

INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS
FWA # 00020736 EL PASO IRB #00009945

EXEMPT FROM FORMAL IRB REVIEW

March 04, 2019

IRB#: E19082

STUDY TITLE: Outcomes of Endoscopic Pancreatic Necrosectomy at a University Center
(Necrosectomy2019)

PRINCIPAL INVESTIGATOR: Antonio Mendoza Ladd, M.D.

SUBMISSION REFERENCE #: 073580

TYPE OF REVIEW: EXPEDITED

DATE CLASSIFIED AS EXEMPT: 03/04/2019

APPLICABLE FEDERAL REGULATION: 45CFR46.104 (d)(4)(iii)

HIPAA WAIVER OF AUTHORIZATION APPROVED: YES

Update Description: Acute pancreatitis is a painful condition that happens when the pancreas becomes inflamed. The most common cause of pancreatitis is stones in the gallbladder, but it can also result from drinking alcohol, having high triglycerides in the blood, and taking certain medications. The condition is usually mild and subsides with bowel rest. Occasionally, inflammation of the pancreas can cause serious complication. Since the pancreas makes enzymes that help digest food, if the pancreas becomes inflamed, it can start leaking enzymes that can kill/digest pancreatic tissue. When this happens, it is called necrotizing pancreatitis. The dead tissue can then cause severe complications, be very painful, or get infected. The treatment for necrotizing pancreatitis involves the insertion of a flexible tube with a light and camera attached to it down the throat and into the esophagus. With this special equipment, the doctor can then find and remove the dead pancreatic tissue – this procedure is called, endoscopic pancreatic necrosectomy. In this study, we will evaluate how patients did after having this procedure at UMC in El Paso, TX.

Recommendations: 1. 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).

Research Personnel Approved:

Antonio Mendoza Ladd, M.D.
Alberto Contreras, MD
Alejandro Robles, M.D.
Onyedika V Umeanaeto

This application was screened for exempt status according to TTUHSC El Paso policies and the provisions of applicable federal regulations. The study was found not to require formal IRB review because the research falls into one of the categories specifically designated as exempt

per 45CFR46.104.

Do not use any subject names or identifiers when presenting or publishing the study results.

There is no expiration date for studies which have been classified as Exempt from formal IRB review.

This exemption covers Texas Tech University Health Sciences Center El Paso, 4800 Alberta Avenue, El Paso, Texas, 79905, University Medical Center of El Paso, 4815 Alameda Avenue, El Paso, Texas, 79905, and El Paso Children's Hospital, 4845 Alameda Ave, El Paso, Texas, 79905, as applicable.

If the research involves a review of TTUHSC El Paso medical records (paper or electronic), please submit an electronic copy of this approval letter, the study application [with HIPAA Waiver] and data collection sheet to designated individuals, for approval.

University Medical Center of El Paso/El Paso Children's Hospital:

If the study will take place at an El Paso County Hospital District Facility (EPCHD; University Medical Center of El Paso or a Thomason CAREs clinic)/El Paso Children's Hospital (EPCH) or if the study will utilize EPCHD/EPCH resources for research purposes (i.e., medical records, lab, radiology, etc.), please contact Dani Joyner for information on the Research Compliance approval process (DJoyner@umcelpaso.org or 544-1200 ext. 80503). **The affiliate approval letter must be received by the investigators prior to initiation of research at this setting.**

Reporting: Modifications to this research proposal must be submitted to and approved by the IRB prior to the implementation of the modification. You must report to the IRB any serious problem, adverse effect, or outcome that occurs in conjunction with this project. You are also required to notify the IRB when this study is completed.

Regulatory Compliance Audits: TTUHSC El Paso IRBs are authorized to monitor research involving human subjects approved by the IRB pursuant to the responsibilities and assurances made by TTUHSC El Paso under federal regulations (FWA 00020736) and TTUHSC El Paso Policy (TTUHSC EP OP 73.06 Research Involving Human Subjects and TTUHSC EP OP 73.14 Research Compliance).

The Office of Research Resources shall be responsible for compliance activities on behalf of the IRB and VPR, including audits and monitoring of IRB approved research. For additional information, refer to the Human Research Protection Program Manual.

Please retain this letter with your research records. Research records include all Institutional Review Board submissions and responses and must be kept in the principal investigator's file for a minimum of three (3) years after completion of the study.

STATEMENT OF COMPLIANCE

The Texas Tech University Health Sciences Center El Paso Institutional Review Board (TTUHSC El Paso IRB) is duly constituted (fulfilling FDA requirements for diversity), allows only those IRB members who are independent of the investigator and sponsor of the study to vote/provide opinion on the study, has written procedures for initial and continuing review, prepares written minutes of convened meetings, and retains records pertaining to the review



and approval process; all in compliance with requirements defined in 21 CFR (Code of Federal Regulations) Parts 50 and 56, and ICH (International Conference on Harmonization) guidance relating to GCP's (Good Clinical Practice). The TTUHSC El Paso IRB is registered with OHRP/FDA; our parent organization number is IORG0008299 and our registration number is 00009945.

The TTUHSC El Paso IRB is guided by ethical principles applicable to all research involving humans as subjects, as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (known as the Belmont Report). The IRB's primary responsibility is to protect the privacy, safety and welfare of the human subject participating in research.

The TTUHSC El Paso IRB Policies and Procedures are available for reference on the TTUHSC El Paso Human Research Protection Program Website:
(<http://www.elpaso.ttuhsc.edu/research/committees/irb/resources/default.aspx>).

TTUHSC El Paso Institutional Review Board
5001 El Paso Drive, Room 2002
El Paso, TX 79905
Telephone: 915-215-4590