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 II COHORT OF THE FRAMINGHAM HEART STUDY
Protocol Number:	H-22681
RE:	Contining Review
Review Type:	Full Board
Action:	Approved
Date of Action:	11/4/2009
Date of Expiration:	11/3/2010
Funding Source:	Government: Pending NIH/NHLBI Supplement to Framingham Heart Study N01-HC-25195 1910G IRB Protocol #H-22762 Government Award #: N01-HC-25195
BU Source # or Record #:	337-30975

Dear EMELIA BENJAMIN, MD, ScM:

The Institutional Review Board (IRB) has reviewed the above referenced protocol and has determined that it meets the requirements set forth by the IRB and is hereby approved. This protocol is valid through the date indicated above.

-Please note, since the IAA is still pending with MGH, no CTScans may be performed until this is resolved.
-The COI issue regarding Dr. Mitchell is still pending, please contact the IRB when this has been resolved.
-Please submit an amendment for an updated Spanish consent form when it has been translated and attested.

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 be aware that only IRB-approved informed consent forms may be used when informed consent is required. Only consent forms validated with current approval dates (either generated by the INSPIR system or by a manual stamp by the IRB office) may be used. Manually stamped consent forms may be found under External Attachments in INSPIR.

Any changes to the protocol or informed consent must be reviewed and approved prior to implementation unless the change is necessary for the safety of subjects. In addition, you must report to the IRB unanticipated problems involving risk to subjects or others according to the process posted on the IRB website. The IRB must 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

as External Attachments.

It is the responsibility of the PI to ensure that all required institutional approvals have been obtained prior to initiating any research activities.

Please note that the IRB is no longer stamping attachments, subject letters, recruitment materials, etc. These documents are each associated with this approved version of the protocol. They can be found by going to Letters/Protocol History in INSPIR and clicking on the highlighted (linked) word "Approved" and then clicking on the paperclip icon in the upper left corner. *This does NOT apply to consent forms, which must be validated.

Sincerely yours,

SANFORD AUERBACH
IRB Chair