

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

FAX:
To: Ousley, Anita
NCI
6116 EXECUTIVE BLVD

Exempt #: 11860

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

This is a survey of 344 clients who contact NCI's Cancer Information Service (CIS) by phone, email, or Live Help to collect information about their satisfaction with the clinical trials information they received. We'd like to know if they used the information provided to them, how they used the materials and information provided to them, if it was shared with others, and if it helped them in decision-making about treatment or clinical trials. A small number (9 or less) of follow-up interviews will be conducted to gain an understanding of why

Original Request Received in OHSR on: 3/19/2013

Responsible NIH Research Investigator(s): Anita Ousley, PhD NCI

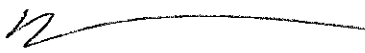
OHSR review of your request dated Wed, Mar 13, 2013 has determined that:

- 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 HB

Admin Assist. CB

Note:
3/27/13: University of Massachusetts, Donahue Institute


Heather Bridge
Signature

Program Analyst, OHSRP
Title

3/27/2013
Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: No

OHSR Use Only
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