

Appendix A

Westat IRB Exemption Letter



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Date:	October 30, 2014
To:	Jennifer Huang, Project Director
From:	Kerry Levin, IRB Administrator, Westat IRB <i>Kerry Levin</i>
Subject:	Exemption of Study of NHLBI GHI Outcome Evaluation, Project 6268 FWA 00005551

As Chair of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **NHLBI GHI Outcome Evaluation, Project 6268**. The Westat IRB reviews all studies involving research on human subjects. This study is sponsored by NIH Heart, Lung and Blood Institute (NHLBI).

Westat will conduct a process evaluation of the Centers of Excellence program which is aimed to contribute to a reduction in the incidence and prevalence of chronic cardiovascular and pulmonary disease in low- and middle-income countries.

Data collection will include the following activities:

Interviews with key COE site staff (e.g., satisfaction with the COE program, sustainability of the program after funding)

- Data extraction from archived systematic reporting database (e.g., number of trainees, publications, awards)
- Data extraction from archived COE Program related documents (e.g., annual reports, proposals, RFPs) in the network.

Per [45 CFR 46.101(b5)] and a letter received on October 27, 2014, from Deshree Belis, MPH, Health Inequities and Global Health Branch, Center for Translation Research and Implementation Science, NHLBI; this research involves a program evaluation and therefore is exempt from IRB review.

The Project Director is required to notify the Board only if there are changes to the protocol or procedures regarding this project. In addition, notify the IRB Office as soon as possible if there are any injuries to the subjects or problems with the study that relate to human subjects.

cc: Institutional Review Board
David Burgess