



Office of Clinical Affairs,
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Bethesda, Maryland 20892-1608

DATE: July 25, 2013
TO: Tiffany M. Powell- Wiley, M.D.,
Principal Investigator, NHLBI
FROM: Richard Cannon, M.D.
Chair, NHLBI IRB
SUBJECT: IRB **Initial Review** of Protocol T-H-0284, Cardiovascular Health and Needs Assessment in Washington D. C. - Development of a Community-Based Behavioral Weight Loss Intervention

Your **Initial review** application was reviewed and approved at the July 16, 2013 NHLBI Institutional Review Board (IRB). You will receive final approval of this initial review once the Office of Protocol Services has completed processing this action.

The protocol expiration date is **July 15, 2014**. You must complete the continuing review, to include the IRB review and the processing of this action by the Office of Protocol Services, prior to this expiration date.

IMPORTANT INFORMATION ABOUT YOUR PROTOCOL:

Please use this final approved version of the protocol and consent as a guide for documents submitted for the next continuing review.

ANY change in research activity MUST receive IRB review and approval prior to implementation. Request for review of changes should be submitted as an amendment.

Adverse or unexpected/unanticipated events or new information that may alter the risk or benefit determination or subjects' willingness to continue in the study must be reported to the Clinical Director and IRB in accord with NIH policy. Additional reporting (for example, to the sponsor or FDA) may also be required.

Please contact the Office of Clinical Affairs if you have any questions and/or concerns.
You can e-mail us at nhlbi_diroca@nhlbi.nih.gov