

BILLING FOR STUDIES INVOLVING HUMAN SUBJECTS

The Institutional Review Board (IRB) must approve all clinical studies at the Health Science Center. For sponsored studies, research should not be undertaken until the Health Science Center and the sponsor enter into a clinical trial or clinical research agreement which details the cost for the study and the costs associated with standard of care for patient medical services, and includes the appropriate liability/indemnification clause.

The Centers for Medicare & Medicaid Services (CMS) allows Medicare to cover the routine costs of qualifying clinical trials, as well as, reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. However, if the sponsor of the clinical trial or clinical research covers the costs, then the services must be paid from this source and not from Medicare. Each Principal Investigator (PI) is responsible for determining which medical services are done for research purposes in the context of the clinical investigation as distinct from services provided as a standard of care or extraordinary situations resulting from the research. These services should be clearly indicated in the clinical trial or clinical research agreement. Each PI also is responsible for ensuring there is proper oversight and a data safety and monitoring plan is in place that also provides for billing for medical services provided under the clinical trial or clinical research.

In order to allow institutional monitoring of funds utilized for clinical studies and to avoid inappropriate billing, investigators submitting protocols involving human subjects must provide the following information.

1. Does this study have a research sponsor? Yes No
2. Are there clinical costs associated with this study? Yes No
3. Will clinical costs during this study be billed to Medicare or other insurers? Yes No

If the answer to question 3 is yes, then on a separate page, please indicate the routine costs that will be billed to Medicare or other insurers.

Please indicate

IRB Protocol Number: _____

Medicare Clinical Trial Identification Number: _____

Clinical Trial Name: _____

Sponsor: _____

Sponsor-Assigned Protocol Number: _____

Signature: _____

Date: _____

PLEASE RETURN COMPLETED FORM TO GRANTS MANAGEMENT

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