Boston University Medical Center

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Office of the Institutional Review Board
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Title of Study: Analyzing the SSA Disability Determination Process-Validation Study
Protocol Number: H-31096

RE: New Protocol
Review Type: Expedited
Action: Approved

Date of Action: Date Revisions: July 27, 2011
Were Accepted: August 24, 2011

Date of Expiration: July 26, 2012

Funding Source: NIH
Award #: HHSN269200900004C

Protocol Version #: 1.2
Consent Version(s) #: N/A (collaborating site obtaining consent and IRB approval for all consent activities, no consent or consent related findings necessary with this BUMC submission)

Dear Alan Jette, PhD,

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. This protocol was approved by the expedited review process in accordance with 45 CFR 46.110 and 21 CFR 56.110.

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
-Approved Expedited Risk Category 7 and HIPAA Exempt

PLEASE NOTE THAT THE APPROVAL LETTER FOR POLIMETRIX MUST BE SUBMITTED TO THE BUMC IRB AND APPROVED VIA THE AMENDMENT PROCESS PRIOR TO THE START OF ANY ACTIVITIES INVOLVING POLIMETRIX.

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.

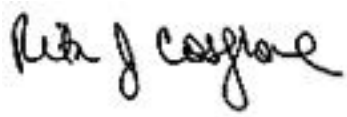
Please be aware that only IRB-approved informed consent forms, validated with current approval dates generated by the INSPIR system, may be used when informed consent is required.

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 Rita Cosgrove on 08/24/2011 10:00:36 AM EDT

[insert title e.g. Analyst, Board Member, etc.]