

**Attachment 11** — NIEHS IRB approval letter to Consolidate Consent documents

The NIEHS IRB was recently installed as the IRB of record for the BLSA, replacing the MedStar IRB. As part of the transition from MedStar, the NIEHS IRB reviewed the entire BLSA protocol and recommended various revisions, among them the consolidation of the separate BLSA screening, clinic visit, and home visit consent forms into one booklet and form. Attached please find the NIEHS IRB approval letter.



DATE: April 15, 2014  
TO: Stephanie A. Studenski  
Principal Investigator, NIA  
FROM: Resnik David, J.D., Ph.D.  
Chair, NIEHS IRB  
NIEHS Office of Human Research Compliance (OHRC)  
SUBJECT: IRB Review of Protocol# 03-AG-N325, Longitudinal Studies of Human Physiology, Biochemistry, and Psychology (The Baltimore Longitudinal Study of Aging - BLSA)  
Final Approval

Your Amendment 02/12/2014 (4) was approved at the April 03, 2014 IRB meeting. All stipulations, if any, have been met.

Your IRB approved application will be forwarded to the Office of Protocol Services for final processing. You will receive notification when the Office of Protocol Services completes the processing of this application.

The protocol expiration date is January 21, 2015.

**IMPORTANT INFORMATION ABOUT YOUR PROTOCOL:**

Please use the final approved version of the protocol and consent as a guide for documents submitted for the next review.

ANY change in research activity MUST receive IRB review and approval prior to implementation. Request for review of changes should be submitted as an amendment.

Adverse or unexpected/unanticipated events or new information that may alter the risk or benefit determination or subjects willingness to continue in the study must be reported in accordance with NIH policy. Additional reporting (for example, to the sponsor or FDA) may also be required.

As Principal Investigator you are responsible for informing the Associate Investigators of the status of this project.

Please contact the NIEHS Office of Human Research Compliance (OHRC) if you have any questions and/or concerns.

03-AG-0325 AM E (4)

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