CLINICAL RESEARCH BILLING CERTIFICATION FORM

Principal Investigator Name:	
Department:	
If funded internally, list account name/UTHealth official making funding decision:	
Research project title:	

Federal Requirements (As Applicable to Medicare and Other Third Party Payers):

1) The billing provider must include in the beneficiary's medical record the following information: trial name, sponsor, and sponsor-assigned protocol number. This information does not need to be submitted with the claim but must be provided if requested for medical review.
2) The billing provider must report a National Clinical Trial (NCT) number on claims for items and services provided in clinical trials that are qualified for coverage. Services that are dictated in the clinical trial protocol, ***including routine care for the condition in the clinical trial***, must be submitted with an NCT identifier number on a Medicare claim related to the clinical trial. Only items dictated in the research protocol are required to have the NCT identifier.
3) The clinical trial number is assigned by the National Library of Medicine website (http://clinicialtrials.gov) when a new study is registered in the NLM Clinical Trials Database.
4) Claims also should include the following identifiers when being submitted to Medicare:
    a) Condition Code 30 (qualified clinical trial)
    b) ICD-10 code z00.6 (clinical research participant) as a secondary diagnosis
    c) Modifier Q0 (investigational item) or Q1 (routine services)

UTHealth Clinical Research Billing Policy:

It is the responsibility of the PI to ensure that the clinical research billing of his or her studies is in compliance with all laws and regulations and adhere to university policy. The PI, his or her research staff, department administrators, and the CRF Team must work together to ensure the components of accurate billing are in place. Please refer to the Coverage Analysis Procedure and the Clinical Research Billing Procedure.

The PI and study staff must prepare and submit a coverage analysis.

The coverage analysis should be consistent with the study protocol and informed consent and should accurately and appropriately allocate the costs associated with the performance of the clinical study to the responsible payer.

The study budget should reflect all charges listed in the coverage analysis as sponsored paid research.

The PI and study staff must ensure that there is an outlined plan to identify research patients prior to providing services.

The PI and study staff must ensure that the services for study subjects enrolled in the clinical research project are billed in accordance with the coverage analysis and that the bills are based on actual services rendered and consistent with the informed consent.

After services are provided, study staff must coordinate with the appropriate personnel to ensure that proper billing information is provided.

Each department and clinic must follow clinical research billing procedures specific to its unit or practice in order to ensure that clinical research billing is conducted appropriately and accurately.

Study staff must conduct periodic reconciliation of clinical research billing charges.

CERTIFICATION:

I certify that I have read and understand the UTHealth Clinical Research Billing Policy and will comply with all applicable laws and UTHealth rules and policies governing clinical research billing.

Principal Investigator Signature _____ Date: _____