**Clinical Research Acronyms**

**AACI:** Association of American Cancer Institutes

**ADR:** Adverse Drug Reaction

**AE:** Adverse Event

**ALCOA:** Attributable, Legible, Contemporaneous, Original, Accurate

**AMC:** Academic Medical Center

**API:** Active Pharmaceutical Ingredient

**API:** Application Program Interface

**ARO:** Academic Research Organization

**BIMO:** Bioresearch Monitoring Program

**BSM:** Biospecimen Management

**CAPA:** Corrective and Preventive Action

**CBER:** Center for Biologics Evaluation and Research

**CCEA:** Complete, Consistent, Enduring, Available

**CCR:** Center for Cancer Research

**CCRC** – Certified Clinical Research Coordinator

**CCRP** – Certified Clinical Research Professional

**CCSG:** Cancer Center Support Grant

**CCTO** or **CTO:** Centralized Clinical Trials Office or Clinical Trials Office

**CDASH:**Clinical Data Acquisition Standards Harmonization

**CDER:** Center for Drug Evaluation and Research

**CDM:** Clinical Data Management

**CDRH:** Center for Devices and Radiological Health

**CDS:** Clinical Data System

**CDUS:** Clinical Data Update System

**CFR:** Code of Federal Regulations

**CITI**: Collaborative Institutional Training Initiative

**CLIA**: Clinical Laboratory Improvement Amendments

**CMO:** Contract Manufacturing Organization

**CMS:** Centers for Medicare & Medicaid Services

**COI:** Conflict of Interest

**COIC:** Conflict of Interest Committee

**CRA:** Clinical Research Associate

**CRC:** Clinical Research Coordinator

**CRF:** Case Report Form

**CRMS:** Clinical Research Management System

**CRO:** Contract Research Organization

**CSO:**Contract Safety Organization

**CSR:** Clinical Study Report

**CTA:** Clinical Trial Agreement

**CTCAE:** Common Terminology Criteria for Adverse Events

**CTMS:** Clinical Trial Management System

**CTRP:** Clinical Trials Reporting Program

**CTSA:** Clinical and Translational Science Award

**CV:** Curriculum Vitae

**DHHS:** Department of Health and Human Services

**DM:** Data Manager

**DMC:** Data Monitoring Committee

**DSMB:** Data and Safety Monitoring Board

**EC:** Ethics Committee

**eCRF:** Electronic Case Report Form

**EDC:** Electronic Data Capture

**EHR:** Electronic Health Record

**EMR:** Electronic Medical Record

**ePRO:** Electronic Patient-Reported Outcomes

**eTMF:** Electronic Trial Master File

**FAIR:** Findable, Accessible, Interoperable, Reusable

**FDA:** Food and Drug Administration

**Form 483 -** Inspectional Findings

**FWA:** Federal-wide Assurance

**GCP:** Good Clinical Practice

**GCRC:** General Clinical Research Center

**GDP:**Good Documentation Practice

**HIPAA:** Health Insurance Portability and Accountability Act

**HRPP:** Human Research Protection Program

**HUD:**  Humanitarian Use Device

**IB:** Investigator’s Brochure

**ICF:** Informed Consent Form

**ICH:** International Council for Harmonization

**IDE:** Investigational Device Exemptions

**IEC:** Independent Ethics Committee

**IHCRA:** In House Clinical Research Associate

**IIT:** Investigator Initiated Trial

**IND:** Investigational New Drug (Application)

**IRB:** Institutional Review Board

**ITT:** Intent to Treat

**IVRS:** Interactive Voice Response System

**IWRS:** Interactive Web Response System

**LTFU:** Long Term Follow Up

**LRAA:** Local Regulatory Affairs Associate

**MAC:** Medicare Administrative Contractor

**MCA:** Medicare Coverage Analysis

**MRN:** Medical Record Number

**NCI:** National Cancer Institute

**NDA:** New Drug Application

**NHV:** Normal Healthy Volunteer

**NIH:** National Institutes of Health

**NLM:** National Library of Medicine

**NTF**: Note to File

**OCT:** Office of Clinical Trials

**OHRP:** Office for Human Research Protections

**OSR:** Outside Safety Report

**PC:** Protocol Coordinator

**PD:** Pharmacodynamic

**PHI:** Protected Health Information

**PI:** Principal Investigator

**PK:** Pharmacokinetics

**PMA:** Premarket Approval (medical devices)

**PRMC:** Protocol Review and Monitoring Committee

**PRMS:** Protocol Review and Monitoring System

**QC:** Quality Control

**QCT:** Qualifying Clinical Trial

**REB:** Research Ethics Board

**SAE:** Serious Adverse Event

**SC:** Study Coordinator

**SDR:** Source Document Review (Also Source Data Review)

**SDTM:** Study Data Tabulation Model

**SDV:** Source Document Verification

**SIF:** Site Investigator File

**SMO:** Site Management Organization

**SOE:** Schedule of Events

**SOP:** Standard Operating Procedure

**SPOREs:** Specialized Programs for Research Excellence

**SRB:** Scientific Review Board

**SRC:** Scientific Review Committee

**SUSAR:** Suspected Unexpected Serious Adverse Reaction

**SVT:** Subject Visit Template

**TMF:** Trial Master File

**TMO:** Trial Management Organization

**UADE:** Unanticipated Adverse Device Effect

**UADR:** Unexpected Adverse Drug Reaction

**UPIRTSO:** Unanticipated Problem Involving Risk to Subjects or Others