

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

FAX: Exempt #: 5469
To: Montello, Michael
NCI
EPN - Executive Plaza North, 7024

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

Though data is being collected by the CIRB, there is no intent to use this information for research in any form. The data being collected is for the sole purpose of fulfilling the mission of the Central Institutional Review Board (CIRB). The data available is not intended in any use other than to conduct IRB review of studies. Therefore, data are not being collected on human subject participants as part of the CIRB Initiative. The CIRB improves access to NCI-sponsored Cooperative Group clinical trials for potential study participants and

Original Request Received in OHSR on: 10/19/2010

Responsible NIH Research Investigator(s): Michael Montello, NCI

OHSR review of your request dated Thu, Oct 14, 2010 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 SPC

Admin Assist. CB

Note:


Charlotte Holden, JD

Signature


Acting Director, OHSR

Title

10/25/2010

Date

Domestic/International:

Domestic

Human Subjects Data: Yes

Biologic Material: No

OHSR Use Only

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