

Attachment 6

IRB Approval Letters

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

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

FAX: 301-402-0711

Exempt #: 11840

To: Faupel-Badger, Jessica
NCI
37/1106

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

The CFPF is a 4-year intramural postdoctoral program and has been in existence for 25 years. Each year, 10-15 individuals are selected to become Fellows; approximately 200 individuals have completed the program and there are 40 current Fellows. Despite its long existence, there has not been a formal external evaluation of the career outcomes of CFPF trainees. With the diversity of disciplines recruited to the program and potential careers for postdoctoral fellows trained in cancer prevention and control, sufficient time was

Original Request Received in OHSR on: 3/8/2013

Responsible NIH Research Investigator(s): Jessica Faupel-Badger, Ph.D., MPH NCI


OHSR review of your request dated Fri, Mar 8, 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

Note:

Office Person HB

Admin Assist. CB


Heather Bridge
Signature

Program Analyst, OHSRP
Title

3/26/2013
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

Memo

Date: November 29, 2012
To: Marsha Dunn, Project Director
From: Kerry Levin, Chair Westat IRB

A handwritten signature in cursive script, appearing to read "Kerry Levin".

Subject: **Exemption of FELLOWSHIP PROGRAM EVALUATION, Project 6048.01
FWA 00005551**

As Chair of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **FELLOWSHIP PROGM EVALUATN, Project 6048.01**. The Westat IRB reviews all studies involving research on human subjects. This project is funded by the National Cancer Institute.

Westat will conduct 25 in-depth interviews with Cancer Prevention Fellowship Program (CPFP) alumni in order to provide a formal external evaluation of the career outcomes of CPFP trainees. Westat is also responsible for designing, administering, and analyzing the survey.

Per 45 CFR 46.101(b) (5) and confirmed by the letter received from Jessica Badger, Deputy director of NCI Cancer Prevention Fellowship Program, this project is a program evaluation and 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
Tim Smith