From: Ahamed Idris
Institutional Review Board Chairperson
IRB - 8843

To: Anil Pillai , Anil Pillai ,

Date: November 27, 2013

Re: Study Approval

IRB Number: STU 092013-049

Title: Transjugular Intrahepatic Portosystemic shunts(TIPS): technical variations influencing outcomes

Documents: Protocol

The UT Southwestern Institutional Review Board (IRB) reviewed the above-referenced research study via an expedited review procedure on November 27, 2013 in accordance with 45 CFR 46.110(a)-(b)(1). Having met all applicable requirements, the research study is approved. The approval period for this research study begins on November 27, 2013 and lasts until November 26, 2014.

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

The research study 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 expiration of research study approval.

The approved number of subjects to be enrolled is 500. If additional subjects are needed, you first must obtain permission from the IRB to increase the sample size.

If you have any questions related to this approval letter or about IRB policies and procedures, please telephone the IRB Office at 214-648-3060.

**General Instructions**

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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, 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 UT Southwestern 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.

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