

ACRONYMS

1572 FDA Form
510K A method of taking a device to market

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
ARENA Applied Research Ethics National Association
ATTC Addiction Technology Transfer Center

B ---

BiMo Bioresearch Monitoring Program, FDA

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
CHTN Collaborative Human Tissue Network (NCI)
CIM Certified IRB Manager
CIP Certified IRB Professional
COC Certificate of Confidentiality
COI Conflict of Interest
CPA Cooperative Project Assurance
CR Continuing Review
CR Common Rule
CRA Clinical Research Associate
CRC Clinical Research Coordinator
CRFs Case Report Form
CRO Clinical Research Organization/
Contract Research Organization

D ---

DHEW Department of Health, Education and Welfare (no longer
exists)
DHHS Dept of Health & Human Services
DIA Drug Information Association
DMC Data Monitoring Committee
DSMB Data Safety Monitoring Board

E ---

ECOG Eastern Co-operative Oncology Group
EIR Establishment Inspection Report (FDA)
EQUIC Enhancing Quality of Informed Consent

F ---

FDA Food and Drug Administration
FOIA Freedom of Information Act
FR Federal Register
FWA Federal Wide Assurance

G ---

GCP Good Clinical Practices
GOG Gynecology Oncology Group
GRAS Generally Recognized as Safe
GXP

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
ICF Informed Consent Form
Individual Consent Form or
Institutional Consent Form
ICF Informed Consent Form
ICH International Committee on Harmonization of Technical
Requirements
IDE Investigational Device Exemption
IEC Institutional Ethics Committee/Independent Ethics
Committee
IIHI Individually Identifiable Health Information -HIPAA
IND Investigational New Drug Exemption
IRB Institutional Review Board

J K L --

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

M ---

MPA MPA Multiple Projects Assurance
MSO Medical Staff Office
National Association of IRB Managers

N ---

NAIM
NBAC National Bioethics Advisory Commission
NCPHSB National Commission for the Protection of Human Subjects of
BR Biomedical and Behavioral Research
NCQA National Committee for Quality Assurance
NDA New Drug Application
NHRPAC National Human Research Protections Advisory Committee
NIA Nonaffiliated Investigator Agreement
NIH National Institutes of Health, DHHS
NMRA NRMI National Registry of Myocardial Infarction
NSABP
NSR Non significant Risk

O ---

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

P ---

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
PRIM&R Public Responsibility in Medicine and Research

Q ---

QA Quality Assurance
QC Quality Control
QI Quality Improvement

R ---

RAPS Regulatory Affairs Professionals Society
RCO Regulatory Compliance Officer
RCR Responsible Conduct of Research
RCT Randomized Control Trial
REB Research Ethics Board
RTOG Radiation Therapy Oncology Group

S ---

SAE Serious Adverse Events
SAP Suspect Adverse Reaction
SMO Site Management Organization
SOP Standard Operating Procedure
SPA Single Project Assurance
SR Significant Risk

SR Safety Report
SR Safety Report/Significant Risk
SRO Sponsored Research Office
SWOG South West Oncology Group

T U V --

UPIRTSO Unanticipated problems involving risk to subjects or others
VA Veteran's Affairs
VAMC VA Medical Center
VPR Vice President for Research

W X Y Z

WMA World Medical Association