

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

FAX: Exempt #: 13016
To: De Moor, Janet
NCI
9609 Medical Center Drive. Room 3E438

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

The present study aims to investigate the current practice of precision medicine in cancer treatment through a nationally representative survey of medical oncologists. Specifically, the survey is designed to assess oncologists' current and potential use of genomic testing in their practice, as well as inform the development of interventions to facilitate optimal use of genomic testing and improving patient-physician discussions of the risks possible benefits and uncertainties surrounding the application of these tests. The objectives of the

Original Request Received in OHSR on: 8/12/2015

Responsible NIH Research Investigator(s): Janet De Moor, PhD, MPH NCI

OHSR review of your request dated Thu, Jun 18, 2015 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 JE

Admin Assist. CB

Note:
9/22/15: Kristine Fahrney, RTI International



Julie M. Eiserman

Policy Analyst, OHSRP

9/22/2015

Signature

Title

Date

Domestic/International:

Domestic

Human Subjects Data: Yes

Biologic Material: No

OHSR Use Only

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