Clinical Trials

Information relevant to clinical trials can be found on the pages within this section. While SPAdmin is involved in parts of these projects, the majority of the effort is handled by UNeHealth and the CRC's clinical research billing team.

UNeHealth (Industry-Sponsored Clinical Trials)

UNeHealth is the contracting and fiscal arm for industry-funded clinical trials on behalf of University of Nebraska Medical Center. It is housed under Center for Clinical and Translational Research (CCTR), operating under the direction of Dr. Christopher Kratochvil, Chief Medical Officer for UNeHealth and Associate Vice Chancellor for Clinical Research.

Clinical Research Billing

The Clinical Trial Master Matrix (CTTM) is a tool that is used to record basic information about a clinical trial along with protocol specific scheduling of research related procedures/treatments and details on how these procedures/treatments will be billed. A CTTM or "Matrix" must be completed for any study that includes clinical care activities conducted at Nebraska Medicine, UNMC, or UNMC-Physicians clinics or facilities irrespective of funding. Information on the Matrix and UNMC's policy for Clinical Trial Billing (#8008) can be found on the UNMC policy wiki.

- UNeHealth
- Clinical Research Billing

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Which Contracts Run Through UNeHealth

UNeHealth contracts include:

- CDAs (non-disclosure agreements)
- Clinical trial agreements involving investigational drugs or devices
- Master clinical trial agreements
- Compassionate use agreements
- Emergency use agreements
- PI-initiated clinical trial agreements
- Material transfer of drug related to patient-oriented research or compassionate use

Submit a New Contract

All new clinical trial submissions are to be submitted through the CRC.
Instructions for submission can be found on their Intake Form page.

The following documents will be required by UNeHealth to begin negotiation:

- Editable contract template from sponsor
- Protocol

Your email communication with the sponsor may also provide valuable information to UNeHealth to help ensure timely negotiation.

UNeHealth Information for Sponsors (Tax ID, etc)

Sponsors typically require information from sites for the purpose of setting up contract templates, vendor payment systems, etc. In most cases, they request this information from clinical coordinators, so it is important for coordinators to understand that the information for UNeHealth

contracts is different than for UNMC contracts. Please share UNeHealth information for the following when working with an industry sponsor:

- CDAs (non-disclosure agreements)
- Clinical trial agreements involving investigational drugs or devices
- Master clinical trial agreements
- Compassionate use agreements
- Emergency use agreements
- PI-initiated clinical trial agreements
- Material transfer of drug related to patient-oriented research or compassionate use

Exceptions: All new master clinical trial agreements will be through UNeHealth, but existing UNMC masters are still in use until they can be converted.

UNeHealth Information	
Parties to Agreement	UNeHealth and Board of Regents, acting by and behalf of the University of Nebraska Medical Center
Indirect Rate	30% (From UNMC's Negotiated Rate for Industry-Sponsored Clinical Trials)
Fringe Benefit Rate	Standard UNMC Rates
Legal Name	UNeHealth
Organization Type	Non-profit ancillary organization of the University of Nebraska formed by UNMC, authorized by the Board of Regents
Payee	UNeHealth
Payee Type	UNeHealth is the fiscal arm of the University of Nebraska Medical Center for the conduct of clinical trials

UNeHealth Information	
Financial Official Payment Address	Linda Combs, BSBA Accounting Manager 985090 Nebraska Medical Center Omaha, NE 68198-5090 Phone: 402-559-5825 email: lvondras@unmc.edu or Craig Poole (cpoole@unmc.edu)
EIN/Federal Tax ID	47-0771713
W-9	UNeHealth W9 (Effective 1/1/22) Contact UNeHealth Contract Associate
Contracting Address	UNeHealth Attn: Chris Kratochvil, MD 985331 Nebraska Medical Center Omaha, NE 68198-5331 Phone: 402-559-7614 email: unehealthdist@unmc.edu
Human Subject Assurance Number	FWA 00002939
NPI Number	1790042786

Clinical Research Billing

Clinical Trial Master Matrix

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Coverage Analysis

Coverage Analysis uses the Matrix to verify what is conventional "standard" care as opposed to research only costs to identify what can or cannot be billed to a third party payer (either private insurance or Medicare). The Coverage Analysis process also compares the Matrix, Informed Consent Document (ICD), and preliminary budget to ensure that all costs are covered, thereby assuring that the study budgets reflect the true cost of research.

When is a Matrix and/or Coverage Analysis Required?

Any study that includes clinical care activities conducted at Nebraska Medicine/UNMC/UNMC-Physicians clinics or facilities regardless of the funding source or lack of funding source. Examples may include but are not limited to:

- Federal, state, foundation, external hospital, or university funding
- Research that may or may not have funding provided
  - Investigator initiated
  - Consortium
  - Cooperative group
  - Collaborative group
- Commercially funded clinical research
- CCTR Pilot Grant Fund

Research that *DOES NOT* Require a CTMM and CA

Any study that does not include clinical care activities or has no potential to create a bill for technical fees and/or professional fees for Nebraska Medicine/UNMC/ UNMC-Physicians clinics or facilities. Examples may include but are not limited to:

- Retrospective studies that evaluate events that have already occurred including studies that rely exclusively on previously collected administrative records, medical data or other available data
- Laboratory analysis studies utilizing residual human tissue samples or human tissue samples obtained from another entity (non-clinical bio-banked materials)
- Studies conducted at sites other than Nebraska Medicine/UNMC/UNMC-Physicians clinics or facilities
- Observational studies
- Survey studies

When and How to Submit Documents

- Materials should be submitted prior to IRB submission
  - IRB will not issue approval without:
    - a reviewed copy of the Clinical Trial Master Matrix **and**
    - a completed Coverage Analysis report **or**
    - a completed CTMM/CA Determination Checklist stating that the study does not require CTMM or CA
  - Documents should be submitted in electronic format via e-mail to:
    - Clinical Research Financial Compliance Specialist (Grace Videtich)
    - Clinical Trials Business Analyst (Katie Penas)