The University of Chicago
Division of the Biological Sciences
and
The University of Chicago Hospitals

Policy Regarding: Identification & Distinction of Clinical Trial Participant Charges

Purpose

To ensure that clinical care services and supplies provided to participants in clinical trials are accurately billed by distinguishing the services and charges provided as research-related or conventional care. This distinction will help ensure that non-billable research-related charges are appropriately and accurately charged to a research account rather than to the research participant and/or their third party payor.

Scope of the Policy

This policy applies to all clinical trials for which patient care charges are generated. Registry studies or studies that involve quality of life assessments or survey administration, do not require Identification & Distinction of Clinical Trial Participant Charges.

Identification & Distinction of Clinical Trial Participant Charges

The University of Chicago (UC) and the University of Chicago Hospitals (UCH) are committed to complying with federal and local regulations that pertain to billing for research-related services required by an IRB-approved clinical trial protocol. Clinical services and supplies provided only for research purposes are never billed to a research participant or their third party payer. Conventional care services provided in compliance with federal, state and local regulations may be billed to the research participant and/or their third party payer. The definition of conventional care services and routine costs as described in the CMS Final National Coverage Decision shall be used when designating charges as research related or conventional care.

This policy requires that the Principal Investigator of a clinical trial, whether the trial is internally or externally funded, review the protocol and identify those services and items that are research-related and those that are considered conventional care. Once reviewed, approved and signed by the principal investigator, this distinction of services will serve as the primary tool for creating an internal line item budget that will be used to establish billing procedures for the services provided to participants in the clinical trial.

To ensure that all active studies have the same fiscal documentation, any clinical research study currently open and resulting in patient care charges must have documentation of distinction of charges on file at the time of annual Institutional Review Board continuing review.

Date of Final Approval: 6/12/06

Oversight Responsibility: This policy is managed by the Medical Center Office of Clinical Research. Revisions to the policy will be made periodically by the Clinical Research Policy Board.