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**Title of Study:** Analyzing the SSA Disability Determination Process-Phase 2
**Protocol Number:** H-31918

**RE:** Change Request & Amendments
**Review Type:** Expedited
**Action:** Approved

**Date of Action:** 03/06/ 2014
**Date of Expiration:** 11/13/2014

**Funding Source:** National Institutes of Health Department of Rehabilitation Medicine (NIH-RMD)
**Award #:** HHSn269201200005C

**Protocol Version #:** 1.6
**Consent Form(s):**

| Study Consent From | | | |
|---|---|---|---|
| Title | Version Number | Version Date | Outcome |
| Claimant Calibration Consent Form | Version 1.2 | 03/04/2014 | Approved |
| Claimant Calibration Consent Form | Version 1.1 | 03/04/2014 | |
| Normative Sample Calibration Study | Version 1.1 | 03/04/2014 | Approved |

Dear Alan Jette Dr, PhD,

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

The expiration date for this protocol has not changed as a result of this amendment.

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

**Amendment Description**

This amendment includes substantial changes to the calibration study component of this protocol. (However, many of these procedures (data transmission/subject

contact/procedures/eligibility criteria) are similar to processes used in previously approved protocols 28485 and 31203.) In addition, we are adding a normative sample calibration study to this protocol as well. We have changed the following:

Section 4: We have removed Meghan Gleasons from NIH-RMD and added Ashley Grosse PI, YouGov; Samantha Luks, YouGov, Data Manager/analyst; Daniel Hobbs NIH-RMD study coordinator.
Section 8: brief description of NIH predictive validity study
Section 9: Added YouGov as additional site
Section 11: added YouGov request for IAA. 11.6 removed Megan Gleason, added Daniel Hobbs. HSC attached, modified role of Westat, added description of YouGov's role.
Section 12: added NIH predictive validity summary/YouGov information
Section 13: updated inclusion/exclusion normative and claimant samples
Section 14: updated design/procedures for norm. and claimant.
Section 15: increased sample size/added norm. sample
Section 20: updated recruitment claimant/normative added recruitment letters (deleted redundant cog. interview recruitment letter)
Section 21: updated screening procedures
Section 24: We believe that HIPAA no longer applies because we will no longer be contacting health care providers.
Section 25: updated compensation for both samples
Added new consents for claimant and normative samples
Added study letters, scripts, screeners, for web/phone administration in claimants and the invitation letter for the normative sample to the study documents section of the protocol. Added calibration items spreadsheet as well, includes the items in survey 1+2, demographics, work/health status questions and a co-morbidity scale.

Please note: The signed YouGov IAA Agreement is attached to the protocol under Other Study Documents-IAA Agreement.

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.

**Requirements**

*At the time of the next amendment or Continuing Review, please change the data BU-HDR receives to ‘anonymous’ in section 23.1, ‘Release of Identifiable Data.’

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 protocol or informed consent must be reviewed and approved by the IRB 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). Also, 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 under Study Attachments. It is also 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 03/06/2014 09:49:35 AM EST

Senior IRB Analyst