POLICY STATEMENT:

It shall be the policy of Texas Tech University Health Sciences Center to be in compliance with all appropriate regulations regarding patients involved in clinical trials, as they may relate to clinic care. Clinic staff will provide communication between the patient's physician and research staff, as needed to facilitate continuity of care.

SCOPE:

This policy applies to all TTUHSC ambulatory clinics that conduct clinical research activities through its Schools.

PROCEDURE:

1. HSC OP 73.06, Research Involving Human Subjects should serve as the source document guiding all aspects of clinical trials/investigational studies conducted at TTUHSC.

2. Screening for patient involvement in clinical trials/investigational studies should be conducted as part of patient assessment at time of clinic visit. Participation in a clinical trial/investigational study should be documented prominently in the medical record.

3. Clinical trial/investigational study patient consent forms that reflect risks and benefits and HIPAA Privacy forms related to the clinical trial/investigational study should be maintained as part of the research medical record.

CERTIFICATION:

This policy was approved by the Council of Deans on March 10, 2011.