

30-Dec-2018

MEMORANDUM

TO: William Mileski
Surgery-General Surgery 145110

Anne Clark

FROM: Dwight Wolf, MD
Chairman, IRB #2

RE: Transition to Flexible IRB Review

IRB #: IRB # 18-0042

TITLE: A retrospective review of gallbladder surgery at UTMB

DOCUMENTS: Protocol Dated March 2, 2018 v.1

The UTMB Institutional Review Board Chairman or designee has reviewed the above-reference research protocol due to recent revisions in the IRB policies. Having met all the applicable requirements, the research protocol is approved for continuation on **30-Dec-2018**.

Please Note: Continuing Review for this research protocol is no longer required under UTMB IRB Policy 24.1 - Flexible IRB Review. However, a Status Report is required to be submitted to the IRB every three (3) years. A reminder will be sent approximately 90 days prior to its due date.

It is your responsibility to:

1. Obtain prior IRB approval for any modifications including addition of new recruiting materials, changes in research personnel or site location, funding source, sponsor amendments or other changes to the protocol or associated study documents.
2. Report all Unanticipated Problems, protocol violations and unresolved subject complaints as outlined in the IRB Policies and Procedures Section 8.
3. Submit a Notice of Study Closure once project is complete, or when personal identifiers are removed from the data/biospecimens and all codes and keys are destroyed.

If you have any questions, please do not hesitate to contact the IRB office via email at IRB@utmb.edu.

14-May-2018

MEMORANDUM

TO: William Mileski
Surgery-General Surgery 145110



FROM: Elena Sbrana, MS, PhD
Vice-Chairman, IRB #2

RE: Initial Study Approval

IRB #: IRB # 18-0042

TITLE: A retrospective review of gallbladder surgery at UTMB

DOCUMENTS: Case Report Form
Research Protocol

The UTMB Institutional Review Board (IRB) reviewed the above referenced research protocol via an expedited review procedure on **02-May-2018** in accordance with 45 CFR 46.110(a)-b(1). Having met all applicable requirements, the research protocol is approved for a period of 12 months. The approval period for this research protocol begins on **14-May-2018** and lasts until **02-May-2019**.

The requirement to obtain informed consent is waived in accordance with 45 CFR 46.116(d).

The research protocol cannot continue beyond the approval period without continuing review and approval by the IRB. In order to avoid a lapse in IRB approval, the Principal Investigator must apply for continuing review of the protocol and related documents before the expiration date. A reminder will be sent to you approximately 90 days prior to the expiration date.

The approved number of subjects/medical records/specimens to be enrolled/utilized is **2000.00**. If, the approved number needs to be increased, you first must obtain permission from the IRB to increase the approved sample size.

If you have any questions, please do not hesitate to contact the IRB office via email at IRB@utmb.edu.

General Instructions

To maintain IRB approval in good standing, please observe the following requirements:

1. Obtain prior IRB approval for any modifications including addition of new recruiting materials, changes in research personnel or site location, sponsor amendments or other changes to the protocol or associated documents. Only those changes that are necessary to avoid an immediate apparent hazard to a subject may be implemented without prior IRB approval.
2. Report all adverse events, protocol violations, DSMB reports, external reports and study closures promptly to the IRB.
3. Make study records available for inspection. All research-related records and documentation may be inspected by the IRB for the purpose of ensuring compliance with UTMB policies and procedures and federal regulations governing the protection of human subjects. The IRB has authority to suspend or terminate its approval if applicable requirements are not strictly adhered to by all research study personnel.
4. When enrolling the prisoner population, this study will also require approval from the Texas Department of Criminal Justice (TDCJ) Executive Services in addition to approval from the UTMB IRB. Approval from TDCJ Executive Services must be received prior to the enrollment of offenders or the acquisition or utilization of offender data. Failure to obtain approval from TDCJ Executive Services constitutes non-compliance with UTMB IRB Policies and Procedures. Instructions regarding the submission and approval process may be found at <http://www.tdcj.state.tx.us/>.