FLORIDA DEPARTMENT OF HEALTH

Jeb Bush
Governor

M. Rony François, M.D., M.S.P.H., Ph.D.
Secretary

NOTIFICATION OF INSTITUTIONAL REVIEW BOARD APPROVAL

August 30, 2006

To: Stratford, Billie D.

Protocol Title: An Economic Empowerment Intervention to Reduce Risk of HIV among Impoverished High-Risk African American Women in the Southeastern US: Exploratory Research and Feasibility Assessment
DOH IRB Number: H06069

Funding Agency: Centers for Disease Control & Prevention
Submission Type: Protocol H06069

Review Type: Expedited Review

Approval Date: August 30, 2006

Expiration Date: August 29, 2007

The Department of Health Institutional Review Board, or representative, determined your study involves no more than minimal risk and meets the criteria for expedited review. It has been granted **expedited approval**. The study is approved for implementation.

As a reminder, the IRB must review and approve all human subjects research protocols at intervals appropriate to the degree of risk, but not less than once per year. **You are responsible for applying for renewal of this project at least 60 days prior to the expiration date of August 29, 2007.** This approval is valid for no more than one year. Re-approval is contingent upon IRB review and approval of a Continuing Review Report prior to the anniversary or expiration date of this approval.

Approval is contingent upon continued ethical research practice and your agreement to obtain informed consent and authorization from your subjects, unless waived. Please make certain that confidentiality is maintained. You must abide by the policies and procedures of the Florida Department of Health with regard to the use of human subjects in research, and keep appropriate records concerning your subjects.

Investigators are required to notify the IRB in writing as soon as possible, but within 10 working days, of the occurrence of any adverse events, unanticipated problems, injuries, side effects, deaths, other problems involving risks to subjects, or deviations from federal or state regulations, or DOH policy.

The IRB has approved exactly what was submitted. Any revisions to this protocol or consent form, no matter how minor, must be presented to the IRB for review and approval before implementation of the changes, except where necessary to eliminate hazard to human subjects. If a change is required to eliminate an immediate hazard, the IRB should be notified as soon as possible but no later than 10 working days.

Researchers are required to notify this IRB, in writing, in the event that this study is not implemented or when termination of this study takes place.

Research records must be maintained for three years after completion of the research; if the study involves medical treatment, it is recommended that records be maintained for eight years.

Please note that this protocol has been assigned the above-referenced DOH IRB protocol number. All inquiries and correspondence concerning this protocol must include (1) the above-referenced IRB number; (2) name of the principal investigator; and, (3) full title of study.

If you have any questions, or if we can be of any assistance, please contact the Department of Health IRB at (850) 245-4585 or toll-free in Florida (866)-433-2775. You may also visit our website at: http://www.doh.state.fl.us/execstaff/irb/

Thank you for your cooperation with the IRB.

Sincerely,

Robert Hood, Ph.D.
Ethics and Human Research Protection Program
Assistant Director, Office of Public Health Research

Encl:

Federal Wide Assurance#: 00004682