

19-Jun-2020

MEMORANDUM

TO: Jacqueline Hirth
OB/GYN Adolescent GYN Research 144110


FROM: Dwight Wolf, MD
Chairman, IRB #2

RE: Initial Study Approval

IRB #: IRB # 20-0130

Submission Number: 20-0130.004

TITLE: Effect of medical school communication on medical student coping during SARS
COV2 pandemic

DOCUMENTS: Research Protocol
Consent/Fast Fact Sheet
Focus Group Questions
Focus Group Invitation
General Recruitment
Instruction for Focus Group Session
Medical Student Survey
Recruitment for Pilot
Reimbursement Text

The UTMB Institutional Review Board (IRB) reviewed the above-referenced research protocol via an expedited review procedure on **11-Jun-2020** in accordance with 45 CFR 46.110(a)-(b)(1). Having met all applicable requirements, the research protocol is approved. The approval for this research protocol begins on **19-Jun-2020**. Continuing Review for this protocol is not required, as outlined in 45 CFR 46.109.

Written documentation of consent is waived in accordance with 45 CFR 46.117(c).

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/specimens to be enrolled/utilized for this project is **5035.00**. 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 related to this approval letter or about IRB policies and procedures, 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 subjects who do not speak or read English, in research involving therapeutic or prophylactic interventions or invasive diagnostic procedures, a bilingual translator must be continuously available to facilitate communications between research personnel and a subject. If a bilingual translator will not always be available, it may be unsafe for an otherwise eligible candidate to participate in the research if that person does not speak and read English.
5. 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/>.
6. Close the project once it ends, or when personal identifiers are removed from the data/biospecimens and all codes and keys are destroyed.