

Dr. John Higgins  
UT-H - MS - Internal Medicine, Cardiology

**NOTICE OF CONTINUING REVIEW APPROVAL**

November 06, 2015

**HSC-MS-13-0043** - *Study of Heart effects from Adults Drinking Energy beverages: ON Endothelial function (SHADE-ONE)*

**PI:** John Higgins

**PROVISOS:** Unless otherwise noted, this approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered at this meeting, e.g. study documents, informed consents, etc.

**NOTE:** If this study meets the federal registration requirements and this is an investigator-initiated study, or if the PI is the study sponsor or holds the IND/IDE applicable to this study, and no one else has registered this trial on the national registry, you are required to register this trial on the national registry at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) in order to publish results in any of the key peer-reviewed journals. For further information write to [clinicaltrials@uth.tmc.edu](mailto:clinicaltrials@uth.tmc.edu) or call 713-500-7909.


**APPROVED:** By Expedited Review and Approval

**REVIEW DATE:** November 5, 2015

**APPROVAL DATE:** November 06, 2015

**EXPIRATION DATE:** 10/31/2016

**CHAIRPERSON:** Rebecca Lunstroth, JD



Upon review, the CPHS finds that this research is being conducted in accord with its guidelines and with the methods agreed upon by the principal investigator (PI) and approved by the Committee. This approval, subject to any listed provisions and contingent upon compliance with the following stipulations, will expire as noted above:

**CHANGES:** The PI must receive approval from the CPHS before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of co-investigators must also receive approval from the CPHS. ALL PROTOCOL REVISIONS MUST BE SUBMITTED TO THE SPONSOR OF THE RESEARCH.

**UNANTICIPATED RISK OR HARM, OR ADVERSE DRUG REACTIONS:** The PI will immediately inform the CPHS of any unanticipated problems involving risks to subjects or others, of any serious harm to subjects, and of any adverse drug reactions.

**RECORDS:** The PI will maintain adequate records, including signed consent documents if required, in a manner which ensures subject confidentiality.