of Protocol Services
OTT	(NIH) Office of Technology Transfer
PD	Pharmacodynamic, or Protocol Deviation
PHERRB	Public Health Emergency Research Review Board
PFH	Personal Financial Holdings
PHI	Protected Health Information
PHS	(US) Public Health Service
PI	Principal Investigator
PII	Personally Identifiable Information
PM	Project Manager
PMA	Premarket Approval
PN	Protocol Navigator
PRIM&R	Public Responsibility in Medicine and Research
PRO	Patient Reported Outcomes
QA	Quality Assurance
QC	Quality Control
QI	Quality Improvement
RBM	Risk Based Monitoring
RCT	Randomized Controlled Trial
RDE	Remote Data Entry
RDRC	Radioactive Drug Research Committee
REB	Research Ethics Board
REF	Reportable Event Form

COMMONLY USED ABBREVIATIONS AND ACRONYMS IN RESEARCH
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RIO	Research Integrity Officer
ROPI	Report of Prior Investigations
RSA	Research Subject Advocate
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
SADE	Serious Adverse Drug Experience
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SC	Safety Cohort, or Study Coordinator, or Subcutaneous
SD	(NIH Institute/Center) Scientific Director
SDV	Source Document Verification
sIRB	(NIH) Single IRB Policy
SMC	Safety Monitoring Committee
SMO	Site Management Organization
SOA	Schedule of Activities
SOP	Standard Operating Procedure
SR	Scientific Review Significant Risk (Device)
STARS	Safety Tracking and Reporting System
SUSAR	Suspected Unexpected Serious Adverse Reaction
SV	Special Volunteer
TMF	Trial Master File
UADE	Unanticipated Adverse Device Effect
UP	Unanticipated Problem
UPIRTSO	Unanticipated Problem Involving Risk to Subjects or
	Others
VAI	Voluntary Action Indicated