

## COMMONLY-USED ABBREVIATIONS AND ACRONYMS IN RESEARCH

\*Blue text indicates abbreviations/acronyms that are specific to the University of Rochester\*

|                       |   |
|-----------------------|---|
| AAHRPP                | Association for the Accreditation of Human Research Protection Programs   |
| <a href="#">AARC</a>  | <a href="#">Administrative Research Review Committee (Highland Hospital)</a>  |
| ACRP                  | Association of Clinical Research Professionals  |
| ADE                   | Adverse Drug Experience   |
| ADR                   | Adverse Drug Reaction   |
| AE                    | Adverse Event   |
| ALCOAC                | Accurate, Legible, Contemporaneous, Original, Attributable, and Complete  |
| BAA                   | Business Associates Agreement   |
| BIMO                  | Bioresearch Monitoring Program (FDA)  |
| <a href="#">CABIN</a> | <a href="#">Center for Advanced Brain Imaging &amp; Neurophysiology (formerly Rochester Center for Brain Imaging)</a> |
| CAPA                  | Corrective and Preventative Action  |
| CBER                  | Center for Biologics Evaluation and Research (FDA)  |
| CCRA                  | Certified Clinical Research Associate   |
| CCRC                  | Certified Clinical Research Coordinator   |
| CCRP                  | Certified Clinical Research Professional  |
| CDER                  | Center for Drug Evaluation and Research (FDA)   |
| <a href="#">CEL</a>   | <a href="#">Center for Experiential Learning</a>  |
| CFR                   | Code of Federal Regulations   |
| <a href="#">CHET</a>  | <a href="#">Center for Human Experimental Therapeutics</a>  |
| CISCRP                | Center for Information and Study on Clinical Research Participation   |
| CIOMS                 | Council for International Organizations of Medical Sciences   |
| cIRB                  | Central Institutional Review Board  |
| CITI                  | Collaborative Institutional Training Initiative   |
| CLIA                  | Clinical Laboratory Improvement Amendments  |
| <a href="#">CMSU</a>  | <a href="#">Clinical Materials Service Unit</a>   |
| COI                   | Conflict of Interest  |
| CPI                   | Certified Principal Investigator  |
| <a href="#">CR</a>    | <a href="#">Continuing Review (Click IRB)</a>   |
| CRA                   | Clinical Research Associate   |

|                        |  |
|------------------------|--|
| CRC                    | <a href="#">Clinical Research Center</a><br>Clinical Research Coordinator  |
| CRF                    | Case Report Form   |
| CRO                    | Clinical Research Organization   |
| CSR                    | Clinical Study Report  |
| CT                     | Clinical Trial   |
| CTA                    | Clinical Trial Agreement   |
| <a href="#">CTCC</a>   | <a href="#">Clinical Trials Coordination Center</a>                        |
| CTM                    | Clinical Trail Material  |
| CTMS                   | Clinical Trial Management System   |
| <a href="#">CTO</a>    | <a href="#">Clinical Trial Office (Cancer Center)</a>                      |
| <a href="#">CTSI</a>   | <a href="#">Clinical &amp; Translation Science Institute</a>               |
| CTTI                   | Clinical Trials Transformation Initiative                                  |
| CV                     | Curriculum Vitae   |
| DB                     | Double Blind   |
| DCF                    | Data Correction Form<br>Data Clarification Form                            |
| DHHS (HHS)             | Department of Health & Human Services                                      |
| DMC                    | Data Monitoring Committee  |
| DMP                    | Data Management Plan   |
| <a href="#">DROIPR</a> | <a href="#">Department of Radiation Oncology Protocol Review Committee</a> |
| DSMB                   | Data and Safety Monitoring Board   |
| DSMP                   | Data and Safety Monitoring Plan  |
| DUA                    | Data Use Agreement   |
| EC                     | Ethics Committee; European Commission                                      |
| ECI                    | Event of Clinical Interest   |
| eCRF                   | Electronic Case Report Form  |
| EDC                    | Electronic Data Capture  |
| <a href="#">EDRA</a>   | <a href="#">Emergency Department Research Associate</a>                    |
| EHR                    | Electronic Health Record   |
| EIR                    | Establishment Inspection Report  |
| EMR                    | Electronic Medical Record  |
| <a href="#">EMRC</a>   | <a href="#">Emergency Medicine Research Committee</a>                      |
| ePRO                   | Electronic Patient Reported Outcomes                                       |

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|                        |  |
|------------------------|--|
| eTMF                   | Electronic Trial Master File                                     |
| FDA                    | Food and Drug Administration                                     |
| FWA                    | Federalwide Assurance  |
| GCP                    | Good Clinical Practice   |
| GLP                    | Good Laboratory Practice   |
| GMP                    | Good Manufacturing Practice                                      |
| HIPAA                  | Health Insurance Portability & Accountability Act                |
| HRPP                   | Human Research Protection Program                                |
| HUD                    | Humanitarian Use Device  |
| <a href="#">HURC</a>   | <a href="#">Human Use of Radiation Committee</a>                 |
| HSP                    | Human Subject Protection   |
| IB                     | Investigator's Brochure  |
| IBC                    | Institutional Biosafety Committee                                |
| ICF                    | Informed Consent Form  |
| ICH                    | International Conference on Harmonisation                        |
| IDE                    | Investigational Device Exemption                                 |
| IDMC                   | Independent Data Monitoring Committee                            |
| <a href="#">IDS</a>    | <a href="#">Investigational Drug Service</a>                     |
| IEC                    | Independent Ethics Committee                                     |
| IND                    | Investigational New Drug   |
| INDSR                  | Investigational New Drug Safety Report                           |
| IO                     | Institutional Official   |
| IORA                   | Integrated Online Research Administration                        |
| IP                     | Investigational Product  |
| IRB                    | Institutional Review Board                                       |
| IRBC                   | Institutional Review Board Coordinator                           |
| IRBD                   | Institutional Review Board Director                              |
| IVRS                   | Interactive Voice Response System                                |
| IWRS                   | Interactive Web Response System                                  |
| LAR                    | Legally Authorized Representative                                |
| LDS                    | Limited Data Set   |
| <a href="#">MOD</a>    | <a href="#">Modification (Click IRB)</a>                         |
| <a href="#">MOD/CR</a> | <a href="#">Modification &amp; Continuing Review (Click IRB)</a> |
| MOO                    | Manual of Operations   |
| MOP                    | Manual of Procedures   |

|                       |   |
|-----------------------|---|
| MRCT                  | Multi-Regional Clinical Trials Center                                 |
| MSS                   | Multi-Site Study  |
| MTA                   | Material Transfer Agreement   |
| NAF                   | Notice of Adverse Findings  |
| NAI                   | No Action Indicated   |
| <a href="#">NCTG</a>  | <a href="#">Neonatal Clinical Trials Group</a>                        |
| NDA                   | New Drug Application  |
| NTF                   | Note to File  |
| OAI                   | Official Action Indicated   |
| OCR                   | Office of Civil Rights<br><a href="#">Office of Clinical Research</a> |
| OHRP                  | Office for Human Research Protections                                 |
| <a href="#">OHSP</a>  | <a href="#">Office for Human Subject Protection</a>                   |
| <a href="#">ORACS</a> | <a href="#">Office of Research Accounting and Costing Standards</a>   |
| OIG                   | Office of the Inspector General                                       |
| <a href="#">ORC</a>   | <a href="#">Obstetrical Research Committee</a>                        |
| <a href="#">ORPA</a>  | <a href="#">Office of Research &amp; Project Administration</a>       |
| OSMB                  | Observational Study Monitoring Board                                  |
| PD                    | Pharmacodynamic   |
| PHI                   | Protected Health Information  |
| PHS                   | Public Health Service   |
| PI                    | Principal Investigator  |
| <a href="#">PRC</a>   | <a href="#">Peer Review Committee (Cancer Center)</a>                 |
| PM                    | Project Manager   |
| PMA                   | Premarket Approval  |
| PRIM&R                | Public Responsibility in Medicine and Research                        |
| PRO                   | Patient Reported Outcomes   |
| PROMIS                | Patient Reported Outcomes Measurement Information System              |
| QA                    | Quality Assurance   |
| QC                    | Quality Control   |
| QI                    | Quality Improvement   |
| RBM                   | Risk Based Monitoring   |
| RCT                   | Randomized Controlled Trial   |
| RDE                   | Remote Data Entry   |

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|         |  |
|---------|--|
| REB     | Research Ethics Board  |
| RNI     | <a href="#">Reportable New Information (Click IRB)</a>                       |
| ROPI    | Report of Prior Investigations   |
| RSA     | Research Subject Advocate  |
| RSRB    | <a href="#">Research Subjects Review Board</a>                               |
| SADE    | Serious Adverse Drug Experience  |
| SAE     | Serious Adverse Event  |
| SC      | Safety Cohort<br>Study Coordinator<br>Subcutaneous                           |
| SCORE   | <a href="#">Study Coordinators Organization for Research &amp; Education</a> |
| SCRS    | Society for Clinical Research Sites  |
| SDV     | Source Document Verification   |
| sIRB    | Single Institutional Review Board  |
| SMO     | Site Management Organization   |
| SO      | Safety Officer   |
| SOCRA   | Society of Clinical Research Associates                                      |
| SOP     | Standard Operating Procedure   |
| SUSAR   | Suspected Unexpected Serious Adverse Reaction                                |
| TMF     | Trial Master File  |
| UADE    | Unanticipated Adverse Device Effect  |
| UAP     | Unanticipated Problem  |
| UPIRTSO | Unanticipated Problem Involving Risk to Subjects or Others                   |
| VAI     | Voluntary Action Indicated   |
| WIRB    | Western Institutional Review Board   |