



TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO

Operating Policy and Procedure

HSCEP OP: 73.20, **Medicaid Attestation Form for Participants of a Qualifying Clinical Trial**

PURPOSE: The purpose of this Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) Operating Policy and Procedure (HSCEP OP) is to establish a standardized process for completing and retaining the Medicaid Attestation Form for Medicaid beneficiaries enrolled in qualifying clinical trials, as required under Section 210 of the Consolidated Appropriations Act of 2021.

REVIEW: This HSCEP OP will be reviewed October 1 of each odd-numbered year by the associate director and senior director of the Office of Research (OR), with recommendations for revisions submitted to the vice president for research (VPR) or designee.

POLICY/PROCEDURE:

I. Introduction

As required under Section 210 of the Consolidated Appropriations Act of 2021, an attestation confirming the trial's eligibility and appropriateness for the Medicaid beneficiary must be completed by the Principal Investigator and maintained in the participant's medical record prior to the initiation of any trial-related services.

II. Applicability

- A. TTUHSC El Paso. This policy applies to all TTUHSC El Paso investigators/research personnel conducting Qualifying Clinical Trials (QCT).

III. Definitions

Clinical Research Coordinator (CRC): Research staff member responsible for operational study tasks, including identifying Medicaid beneficiaries, initiating the attestation process, and managing form distribution and storage.

Electronic Medical Record (EMR) or Electronic Health Record (EHR): The digital health record system.

Medicaid Attestation Form: A form required under Section 210 of the Consolidated Appropriations Act of 2021 that confirms a clinical trial qualifies as a Qualified Clinical Trial (QCT) and is appropriate for a Medicaid beneficiary.

Medicaid Beneficiary: An individual enrolled in Medicaid as either the primary or secondary insurance provider.

Principal Investigator (PI): The individual responsible for the overall conduct of the clinical trial at the site, including reviewing and signing the Medicaid Attestation Form.

- IV. *Qualifying Clinical Trial (QCT):* A clinical trial that meets the federal criteria established by the Centers for Medicare & Medicaid Services (CMS) for coverage of routine costs under Medicaid.

V. Responsibilities of Investigators/Research Personnel

- A. TTUHSC El Paso investigators/research personnel shall have the following responsibilities with regard to completing the Medicaid Attestation Form.

Identifying Medicaid Beneficiaries. For each qualified clinical trial, the Clinical Research Coordinator (CRC) or designee, must verify participant's insurance provider. If participant is a Medicaid beneficiary, CRC will initiate form request for PI review and approval.

Attestation Form Completion. CRC may complete the required fields of the current version of the Medicaid Attestation Form. The PI and referring Health Care Provider (if applicable and different than the PI) must review and sign the form prior to initiating any trial-related services.

Upload to EMR. PI or designee must upload the signed form to the "Research Folder" within the EMR. If services will be provided at University Medical Center (UMC) El Paso, the CRC must email the signed form to the UMC Health Information Management Team for upload to UMC's EMR. CRC must maintain a copy of the form in the subject binder.

Retaining the form in the EMR/HER: The CRC and/or the associate director of clinical research finance will confirm the completed form has been uploaded

VI. **Noncompliance**

Failure to complete and retain the form may result in denied claims, overturned claims, delayed reimbursement, or findings of noncompliance during an audit. The form must be retained in the EMR/EHR and will be reviewed for completion periodically by the Office of Research.

VII. **Amendments**

TTUHSC El Paso reserves the right to modify, amend, or terminate this policy at any time.