

ATTACHMENT 12
INSTITUTIONAL REVIEW BOARD'S DOCUMENTATION



Combined NeuroScience IRB NEI, NIAAA, NIDA, NIDCD, NIMH, NINDS

Date: December 2, 2010
From: Barbara I. Karp, MD
Chair, CNS IRB

To: Bridget Grant, PhD
Principal Investigator

Subject: Protocol T-AA-0015: National Epidemiologic Survey on Alcohol and Related Conditions-III

The stipulations for Protocol T-AA-0015: National Epidemiologic Survey on Alcohol and Related Conditions-III have been satisfied.

This protocol has received final approval from the Combined NeuroScience IRB- White Panel.



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Memo

Date: December 13, 2010

To: Dave Maklan, Project Director

From: Kerry Levin; Chair, Westat IRB *Kerry Levin*

Subject: **Full Approval of The National Epidemiologic Survey on Alcohol and Related Conditions-III (NESARC), Project Number 8690 FWA5551**

On Tuesday, October 12th, 2010 the **NESARC Study, Project Number 8690**, was presented to the full Board. Pursuant to 45 CFR pt. 46, the IRB reviews all studies involving research on human subjects. It was considered minimal risk and assigned a conditional approval.

During the November 2010 full Board meeting, several additional issues were discussed by the IRB.

At this time all conditions have been met.

Action Taken: Per 45 CFR 46, this project meets criteria for classification as minimal risk and is assigned a full approval.

As the Project Director you are responsible for the following:

- If you received a conditional approval, project activities (e.g., recruiting, enrolling) may not begin until your responses have been received by the IRB and final approval is granted.
- You are required to submit this study for a continuing review on or before October 12, 2011.
- In the interim, you are responsible for notifying the IRB Office as soon as possible if there are any injuries to the subjects, problems with the study, or changes to the study design that relate to human subjects.

cc: Institutional Review Board
Gayle Wisdom
Katie Gasque