

| Acronym | Name   |
|---------|--|
| ADR     | Adverse Drug Reaction                                  |
| AE      | Adverse Event  |
| AKA     | Also known as  |
| APEX    | Epic based electronic medical records at UCSF          |
| BID     | Twice a day  |
| CA      | Coverage Analysis                                      |
| CAPA    | Corrective & Preventional Action Plan                  |
| CCRP    | Certified Clinical Research Professional               |
| CBER    | Center for Biologics Evaluation and Research           |
| CDER    | Center for Drug Evaluation and Research                |
| CFR     | Code of Federal Regulations                            |
| CGA     | Contracts and Grants Accounting                        |
| CHR     | Committee on Human Research (former name for UCSF IRB) |
| CITI    | Collaborative IRB Training Initiative                  |
| COI     | Conflict of Interest                                   |
| CR      | Continuing Review                                      |
| CRA     | Clinical Research Associate                            |
| CRC     | Clinical Research Coordinator                          |
| CRF     | Case Report Form                                       |
| CRO     | Contract Research Organization                         |
| CRRM    | Clinical Research Risk Manager                         |
| CRS     | Clinical Research Services                             |
| CTA     | Clinical Trials Agreement                              |
| CTCAE   | Common Terminology Criteria for Adverse Events         |
| CTO     | Clinical Trial Operations Unit                         |
| CTSI    | Clinical and Translational Science Institute           |
| CV      | Curriculum Vitae                                       |
| DA      | Division Administrator                                 |
| DARF    | Drug Accountability Record Form                        |
| DM      | Department Manager                                     |
| DMF     | Drug Master File                                       |
| DSI     | Division of Scientific Investigations                  |
| DSMB    | Data Safety Monitoring Board                           |
| DSMC    | Data and Safety Monitoring Committee                   |
| DSMP    | Data and Safety Monitoring Plan                        |
| DUA     | Data Use Agreement                                     |
| ECRF    | Electronic Case Report Form                            |
| EDC     | Electronic Data Capture                                |
| EHR/EMR | Electronic Medical Record                              |
| EIR     | Establishment Inspection Report                        |
| FDA     | Food and Drug Administration                           |
| FWA     | Federal wide Assurance                                 |
| GCP     | Good Clinical Practice                                 |

|       |   |
|-------|---|
| HIPAA | Health Insurance Portability and Accountability Act |
| HRPP  | Human Research Protection Program                   |
| IB    | Investigator's Brochure                             |
| ICF   | Informed Consent Form                               |
| ICD   | Industry Contracts Division                         |
| ICH   | International Conference on Harmonization           |
| IDE   | Investigational Device Exemption                    |
| IIT   | Investigator Initiated Trial                        |
| IMV   | Interim Monitoring Visit                            |
| IND   | Investigational New Drug                            |
| IP    | Investigational Product                             |
| IRB   | Institutional Review Board                          |
| iRIS  | Online IRB application system at UCSF               |
| ITA   | Office of Innovation, Technology and Alliances      |
| ITR   | Investigational Trial Resource (Cancer Center)      |
| LOA   | Letter of Authorization                             |
| MCA   | Medicare Coverage Analysis                          |
| MOP   | Manual of Procedures                                |
| MRN   | Medical Record Number                               |
| MTA   | Material Transfer Agreement                         |
| NDA   | New Drug Application                                |
| NIH   | National Institutes of Health                       |
| NTF   | Note to File  |
| OCTA  | Office of Clinical Trial Activation                 |
| OH    | Overhead (indirect costs)                           |
| OHRP  | Office for Human Research Protection                |
| OSR   | Office of Sponsored Research                        |
| OTC   | Over the counter                                    |
| PHI   | Protected Health Information                        |
| PI    | Principal Investigator                              |
| PMOA  | Primary Mode of Action                              |
| PRN   | As Needed   |
| QA    | Quality Assurance                                   |
| QC    | Quality Control                                     |
| QIU   | Quality Improvement Unit                            |
| RFA   | Research Financial Analyst                          |
| RMIS  | Risk Management and Insurance Services              |
| RMS   | Research Management Services                        |
| RN    | Registered Nurse                                    |
| RSC   | Research Services Coordinator                       |
| SAE   | Serious Adverse Event                               |
| SAP   | Statistical Analysis Plan                           |
| SDV   | Source Data Verification                            |
| SEV   | Site Evaluation Visit                               |

|        |  |
|--------|--|
| SFVAMC | Veterans Administration Medical Center |
| SIV    | Site Initiation Visit                  |
| SOC    | Standard of Care                       |
| SOE    | Schedule of Events                     |
| SOP    | Standard Operating Procedure           |
| SSV    | Site Selection Visit                   |
| Sub-I  | Sub-Investigator                       |
| TMF    | Trial Master File                      |