

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

FAX:
To: Patrick, Heather
NCI
BG 9609 RM 3E112

Exempt #: 12257

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

This project involves running focus groups of women to determine values and goals that may be important in determining physical activity behavior. The project is guided by a self-determination theory framework. Please see attached OMB package for additional information.

Original Request Received in OHSR on: 1/3/2014

Responsible NIH Research Investigator(s): Heather Patrick, PhD NCI


OHSR review of your request dated Thu, Dec 12, 2013 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:
1/27/2014: No Collaborator: Survey


Takunda Matose
Signature

Program Analyst, OHSRP
Title

1/27/2014
Date

Domestic/International:
Domestic

Human Subjects Data: Yes

Biologic Material: No

OHSR Use Only

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