

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

FAX: Exempt #: 12656

To: Dickherber, Anthony
NCI
BG 31 RM 10A33

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

Investigator is surveying applicants and awardees of the NCI IMAT program as part of a process and outcome evaluation of the program's activities and investments. The purpose of this evaluation is to determine the appropriateness of the program structure and goals for serving the mission of the NCI.

Original Request Received in OHSR on: 10/16/2014

Responsible NIH Research Investigator(s): Anthony Dickherber, PhD NCI

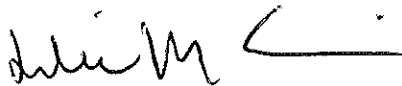
OHSR review of your request dated Tue, Jul 29, 2014 has determined that:

- 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 JE

Admin Assist. CB

Note:
QA/QI



Julie M. Eiserman

Policy Analyst, OHSRP

11/6/2014

Signature

Title

Date

Domestic/International:

Domestic

Human Subjects Data: Yes

Biologic Material: No

OHSR Use Only

1 2 3 4 5 6

Eiserman, Julie (NIH/OD) [C]

From: OHSR (NIH/DDIR)
To: Dickherber, Tony (NIH/NCI) [E]
Cc: Grant, Nicole (NIH/NCI) [E]; Dahut, William (NIH/NCI) [E]
Subject: FW: Determination of OHSRP #12656
Attachments: Request for Amendment OHSRP #____

Dear Dr. Dickherber,

Thank you for your patience. We have recently experienced a staff turnover. Attached is the OHSRP determination of **Excluded from IRB Review** per 45 CFR 46 and NIH policy for the collection of survey data for your quality improvement project, 'Outcome evaluation of the NCI Innovative Molecular Analysis Technologies (IMAT) extramural grant program'. **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 #12656** 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.

Sincerely,

Julie M. Eiserman, MA, CCRP [C]

Health Science Policy Analyst

Office of Human Subjects Research Protections

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Bethesda, MD 20892-1154

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OHSRP website: <https://federation.nih.gov/ohsr/nih/index.php> (NIH login required)

Public site: <http://ohsr.od.nih.gov/>