



THE UNIVERSITY of TEXAS
HEALTH SCIENCE CENTER AT HOUSTON

The Committee for the Protection of Human Subjects
Office of Research Support Committees

6410 Fannin, Suite 1100
Houston, TX 77030

Dr. Karen Chronister, PhD
UT-H - SPH - Ctr Health Prom & Prev Resrch

NOTICE OF APPROVAL TO BEGIN RESEARCH

June 13, 2011

HSC-GEN-11-0022 - Assessing the Accuracy of Self-Reported HIV Testing Behavior

Number of Subjects Approved: 900

PROVISIONS: 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 consent, 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 at <https://register.clinicaltrials.gov/> before enrollment or no later than 21 days after the first patient is enrolled.** For website access and further information visit <http://www.uth.tmc.edu/research/clinical/ctregistration.htm> . For further information write to clinicaltrials@uth.tmc.edu or call 713-500-7909.

APPROVED: At a Convened Meeting on 04/08/2011

EXPIRATION DATE: 3/31/2012

CHAIRPERSON: F Gerard Moeller, MD

Subject to any provisions noted above, you may now begin this research.

CHANGES: The principal investigator (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 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 that ensures subject confidentiality.