Boston University Medical Center

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Office of the Institutional Review Board
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Title of Study: EVALUATION OF THE OMNI GENERATION I COHORT OF THE FRAMINGHAM HEART STUDY
Protocol Number: H-24583

RE: Continuing Review
Review Type: Full Board
Action: Approved

Date of Action: January 09, 2013
Date Revisions Were Accepted: January 13, 2013
Date of Expiration: January 08, 2014

Funding Source: NIH/National Heart Lung, and Blood Institute (NHLBI)
Award #: NO1-HC-25195 (contract) & 1 R01 HL107385 grant

Protocol Version #: 1.769039
Consent Form(s):

Study Consent From			
Title	Version Number	Version Date	Outcome
1-Omni 1 Spanish Cell Line Consent Form	Version 2.2	01/19/2012	Approved
1-Omni 1 Cell Line Consent Form English	Version 2.2	01/19/2012	Approved
1-Omni 1 Examination 4 Spanish Consent Form	Version 2.4	07/24/2012	Approved
1-Omni I Examination 4 Consent Form	Version 2.4	07/24/2012	Approved
Blood Draw Consent for Cell Line Creation	Version 1.769035.2	02/15/2011	Approved
CTADD Omni 1 - Offsite	Version 1.769035.2	02/15/2011	Approved

Dear Dr. Philip A. Wolf,

At the January 09, 2013th Panel Purple Institutional Review Board (IRB) meeting, chaired by Sanford Auerbach, M.D., the above referenced protocol was reviewed. It has been determined that this study meets the requirements set forth by the IRB and is hereby approved. This protocol is valid through the expiration date indicated above.

The study may not continue after the approval period without additional IRB review and approval for continuation. You will receive an email renewal reminder notice prior to study expiration; however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

Please note: this approval does NOT represent approval of any aspects of this study that have not been previously approved by the IRB unless they are specifically noted in the amendment description.

Please be aware that only IRB-approved informed consent forms, validated with current approval dates generated by the INSPIR system, may be used when informed consent is required. Any

changes to the approved protocol or informed consent documents must be reviewed and approved prior to implementation unless the change is necessary for the safety of subjects.

You must report to the IRB unanticipated problems involving risk to subjects or others according to the process posted on the IRB website (www.bumc.bu.edu/irb). The IRB must also be informed of any new or significant information that might impact a research participant's safety or willingness to continue in your study.

Investigators are required to ensure that all HIPAA requirements have been met prior to initiating this study. Once approved, validated HIPAA forms may be found within INSPIR under Study Documents.
It is the responsibility of the PI to ensure that all required institutional approvals have been obtained prior to initiating any research activities.

Sincerely yours,

Signature applied by Debora Perez on 01/13/2013 07:13:52 PM EST

IRB Analyst