Memo

Date: June 17, 2016

To: David Maklan, Project Director

From: Sharon Zack, Westat IRB Administrator

Subject: Expedited Amendment Approval of PATH, Project Number 8954

FWA 00005551

I reviewed the materials submitted for the following: **PATH, Project Number 8954**. The Westat IRB reviews all studies involving research on human subjects. This project was last reviewed in June 2016.

Sharm Back

This request was to approve the Wave 4 (third follow-up) collection of data and biospecimens, scheduled to begin December 2016. Included in this review were questionnaires, procedures and protocols, and informed consent and assent forms.

The regulations (45 CFR 46) permit expedited review of minor changes in previously approved activities. I am therefore approving the modifications under expedited authority.

- You are required to submit this study for a continuing review before April 18, 2017.
- In the interim, you are responsible for notifying the IRB Office as soon as possible if there are any injuries to the subjects as well as problems or changes with the study that relate to human subjects.

cc: Institutional Review Board Katie Gasque Jocelyn Newsome