Resources for Clinical Research

Introduction

UNMC has developed many resources for clinical and translational research through the Center for Clinical and Translational Research (CCTR) as well as partnerships with other collaborators.

Center for Clinical and Translational Research (CCTR)

The CCTR serves as a repository of clinical research resources, policies, education and training opportunities, and has navigators to assist researchers conducting clinical and translational research. The CCTR managed core facilities include the Clinical Research Center, the Electronic Health Record Access Core, The Nebraska Biobank, and the Research Subject Advocate Office.

Clinical Research Center

The Clinical Research Center (CRC) is an outpatient clinical research facility that supports a broad range of clinical trials. The CRC contains exam rooms, procedure rooms, a dental/ENT room, a treadmill room, a phlebotomy room, a coordinator/investigator workroom, and a processing lab. Skilled research nurses in the CRC can also assist with inpatient protocols and serve as monitors for multi-center clinical trials. Facility use and personnel support are available on a fee-for-service basis to researchers.

The CRC can provide research assistance in all aspects of developing and conducting a clinical trial. These services can include but are not limited to:

- Developing and negotiating a budget
- Coverage analysis
- Preparing and submitting IRB documents
- Case report form and order set development
- Study recruitment
- Coordinating study visits and data collection
- Administering study infusions and monitoring patients for adverse events
- Sample drawing/processing and shipping
- Monitoring multi-center protocols and working with the investigator to develop an appropriate monitoring plan.
- Providing research support for pilot studies involving our faculty.
- Providing mentoring and education for new coordinators on campus.
- Assisting with development of advertisements and brochures

Electronic Health Record Data Access Core

The Electronic Health Record Data Access (EHR) core supports requests to assess the available patient population prior to initiating a clinical trial, as well as preparation of de-identified and well-annotated dataset queries of the electronic health record, including both legacy and new Epic data.

Nebraska Biobank

The Nebraska Biobank is a bio-repository of de-identified human biological material (HBM) (serum/plasma, and DNA) isolated from left-over patient blood samples collected at the UNMC/Nebraska Medicine clinics and facilities.

Research Subject Advocate Office

The Research Subject Advocate (RSA) Office was created as one of several mechanisms to ensure the highest level of protection for participants in a clinical research study.

The Research Subject Advocate:

- assists UNMC clinical and translational researchers in developing protocols that minimize

research subject risk and optimize benefits.
- facilitates development of consent/assent documents and processes to clearly communicate to potential participants risks and benefits of the research.
- provides education and advocacy to support the safe conduct of clinical research.
- is available to research participants who are directed to the RSA office if they have concerns regarding a research study in which they are participating, or if they have questions about research in general.

Research Clinical Informatics Lead

The Research Clinical Informatics Lead (CIL) is a resource for One Chart and other Clinical Information Systems (CIS). The Research CIL is available to assist with One Chart questions, training requests, workflow development, OrderSet/SmartSet requests, One Chart documentation tool requests, and the use of One Chart to assist with patient recruitment. The Research CIL is primarily responsible for One Chart requests but may also assist in the implementation and development of workflows for other Clinical Information Systems.

The Child Health Research Institute (CHRI)

The Child Health Research Institute aims to create vibrant interfaces between biomedical, genomics and computational approaches to drive innovative clinical and translational studies.

The CHRI is home to the Pediatric Research Office (PRO), a team of research nurses, coordinators, administrators, and support staff that oversees pediatric research being conducted at Children's Hospital and Medical Center and Nebraska Medicine.

More information about the CHRI and the PRO is available on their website.

Investigational Pharmacy

The Nebraska Medicine Investigational Drug Service provides custom pharmaceutical services for the clinical and translational researcher. The Investigational Drug Service Pharmacist is available to address questions or concerns regarding pharmaceutical and investigational agents used in clinical trials. Contact the Investigational Drug Services Pharmacist at 402-559-5255 or view additional contact information on their website.

Study Design, Biostatistics, and Epidemiology Consultation/Resources

The Center for Collaboration on Research Design and Analysis (CCORDA) 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.

Requests for CCORDA services may be made by contacting the Center Director or Associate Director or by completing a request for consultation using the CCORDA online request web page. Investigators who have previously worked with other CCORDA members may contact the center member directly.

Study Data Management Resources

Research Electronic Data Capture (REDCap) software.

REDCap is an open-source clinical research management tool developed by Vanderbilt University, as part of its Clinical Translational Science Award (CTSA). UNMC is one of over 870 institutions in 71 countries that host this program designed to build, manage, and support clinical research including secure on-line surveys and databases. Additional information may be available on the Project REDCap website.

The UNMC Research IT Office (RITO) can orient investigators in its use and hosts the REDCap database.

Clinical Trial Management System

The Clinical Trial Management System (CTMS) is available to UNMC and Nebraska Medicine researchers. The CTMS supports centralized management of therapeutic protocols and subjects. The CTMS allows administrative, regulatory, financial, and clinical functions to interact in a centralized area.

Additional information and training on the CTMS is available through the CCTR training website.

Forte Electronic Data Capture

Forte's Electronic Data Capture System (EDC) is targeted to assist investigator initiated trials (IIT's). The EDC allows a research team to record subject clinical data through forms, customized by the CTMS Analysts, specifically for your study. Forte EDC is validated as 21 CFR part 11 compliant.

Additional information and training on the Forte EDC is available through the CCTR training website.

Centralized Protocol & Data Management Unit of the Fred & Pamela Buffett Cancer Center

Centralized Protocol & Data Management Unit is a shared resource that provides centralized support for protocol development, quality assurance monitoring, coordination of regulatory agency compliance requirements, and evaluation of clinical research at the Fred & Pamela Buffett Cancer Center.

Center for Collaboration on Research Design and Analysis (CCORDA)

CCORDA can establish a research study database for any study on which they are collaborating.

Biobanks and Data Registries

There are a number of biobanks available to investigators:

- The Nebraska Biobank for DNA and serum linked to de-identified health information.
- Disease specific cancer biobanks and data registries

Revision #4
★ Created Mon, Sep 16, 2019 8:00 PM by James Geiger
Updated Tue, Oct 22, 2019 8:28 PM by James Geiger