

Attachment 13
IRB Approval Letters

- 1. NIH**
- 2. Westat**

OHSR RESPONSE TO REQUEST FOR REVIEW OF RESEARCH ACTIVITY
INVOLVING HUMAN SUBJECTS

FAX:

Exempt #: 12367

To: Ginexi, Elizabeth
NCI
BG 9609 RM 3E564

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

The purpose of the State and Community Tobacco Control (SCTC) Research Initiative evaluation is to assess the dissemination, implementation, and community collaboration processes of the grantees and their respective state and community partners and stake holders. Results will address research-to-practice gaps by providing a critical window into the process of disseminating evidence-based research tools, products, and science findings in community public health settings. Intended audiences include staff at NIH Institutes and

Original Request Received in OHSR on: 3/26/2014

Responsible NIH Research Investigator(s): Elizabeth Ginexi, NCI

OHSR review of your request dated Mon, Mar 24, 2014 has determined that:

- Federal regulations for the protection of human subjects do not apply to above named activity. The OHSR determination of Not Human Subjects Research is based on the interpretation of 45 CFR 46 under "Research Involving Coded Private Information or Biological Specimens" (OHRP, Revised October 16, 2008) and Guidance on Engagement of Institutions in Human Subjects Research (October 16, 2008). NOTIFY OHSR VIA AN E-MAIL AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESEARCH ACTIVITY.
- The activity is designated **EXEMPT**, and has been entered in the OHSR database. **PLEASE NOTIFY OHSR OF ANY SIGNIFICANT CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.**
- NOT EXEMPT.** OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additional information in order to determine whether expedited or full review is appropriate.
- Confidentiality Agreement
- Reliance
- Amendment
- Other

Note:

4/28/2014: No Collaborators: Survey

Office Person TM

Admin Assist. CB



Takunda Matose

Signature

Program Analyst, OHSRP

Title

4/28/2014

Date

Domestic/International:

Domestic

Human Subjects Data: Yes

Biologic Material: No

OHSR Use Only

1 2 3 4 5 6



An Employee-Owned
Research Corporation

1600 Research Boulevard
Rockville, MD 20850-3129
tel: 301-251-1500
fax: 301-294-2040
www.westat.com

Date: February 5, 2014

To: Sophia Tsakraklides, Project Director

From: Sharon Zack, IRB Administrator, Westat IRB

Subject: Exemption of Study of the SCTC EVALUATION, Project
6048.06.01
FWA 00005551

As Chair of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: Study of the SCTC EVALUATION, Project 6048.06.01. The Westat IRB reviews all studies involving research on human subjects. This study is sponsored by the National Cancer Institute.

The purpose of this research is to conduct an evaluation of the State and Community Tobacco Control Research (SCTC) Initiative. This initiative investigates under-studied aspects of tobacco control policy and media interventions, including the following areas:

- Secondhand smoke policies,
- Tobacco tax and pricing policies,
- Mass media countermeasures and community and social norms, and
- Tobacco industry practices.

Data collection will include a web survey instrument, telephone interviews and focus groups, in conjunction with archival analysis.

Per [45 CFR 46.101(b5)] and a letter received from Elizabeth M. Ginexi, Ph.D., Program Director/Health Scientist, Tobacco Control Research Initiative, NCI; 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
Nancy Weinfield