Clinical Research Billing

Clinical Trial Master Matrix

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.

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)

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