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Office of the Institutional Review Board
560 Harrison Ave, Suite 300
Boston, Massachusetts
02118-2526
Tel: 617-638-7207
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Title of Study: THE FRAMINGHAM HEART STUDY (All Cohorts)N01-HC-25195 1910G
Protocol Number: H-32132

RE: New Protocol
Review Type: Full Board
Action: Approved

Date of Action: January 16, 2013
Date Revisions Were Accepted: February 07, 2013
Date of Expiration: January 16, 2014

Funding Source: NIH/National Heart Lung, and Blood Institute (NHLBI)
Award #: NO1-HC-25195 and R01HL107385

Protocol Version #: 1.1
Consent Form(s):

Study Consent From			
Title	**Version Number**	**Version Date**	**Outcome**
English Cell line consent form	Version 1.2	01/25/2013	Approved
English Cell line consent form	Version 1.0	01/11/2013	Void
Spanish Cell line consent form	Version 1.1	01/25/2013	Approved
Spanish Cell line consent form	Version 1.0	01/11/2013	Void
Omni 1(4) Spanish Consent	Version 1.1	01/25/2013	Approved
Omni 1(4) Spanish Consent	Version 1.0	01/11/2013	Void
Omni 1(4) English Consent Form	Version 1.1	01/25/2013	Approved
Omni 1(4) English Consent Form	Version 1.0	01/11/2013	Void
Offspring Exam 9 Consent Form	Version 1.1	01/25/2013	Approved
Offspring Exam 9 Consent Form	Version 1.0	01/11/2013	Void

Dear Philip A. Wolf, MD:

At the 01/16/2013th Panel Orange Institutional Review Board (IRB) meeting, chaired by David Kaufman, 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.

This approval corresponds with the versions of the protocol and consent form(s) indicated above.

Protocol Specific Determinations and Findings

- This protocol is minimal risk.
- This protocol will be expedited in the future.
- The waiver of consent for Gen. 1, Gen. 2, and Omni 1 cohorts is approved for this study.

Requirements

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, 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 Jesse Anderson on 02/07/2013 09:18:22 AM EST

Jesse Anderson
IRB Analyst

Boston University Medical Center

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Title of Study: THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G
Protocol Number: H-22762

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

Date of Action: May 09, 2012
Date of Expiration: May 08, 2013

Funding Source: NIH/National Heart Lung, and Blood Institute (NHLBI)
Award #: NO1-HC-25195 plus ancillary grant R01HL107385

Protocol Version #: 1.769336
Consent Form(s):

Study Consent From			
Title	Version Number	Version Date	Outcome
1 - Offspring Examination 9	Version 1.769333.11	05/09/2012	Approved
1-Generation III Exam 2- may 9	Version 1.769333.4	05/09/2012	Approved
1-Blood Draw Consent for Cell Line Creation	Version 1.769333.5	05/09/2012	Approved
1-New Offspring Spouse Exam 2	Version 1.769333.4	05/09/2012	Approved

Dear Dr. Philip A. Wolf:

At the May 9, 2012th Panel Purple Institutional Review Board (IRB) meeting, chaired by Sanford Auerbach, 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 05/17/2012 09:26:45 AM EDT

IRB Analyst