

The University of Tennessee Health Science Center

Clinical Trial Billing Procedure

1. PURPOSE

To ensure Principal Investigators (PI's) and other UTHSC personnel perform their responsibility to assist in billing appropriately for services provided to clinical trial participants.

2. REQUIREMENTS

a. All personnel engaged in clinical trial financial operations (budgeting, billing, etc.) will be required to attend training on the requirements of this policy. This includes, but is not limited to, PI's, research coordinators, research nurses, business managers and other administrative personnel.

b. All Principal Investigators (PI's), with their study coordinators, will be required to prepare a detailed billing grid for each trial that has participants who will receive clinical services with the assistance of the medical provider/facility at which the study is to take place. For each service that is provided during the course of the trial, the PI will indicate on the grid who the payor is for each service (sponsor, third party billing or subject), and also indicate which services are not funded by the sponsor and/or those which cannot be billed to the patient or third party (Attachment A). The grid should be done at the same time as the budget for the study, prior to the execution of the Clinical Trial Agreement (CTA).

c. Once the CTA is signed, a copy of the final grid is to be provided to the Office of Research Administration and to the applicable medical provider/facility.

3. PROCEDURE

a. The Principal Investigator (with the study coordinator):

(1) with the assistance of the medical provider/facility at which the study is to take place, prepares billing grids for each clinical trial that has, or will have, enrolled subjects who will receive clinical services. The PI will provide a copy of this billing grid to ORA and the appropriate billing office.

(2) may delegate these duties to research team members or administrative personnel; however the PI is responsible for compliance with applicable laws regarding third-party billing and the accuracy of these documents.

(3) sends the Request to Conduct Research Form to the applicable facility(ies), if required, and **Study Site/Services Agreement** to Finance & Operations, if required, prior to any participants receiving clinical services, and/or complies facility-specific requirements to provide study information.

b. Departmental Chairs (or their designees) will ensure the appropriate departmental personnel (as specified in paragraph 2.b) attend training.

c. The PIs and/or study coordinator(s) will identify all study procedures in the records as they occur and assist the medical provider/facility with any back-end review of subjects' bills.

d. The Office of Research Administration (ORA) will:

(1) provide detailed guidance on the procedures.

(2) assist with training staff.

Dr. Deborah L. Smith, Ed.D.
Assistant Vice Chancellor for Research