UTHealth
The University of Texas
Health Science Center at Houston

Committee for the Protection of Human Subjects
6410 Fannin Street, Suite 1100
Houston, Texas 77030

Joseph Mccormick, MD
UT-H - SPH - Brownsville Regional Camp/RAHC

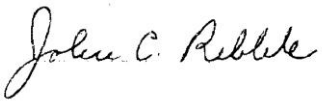
NOTICE OF CONTINUING REVIEW APPROVAL November 25, 2014

HSC-SPH-03-007-B - *EXPORT Grant: Diabetes Core Substudies - Diabetes Impact Study" & "Genetic Behavior and Lifestyle Risk Factors for Complications of Type 2 Diabetes in a Mexican American Population in the LRGV"; Slowing the Epidemic of Obesity and Type 2 Diabetes and their consequences in Mexican Americans in South Texas Border Region IAC- University of Texas Health Science Center San Antonio and University of Texas Health Science Center Houston*

PI: Joseph Mccormick, MD

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 in order to publish results in any of the key peer-reviewed journals. For further information write to clinicaltrials@uth.tmc.edu or call 713-500-7909.

APPROVED:	By Expedited Review and Approval	
REVIEW DATE:	November 25, 2014	
APPROVAL DATE:	November 25, 2014	**EXPIRATION DATE**: 10/31/2015
CHAIRPERSON:	John C. Ribble, M.D.	

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.

INFORMED CONSENT: Informed consent must be obtained by the PI or designee(s), using the format and procedures approved by the CPHS. The PI is responsible to instruct the designee in the methods approved by the CPHS for the consent process. The individual obtaining informed consent must also sign the consent document. **Please note that only copies of the appropriately dated, stamped approved informed consent form can be used when obtaining consent.**

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.