Abbreviations and Terms

A

AAALAC

Association for Assessment and Accreditation of Laboratory Animal Care

ADIS

Academic Department Information System: addresses record retention of specified faculty academic records including scholarly publications, research funding, faculty appointments, clinical service and teaching. ADIS is the sole repository of these records. ADIS is a UNMC-wide repository, but is not NU system-wide.

B

BMC

Bellevue Medical Center

Biobank

A biobank or tissue bank stores human biological material (HBM) to provide a resource for future, unspecified research. A bio/tissue bank may be created from leftover/extra tissue collected during a research study or non-research clinical procedure.

BPF

Biologics Production Facility is a Good Manufacturing Practices (GMP) compliant facility for the manufacture, processing, cryopreservation, and/or storage of cells, tissues, and cellular and tissue-derived products for administration to humans, such as bone marrow, peripheral blood stem cells, cord blood cells, and vaccines.

C

Cayuse

UNMC's Web-based tool for preparing and submitting NIH applications to grants.gov. In addition, Cayuse will support submissions to most other federal agencies, including HRSA, AHRQ, CDMRP, and NSF

CDA

Confidentiality Disclosure Agreement

CCORDA

Center for Collaboration on Research Design and Analysis is a UNMC center that provides expertise in the quantitative sciences, including biostatistics, epidemiology, and health services research, and coordinates the collaborative design, planning, conduct, analysis and interpretation of laboratory, clinical, and public health research studies.

CRC

Clinical Research Center is a centralized clinical research unit on the UNMC/Nebraska Medicine campus that supports a broad range of sponsored, investigator-initiated, and cooperative trials, and

monitors multi-center trials. The CRC provides many services for a clinical research trial and administrative support to the clinical investigator.

CTMM

Clinical Trial Master Matrix is an Excel spreadsheet workbook that records basic information about a clinical trial with protocol-specific scheduling of research- related procedures/treatments and details how these will be billed. The CTMM functions as a “stand-alone” document serving as a resource for authorized personnel who do not have immediate access to the contract, budget, and/or protocol.

CFR

Code of Federal Regulations the codification of the general and permanent rules and regulations of the federal government of the United States.

CITI

Collaborative Institutional Training Initiative: Web-based training program in the protection of human subjects, which all personnel involved in the conduct of human subject research at UNMC are required to complete.

CMAG

Comparative Medicine Advisory Group: A campus-wide advisory group that maintains and improves the quality of research animal facilities, equipment and services.

CMMS

Comparative Medicine Business Management System: An online software system that integrates the IACUC and the SPAdmin databases to enhance campus regulatory compliance.

COIC

Conflict of Interest Committee: The UNMC COI Committee (COIC) is appointed and operates in accordance with UNMC Policy No. 8010 and is responsible for reviewing potential conflicts of interest which have been determined to be significant by the COI Officer/designee.

CRO

Contract Research Organization

CRSO

Chemical and Radiation Safety. *See* EHS.

CRFCS

Clinical Research Financial Compliance Specialist

CTA

Clinical Trial Agreement

D

DSM

Data Safety Monitoring. Procedures set up before the start of human subject research monitoring data to ensure subject safety, considering the risks, complexity, and nature of the research.

DUNS

Data Universal Numbering System, https://www.unmc.edu/spa/about/institutional.html

E

EHS

Department of Environmental Health & Safety: The department provides a broad range of services to the University to promote the protection of patients, students, faculty and administrative staff of the University, as well as the larger community and environment regarding the use, storage and disposal of chemicals and radiation on campus. https://www.unmc.edu/ehs/

EIN

Entity Identification Number, https://www.unmc.edu/spa/about/institutional.html

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F

F&A

Facilities & Administrative rate Current agreement

FICE

Federal Interagency Committee on Education institutional code, https://www.unmc.edu/spa/about/institutional.html

FWA

Human subject Federal Wide Assurance number, https://www.unmc.edu/spa/about/institutional.html

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H

HRPP

Human Research Protection Program is a comprehensive system to ensure the protection of human subjects participating in research. UNMC's HRPP consists of four IRBs, other review committees, administrative offices, and administrative officials.

I

IDE

Investigational New Device Exemption. An investigational new device exemption (IDE) is an application submitted to FDA to conduct a clinical investigation with an investigational device subject to 21 CFR 812.2 and classified as an SRD. The IDE is submitted by the sponsor of the research. The FDA will provide a written authorization to conduct a clinical investigation within 30 days after receipt of the IDE. If the device is not an SRD, the investigation is considered by the FDA to have an approved IDE unless the FDA notifies the sponsor otherwise.

IND

Investigational New Drug Application to FDA by sponsor to obtain an exemption that allows a new drug to be transported or distributed across state lines to facilitate testing diagnostic or therapeutic potential in humans. There are three IND types – Investigator IND, Emergency Use IND, Treatment IND4. There are two IND categories – Commercial and Research IACUC Institutional Animal Care and Use Committee A review committee to oversee and evaluate all aspects of the institution's animal care and use program involving any vertebrate.

IBC

Institutional Biosafety Committee by Federal law this committee is charged with the planning and implementation of the campus Biosafety Program to ensure the health and safety of all personnel

working with biohazardous agents.

IRB

Institutional Review Board: is a board composed of members from scientific disciplines and individuals from the community, it assists investigators in the protection of the rights and welfare of human subjects in research projects conducted by anyone on the premises of UNMC, Nebraska Medicine, Children's Hospital & Medical Center (CH&MC), and the University of Nebraska at Omaha (UNO).

IPF

Institutional Profile File number, https://www.unmc.edu/spa/about/institutional.html

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M

MSP&T

Medical Staff Pharmacy and Therapeutics Committee. Clinical trials which use medication or investigational products supplied to the institution from a sponsor must have the protocol reviewed by this committee.

MTDC

Modified Total Direct Cost: Includes salaries and wages, fringe benefits, materials and supplies, services, travel, and subgrants and subcontracts up to the first $25,000 of each subgrantor subcontract (regardless of the period covered by the subgrant or subcontract). MTDC excludes equipment (defined as having a useful life of over one year and an acquisition cost of $5,000 or more per unit), capital expenditures, charges for patient care and tuition remission, rental costs, scholarships and fellowships, as well as the portion of each subgrant and subcontract in excess of $25,000.

N

NCT Number

A unique identification code assigned to each clinical study registered on ClinicalTrials.gov. The format is the letters "NCT" followed by an 8-digit number (for example, NCT00000419). Also called a ClinicalTrials.gov identifier.

NRC

Nuclear Regulatory Commission license number, https://www.unmc.edu/spa/about/institutional.html

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O

ORA

Office of Regulatory Affairs department that exercises oversight for UNMC's Human Research Protection Program (HRPP)

One Chart

Electronic Health Record system used at Nebraska Medicine, UNMC-Physicians, Nebraska Medicine - Bellevue, and Children's Hospital & Medical Center.

P

Part 11 Compliance

Refers to the part 11 of Title 21 of the Code of Federal Regulations; Electronic Records; Electronic

Signatures (21 CFR Part 11). When participating in human subject research, sponsors require verification that the Nebraska Medicine electronic medical record system is compliant with these regulations. Documentation to verify this compliance is provided by UNMC/Nebraska Medicine with the following letter at https://www.unmc.edu/spa/_documents/21cfrpart11document8412.pdf

PRO

Pediatric Research Office. The clinical research unit supporting Pediatric Clinical Research at UNMC/NEMed and Children's Hospital & Medical Center, PRO provides many services for clinical research trials and administrative support to clinical investigators.

PRMS

Protocol Review and Monitoring System. The PRMS of the Fred & Pamela Buffett Cancer Center provides central management and oversight functions for all cancer-related trials involving human subjects conducted by members of the cancer center.

R

RITO

Research IT Office is a core facility on the UNMC campus that serves the growing information technology needs of the research community.

S

SRC

PRMS Scientific Review Committee: this review committee is a mandatory element of a National Cancer Institute (NCI) designated Clinical Cancer Center. The SRC oversees the scientific aspects of cancer-related research involving human subjects and conducted by members of the University of Nebraska Medical Center (UNMC) faculty and students, and members of the Fred & Pamela Buffett Cancer Center.

SAP

The centralized accounting system used by NU system campuses.

SPAccting

Sponsored Programs Accounting

SPAdmin

Sponsored Programs Administration

T

TIN

Federal Tax Identification Number, https://www.unmc.edu/spa/about/institutional.html

Tissue Bank

A biobank or tissue bank is a repository of human biological material (HBM) that provides resources for future, unspecified research.

U

UNeHealth

The front door for industry-sponsored, clinical research contracting for UNMC and Nebraska Medicine. Led by representatives from these entities, UNeHealth centralizes and streamlines processes between the organizations.

UNeMed

UNeMed is a for-profit corporation owned by the Board of Regents of the University of Nebraska. UNeMed is responsible for a spectrum of technology transfer activities, including protecting, marketing and commercializing UNMC inventions.

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