

DATE: February 13, 2013

TO: Jay M. Bernhardt, PhD; Tracey Barnett, PhD
PO Box 118210
Campus

FROM: Ira S. Fischler, PhD, Chair *ISF*
University of Florida
Institutional Review Board 02

SUBJECT: **Approval of Protocol #2013-U-0130**
Games for Health for Tobacco Prevention

SPONSOR: Ogilvy Public Relations Washington DC Office

I am pleased to advise you that the University of Florida Institutional Review Board has recommended approval of this protocol. Based on its review, the UFIRB determined that this research presents no more than minimal risk to participants, and based on 45 CFR 46.117(c), An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either: (1) *That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.*

The IRB authorizes you to administer the informed consent process as specified in the protocol. If you wish to make any changes to this protocol, ***including the need to increase the number of participants authorized***, you must disclose your plans before you implement them so that the Board can assess their impact on your protocol. In addition, you must report to the Board any unexpected complications that affect your participants.

This approval is valid through **February 3, 2014**. If you have not completed the study prior to this date, please telephone our office (392-0433), and we will discuss the renewal process with you. **Additionally, should you complete the study on or before the expiration date, please submit the study closure report to our office. The form can be located at http://ib.ufl.edu/irb02/Continuing_Review.html** It is important that you keep your Department Chair informed about the status of this research protocol.

ISF:dl

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

FAX: 301-496-7063
To: Goodman, Nina
NCI
Building 6116

Exempt #: 12051

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

The information collection request described in this memo supports the National Cancer Institute (NCI) Office of Communications and Education (OCE) and FDA Center for Tobacco Products, Office of Health Communication and Education partnership. This data collection will focus on the role of using games for promoting health in the US, including digital video games and gaming-based approaches, and how they can be used successfully as tools to prevent tobacco product use and improve smoking cessation rates

Original Request Received in OHSR on: 7/17/2013

Responsible NIH Research Investigator(s): Nina Goodman, MPH NCI

OHSR review of your request dated Wed, Jul 17, 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:
8/21/2013: Jay Bernhardt



Takunda Matose

Program Analyst, OHSRP

8/21/2013

Signature

Title

Date

Domestic/International:

Domestic

Human Subjects Data: Yes

Biologic Material: No

OHSR Use Only

1 2 3 4 5 6

Matose, Takunda (NIH/OD) [C]

From: OHSR (NIH/DDIR)
To: OHSR (NIH/DDIR); Goodman, Nina (NIH/NCI) [E]
Cc: Rawlings, Maria (NIH/NCI) [C]; Grant, Nicole (NIH/NCI) [E]
Subject: Determination for OHSRP 12051
Attachments: Request for Amendment OHSRP #____

Good morning, Dr. Goodman,

Attached is the OHSRP determination of **Not Human Subjects Research** as defined in 45 CFR 46.102 for your project *Reducing the Negative Impact of Tobacco on Youth Through Gaming: Interviews with Key Informants* with your collaborator Jay Bernhardt, University of Florida. You may proceed with the project.

Please retain this documentation as you would other research records. Amendments and or changes to the research must be submitted to OHSRP for review as changes may affect the determination. Please refer to **OHSRP #12051** for future amendments to this activity. To request future amendments, please use the attached email template modified to meet the specific changes needed for your project. If you have any questions or need further assistance, please feel free to contact us.

Best,

Takunda

OHSRP - National Institutes of Health
Bldg 10, Suite 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

From: OHSR (NIH/DDIR)
Sent: Friday, July 19, 2013 3:05 PM
To: Goodman, Nina (NIH/NCI) [E]
Cc: Rawlings, Maria (NIH/NCI) [C]
Subject: Req for Determination Rec'd_OHSRP 12051

Good afternoon Ms. Goodman,

This email is to verify that OHSR has received your Request for Determination and it is currently being processed as **OHSRP #12051**. Please use this number in any future correspondence regarding this study. We will contact you via email if any additional information is needed. If you have not heard from OHSR within 7 business days, please contact us.

Protocol Title: Reducing the Negative Impact of Tobacco on Youth Through Gaming: Interviews with Key Informants

Sincerely,
OHSRP - National Institutes of Health
Bldg 10, Suite 2C146
Bethesda, MD 20892