

**Attachment A.10.1: Letter from the NIH Office of Human Subjects Research
Protections**

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

FAX:

Exempt: #: 12601

To: Labosky, Patricia
OD

1 CENTER DR RM 214A

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

The proposed activity is to conduct a cross-site evaluation of the NIH Director's Workforce Innovation Award to Enhance Biomedical Research Training, also generally referred to as the Broadening Experiences in Scientific Training (BEST) program. The purpose of the NIH national cross-site evaluation is to identify best practices in the field of biomedical training. This will be accomplished by assessing two desired outcomes for trainees (graduate students and postdoctoral scientists) and one desired outcome for the grantee institution

Original Request Received in OHSR on: 9/11/2014

Responsible NIH Research Investigator(s): Patricia Labosky, OD

OHSR review of your request dated Tue, Sep 9, 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:
Program Evaluation

Office Person TM

Admin Assist. CB



Takunda Matose

Program Analyst, OHSRP

9/18/2014

Signature

Title

Date

Domestic/International:

Domestic

Human Subjects Data: Yes

Biologic Material: No

OHSR Use Only

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