THE UNIVERSITY OF NEW MEXICO
HEALTH SCIENCES CENTER

Human Research Review Committee
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10-Nov-2011

Borrego, Matthew Elvi, Ph.D., R.Ph.
College of Pharmacy

SUBJECT: HRRC Approval of Research - Initial Review
Project Title: Relationship between Health Literacy and Chronic Kidney Disease Outcomes
HRRC#: 11-545
Type of Review: Expedited Review
Approval Date: 10-Nov-2011
Expiration Date: 09-Nov-2012

Dear Dr. Borrego:

The Human Research Review Committee (HRRC) has **approved*** the above mentioned research protocol action based on review of the following:

1. Expedited Review Study Application, submitted 11/10/2011;
2. Investigator's Protocol 11/07/2011;
3. UNMHSC Combined Consent Form & HIPAA Authorization version 11/09/2011;
4. Study Instruments: Six Item Screener, Health Literacy Screening Instrument, Awareness of Having CKD, CKD Knowledge Instrument, Demographics Form - all submitted 11/07/2011.

Consent Decision:
Requires a signed consent form
Consent and HIPAA included in same document

VA Studies Only:
Not applicable.

If a consent is required, we have attached a date stamped consent that must be used for consenting participants during the above noted approval period.

If HIPAA Authorization is required, the HIPAA Authorization version noted above should be signed in conjunction with the consent form.

This study is approved to enroll only the number of subjects listed in the application, current protocol and consent form(s). If the PI wants to enroll additional subjects, it is the responsibility of the PI to submit an Amendment/Change to the HRRC before the approved number of enrolled subjects is exceeded. If increased enrollment is requested the application, protocol and/or consent form(s) must also be amended to include the new target.

When consent is required, it is the responsibility of the Principal Investigator (PI) to ensure that ethical and legal informed consent has been obtained from all research participants.

Sincerely,

Mark Holdsworth, PharmD
Executive Chair
Human Research Review Committee

* Under the provisions of this institution's Federal Wide Assurance (FWA00003255), the HRRC has determined that this proposal provides adequate safeguards for protecting the rights and welfare of the subjects involved in the study and is in compliance with HHS Regulations (45 CFR 46), FDA Regulations (21 CFR 50, 56).