

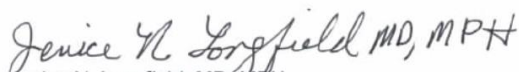
University of Texas Health Science Center at San Antonio

Chapter 1	Clinical Trial Management	Effective:	April 30, 2009
Section 1.3	Resource Management	Revised:	May 25, 2010
Policy 1.3.2	Clinical Trial Billing	Version:	1.1

Policy: Clinical Trial Billing Policy

1. **PURPOSE:** To ensure Principal Investigators (PI's) perform their responsibility to bill appropriately for services provided to clinical trial participants per Handbook of Operating Procedures (HOP) Policy 7.7.1, "Budgeting and Billing for Clinical Services Provided as Part of Research Involving Human Subjects."
2. **POLICY:**
 - a. All Principal Investigators (PI's) are required to prepare a detailed billing grid and Research Activity Billing Trigger (RABT) for each trial that has participants who will receive clinical services, and for which the rules specified in HOP 7.7.1 are applicable. The RABT is not required for studies conducted solely at a VA facility. These documents are used to clearly identify the appropriate payor for each service provided.
 - b. If any study services will be provided by a Health Science Center health care provider, regardless of location (other than a VA facility), the PI must provide the RABT to UT Medicine prior to any participants receiving clinical services.
 - c. If any study services will occur at a University Health System (UHS) facility, PIs will follow the UHS Research Department's instructions for ordering services and any other UHS required procedures. If any services ordered at UHS are research funded, the PI will also use the RABT to create a monthly report as required in the agreements between UTHSCSA and UHS.
 - d. If study services will be provided at other affiliates or facilities, PI's will contact the facility billing office and comply with any specific instructions from that office to ensure the appropriate party is billed.
 - e. At least one individual from each research team must attend training on the requirements of this policy.
3. **RESPONSIBILITY:**
 - a. The Principal Investigator:
 - (1) prepares billing grids and RABT for each clinical trial that has, or will have, enrolled subjects who will receive clinical services. The PI will provide a copy of the RABT to the appropriate billing office.
 - (2) may delegate these duties to research team members or administrative personnel; however the PI is responsible for the compliance to this policy and the accuracy of these documents.
 - (3) sends the RABT to UT Medicine prior to any participants receiving clinical services, uses the RABT to create a monthly report for UHS, and/or complies with UHS and other facility-specific requirements to provide study information.
 - b. Departmental Chairs (or their designees) will ensure the appropriate departmental personnel (as specified in paragraph 2.c.) attend training.
 - c. The Office of Clinical Research (OCR) will:
 - (1) provide detailed guidance on this policy.
 - (2) train staff on HOP policy 7.7.1 and the requirements of this policy.
 - (3) assess the PI's compliance with these requirements.

Detailed guidance on this policy, samples, forms, a grid template, and a training schedule are available on the OCR website.


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