

1572	FDA form completed by investigators
510K	A method of taking a device to market
3455	FDA Financial Disclosure Form

A ---

AAHRPP	Association for the Accreditation of Human Research Protections Programs
ACRP	Association of Clinical Research Professionals
ADR	Adverse Device report
AE	Adverse Event
AES	Acronym Exploitative Syndrome
ATTC	Addiction Technology Transfer Center

B---

BiMo	Bioresearch Monitoring Program, FDA
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C ---

CBER	Center for Biologics Evaluation & Research, FDA
CDC	Center for Disease Control, DHHS
CDER	Center for Drug Evaluation & Research, FDA
CDRH	Center for Devices and Radiologic Health, FDA
CE	Covered Entity
CF	Consent Form
CFR	Code of Federal Regulations
CIM	Certified IRB Manager (NAIM)
CIP	Certified IRB Professional (PRIM&R)
CIRB	Consortium of Independent IRBs
COC	Certificate of Confidentiality
COG	Children's Oncology Group
COI	Conflict of Interest
CR	Continuing Review
CR	Common Rule
CRA	Clinical Research Associate
CRC	Clinical Research Coordinator
CRFs	Case Report Forms
CRO	Clinical Research Organization/ Contract Research Organization

D E---

DHEW	Department of Health, Education and Welfare (no longer exists)
DHHS	Dept of Health & Human Services
DHF	Design history file (Devices)
DHR	Device History Record
DIA	Drug Information Association
DMC	Data Monitoring Committee
DMR	Device Master Record
DSMB	Data Safety Monitoring Board
DSMP	Data Safety Monitoring Plan

ECOG	Eastern Co-operative Oncology Group
EQUIC	Enhancing Quality of Informed Consent
EPA	Environmental Protection Agency
ESCRO	Embryonic Stem Cell Research Oversight Committee (see also SCRO)

F G ---

FDA	Food and Drug Administration
FERPA	Family Educational Rights and Privacy Act
FOIA	Freedom of Information Act
FR	Federal Register
FWA	Federal Wide Assurance
GCP	Good Clinical Practices
GOG	Gynecology Oncology Group
GMP	Good Manufacturing Practice
GRAS	Generally Recognized as Safe

H ---

HDE	Humanitarian Device Exemption
HHS	see DHHS
HIPAA	Health Insurance Portability and Accountability Act
HMO	Health Maintenance Organization
HPA	Human Protection Administrator
HRPP	Human Research Protection Program
HSR	Health Services Research
HUD	Humanitarian Use Device

I ---

IACUC	Institutional Animal Care and Use Committee
IB	Investigator's Brochure
IBC	Institutional Biohazard Committee
IC	Informed Consent
ICF	Informed Consent Form Individual Consent Form or Institutional Consent Form
ICH	International Committee on Harmonization of Technical Requirements
IDE	Investigational Device Exemption
IEC	Institutional Ethics Committee/Independent Ethics Committee
IND	Investigational New Drug Exemption
IO	Institutional Officer
IRB	Institutional Review Board

J K L --

JCAHO	Joint Commission on Accreditation of Healthcare Organizations
JIT	Just in Time (procedure)
LAR	Legally Authorized Representative
LCME	Liaison Committee for Medical Education
LTF	Subjects Lost to Follow-up

M N--

MPA	Multiple Projects Assurance
MSO	Medical Staff Office
NAIM	National Association of IRB Managers
NBAC	National Bioethics Advisory Commission

NCPHSBBR	National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
NCQA	National Committee for Quality Assurance
NDA	New Drug Application
NHRPAC	National Human Research Protections Advisory Committee (obsolete)
NIA	Nonaffiliated Investigator Agreement
NIH	National Institutes of Health, DHHS
NRMI	National Registry of Myocardial Infarction
NSF	National Science Foundation
NSR	Non significant Risk

O P ---

OHRP	Office of Human Research Protections, DHHS (formerly OPRR)
OPRR	Office of Protection from Research Risks, NIH (anachronism)
ORA	Office of Regulatory Affairs
ORCA	Office of Research Compliance & Assurance
ORI	Office of Research Integrity
OSHA	Occupational Safety and Health Administration
PD	Pharmacodynamics
PHI	Private Healthcare Information/ Public Health Information/ Protected Health Info.
PHS	Public Health Service (USPHS United States Public Health Service)
PI	Principal Investigator
PK	Pharmacokinetics
PMA	Pre Market Approval
PMA	PreMarket Approval (device)
POG	Pediatric Oncology Group
PPRA	Protection of Pupil Rights Amendment
PRIM&R	Public Responsibility in Medicine and Research

Q ---

QA	Quality Assurance
QC	Quality Control
QI	Quality Improvement
QSR	Quality Systems Regulations (previously GMP)

R ---

RAPS	Regulatory Affairs Professionals Society
RCO	Regulatory Compliance Officer
RCR	Responsible Conduct of Research
RCT	Randomized Control Trial
REB	Research Ethics Board
REMS	FDA – Risk Evaluation and Mitigation Strategies
RTOG	Radiation Therapy Oncology Group

S T U--

SACHRP	Secretary's Advisory Committee on Human Research Protection
SAE	Serious Adverse Event
SAP	Suspect Adverse Reaction
SBER	Social, Behavioral, Educational Research
SCRO	Stem Cell Review Organization

SMO	Site Management Organization
SOP	Standard Operating Procedure
SPA	Single Project Assurance
SR	Significant Risk
	Safety Report
SR	Safety Report/Significant Risk
SRO	Sponsored Research Office
SUSAR	Suspected Unexpected Serious Adverse Reaction
SWOG	South West Oncology Group
UADE	Unanticipated adverse device effect
UAE	Unexpected Adverse Event
UPIRTHSO	Unanticipated Problem Involving Risk to the Human Subjects or Others

V W X Y Z--

VA	Veteran's Affairs
VAMC	VA Medical Center
VPR	Vice President for Research
WMA	World Medical Association

