

Boston University Medical Center

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**Boston University
Medical Center**



**Office of the Institutional
Review Board**
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Boston, Massachusetts
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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: Expedited

Action: Approved

Date of Action: 2/5/2010

Date of Expiration: 2/4/2011

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.

NOTE: The IAA between MGH and BUMC is still pending. Subjects may not participate in study activities to be conducted at MGH until this agreement is signed. MGH Investigators may not participate in human subjects research activities for this study until this agreement is signed.

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,

A handwritten signature in black ink, appearing to read 'Danielle DeLosh', written over a faint circular stamp or watermark.

DANIELLE DELOSH
IRB Board Member