Boston University Medical Center

SCHOOL OF MEDICINE * SCHOOL OF PUBLIC HEALTH * GOLDMAN SCHOOL OF DENTAL MEDICINE * BOSTON MEDICAL CENTER

Boston University Medical Center

BOSTON MEDICAL CENTER

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: SSA Test Retest Study
Protocol Number: H-32407

RE: New Protocol
Review Type: Expedited
Action: Approved

Date of Action: September 20, 2013
Date Revisions Were Accepted: January 13, 2014

Date of Expiration: September 19, 2014

Funding Source: NIH (ARRA)
Award #: HHSN269201200005C

Protocol Version #: 1.4
Consent Form(s):

Study Consent From			
Title	Version Number	Version Date	Outcome
Functional Assessment Study	Version 1.1	07/03/2013	Approved
Functional Assessment Study	Version 1.0	07/03/2013	Void

Dear Dr. Alan Jette,

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

- This protocol is minimal risk.
- This protocol will be expedited in the future.

Please Note: No research activities can begin by the NIH external investigators until you receive confirmation from IRB coordinator Roz Schomer that the fully signed IAA agreement is attached to the 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 Jesse Anderson on 01/13/2014 02:26:43 PM EST

IRB Analyst