



El Paso - Ambulatory Clinic Policy and Procedure

Title: SUBJECTS PARTICIPATING IN RESEARCH	Policy Number: EP 1.18
Regulation Reference: HSCEP OP: 73.06, Research Involving Human Subjects	Effective Date: 10/2022

Policy Statement:

It is the policy of Texas Tech Physicians of El Paso (TTP-EP) to delineate the conditions under which research subjects may be seen within its facilities.

Scope and Distribution:

This policy applies to all TTP-EP Clinics and to all research studies that include subjects' visits to clinic-designated spaces regardless of the nature of the research visit.

Procedure:

1. All research activities, personnel and equipment shall be in accordance with any applicable Institutional Review Board approved protocol and stipulations, institutional research policies, and research related federal regulations. The principal investigator shall be responsible for assuring compliance with those.
2. TTP-EP Clinics provides space, basic equipment for routine examination and available staff for basic functions, not research specific, if needed. These assignments require agreement between the principal investigator, clinic manager and the clinic medical director.
3. **Research specific visits:** TTP-EP oversight, policies and procedures do not apply to these visits, including registration, scheduling, documentation in the electronic medical record, ordering systems, and clinic quality improvement assessments. These visits shall not be scheduled using the clinics scheduling system and not be documented in the clinic electronic medical record. Neither third party payers nor patients shall be billed for these visits or any research specific intervention.
4. **Patient care visits with additional research component:** visits that are standard of care but include additional elements related to a subject's participation in a research trial are subject to clinics policies and procedures and shall be billed to the patient and/or third party payer. Those additional research elements shall be documented outside the electronic medical record or clearly marked as research specific not to be included for billing purposes. Any test or treatment that is research specific shall be ordered separately from clinical orders to assure not billing the patient or third party payer. The Principal Investigator is responsible to assure the study is planned and executed in accordance to this policy.

Policy Number: EP 1.18	Original Approval Date: 07/2014
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Signatory approval on file by: Juan Figueroa, M.D. Director of Clinical Operations Clinic Medical Directors Committee, Chair Texas Tech Physicians of El Paso	