Authorization Agreement between

THE NATIONAL INSTITUTES OF HEALTH
and
BOSTON UNIVERSITY MEDICAL CENTER (BUMC)

To Rely on BUMC IRB

Pursuant to 45 C.F.R. 46.114, the National Institutes of Health (NIH) and BUMC are entering into this agreement for BUMC to conduct Institutional Review Board (IRB) review of the research protocol or activities identified below, which are jointly conducted by NIH and BUMC.

Name of Institution Providing IRB Review (Institution A):
Boston University Medical Center
FWA # 00000301, expiration date 5/3/2014
IRB # of IRB at Institution A: IRB00000376, IRB00000377, IRB000001093, and IRB000008404

Name of Institution Relying on the Designated IRB (Institution B):
National Institutes of Health
Federal Wide Assurance (FWA) #: 00005897, expiration date 2/25/2014

NIH will rely on the IRB of Institution A for review and continuing oversight of its human subjects research described below. This agreement is limited to the following specific protocol(s) or research activity:

Name of Research Project/Activity: Analyzing the SSA Disability Determination Process-Phase 2
Protocol Number(s): H-31918
Name of Principal Investigator (Institution A): Alan Jette, PhD
Name of Principal Investigator (Institution B): Leighton Chan, MD, MPH
Name of NIH Principal Investigator's Institute or Center: RMD

The review performed by Institution A's IRB will meet the human subject protection requirements of NIH's OHRP-approved FWA. The protocol(s) reviewed by Institution A's IRB must include a description of the research to be conducted by NIH. The extent to which NIH may rely upon the review by Institution A's IRB is limited to the description of those research activities in the protocol. Institution A's IRB will follow written procedures for reporting its findings and actions to appropriate officials at NIH. Relevant minutes of IRB meetings will be made available to NIH upon request. NIH remains responsible for ensuring compliance with the reviewing IRB's determinations and with the terms of its OHRP-approved FWA.

Both Institutions will maintain current copies of the IRB- approved protocol. NIH will conduct its portion of this joint research in accord with the terms and conditions of its OHRP-approved FWA. Institution A will conduct its portion of this joint research in accord with the terms and conditions of its OHRP-approved FWA. This Agreement will be kept on file at both Institutions and will be available to OHRP upon request.

Institution A's IRB retains responsibility for compliance with regulatory requirements under 45 C.F.R. Part 46 and 21 C.F.R. 56 (as applicable) related to the administration and operation of the IRB. These include, for example, following written procedures and maintaining records in accord with 45 C.F.R. parts 46.103 and 115, respectively. NIH agrees that Institution A's IRB may suspend or terminate approval of research that is not conducted in accordance with its requirements or that is associated with unexpected serious harm to subjects pursuant to 45 C.F.R. 46.113.

NIH will ensure that before implementing a change to Institution A's IRB-approved protocol its investigator will obtain Institution A's IRB approval for the change (unless the change is designed to eliminate an apparent immediate hazard to subjects), pursuant to 45 C.F.R. 46.103. NIH retains responsibility, pursuant to 45 C.F.R. Part 46, including subsections 103 and 113, to report promptly to Institute A's IRB, appropriate institutional officials, and the HHS or NIH agency head any unanticipated risks to subjects or others, and any serious or continuing noncompliance with 45 C.F.R. Part 46 or the IRB's requirements or determinations. Institute A's IRB may also make these reports, but doing so does not relieve Institute A of the obligation to report to it institutional officials and HHS or NIH officials.

This Agreement is effective on the date that the last official signs and may be terminated by either party at any time. If the Agreement is terminated prior to the completion of the research, NIH will need to obtain alternative IRB review.

Signatory Officials:

x Mary Banks
Boston University Medical Center

Designee: Mary A. Banks, BS, BSN
Signing on behalf of
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Date: 2/15/13

x Charlotte Holden
National Institutes of Health

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Date: 2/19/13