TEXAS TECH UNIVERSITY
HEALTH SCIENCES CENTER

INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS
FWA # 00006767 EL PASO IRB #00000098

NOTIFICATION OF EXPEDITED APPROVAL WITH WAIVED CONSENT FORM

August 02, 2013

IRB#: *E13099*
STUDY# : Evaluation of gastric polyps and its clinical correlations in Hispanic predominant population. A single center study. (Gastric Polyps 2013)
PRINCIPAL INVESTIGATOR: Mohamed O Othman, MD

SUBMISSION REFERENCE #: 047518

TYPE OF REVIEW: EXPEDITED

APPROVAL DATE: 08/02/2013
REVIEW PERIOD: 12 Months
RISK ASSIGNMENT: Expedited/Minimal
EXPIRATION DATE: 08/01/2014
(based upon date recommended for approval)

 # LOCAL SUBJECTS: 2000

SPECIFIC INFORMATION PERTAINING TO THIS APPROVAL

IRB members abstaining from discussion/vote due to a potential, or actual, conflict of interest: N/A

Documents reviewed and approved include:
1) Study Application (version: 1.0)
2) Gastric Polyps Protocol (version: 1.0)
3) HIPAA Waiver of Authorization Form (version: 1.0)
4) Gastric Polyps Data collection sheet (version: 1.0)

Research Personnel Approved:
Mohamed O Othman, MD
Mohammed Saadi, M.D.
Sherif Elhanafi, MD

The Institutional Review Board expedited approval of the above-referenced study per 45 CFR 46.110 (Category 5).

IRB Recommendation: 1. This study was reviewed by the TTUHSC IRB. The study has been found to be in compliance with 45 CFR 46.111 and/or 21 CFR 56.111 and can be approved. This study has been assigned expedited/minimal risk and will require continuing review every 12 months.

Approval Period: This approval is for a period of 12 Months. You should receive electronic notification 30 days prior to the expiration of this project's approval. *However, it is your responsibility* to insure that a Continuing Review Submission Form has been submitted by the required time.

Consent Form: Informed consent is waived per 45CFR46.116 (d) because "1) The research involves no more than minimal risk to the subjects 2) The waiver will not adversely affect the rights and welfare of the subjects 3)

The research could not practicably be carried out without the waiver and 4) Whenever appropriate, the subjects should be provided with additional pertinent information after participation."

If any of the above does not apply, please notify the IRB immediately.

If the research involves a review of medical records, please provide TTUHSC Medical Records with an electronic copy of this approval letter, the study application, data collection sheet, and HIPAA Waiver.

University Medical Center of El Paso: 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) or if the study will utilize EPCHD 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. 1394).

El Paso Children's Hospital: If the study will take place at El Paso Children's Hospital (EPCH) or if the study will utilize EPCH resources for research purposes (i.e., medical records, lab, radiology, etc.), please contact Dani Joyner, Interim Compliance Research Manager, for information on the Research Compliance approval process (djoyner@elpasochildrens.org) or (915) 298-5444x40524).

Reporting: The principal investigator must report to the IRB any serious problem, adverse effect, or outcome that occurs with frequency or degree of severity greater than that anticipated. In addition, the principal investigator must report any event or series of events that prompt the temporary or permanent suspension of a research project involving human subjects.

Modifications: Changes or modifications in a research project **must have approval** by the IRB prior to initiation. When modifications are deemed necessary to prevent immediate harm to a subject, changes or modifications must be reported to the IRB within 24 hours.

Study Completion:
If this project is completed within the approval period, you are required to submit a Study Update indicating "Final Closure". The study project is considered completed when:

1) Investigators will not contact subjects for further information related to this project
2) Access to subject health care records are no longer required for information related to this project
3) All IRB requests for information have been completed and no longer require an investigator response
4) A summary report has been completed. This must be attached as a Supporting Document in the Study Update submission.

GENERAL INFORMATION

The Texas Tech University Health Sciences Center Institutional Review Boards are 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 Texas Tech University Health Sciences (TTUHSC) Center Policies and Procedures are available for reference on the TTUHSC Human Research Protection Program Website (http://www.ttuhsc.edu/research/hrpo/irb/).

TTUHSC El Paso Institutional Review Board
5001 El Paso Drive, Room 4109

El Paso, TX 79905
915-215-4162