“HIV Testing Factors among Rural Among Rural Black Men (HiTFARM)”

Attachment 4b. Local IRB Approval – Western IRB

WIRB®

(360) 252-2500
1-800-562-4789
FAX: (360) 252-2498

Western Institutional Review Board ®

3535 SEVENTH AVENUE, SW, OLYMPIA, WA 98502-5010
P.O. BOX 12029, OLYMPIA, WA 98508-2029

Certificate of Approval

THE FOLLOWING WERE APPROVED:

INVESTIGATOR: Emma J. Brown Ph.D.
2198 South Marion Avenue
Lake City, Florida 32025

BOARD ACTION DATE: 5/27/2010
PANEL: 13
STUDY APPROVAL EXPIRES: 5/27/2011
STUDY NUM: 1117361
WIRB PRO NUM: 20100641
INVEST NUM: 157372
WO NUM: 1-609284-1
CONTINUING REVIEW: Annually
SITE STATUS REPORTING: Annually

SPONSOR: Emma J. Brown, Ph.D.
PROTOCOL NUM: None
AMD. PRO. NUM:
TITLE:
HIV TESTING FACTORS AMONG RURAL/SMALL CITY BLACK MEN (HiTFARM)

APPROVAL INCLUDES:

Investigator
Administrative Change to Protocol (05-27-2010)
Contact Information Form #7796446.0 - As Submitted
Demographic Data Sheet #7796444.0 - As Submitted

Continued on Next Page...

WIRB APPROVAL IS GRANTED SUBJECT TO:

The Board requires that all subjects must be able to consent for themselves to be enrolled in this study. This means that you cannot enroll incapable subjects who require enrollment by consent of a legally authorized representative.

IF YOU HAVE ANY QUESTIONS, CONTACT WIRB AT 1-800-562-4789

This is to certify that the information contained herein is true and correct as reflected in the records of the Western Institutional Review Board (WIRB), OHRP/FDA parent organization number IORG 0000432, IRB registration number IRB00000533. WE CERTIFY THAT WIRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.

Robert A Taylor DO for

Theodore D. Schultz, J.D., Chairman

6/2/2010
(Date)

This document electronically reviewed and approved by Taylor, Robert on 6/2/2010 9:49:06 AM PST. For more information call Client Services at 1-360-252-2500

APPROVAL INCLUDES, Continued From Previous Page:

Focus Group Script #7798291.0 - As Submitted
Protocol (04-19-2010)
Recruitment of Subjects under the Grant (Minority HIV/AIDS Research Initiative (MARI))
Screening Survey #7796443.0 - As Submitted
Survey Instrument #7796445.0 - As Submitted
Consent Form - Focus Groups (Phase II, Component III) [S0]
Consent Form - HIV Testing RCT (Phase I, Component II) [S0]
Consent Form - Survey Completion (Phase I, Component I) [S0]
Recruitment Script For Phase 1 #7796442.0 - As Submitted
Script for Providing OraQuick HIV Test Results #7796447.0 - As Submitted
Advertisement - Flyer #7796441.0 We are interested in learning - As Submitted

WIRB HAS APPROVED THE FOLLOWING LOCATIONS TO BE USED IN THE RESEARCH:

- CHARM, INC., 2198 South Marion Avenue, Lake City, Florida 32025

If the PI has an obligation to use another IRB for any site listed above and has not submitted a written statement from the other IRB acknowledging WIRB's review of this research, please contact WIRB's Client Services department.

ALL WIRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

1. Conduct the research in accordance with the protocol, applicable laws and regulations, and the principles of research ethics as set forth in the Belmont Report.

2. Although a participant is not obliged to give his or her reasons for withdrawing prematurely from the clinical trial, the investigator should make a reasonable effort to ascertain the reason, while fully respecting the participant's rights.

3. Unless consent has been waived, conduct the informed consent process without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate. (Due to the unique circumstances of research conducted at international sites outside the United States and Canada where WIRB approved materials are translated into the local language, the following requirements regarding consent forms bearing the WIRB approval stamp and regarding certification of translations are not applicable.)

    a. Use only the most current consent form bearing the WIRB "APPROVED" stamp.

    b. Provide non-English speaking subjects with a certified translation of the approved consent form in the subject's first language. The translation must be approved by WIRB.

    c. Obtain pre-approval from WIRB for use of recruitment materials and other materials provided to subjects.

4. Obtain pre-approval from WIRB for changes in research.

5. Obtain pre-approval from WIRB for any planned deviations that could adversely affect the rights, safety or welfare of subjects, or the integrity of the research data and any changes in the research activity. The only exception is when changes are necessary to eliminate apparent immediate hazards to subjects. Deviations necessary to eliminate apparent immediate hazards to the human subjects should be reported within 10 days.

6. Promptly report to WIRB all unanticipated problems (adverse events, protocol deviations and violations and other problems) that meet all of the following criteria:

    a. Unexpected (in terms of nature, severity or frequency);

    b. Related or possibly related to participation in the research; and

    c. Suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.

    Please go to www.wirb.com for complete definitions and forms for reporting.

7. Provide reports to WIRB concerning the progress of the research, when requested.

8. Ensure that prior to performing study-related duties, each member of the research study team has had training in the protection of human subjects appropriate to the processes required in the approved protocol.

Federal regulations require that WIRB conduct continuing review of approved research. You will receive Continuing Review Report forms from WIRB. These reports must be returned even though your study may not have started.

DISTRIBUTION OF COPIES:

Contact	**Company Name**
Emma J. Brown Ph.D.	Coalition for the Health and Advocacy of Rural Minorities (CHARM, INC.)

