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Office of the Institutional Review Board
560 Harrison Ave, Suite 300
Boston, Massachusetts
02118-2526
Tel: 617-638-7207
Fax: 617-638-7234

Title of Study: RETURNING INDIVIDUAL GENETIC RESULTS TO PARTICIPANTS IN COHORT STUDIES
Protocol Number: H-29136

RE: Continuing Review
Review Type: Expedited
Action: Approved

Date of Action: December 13, 2014
Date of Expiration: December 12, 2015

Funding Source: NIH/National Cancer Institute (NCI)
Award #: HG0050831-01

Protocol Version #: 1.766624
Consent Form(s): subjects already consented

Dear Greta Lee Splansky, MS,

The BUMC Institutional Review Board (IRB) has reviewed the protocol referenced above. It has been determined that the study meets the requirements set forth by the IRB and is hereby approved for continuation. This protocol was approved by the expedited review process in accordance with 45 CFR 46.110 and 21 CFR 56.110.

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.

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

This study has been approved under expedited category 7.

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 Debora Perez on 11/19/2014 12:41:59 PM EST

Senior IRB Analyst II

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Title of Study: BUILDING ON GWAS FOR NHLBI-DISEASES: THE CHARGE CONSORTIUM
Protocol Number: H-29050

RE: Continuing Review
Review Type: Expedited
Action: Approved

Date of Action: October 29, 2014
Effective Date: 11/20/2014
Date of Expiration: 11/19/2015

Funding Source: NIH/American Recovery and Reinvestment Act (ARRA)
Award #: 1 RC2HL102419-01

INSPIR Application Version #: 1.766646
Consent Form(s): n/a

Dear L Adrienne Cupples, PhD,

The BUMC Institutional Review Board (IRB) has reviewed the continuing review submission. It has been determined that the study meets the requirements set forth by the IRB and is hereby approved for continuation. Based on the protocol version listed above, the continuation of this protocol was approved by the expedited review process in accordance with 45 CFR 46.110 and 21 CFR 56.110.

No changes to the study application have been approved as part of this continuing review.

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.

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
-Expedited category 7.

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 Debora Perez on 10/29/2014 08:37:44 AM EDT

Senior IRB analyst II

Boston University Medical Center

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Title of Study: EVALUATION OF THE OMNI GENERATION II COHORT OF THE FRAMINGHAM HEART STUDY
IRB Number: H-22681

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

Date of Action: August 21, 2015
Effective Date: 08/27/2015
Date of Expiration: 08/26/2016

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

IINSPIR Application Version #: 1.766478

Dear Vasan Ramachandran, MD:

At the 08/19/2015th Panel Orange Institutional Review Board (IRB) meeting, chaired by David Kaufman, ScD, the continuing review submission 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.

No changes to the study application have been approved as part of this continuing review.

Please note: this approval does NOT represent approval of any aspects of this study that have not been previously approved by the IRB.

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.

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 note this important change regarding approved consent forms:

- The approved consent forms for this study no longer have an expiration date. This means that as long as there are no changes to the consent form, it will not expire.
- When any future changes are made to the consent form by an amendment, a new approval date will then be stamped on the new version of the consent form. This new

version of the consent form must be used going forward until the next amendment for a consent change.

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 Audrey Recupero on 08/21/2015 01:46:03 PM EDT

IRB Analyst

Boston University Medical Center

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Title of Study: THE FRAMINGHAM HEART STUDY SNP HEALTH ASSOCIATION RESOURCE
IRB Number: H-26671

RE: Continuing Review
Review Type: Expedited
Action: Approved

Date of Action: June 08, 2015
Effective Date: June 10, 2015
Date of Expiration: June 09, 2016

Funding Source: NIH/National Heart Lung, and Blood Institute (NHLBI)(NHLBI)
Award #: N01-HC-25195

INSPIR Application Version #: 1.767352
Consent Form(s): N/A

Dear Vasan Ramachandran, MD,

The BUMC Institutional Review Board (IRB) has reviewed the continuing review submission. It has been determined that the study meets the requirements set forth by the IRB and is hereby approved for continuation. Based on the protocol version listed above, the continuation of this protocol was approved by the expedited review process in accordance with 45 CFR 46.110 and 21 CFR 56.110.

No changes to the study application have been approved as part of this continuing review.

Please note: this approval does NOT represent approval of any aspects of this study that have not been previously approved by the IRB.

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.

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 note this important change regarding approved consent forms:

- The approved consent forms for this study no longer have an expiration date. This means that as long as there are no changes to the consent form, it will not expire.
- When any future changes are made to the consent form by an amendment, a new approval date will then be stamped on the new version of the consent form. This new version of the consent form must be used going forward until the next amendment for a consent change.

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,

Teresa Erin Schrader

Signature applied by Teresa Erin Schrader on 06/08/2015 03:25:16 PM EDT

Senior IRB Analyst

Boston University Medical Center

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Title of Study: FRAMINGHAM HEART STUDY: CANDIDATE GENE RESOURCE (CARE) PROJECT
Protocol Number: H-26974

RE: Continuing Review
Review Type: Expedited
Action: Approved

Date of Action: January 05, 2015
Effective Date: 01/14/2015

Date of Expiration: 01/13/2016

Funding Source: NIH/National Heart Lung, and Blood Institute (NHLBI)(NHLBI)
Award #: #N01-HC-25195 & #HHSN268200900055C 5215810-5500000

INSPIR Application Version #: no changes
Consent Form(s): n/a

Dear Vasan Ramachandran, MD,

The BUMC Institutional Review Board (IRB) has reviewed the continuing review submission. It has been determined that the study meets the requirements set forth by the IRB and is hereby approved for continuation. Based on the protocol version listed above, the continuation of this protocol was approved by the expedited review process in accordance with 45 CFR 46.110 and 21 CFR 56.110.

No changes to the study application have been approved as part of this continuing review.

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.

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
-Expedited category 9.

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 Debora Perez on 01/05/2015 10:36:10 AM EST

Senior IRB analyst II

Boston University Medical Center

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Title of Study: FRAMINGHAM HEART STUDY BIOMARKER PROJECT : SYSTEMS APPROACH TO BIOMARKER RESEARCH (SABRE) IN CARDIOVASCULAR DISEASE
Protocol Number: H-27984

RE: Continuing Review
Review Type: Expedited
Action: Approved

Date of Action: January 07, 2015
Effective Date: 01/21/2015
Date of Expiration: 01/20/2016

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

INSPIR Application Version #: 1.768776
Consent Form(s): n/a

Dear Vasan Ramachandran, MD,

The BUMC Institutional Review Board (IRB) has reviewed the continuing review submission. It has been determined that the study meets the requirements set forth by the IRB and is hereby approved for continuation. Based on the protocol version listed above, the continuation of this protocol was approved by the expedited review process in accordance with 45 CFR 46.110 and 21 CFR 56.110.

No changes to the study application have been approved as part of this continuing review.

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.

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
-Expedited category 9.

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 Debora Perez on 01/07/2015 11:32:02 AM EST

Senior IRB analyst II

Boston University Medical Center

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Title of Study: Analysis of the Exome Sequencing Project dataset by the Framingham Heart Study.
IRB Number: H-30343

RE: Continuing Review
Review Type: Expedited
Action: Approved

Date of Action: August 13, 2015
Effective Date: 08/28/2015
Date of Expiration: 08/27/2016

Funding Source: NIH/National Heart Lung, and Blood Institute (NHLBI)(NHLBI)
Award #: N01-HC-25195; 1 RC2 HL103010

INSPIR Application Version #: 1.768715
Consent Form(s): n/a

Dear Vasan Ramachandran, MD,

The BUMC Institutional Review Board (IRB) has reviewed the continuing review submission. It has been determined that the study meets the requirements set forth by the IRB and is hereby approved for continuation. Based on the protocol version listed above, the continuation of this protocol was approved by the expedited review process in accordance with 45 CFR 46.110 and 21 CFR 56.110.

No changes to the study application have been approved as part of this continuing review.

Please note: this approval does NOT represent approval of any aspects of this study that have not been previously approved by the IRB.

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.

-Expedited category 7.
-HIPAA exempt.

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.

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 08/13/2015 02:34:42 PM EDT

Senior IRB analyst II

Boston University Medical Center

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Title of Study: Health and Retirement Study Database:CVD, longevity and aging
Protocol Number: H-31456

RE: Continuing Review
Review Type: Expedited
Action: Approved

Date of Action: January 27, 2015
Effective Date: 02/10/2015
Date of Expiration: 02/09/2016

Funding Source: NIH/National Heart Lung, and Blood Institute (NHLBI)(NHLBI)
Award #: Contract No. NOI-HC-25195, Modification #13

INSPIR Application Version #: 1.4
Consent Form(s): waiver

Dear Vasan Ramachandran, MD,

The BUMC Institutional Review Board (IRB) has reviewed the continuing review submission. It has been determined that the study meets the requirements set forth by the IRB and is hereby approved for continuation. Based on the protocol version listed above, the continuation of this protocol was approved by the expedited review process in accordance with 45 CFR 46.110 and 21 CFR 56.110.

No changes to the study application have been approved as part of this continuing review.

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.

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
-This study has been approved under expedited category 9.
- A waiver of consent is approved for this protocol.

- A HIPAA Waiver of Authorization is approved for this protocol.

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 Debora Perez on 01/27/2015 10:40:53 AM EST

Senior IRB analyst II

Boston University Medical Center

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Title of Study: THE FRAMINGHAM HEART STUDY (All Cohorts)N01-HC-25195 1910G
Protocol Number: H-32132

RE: Continuing Review
Review Type: Expedited
Action: Approved

Date of Action: 12/12/2014
Effective Date: 01/06/2015
Date of Expiration: 01/05/2016

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

INSPIR Application Version #: 1.11
Consent Form(s):

Study Consent Form			
Title	Version Number	Version Date	Outcome
FHS Generation 3 Informed Consent	Version 1.1	08/20/2014	Approved
English Cell line consent form	Version 1.3	01/25/2013	Approved
Spanish Cell line consent form	Version 1.2	01/25/2013	Approved
Omni 1(4) Spanish Consent	Version 1.2	01/25/2013	Approved
Omni 1(4) English Consent Form	Version 1.3	01/25/2013	Approved
Offspring Exam 9 Consent Form	Version 1.2	01/25/2013	Approved

Dear Vasan Ramachandran, MD,

The BUMC Institutional Review Board (IRB) has reviewed the continuing review submission. It has been determined that the study meets the requirements set forth by the IRB and is hereby approved for continuation. Based on the protocol version listed above, the continuation of this protocol was approved by the expedited review process in accordance with 45 CFR 46.110 and 21 CFR 56.110.

No changes to the study application have been approved as part of this continuing review.

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.

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

- This study has been approved for an additional year as minimal risk, under expedited category 9.

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.

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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 Matthew Ogrodnik on 01/14/2015 03:14:15 PM EST

Senior IRB Analyst