

Clinical Research Abbreviations/Acronym Reference Sheet

ACOSOG	American College of Surgeons Oncology Group
AdEERS	Adverse Event Expedited Reporting System (old name, now called CTEP-AERS)
ACR	American College of Radiology
ADR	Adverse Drug Reaction
AE	Adverse Event
Alliance	<i>new group which includes ACOSOG, CALGB and NCCTG</i>
ASCO	American Society of Clinical Oncology
caBIG	Cancer Biomedical Informatics Grid
CALGB	Cancer and Leukemia Group B
CAEPR	Comprehensive Adverse Event and Potential Risks
CBER	Center for Biologics Evaluation in Research
CDA	Confidential Disclosure Agreement
CDER	Center for Drug Evaluation and Research
CDRH	Center for Device Radiological Health
CDUS	Clinical Data Update System
CFR	Code of Federal Regulations
COG	Children's Oncology Group
COI	Conflict of Interest
CRF	Case Report Form
CRO	Clinical Research Organization
CTA	Clinical Trial Agreement
CTCAE	Common Terminology Criteria for Adverse Events
CTEP	Cancer Therapy Evaluation Program
CTEP AERS	CTEP Adverse Event Reporting System
CTEP IAM	CTEP-Identity and Access Management
CTRP	Clinical Trials Registration Program
CTSA	Clinical and Translational Science Award
CTSU	Cancer Trials Support Unit
CTU	Clinical Trials Unit
CV	Curriculum Vitae
DCF	Data Correction Form
DMC	Data Monitoring Committee
DSMB	Data and Safety Monitoring Board
DSMP	Data and Safety Monitoring Plan
DSTC	Data Safety Toxicity Committee
ECOG-ACRIN	Eastern Cooperative Oncology Group – American College of Radiology Imaging Network
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GOG	Gynecologic Oncology Group
HSP	Human Subjects Protection
ICF	Informed Consent Form
ICH-GCP	International Conference on Harmonisation -Good Clinical Practice
IDB/IB	Investigator Drug Brochure
IDE	Investigational Device Exemption
IIT	Investigator Initiated Trial
IND	Investigational New Drug
IRB	Institutional Review Board
IROC	Imaging and Radiation Oncology Core
LOI	Letter of Intent

Clinical Research Abbreviations/Acronym Reference Sheet *continued*

NCI	National Cancer Institute
NCIC CTG	National Cancer Institute of Canada Clinical Trials Group
NCCTG	North Central Cancer Treatment Group
NCTN	National Clinical Trials Network (NCI)
NIH	National Institutes of Health
NRG	<i>this is not an acronym but was created for the new group <u>NSABP/RTOG/GOG</u></i>
NSABP	National Surgical Adjuvant Breast and Bowel Project
OnCore	Online Clinical Oncology Research Environment
OPEN	Oncology Patient Enrollment Network
PI	Principal Investigator
PMB	Pharmaceutical Management Branch
QA	Quality Assurance
QARC	Quality Assurance Review Center
RECIST	Response Evaluation Criteria in Solid Tumors
RPC	Radiological Physics Center
RTOG	Radiation Therapy Oncology Group
SAE	Serious Adverse Event
SOP	Standard Operating Procedures
SPEER	Specific Protocol Exceptions to Expedited Reporting (SPEER)
SRC	Safety Review Committee (GOG) <u>or</u> Scientific Review Committee
SWOG	Southwestern Oncology Group