

Signed Informed Consent Form(s) or Document(s)

INSTITUTION: Texas Tech University Health Sciences Center – El Paso

STUDY TITLE: Endoscopic mucosal ablation: An alternative therapy for colonic polyps: A case series.

PRINCIPAL INVESTIGATOR: Antonio Mendoza Ladd, M.D.

HIPAA WAIVER OF AUTHORIZATION APPROVED: YES

The study was considered exempt from needing to obtain informed consent. The IRB acknowledges that this project meets the criteria for exemption from formal IRB review in accordance with 45 CFR 46.104 (d)(4)(iii). A Waiver of HIPAA Authorization for Research approved under 45 CFR164.512 (i)(2)(ii).

November 16, 2020

To Whom It May Concern,

Academic physicians often recognize unusual presentations or clinical findings in their patients that are associated with both common and uncommon diseases. These are opportunities to educate others in the form of a case report to a medical journal.

This letter serves as official documentation that patient case reports conducted at Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) are not to be submitted for Institutional Review Board review or approval.

As you may know, the TTUHSC El Paso IRB Policies and Procedures do not require IRB review or approval of case studies. A research project is defined by the federal regulations as “a systematic investigation....designed to develop or contribute to generalizable knowledge” (45 CFR 46.102(l)). We do not consider case reports to meet either the “systematic” or “generalizable” components of the definition. Because the TTUHSC El Paso IRBs are only charged with review of research projects that involve human subjects, and because we do not consider patient case reports to be research projects, the TTUHSC El Paso IRBs do not require review of these types of projects.

If the manuscript that you are intending to submit is a case study or series, you and your co-authors should not attempt to seek IRB review or approval of the project before drafting the manuscript. The fact that you do not have IRB approval for these sorts of manuscripts should not impede your efforts to publish patient case reports.

Here are some points to consider if you are planning to develop a case report:

1. Obtain consent to use clinical information from the patient or if a minor child, the patient’s parent. A TTUHSC El Paso consent form is available through the Office of Institutional Compliance. A copy of the form must be included in the patient’s medical record.
2. If you work at an affiliated hospital, the consent to treat form may be sufficient, but this should be verified. For example, at Transmountain Hospital, you also will need to complete the consent form of the Hospitals of Providence.

Sincerely,



Myrna Arvizo, BMS, CIP, CHRC

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