utmb Health
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Institutional Review Board
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14-Jul-2016

MEMORANDUM

TO: Sharon Croisant
PMCH-Administration 144605

Bethany Jo Baker

FROM: Dwight Wolf, MD
Institutional Review Board, Chairman

RE: Initial Study Approval

IRB #: IRB # 16-0118

TITLE: UTMB Rapid Acquisition of Pre and Post Incident Disaster Data Protocol

DOCUMENTS: Informed Consent Form Template
Research Protocol – dated 08-Apr-2016

The UTMB Institutional Review Board (IRB) reviewed the above-referenced research protocol at a convened meeting on 27-May-2016. 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-Jul-2016 and lasts until 27-May-2017.

This study is not approved to enroll non-English speaking subjects until written acknowledgment of the proposed translated consent form(s) has been issued by the IRB.

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 to be enrolled is . The IRB considers a subject to be enrolled once s/he signs a Consent Form. If, additional subjects are needed, 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, please telephone the IRB Office at 409-266-9475.

Please Note that the IRB understands that as the research protocol is currently written, each sub-study will be submitted as an amendment under the umbrella study. However, the IRB requests that a stand-alone initial application be submitted that references the umbrella protocol each time an ancillary study will occur. This is primarily to adequately capture the necessary information for each sub-study (e.g. the number of subjects being enrolled, the specific procedures and personnel who will perform the procedures, etc.). Please note that each sub-study can be added as an appendix to the existing research protocol so there will be limited additional work to you as a research team other than completing an initial application form. Additionally, please be reminded that each sub-study will have its own informed consent form, questionnaires, and applicable recruitment material.

General Instructions

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

1. The research consent form(s) (if applicable) with the date of the IRB approval is available in infoED. Please use the IRB stamped consent form(s) with the current approval/expiration dates and make additional copies as they are needed.
2. All subjects must sign the consent form before undergoing any research study procedures, including screening procedures unless this requirement has been waived by the IRB. When conducting research involving children, a child assent form must be reviewed with and signed by the child (if applicable) in addition to obtaining a signed parental permission form unless these requirements are waived by the IRB. A photocopy of the signed consent form(s) should be given to each participant. The copy of the consent form(s) bearing original signature(s) should be kept with other records of this research for at least six years past the completion of the research study.
3. 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.
4. Report all adverse events, protocol violations, DSMB reports, external reports and study closures promptly to the IRB.
5. 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.
6. 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.
7. 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/.