

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](#)

UNeHealth

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Contract Types Handled by UNeHealth:

- 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

[UNeHealth Guidebook](#)

[Information for Sponsors](#)

[Frequently Asked Questions](#)

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. Consult the [UNeHealth Guidebook](#) for additional information.

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 <u>UNMC's Negotiated Rate</u> for Industry-Sponsored Clinical Trials) |
| Fringe Benefit Rate | <u>Standard UNMC Rates</u> |
| 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 |

UNeHealth Information

| | |
|---------------------------------------|---|
| Payee Type | UNeHealth is the fiscal arm of the University of Nebraska Medical Center for the conduct of clinical trials |
| Financial Official Payment Address | Charles Miller Accounting Manager 985090 Nebraska Medical Center Omaha, NE 68198-5090 Phone: 402-559-5825 email: studyfinance@unmc.edu |
| EIN/Federal Tax ID | 47-0771713 |
| W-9 | <u>UNeHealth W9</u> (Effective 1/1/22) Contact UNeHealth Contract Associate |
| Contracting Address | UNeHealth Attn: Russell McCulloh, 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 |

Frequently Asked Questions

Who invoices for UNeHealth studies?

SPA Accounting invoices for start-up costs and IRB fees unless other arrangements have been made between the Department and SPA Accounting. All other invoices are submitted by the Department Administrator who ensures the Study WBS is reconciled regularly.

Why is a CDA necessary? Who signs?

Confidential Disclosure Agreements (CDAs), are completed at the beginning of the Study review process to allow the PI to receive proprietary information (normally the Protocol and Investigator's Brochure) related to the Study. Without a CDA, the recipients of confidential information are not prohibited from using and disclosing any confidential information received. Sponsor's want to ensure that any such confidential information is appropriately protected.

A UNMC Authorized Signatory should sign CDA's. If the PI is the party to and signs the CDA, they bear the responsibility and obligations of ensuring that all of the agreement terms are followed.

If we choose to use an external IRB for a study, how do they get paid?

Ideally, the Sponsor will work directly with the external IRB, which will submit all invoices directly to the Sponsor. However, there have been Sponsors who choose how to work directly or indirectly with an external IRB, so UNMC and/or the department has to act as the middle man. This is important to consider when deciding which IRB to use, as departments must weigh the costs of taking on those invoicing and payment responsibilities.

What if the Study is closed to enrollment, and the IRB is expiring, but all final payments have not been received, does the IRB have to be extended?

No, as long as there are no further activities taking place related to patient information. At this time, SPA Accounting will likely lock the account to new expenses, but keep it open to receive new revenue.

Is cost sharing allowed on an industry-sponsored clinical trial?

No, not without a waiver which requires justification and approval.

F&A Waivers are considered on a case-by-case basis by the Vice Chancellor for Research. [Download](#) the F&A Waiver Form.

How can the PI and Department help with Contract negotiations?

When asked, the PI and Department can be of help with communicating with the Sponsor.

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)