

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

FAX: 301-435-3710
To: Hartman, Anne
NCI
EPN 4005

Exempt #: 12287

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

The TUS- is a periodic tobacco survey used by NCI and other federal partners and researchers to assess tobacco use in the US household population, and is administered as a Supplement to the Current Population Survey, administered by the US Census Bureau. The 2014-15 survey will be administered to approximately 255,000 respondents, and the resulting data delivered by the Census Bureau (absent identifying information as required by law) to NCI and FDA (co-sponsor) staff. The data will be analyzed by NCI and FDA staff and

Original Request Received in OHSR on: 1/30/2014

Responsible NIH Research Investigator(s): Anne Hartman, MS NCI

OHSR review of your request dated Tue, Jan 28, 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

Office Person TM

Admin Assist. CB

Note:
2/26/2014: Lisa Clement, US Census Bureau



Takunda Matose

Program Analyst, OHSRP

2/26/2014

Signature

Title

Date

Domestic/International:

Domestic

Human Subjects Data: Yes

Biologic Material: No

OHSR Use Only

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