

June 25, 2013

To: Alexander Papanastassiou, M.D. (papanastassiou@uthscsa.edu)  
UTHSCSA

Cc: (amp@uthscsa.edu)

From: Institutional Review Board

Subject: **Expedited Approval of a New Human Research Protocol (Initial Review)**

<p><b>Protocol Number: HSC20130310H</b> <b>Title: The EpiNet Project</b></p>
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Dear Principal Investigator,

Your request to conduct this minimal risk research was approved by Expedited Review on June 21, 2013, under the following regulation(s):

Collection of existing research or clinical data and/or prospective clinical data (refer to Form B-1, Category 5 for details).

Children (refer to Form W of the protocol for details). Cognitively impaired individuals (refer to Form T of the protocol for details).

**The IRB expiration date:** June 21, 2014. Your progress report must be submitted to the IRB Office 34 days before the IRB meeting that will occur before the study's expiration date.

The following documents were reviewed: Signature Assurance Sheet; Form B - General Information; Form B-2 - Personnel List; Form C - Research Description; Form D - HSC Consent, Form K - Intent to Conduct Research at Another Institution; Form N - Off-Site Research; Form S - Package Insert for Approved Drug or Device Studies, VNS Therapy™ Pulse Generators;; Form T - Decisionally Impaired; Form U - Pregnant Women, Fetuses, and/or Neonates; Form W - Children; Form Y - Monitoring Plan - Lead PI; **Other:** Lead PI Statement of Assurance; FDA 510K approval letter; Protocol for EpiNet project dated 10/04/2012;

The attached informed consent document(s) digitally stamped with **IRB APPROVED June 21, 2013** must be used.

Affiliated institutions which are engaged in this research: UTHSCSA University Health System Baptist Health System

Note: Only personnel listed on the currently approved Form B-2 are allowed to be engaged in this research and can only perform the research procedures/roles as described on the Form.

Sincerely,

Senior Research Compliance Coordinator  
Research Regulatory Program Office

*Please retain this document in your IRB correspondence file*

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**Institutional Review Board Office** | Mail Code 7830 | 7703 Floyd Curl Drive | San Antonio, Texas 78229-3900  
210.567.8250 | Fax 210.567.8242 | <http://research.uthscsa.edu/irb> | FWA00005928 | IORG0000312