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Office of the Institutional Review Board
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Title of Study: SSA Computer Adaptive Testing (CAT) Usability Project
Protocol Number: H-32412

RE: New Protocol
Review Type: Exempt
Action: Not Human Subjects Research

Date of Action: August 15, 2013

Protocol Version #: 1.1

Dear Alan Jette Dr, PhD,

A qualified member of the BUMC Institutional Review Board (IRB) staff has reviewed the above referenced protocol and has determined that it does not require further review by the BUMC IRB because it does not meet the definition of “human subject research”.

The BUMC IRB has made this determination based on the regulatory definitions of Human Subject and Research per the following:

1. According to HHS, Human Subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information (45 CFR 46.102(f)).

2. According to FDA, a Human Subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control (21 CFR 50.3(g)).

3. Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 45.102(d)).

Protocol Specific Determinations

As a QA Project this falls under "clinical HIPAA" not research HIPAA. Please consult with Mr. Sumit Sehgal the BMC Privacy Officer regarding any questions about HIPAA requirements for QA projects.

Requirements

This approval corresponds with the version of the protocol indicated above.

All determinations regarding this project have been made based on the information submitted by the investigator. Any modifications to the research plan (including any

changes in funding) must be submitted to the IRB for review and approval prior to initiation, and may change the IRB's determination.

You may retain this letter in your files as documentation of this decision by the BUMC IRB. No progress reports are required for this project as long as no changes are made to the protocol.

It is the responsibility of the PI to ensure that any relevant HIPAA requirements have been met. It is also the responsibility of the PI to ensure that all required institutional approvals have been obtained prior to initiating any protocol related activities.

Sincerely yours,

Signature applied by Ashley Faber on 08/16/2013 02:12:06 PM EDT

Senior IRB Analyst