

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

FAX: Exempt #: 12434
To: Seminara, Daniela
NCI
9609 Medical Center Drive Room 4E130

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

The mission of the Epidemiology and Genomics Research Program (EGRP) - located in the Division of Cancer Control and Population Sciences, National Cancer Institute's (NCI's), National Institutes of Health (NIH)- is to support collaborative research among investigators and to implement research based on cancer epidemiology cohorts. EGRP fosters collaborations among cohorts through which cohort investigators and

Original Request Received in OHSR on: 5/19/2014

Responsible NIH Research Investigator(s): Daniela Seminara, NCI

OHSR review of your request dated Mon, May 19, 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

Office Person TM

Admin Assist. CB

Note:
6/4/2014: No collaborators: Survey



Takunda Matose

Signature

Program Analyst, OHSRP

Title

6/4/2014

Date

Domestic/International:

Domestic

Human Subjects Data: Yes

Biologic Material: No

OHSR Use Only

1 2 3 4 5 6

Matose, Takunda (NIH/OD) [C]

From: OHSR (NIH/DDIR)
To: Seminara, Daniela (NIH/NCI) [E]
Cc: Lai, Gabriel (NIH/NCI) [E]; Grant, Nicole (NIH/NCI) [E]
Subject: Determination for OHSRP 12434
Attachments: Request for Amendment OHSRP #____

Dear Dr. Seminara,

Attached is the OHSRP determination of **Excluded from IRB Review** per 45 CFR 46 and NIH policy for your project *Data Collection for Public Descriptive Cohorts Database*. **You may proceed with the project.**

Please retain this documentation as you would other research records. Amendments and or changes to the research must be submitted to OHSRP for review as changes may affect the determination. Please refer to **OHSRP #12434** for future amendments to this activity. To request future amendments, please use the attached email template modified to meet the specific changes needed for your project. If you have any questions or need further assistance, please feel free to contact us.

Best,

Takunda Matose
OHSRP - National Institutes of Health
Bldg 10, Suite 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

From: OHSR (NIH/DDIR)
Sent: Tuesday, May 27, 2014 12:39 PM
To: Seminara, Daniela (NIH/NCI) [E]
Cc: Lai, Gabriel (NIH/NCI) [E]
Subject: Req for Determination Rec'd_OHSRP 21434

Good afternoon Dr. Seminara,

This email is to verify that OHSR has received your Request for Determination and it is currently being processed as **OHSRP #12434**. Please use this number in any future correspondence regarding this study. We will contact you via email if any additional information is needed. Please note that due to ongoing project deadlines, determinations are taking longer than normal to process.

Protocol Title: Data Collection for Public Descriptive Cohorts Database

Thank you.

Sincerely,

Chris Brentin

OHSRP - National Institutes of Health
Bldg 10, Suite 2C146
Bethesda, MD 20892