Glossary

A

Abbreviated: A category for CTRP registration. Trials in this category are industrial, or pharmaceutical company sponsored trials. The design and implementation of these studies is controlled by the pharmaceutical company. A protocol document is not required for registration of trials in this category.

Abstraction: Identification and extraction ("abstraction") of information from the submitted protocol document by the NCI Clinical Trials Reporting Office (CTRO) staff to complete data element fields in the CTRP database.

ACOS: American College of Surgeons

ACOSOG: American College of Surgeons Oncology Group (NCI)

ACRP: Association of Clinical Research Professionals

Activation: The official start date of a trial determined as follows: 1) the date of an official clinical trial activation announcement or 2) the date of first patient accrual if the trial in question did not have a formal activation announcement.

Adenocarcinoma: A cancerous tumor that arises or resembles glandular tissue.

Adjunct agent: In cancer therapy, a drug or substance used in addition to the primary therapy.

Adjuvant chemotherapy: A term used to describe the role of chemotherapy relative to other cancer treatments. It is typically given alone or with radiation after surgical resection.

Adjuvant radiation therapy: The use of radiation after treatment in order to prevent a cancer from recurring

ADR: Adverse Drug Reaction

Adverse Event (AE): An adverse event is an untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.

ALL: Acute Lymphoblastic Leukemia

Allocation: A clinical trial design strategy used to assign participants to an arm of a study. Types of allocation include Randomized and Nonrandomized.

Amendment: Amendments include changes that: 1) substantively alter the treatment administered; and/or 2) the study design; and/or 3) the sites in which patients are being enrolled on the trial. Amendments are to include all changes (including updates) since the last change to the protocol was submitted.

AML: Acute Myeloid Leukemia

Anaplastic: A term used to describe cancer cells that divide rapidly and have little or no resemblance to normal cells.

Anastomosis: The joining together of two ends of healthy bowel after diseased bowel has been cut out (resected) by the surgeon. This may be contrasted to a colostomy, when the bowel ends may be permanently diverted, or anastomosed at a later surgery.

Ancillary/Correlative: A trial that is secondary to another trial, or a type of trial that tests for a relationship between a condition and a potential causal factor of the condition.

ANLL: Acute Non-Lymphatic Leukemia

Antigen: A substance that is recognized by the body as being foreign and, as such, can trigger an immune response.

Applicable/Required Clinical Trials: Generally include interventional studies (with one or more arms/groups or cohorts) of drugs, biological products, or devices that are subject to FDA regulation, conducted at one or more sites in the U.S and involving a drug, biologic, or device that is manufactured in the US (or its territories), or is conducted under an investigational new drug application (IND) or investigational device exemption (IDE).

> Phase I studies are excluded from federally mandated reporting on www.clinicaltrials.gov, but can be reported on that website to satisfy ICJME publication requirements. NCI-Designated Cancer Centers must also report observational and epidemiologic studies to the NIH NCI website, CTRP.

Approval in relation to Institutional Review Boards: The affirmative decision of an IRB that the clinical trial has been reviewed and may be conducted at a given institutional site within the constraints set forth by the IRB, the institution, Good Clinical Practice (GCP), and applicable regulatory requirements.

Archived Tumor Sample: A tumor sample that has been routinely preserved and stored. Tumor tissue is commonly preserved for storage by being treated with a preservative called formalin and then embedded in paraffin (wax).

ARM: A group of subgroup of participants in a clinical trial who receives specific interventions, or no intervention, according to the study protocol. This is decided before the trial begins.

Arm description: A brief description of the arm.

Arm label: The short name used to identify the arm.

Arm type:

> **Active comparator**: An arm or group in which active drugs are given. This will include arms that are mixing active drugs and placebos. This will be used when the term "control arm" is specified in the protocol and when another arm is designated as the experimental arm. There can be more than one active comparator arm.

Experimental: An arm or group in which an experimental drug or regimen is being administered. This will be used when the trial specifies that one arm is a control arm and the other is experimental, or when the other arm is a placebo arm. In cases where patients are not randomized but assigned to groups according to certain characteristics (e.g., risk characteristics, age, diagnosis), use "experimental" for all groups/strata because they are not being compared.

No intervention: An observational arm or group.

Placebo comparator: An arm or group in which ONLY a placebo is given.

Sham comparator: An arm or group in which ONLY a mock therapy that is not a drug is administered.

Other: An arm or group which does not fall into any of the categories above.

Aromatase Inhibitor: A medication that reduces the amount of estrogen in the body. Aromatase inhibitors may be used to treat women with estrogen-receptor positive breast cancer.

ASCO: American Society of Clinical Oncology

B

B-ALL: B-cell Acute Lymphoblastic Leukemia

Barium enema: A barium enema is a series of x-rays of the lower gastrointestinal tract. The barium enema procedure consists of the insertion of barium (a radiolucent solution) to coat the lower gastrointestinal tract. The barium coats the lower gastrointestinal tract and x-rays are taken. On X-ray, areas in which the barium “lights up” may indicate abnormal cell proliferation. This procedure is also called a lower GI series.

Baseline Characteristics: Data collected at the beginning of a clinical study for all participants and for each arm or comparison group. These data include demographics, such as age and gender, and study-specific measures (for example, systolic blood pressure, prior antidepressant treatment).

Basic Science: A protocol designed to examine the basic mechanism of action (e.g., physiology, biomechanics) of an intervention.

BCC: Basal Cell Carcinoma

BID/BD: Twice a day (bis in die)

Biopsy: A procedure where tumor tissue is removed from the body for laboratory examination to determine whether or not cancer is present. A biopsy can be performed using a needle to extract a small piece of tissue or as a surgical procedure to remove a larger piece of tissue.

BM: Bone Marrow

BRCA1 and BRCA2: Genes that normally help control cell growth. A person who inherits an altered version of the BRCA1 and/or BRCA2 gene(s) has a higher risk of developing breast and ovarian cancer.

BRM: Biological Response Modifier

Bx: Biopsy

C

CALGB: Cancer and Leukemia Group B (NCI)

Cancer: A condition in which abnormal cells divide without control or fail to die as part of a normal cell's lifecycle. Cancer cells can also invade nearby tissues and can spread through the bloodstream and lymphatic system to other parts of the body.

Cancer Staging: The process of assigning a descriptor (usually numbers I to IV) of how much a cancer has spread in the body. Criteria for staging include: size of tumor, amount of tissue penetration, whether it has invaded adjacent organs, and how many lymph nodes are involved.

Carcinoma: Any malignant cancer that comes from epithelial cells. Carcinomas will invade surrounding tissue, and have the propensity to metastasize to the lymph nodes and beyond.

Carcinoma in situ: Epithelial tumor cells confined to the tissue of origin, without invasion through the basement membrane.

CAT (CT): Computed Axial Tomography (scan)

Categories for Trials in CTRP:

> **Externally Peer-Reviewed:** R01s, SPORES, U01s, U10s, and P01s or other trial mechanisms supported by the NIH or supported by other peer-reviewed funding organizations.
>
> **Industrial:** Design and implementation of the study is controlled by the pharmaceutical company.

Institutional: In-house clinical research studies authored or co-authored by Cancer Center investigators and undergoing scientific peer-review solely by the Protocol Review and Monitoring System of the Cancer Center. The Cancer Center investigator has primary responsibility for conceptualizing, designing, and implementing the clinical research study and reporting results. It is acceptable for industry and other entities to provide support (e.g., drug, device, other funding), but the trial should clearly be the intellectual product of the Center investigator.

This category may also include: 1) Institutional studies authored and implemented by investigators at anotherCenter; 2) Multi-site institutional studies authored and implemented for which the Cancer Center is the lead organization.

National: NCI National Clinical Trials Network (NCTN) and other NIH-supported National Trial Networks.

CCR: NCI's Center for Cancer Research (listed as one of the NCI Division/Program Codes in CTRP) is the basic and clinical intramural research program of NCI, which conducts research with the goal of improving the lives of people affected by cancer and HIV/AIDS.

CCRP: Certified Clinical Research Professional (SoCRA)

CCSG: Cancer Center Support Grant (NCI)

CDP: NCI's Cancer Diagnosis Program (listed as one of the NCI Division/Program Codes in CTRP) stimulates and supports diagnostics research, resources, and improved technologies to guide the choice of treatment for cancer patients.

CDUS: The Clinical Data Update System is the primary data reporting mechanism for CTEP and DCP PIO managed clinical trials and is used by CTEP and DCP to enter and submit accrual data to CTRP.

CEA: Carcinoembryonic Antigen (tumor marker)

CFR: FDA Code of Federal Regulations

Chemotherapy: Treatment with cytotoxic drugs that destroy cancer cells (fast-growing cells). Chemotherapy may be used in addition to surgery, and is sometimes used in combination with other therapies such as radiation therapy or hormonal therapy.

Chromosome: A microscopically visible carrier of genetic information.

CIP: NCI's Cancer Imaging Program (listed as one of the NCI Division/Program Codes in CTRP) evaluates imaging in diagnosis, disease staging, and treatment monitoring.

CIRB: Central Institutional Review Board (NCI)

CITI: Collaborative IRM Training Initiative

Clinical Laboratory Services: The biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of—or the assessment of the health of—human beings.

Clinical Trial: A research study to test drugs, procedures or testing technologies to determine whether these are effective and/or safe.

Clinical Trials Reporting Program (CTRP**)**: CTRP is a comprehensive database of regularly updated information, including trial accrual, on all NCI-supported clinical trials.

Clinical Trials Reporting Office (CTRO): The functional unit that performs the operational work of the Clinical Trials Reporting Program (CTRP), including protocol abstraction.

Clinically Validated: Determination that a test is accurate in determining the presence of, or predicting the risk for, a health condition or phenotype, including determination of sensitivity, specificity and positive and negative predictive values.

CLL: Chronic Lymphocytic Leukemia

CML: Chronic Myeloid Leukemia

COG: Children's Oncology Group (NCI)

COIC: Conflict of Interest Committee

COIF: Conflict of Interest Form

Colectomy: Surgical resection of all or part of the colon (also called the large intestine).

Colitis: Inflammation of the colon. Colitis has many forms including ulcerative, Crohn´s, infectious, pseudomembranous, and spastic.

Colon polyp: A fleshy growth on the inside (the lining) of the colon.

Colonoscopy: Inspection through a fiber-optic scope of the inside of the colon.

Colorectal: Related to the colon and/or rectum.

Conflict of interest: A situation associated with an investigator's participation in UNM research where it reasonably appears, on an actual or potential basis, that the investigator's significant financial interest could directly and significantly affect the design, conduct or reporting of UNM research activities; or the investigator's situation could directly and significantly compromise his or her professional commitments or allegiance to UNM.

Cooperative Oncology Group: A group of researchers, cancer centers, and community doctors who are involved in studies of new cancer treatment, prevention, early detection, quality of life, and rehabilitation. Clinical trials carried out by cooperative groups are sponsored by the National Cancer Institute, and large numbers of patients take part in many locations. Examples include the Radiation Therapy Oncology Group (RTOG), Gynecologic Oncology Group (GOG), and Children's Oncology Group (COG).

Core Biopsy: A procedure which uses a needle to remove a small, intact sample of tissue from an identified breast mass in order to examine it and obtain a preliminary diagnosis.

COV: Close Out Visit

CPDMI: Clinical Protocol and Data Management Informatics

CR: Complete Response

CRA: Clinical Research Associate

CRC: Colorectal Carcinoma

CRF: Cancer Research Facility or Case Report Form

CRO: Contract Research Organization or Clinical Research Office

CRTC: Cancer Research & Treatment Center

CTEP: The Cancer Therapy Evaluation Program (listed as one of the NCI Division/Program Codes in CTRP), located within the Division of Cancer Treatment and Diagnosis, assesses new anticancer agents, radiation treatments, and surgical methods.

CT.GOV: www.ClinicalTrials.gov website

CTMS: The Clinical Trials Monitoring Service, a data service used to submit data on early phase trials to CTEP.

CTRO: NCI Clinical Trials Reporting Office

CTRP: NCI Clinical Trials Reporting Program

CTSU: Cancer Trial Support Unit (NCI)

D

Data monitoring Committee (DMC): A group of independent scientists who monitor the safety and scientific integrity of a clinical trial. The group can recommend to the study sponsor that the study be stopped if it is not effective, if it is causing harm to participants, or if it is not likely to serve its scientific purpose. Committee members are chosen based on the scientific skills and knowledge needed to monitor the particular study. Also referred to as a data safety and monitoring board (DSMB).

Data Table 4: The revised version of the NCI Cancer Centers Program's Summary 4 Report.

DCB: NCI's Division of Cancer Biology (listed as one of the NCI Division/Program Codes in CTRP) supports and facilitates basic research in all areas of cancer biology at academic institutions and research foundations across the United States and abroad.

DCCPS: NCI's Division of Cancer Control and Population Sciences (listed as one of the NCI Division/Program Codes in CTRP) supports a comprehensive program of genetic, epidemiologic, behavioral, social, and surveillance cancer research.

DCP: NCI's Division of Cancer Prevention (listed as one of the NCI Division/Program Codes in CTRP) supports research to determine and reduce a person's risk of developing cancer, as well as, research to develop and evaluate cancer screening procedures.

DCTD: NCI's Division of Cancer Treatment and Diagnosis (listed as one of the NCI Division/Program Codes in CTRP) supports the translation of promising research areas into improved diagnostic and therapeutic treatments for cancer patients.

DEA: NCI's Division of Extramural Affairs (listed as one of the NCI Division/Program Codes in CTRP) coordinates the scientific review of extramural research before funding, and provides systematic surveillance of that research after awards are made.

Delayed (Results) Submission (CT.gov): May be requested for an applicable clinical trial which:

a. Is completed before the drug or device is initially approved, licensed, or cleared by the FDA (i.e., “seeking *initial* approval”)
b. Is conducted to assess a new use of an FDA-approved drug or device (i.e., a use not included in the labeling) for which the manufacturer of a drug or device is the sponsor of the trial and has filed or will file within a year an application to the FDA for approval or clearance of that use (“seeking approval of a new use”)
c. Due to unforeseen circumstances, cannot be provided in the stipulated time frame (for instance, PI becomes ill or leaves the institution before a study is completed). By law the NIH may provide an extension of the deadline for submission of results information for an applicable clinical trial “…if the responsible party submits a written request that demonstrates good cause for the extension and provides an estimate of

the date on which the results information will be submitted." Note: "pending publication" is not viewed as a good cause for an extension.

DFI: Disease Free Interval

DFS: Disease Free Survival

Diagnosis: Identification of a condition, such as breast cancer, by its signs and symptoms and the results of laboratory tests or other examinations.

Diagnostic: Protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition.

Diagnostic procedure: Methods, procedures, and tests performed to diagnose disease, disordered function, or disability.

DNA: Deoxyribonucleic Acid

DSMB: Data Safety and Monitoring Board

DSMC (2011): Data Safety and Monitoring Committee (Formerly PMC)

DSMP: Data Safety and Monitoring Plan

DTP: NCI's Development Therapeutics Program (listed as one of the NCI Division/Program Codes in CTRP) is a program within the Division of Cancer Treatment and Diagnosis, which funds drug discovery and development and provides related services.

Dukes staging system: A system of staging rectal cancers developed by Cuthbert Duke in 1932. The original system had 3 stages but has been modified over time to include four stages with variations on two of the four stages.

Dysplasia: A term that refers to abnormal cells that have the potential to progress to cancer.

E

Early-Stage Breast Cancer: A term that can be used to describe stage I and II, lymph-node-negative breast cancer.

ECOG: Eastern Cooperative Oncology Group

EDC: Electronic Data Capture

Endoscope: A long slender medical instrument for examining the interior of a bodily organ or performing minor surgery.

Endoscopy: Visual examination of a bodily orifice, canal or organ using an endoscope.

ER (Estrogen Receptor): A feature (protein) that may be present on certain cells to which estrogen molecules can attach. The term "ER positive" refers to tumor cells that contain the estrogen-receptor protein. These cells are generally sensitive to hormone therapy.

eVelos: Velos, Inc. Electronic clinical research software systems

Expanded Access: A study type that addresses the process for obtaining an experimental drug or device for patients who are not adequately treated by existing therapy, who do not meet the eligibility criteria for enrollment on a clinical trial, or who are otherwise unable to participate in a controlled clinical study. Expanded Access records are used to register all types of non-protocol access to experimental treatments, including protocol exception, single-patient Investigational New Drug (IND), treatment IND, compassionate use, emergency use, continued access and parallel track. (Source: Protocol Registration System Information)

Extensible Markup Language (XML): A general-purpose markup language for creating special-purpose markup languages that is capable of describing many different kinds of data. Its primary purpose is to facilitate the sharing of data across different systems, particularly systems connected via the Internet.

External: Generated from research sites unaffiliated with the New Mexico Cancer Care Alliance.

F

Factorial Design: Describes a clinical study in which groups of participants receive one of several combinations of interventions. For example, a two-by-two factorial design involves four groups of participants. Each group receives one of the following pairs of interventions: 1) drug A and drug B, 2) drug A and a placebo, 3) a placebo and drug B, or 4) a placebo and a placebo. So during the trial, all possible combinations of the two drugs (A and B) and placebos are given to different groups of participants. One type of Intervention Model (Design).

FCOI: Financial Conflict of Interest disclosure

FDA: Food and Drug Administration. One of the agencies of the U.S. Department of Health and Human Services. It assures the safety of foods and cosmetics, and the safety and efficacy of pharmaceuticals, biological products, radiation emitting products, medical devices, and also, animal feed and drugs.

FDAAA: The Food and Drug Administration Amendments Act of 2007, P.L. 110-85 that defines requirements for clinical trials reporting to ClinicalTrials.gov.

FU: Follow up

G

Gastroenterologist: A physician who specializes in diseases of the gastrointestinal tract.

Gastroenterology: The branch of medicine that focuses on the digestive system and its disorders.

GCP: Good Clinical Practice (guidelines)

GCRC: General Clinical Research Center (UNM facility)

Gene: The functional and physical units of inheritance that are passed from parents to their offspring. The genes found in normal breast tissue can change their “expression” (see below), which can give rise to breast cancer.

Gene Expression: The level of activity of a gene or group of genes.

Gene Expression Profile: A picture of the activity or expression of multiple genes from a single specimen.

Genetics: The study of genes and heredity. Heredity is the passing of genetic information and traits, such as eye color or an increased chance of getting a certain disease, from parents to offspring.

Genome: The complete genetic material of a living thing

Genomic Test: A test that looks at groups of genes and how active they are. This activity can influence how a cancer is likely to grow and respond to treatment.

Genomics: The study of complex sets of genes, how they are expressed in cells (what their level of activity is), and the role they play in biology.

Grant number (NIH and/or NCI grants): A grant number is a series of a number of elements that identifies grants specifically funded by NCI or NIH, which provide the monies for the trials or infrastructure associated with the research.

> **Funding Mechanism:** A three-character code, located at position 2-4. It is used to identify areas of extramural research activity applied to funding mechanisms.
>
> **Institute Code:** A two-character code, position 5-6 which identifies the NIH Institute that directly funded the award. It identifies the first major-level subdivision and the organization that supports a grant, contract, or inter-agency agreement. The support may be financial or administrative.

Serial Number: A 6 digit number, position 7-12. Assigned sequentially to a series within an Institute, Center, or Division. Used as an identifier for the grant.

Suffix: A numeric or alphanumeric string, beginning in position 15. It is the code that identifies grant supplement, amendment or a fellowship's institutional allowance. Suffix designation follows the grant year.

Type: A single-digit code that appears at position 1 of the example. It identifies the type of application received and processed.

Year: A two-digit number, position 13-14 usually indicating the current year within an award. Indicates the actual segment or budget period of a project.

H

Hand Foot Syndrome (Palmar-Plantar Erythrodysesthesia): Also called hand-foot syndrome or hand-to-foot syndrome, Palmar-Plantar Erythrodysesthesia is a side effect, which can occur with several types of chemotherapy or biologic therapy drugs used to treat cancer. Leakage of the drug through the capillaries of the skin of the hands and feet can cause redness, tenderness, and peeling of the skin of the palms and soles.

Health Services Research: A protocol designed to evaluate the delivery, processes, management, organization or financing of health care.

Hereditary Nonpolyposis Colon Cancer (HNPCC): An inherited cancer syndrome. Individuals with HNPCC have an increased risk of developing colon and rectal cancer, as well as other types of cancer.

HIPAA: Health Insurance Portability & Accountability Act

HIPAA statement: A written statement, included within an Informed Consent Form or produced separately, written in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA is a set of rules followed by doctors, hospitals, and other health care providers and took effect on April 14, 2006. HIPAA helps ensure that all medical records, medical billing, and patient accounts meet certain consistent standards with regard to documentation, handling and privacy. Also, HIPAA requires that all patients be permitted access to their own medical records, correct errors or omissions, and be informed about how personal information is shared and used. For clinical research participants, it is important to provide specific information regarding those individuals and entities which may be permitted access to their private health information.

HOA: Hematology Oncology Associates

Hormonal Treatment (Hormone Therapy): Medications used to reduce the effect of hormones in the body. In many cases of breast cancer, hormones can fuel the growth of breast cancer. Common hormonal therapies include tamoxifen and a newer class of drugs called aromatase inhibitors. Hormonal therapies are used to treat women with estrogen-receptor-positive breast cancer.

Hormone Receptor: A protein on the surface of a tumor cell that binds to a certain hormone, activating tumor growth.

HRRC: Human Research Review Committee (UNM HSC IRB)

HSC: Health Sciences Center (UNM)

Human Genome Project: An international research and technology-development effort aimed at mapping and sequencing the entire genome of human beings.

Human Subjects Review Board: A group of people who review, approve, and monitor the clinical study protocol. Their role is to protect the rights and welfare of human research subjects participating in a study. The group typically includes people with varying backgrounds, including a community member, to make sure that research activities conducted by an organization are completely and adequately reviewed. Also known as an institutional review board (IRB) or ethics committee.

HUS: Radiation Control Committee Human Use Subcommittee (UNM)

I

IBC: Institutional Biosafety Committee (UNM)

ICF: Informed Consent Form

ICH: International Conference on Harmonization

IDE: Investigational Device Exemption, an FDA exemption that allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data.

IND: Investigational New Drug (application, FDA form 1571)

Informed Consent: A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of written, signed and dated informed consent form (ICF) document(s). For all CTO/NMCCA studies, ICFs and related HIPAA language must be prepared in both English and Spanish whenever possible and when approved by study sponsors, to best serve the CTO/NMCCA patient population.

In Situ: Non-invasive cancer in which abnormal cells are isolated within the lobes or milk ducts of the breast and have not spread to nearby tissue.

Institutional Review Board (IRB): An independent body constituted of medical scientific and non-scientific members, whose responsibility it is to ensure the protection of rights, safety and well-being of human subjects involved in a research study. This is accomplished, among other things, by reviewing, approving and providing continuing review (at least annually) of protocols and amendments, as well as the methods and materials to be used in obtaining and documenting informed consent of the trial subjects. The UNM IRB is known as the Human Research Review Committee (HRRC). UNM CC and NMCCA also use a centralized (national) IRB, named the Western Institutional Review Board or WIRB and the National Cancer Center's Centralized IRB.

Intervention: A process or action that is the focus of a clinical study. This can include giving participants drugs, medical devices, procedures, vaccines, and other products that are either investigational or already available. Interventions can also include noninvasive approaches such as surveys, education, and interviews.

Intervention Model (Design): The general design describing the strategy in which interventions will be assigned to participants in a clinical study. Types of intervention models include Single group design, Parallel design, Crossover design, and Factorial design.

Interventional trial: Studies in human beings in which individuals are assigned by an investigator based on a protocol to receive specific interventions. Subjects may receive diagnostic, therapeutic, behavioral or other types of interventions. The assignment of the intervention may or may not be random. The individuals are followed and biomedical and/or health outcomes are assessed.

Invasive Breast Cancer: Cancer that has spread from where it started in the breast into surrounding, healthy tissue. Most invasive breast cancers start in the ducts (tubes that carry milk from the lobules to the nipple). Invasive breast cancer can spread to other parts of the body through the blood and lymph systems. Invasive breast cancer is also called infiltrating breast cancer.

Investigational New Drug (IND): The legal mechanism under which experimental agent research is performed in the United States. An IND is submitted to the Food and Drug Administration (FDA) in order to receive an exception from premarketing approval requirements so that experimental clinical trials may be conducted.

Investigational New Drug (IND) Application: Treatment Investigational New Drugs (IND; *Federal Register*, May 22, 1987) are used to make promising new drugs available to ill patients as early in the drug development process as possible. FDA will permit an investigational drug to be used under a treatment IND if there is preliminary evidence of drug efficacy and the drug is intended to treat a serious or life-threatening disease, or if there is no comparable alternative drug or therapy available to treat that stage of the disease in the intended patient population. An Investigational New Drug Application (IND) is a request for authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug or biological product that is not the subject of an approved New Drug Application or Biologics/Product License Application.

Investigator: The principal investigator, the co-principal investigator, and any person (whether faculty, staff, student, consultant, or collaborator) who is responsible for the design, conduct, or reporting of a UNM research activity. Any individual responsible for a task that could have a significant effect on the design, conduct, or reporting of a project is considered to be an "**investigator**," even if that individual does not have sole or primary responsibility for the task or the activity undertaken. This term is not synonymous with key personnel.

IRB: Institutional Review Board. A specially constituted independent review body comprised of medical, scientific, and non-scientific members established and designated by an entity to ensure the protection of the rights, safety and well-being of human subjects recruited to participate in biomedical or behavioral research according to the requirements outlined in Title 38, part 16 (same as Title 45, part 46 and Title 21, part 56) of the U.S. Code of Federal Regulations. IRB responsibility include but not limited to the reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material(s) to be used in obtaining and documenting informed consent of the trial. Other equivalent committees with the same or similar functions are also considered to be IRBs.

IV: Intravenous

IVRS: Interactive Voice Response System

J

JCAHO: Joint Commission on Accreditation of Healthcare Organizations

L

Lead organization: The organization responsible for the overall scientific and administrative coordination, study monitoring, and data management activities of a particular clinical trial.

Lead organization trial identifier: One or more characters assigned by the organization providing oversight for the study to identify, name, or characterize the protocol document.

Local Recurrence: The reappearance of cancer in the part of the body where it first occurred.

LTFU: Long Term Follow Up

Lumpectomy: A surgical procedure that removes a localized mass of tissue, including the breast cancer tumor and a small amount of normal, non-cancerous tissue surrounding the tumor.

M

Malignant: Tending to be severe and become progressively worse; a malignant tumor is one that has the ability to invade and destroy nearby tissue and/or spread (metastasize) to other parts of the body.

Mastectomy: A surgical procedure to remove all or a large part of the breast.

MBCCOP: Minority-Based Community Clinical Oncology Program (NCI)

Metastasize: A term that is used to refer to cancer spreading from its site of origin to other sites in the body.

Metastatic Breast Cancer: Breast cancer that has spread beyond the breast and local lymph nodes to other parts of the body such as the lungs, liver, brain or bones or other tissues.

Molecular Diagnostics: The measurement of DNA, RNA, proteins or metabolites to detect genotypes, mutations or biochemical changes.

MOU: Memo of Understanding

MSRC: Medical Scientific Review Committee (NMCC Alliance)

N

NCAB: The National Cancer Advisory Board (NCAB). Advises the HHS secretary and the NCI director with respect to the activities of the NCI, including reviewing and recommending for support grants and cooperative agreements, following technical and scientific peer review.

NCCTG: North Central Cancer Treatment Group – as of 2014 (NCI)

NCI: National Cancer Institute

NCI-supported (trials): All trials sponsored or otherwise financially supported by NCI.

Newly Diagnosed: A term used to describe breast cancer that has recently been identified.

New Trial (CTRP): A trial that opened to accrual on or after January 1, 2009 and has not been reported previously to CTRP.

NMCCA: New Mexico Cancer Care Alliance or New Mexico Cancer Care Associates (Santa Fe)

NMOHC: New Mexico Oncology Hematology Consultants

NMR: Nuclear Magnetic Resonance (scan)

Node-Negative Breast Cancer: Breast cancer that has not spread to the lymph nodes.

Node-Positive Breast Cancer: Breast cancer that has spread to the lymph nodes (most commonly the axillary lymph nodes under the arms).

Non-interventional studies: Studies in human beings in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study

Non-publicly traded entity: Refers to any domestic or foreign organization owned by non-governmental organizations or by a relatively small number of shareholders or company members which does not offer or trade its company stock (shares) to the general public on the stock market exchanges, but rather the company's stock is offered, owned and traded or exchanged privately.

NSABP: National Surgical Adjuvant Breast and Bowel Project (NCI)

NSCLC: Non-Small Cell Lung Cancer

O

Observational trials/studies: Studies among cancer patients and healthy populations that involve no interventions or alteration of the participants

OD: NCI's Office of the Director (listed as one of the NCI Division/Program Codes in CTRP).

OGA: NCI's Office of Grants Administration manages all NCI business-related activities associated with the negotiation, award, and administration of grants and cooperative agreements.

OHRP: Office of Human Research Protections

Oncologist: A physician who specializes in the study and treatment of tumors.

Oncology: The study and treatment of cancer.

Oncotype DX® Test: The Oncotype DX breast, colon, and prostate cancer assays are unique diagnostic tests that help patients and their physicians make informed, individualized treatment decisions. To learn more about the Oncotype DX tests for DCIS, breast, colon and prostate cancer please visit the Oncotype DX product website or call Tel: +1 (888) ONCOTYPE

OS: Overall Survival

OSB/SPOREs: NCI's Organ Systems Branch/Specialized Programs of Research Excellence (listed as one of the NCI Division/Program Codes in CTRP).

P

Pathologist: Physician who identifies diseases by studying cells and tissues under a microscope.

Pathology Report: A report ordered by authorized healthcare professionals that describes what was found in tissue removed from the patient's body. The report is generated after the tumor and surrounding tissue are checked by a pathologist. It usually includes information on the tumor's grade and stage.

PCR: Polymerase Chain Reaction

PET: Positron Emmission Tomography (scan)

PFS: Progression Free Survival

Phase (trial): Phase of investigation, as defined by the US FDA for trials involving investigational new drugs

Phase 0 (trial): Exploratory trials, involving very limited human exposure, with no therapeutic or diagnostic intent (e.g., screening studies, microdose studies)

Phase I (trial): Includes initial studies to determine the metabolism and pharmacologic action of drugs in humans and the side effects associated with increasing dose may include healthy participants and/or patients.

Phase I/II (trial): For trials that are a combination of Phases 1 and 2.

Phase II (trial): Includes controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks.

Phase II/III (trial): For trials that are a combination of phases 2 and 3

Phase III (trial): Includes expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained. Phase III trials are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling

Phase IV (trial): Studies of FDA-approved drugs to delineate additional information including the drug's risks, benefits, and optimal use

Phase-N/A (trial): For trials without phases. This includes pilot trials in CTRP.

PI: Principal Investigator

Pilot Trials: The initial study examining a new method or treatment.

PIO: A Protocol and Information Office within NCI's CTEP and DCP that is responsible for registering and reporting accrual data associated with the interventional trials they manage to CTRP.

PMC: Protocol Monitoring Committee

Polyethylene glycol: An electrolyte-based laxative solution used to clean the bowel before a gastrointestinal exam.

Polyp: A usually nonmalignant growth or tumor protruding from the mucous lining of an organ, such as the colon. Colon polyps are fleshy growths that occur on the inside (the lining) of the large intestine.

Possibly Related: An event is more likely than not related to participation in the research or, in other words, there is a >50% likelihood that the event is related to the research procedures.

PR (Progesterone Receptor): A feature (protein) that may be present on certain cells to which progesterone molecules can attach. The term “PR positive” refers to tumor cells that contain the progesterone receptor protein. These cells are generally sensitive to hormone therapy.

PR: Partial Response

Predispose: To make more likely or render susceptible.

Prevention: Protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition

Primary Completion Date: the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated.

Primary Purpose - Reason for the protocol. The primary purpose of protocols is classified as follows:

> **Basic Science:** Protocol designed to examine the basic mechanism of action (e.g., physiology, biomechanics) of an intervention.
>
> **Diagnostic:** Protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition.
>
> **Health Services Research:** Protocol designed to evaluate the delivery, processes, management, organization or financing of health care.
>
> **Prevention**: Protocol designed to assess one or more interventions for preventing, or decreasing the chance of getting, a specific disease or condition. For example, cancer prevention may include avoiding risk factors and increasing protective factors.
>
> **Screening**: Protocol designed to assess or examine methods of identifying a condition (or risk factors for a condition) in people who are not yet known to have the condition (or risk factor).
>
> **Supportive Care:** Protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects or mitigate against a decline in the subject's health or function. In general, supportive care interventions are not intended to cure a disease.
>
> **Treatment**: Protocol designed to evaluate one or more interventions for treating a disease, syndrome or condition.
>
> **Other:** Protocol not in other categories, and is defined in free text.

Principal Investigator (PI): Name of the physician who has organizational and fiscal responsibility for the use of federal funds to conduct a clinical study.

PRMC (2011): Protocol Review and Monitoring Committee (formerly MSRC)

Program Code: A unique reference code (e.g., 01, 02, or GYN, GU) assigned by the Cancer Center to each program and reported to CTRP at time of initial trial registration.

Protocol Amendment: A written description of a change or changes to, or formal clarification of a specific protocol. For NCI studies, similar changes are often issued in protocol “Revisions” and “Updates” which also may require IRB approval.

Protocol Deviation Exception: A divergence or departure from the expected conduct of an approved study that is not consistent with the current research protocol, consent document or study addenda that has been anticipated and has not been defined by this SOP or applicable regulation or guideline as a reportable deviation.

Protocol Deviation: A divergence or departure from the expected conduct of an approved study that is not consistent with the current research protocol, consent document or study addenda that had not been anticipated.

Protocol: A document that describes the objective(s), background research, rationale, design, methodology, statistical considerations, and organization of a research study (clinical trial). Throughout the ICH GCP Guideline, the term protocol refers to protocol documents and protocol amendment documents.

PRS: Protocol Registration System (software system used for reporting to CT.GOV)

PSA (Prostate-specific antigen): A protein exclusively produced by the prostate. Increased levels of PSA may be found in the blood of men who have prostate cancer or other prostate diseases such as BPH (benign prostatic hyperplasia) or inflammation of the prostate.

Publicly traded entity: Refers to any domestic or foreign, public organization (excluding a Federal agency) that offers its securities (stocks/shares, bonds/loans, etc.) for sale to the general public, typically through a stock exchange or through market makers operating in over the counter markets.

Q

QA: Quality Assurance

QC: Quality Control

QID: Four times a day (quater in die)

QOL: Quality of Life

R

Radiation Therapy: The use of radiation to destroy cancer cells. Radiation therapy may be used before or after surgery, and is sometimes used in combination with chemotherapy. Radiation is used for local control of the cancer at the site of the tumor.

RCC: Renal Cell Carcinoma

RECIST: Response Evaluation Criteria in Solid Tumours

Recurrence: The return of cancer after treatment. This can be either local (at the site of the original tumor), or distant (beyond the original site).

Registration (as it pertains to CTRP trial): The initial clinical trial data provided to CTRP by an NCI-awardee and/or site.

Related: Evidence to suggest a causal relationship between the drug and the adverse event.

Reportable Protocol Deviation: A divergence or departure from the expected conduct of an approved study that is not consistent with the current research protocol, consent document or study addenda that had not been anticipated in which the subject's rights, safety, well-being or the data integrity of the study has been compromised.

Resection: Surgery to remove a cancer and some surrounding tissue.

Responsible Party: The sponsor of the clinical trial (as defined in 21 CFR 50.3 or any successor regulation) or the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements for the submission of clinical trial information. (NOTE: For NMCCA trials, the sponsor is the NMCCA and not the study PI).

RFS: Relapse Free Survival

RNA: Ribonucleic Acid

ROA: Radiation Oncology Associates

RT: Radiotherapy

RTOG: Radiation Therapy Oncology Group (NCI)

RT-PCR: Reverse Transcription Polymerase Chain Reaction

Rx: Treatment

S

SAE: Serious Adverse Event

Sarcoma: A malignant tumor growing from connective tissues, such as cartilage, fat, muscle, or bone.

SC: Subcutaneous

SCC: Squamous Cell Carcinoma

SCLC: Small Cell Lung Cancer

Screening (for breast cancer): Looking for masses or suspicious areas in breast tissue on a periodic basis.

Screening (for colon cancer): Looking for masses or suspicious areas in colon tissue on a periodic basis.

Screening: Protocol designed to assess or examine methods of identifying a condition (or risk factors for a condition) in people who are not yet known to have the condition (or risk factor).

SD: Stable Disease

SDV: Source Data Verification

Serious Adverse Event: Any event temporally associated with the subject's participation in research that meets any of the following criteria:

- Results in death
- Is life threatening (places the subject at immediate risk of death from the event as it occurred)
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in a persistent or significant disability/incapacity
- Results in a congenital anomaly/birth defect

Sigmoidoscopy: Inspection through a fiber-optic scope of the inside of the sigmoid colon, which is part of the large intestine that empties into the rectum. The test is useful for diagnosing the cause of diarrhea, constipation, or abdominal pain, and for identifying cancerous tissue.

SIM: Site Initiation Meeting

SIV: Site Initiation Visit

SoCRA: Society of Clinical Research Associates

SOP: Standard Operating Procedure

Sponsor: Primary organization that oversees implementation of the study and is responsible for data analysis. [21 CFR 50.3] Sponsor means a person who initiates a clinical investigation, but who does not actually conduct the investigation, i.e., the test article is administered or dispensed to or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., corporation or agency) that uses one or more of its own employees to conduct a clinical investigation it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.

Stages of Breast Cancer:

> **Stage I Breast Cancer:** The tumor is up to 2 centimeters in diameter and has not spread beyond the breast.
>
> **Stage IIA Breast Cancer:** The tumor is up to 2 centimeters and has spread to the axillary lymph nodes under the arm, or the tumor is between 2 and 5 centimeters and has not spread to the lymph nodes.
>
> **Stage IIB Breast Cancer:** The tumor is between 2 and 5 centimeters and has spread to the lymph nodes under the arm, or the tumor is larger than 5 centimeters in diameter and has not spread to the lymph nodes.
>
> **Stage IIIA Breast Cancer:** The tumor is larger than 5 centimeters in diameter and has spread to the lymph nodes under the arm, or the tumor is any size and has spread more extensively in the lymph nodes.
>
> **Stage IIIB Breast Cancer:** The tumor is any size and has extended to other tissues near the breast; the tumor may or may not have spread to the lymph nodes.
>
> **Stage IV Breast Cancer:** Cancer that has spread (metastasized) to other locations in the body, such as the lungs, liver, bones or brain.

Staging: Describes the severity of a person’s cancer based on the size and/or extent (reach) of the original (primary) tumor and whether or not cancer has spread in the body

Status Change: Status changes include changes in the overall status of the trial (e.g., a change from active to temporarily closed to accrual, a change from temporarily closed to accrual to complete, etc).

Submitting organization: Awardee and/or site who is supplying trial data to NCI's Clinical Trials Reporting Program (CTRP).

Supportive care: Protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects or mitigate against a decline in the subject's health or function. In general, supportive care interventions are not intended to cure a disease.

Surveillance/Follow-Up: An ongoing assessment by a patient´s medical team, once treatment has been completed, to assess the cancer´s remission and to look for any evidence of a cancer´s return.

SUSAR: Suspected Unexpected Series Adverse Reaction is a serious adverse reaction in a subject given a drug that may or may not be dose related, but are unexpected, as they are not consistent with current information.

SWOG: Southwest Oncology Group (NCI)

Synchronous cancer: Multiple primary cancers occurring simultaneously.

Syndrome: A set of signs and symptoms that tend to occur together and which reflect the presence of a particular disease or an increased chance of developing a particular disease.

T

TAILORx: Although the Oncotype DX test has already been approved for use, research involving the test is ongoing. The Oncotype DX test plays a key role in a current clinical trial, the Trial Assigning IndividuaLized Options for Treatment (Rx), known as TAILORx. Participants will be divided into different treatment groups depending on their Recurrence Score® results. Patients with Recurrence Score results of less than 11, who are at low risk for recurrence and for whom chemotherapy is expected to provide little benefit, will receive hormone therapy alone. Patients with Recurrence Score results greater than 25, who are at higher risk for recurrence and for whom chemotherapy is expected to provide substantial benefit, will receive hormonal therapy and chemotherapy. Patients with Recurrence Score results between 11 and 25, whose risk for recurrence is moderate and for whom the benefit of chemotherapy is unclear, will be randomized to treatment with hormonal therapy plus chemotherapy versus hormonal therapy alone. The primary objective of the trial is to determine whether hormonal therapy alone offers no less benefit than chemotherapy plus hormonal therapy in women whose Recurrence Score results range from 11 to 25.

Tamoxifen: A medication that interferes with the activity of the hormone estrogen to prevent it from fueling the growth of breast cancer. Tamoxifen is used to treat women with estrogen-receptor-positive breast cancer.

TCC: Transitional Cell Carcinoma

TID: Three times a day (ter in die)

TNM Classification of Malignant Tumors (TNM): A cancer staging system that describes the extent of cancer in a patient´s body. TNM literally describes Tumor/Nodes/Metastasis. T describes the size of the tumor and whether it has invaded nearby tissue, N describes the number of regional lymph nodes that are involved, and M describes the presence of other

metastases. This system is jointly maintained by the International Union Against Cancer (UICC), and the American Joint Committee on Cancer.

Treatment Monitoring: An ongoing and frequent assessment by the medical team, during the time of treatment, to monitor how the patient is tolerating the treatment and how the cancer is responding.

Treatment: Protocol designed to evaluate one or more interventions for treating a disease, syndrome or condition.

Trial status: The current stage or state of a clinical trial or study relative to other stages and its ability to enroll participants / patients. Trial status types include: Approved; Active; Temporarily Closed to Accrual and Intervention; Temporarily Closed to Accrual; Administratively Complete; and Complete.

Trial type: Nature of the investigation that includes interventional, non-interventional (observational and ancillary/correlative), and expanded access studies.

Tumor Grade: The characterization of a tumor based on how similar in appearance the cancer cells are to normal cells, and on how many of those tumor cells are dividing. Tumor grade is one of many factors that, when used in combination, can indicate how aggressive a patient's cancer is.

Tumor Stage: This is a number that refers to the size of the tumor and whether the cancer has spread. Tumor stage, expressed as the tumor T score, is one of many factors that, when used in combination, can indicate how aggressive a patient's cancer is.

Tumor: Tissue growth where the cells that make up the tissue have multiplied uncontrollably. A tumor can be benign (non-cancerous) or malignant (cancerous).

U

Ulcerative colitis: A disease where sores, or ulcers, form in the top layers of the lining of the large intestine. Inflammation usually occurs in the lower part of the colon and rectum.

ULN: Upper Limits of Normal

Unanticipated: Any problem, incident, experience of outcome that is unexpected, related or possibly related AND places subject or others at a greater risk of harm than was previously known or recognized.

Unexpected: An adverse event or a suspected adverse reaction is considered "unexpected" if it is not listed in the investigator brochure or is not listed at the specificity or severity that has been observed; or if an investigator brochure is not required or available, is not consistent with the

risk of information described in the general investigational plan or elsewhere in the current application, as amended.

UNM CC: UNM Cancer Center

UNM: University of New Mexico

Update: Changes to the protocol that do not substantively affect the scientific conduct of the study, the study design, and/or the sites in which patients are being enrolled on the trial (e.g., all changes to the protocol that do not fall into the definition of amendments).

US: Ultrasound (scan)

V

VA: Veterans Administration

W

WIRB: Western Institutional Review Board

Wire Localization Biopsy: A type of biopsy performed when an abnormality can be seen on a mammogram but cannot be felt. A wire localization biopsy utilizes a mammogram to locate and identify the breast abnormality, after which a biopsy is performed.

X

XRT: External Radiotherapy