

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

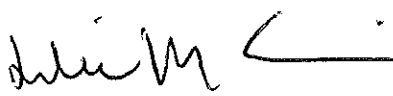
OHSR review of your request dated Tue, Jul 29, 2014 has determined that:

- 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
Signature

Policy Analyst, OHSRP
Title

11/6/2014
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

10 Center Drive, Bldg. 10, Suite 2C146

Bethesda, MD 20892-1154

Office Phone: 301-402-3444

Fax: 301-402-3443

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

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

REQUEST FORM: OHSRP DETERMINATION FOR SURVEYS, INTERVIEW PROCEDURES, PROGRAM EVALUATION, EDUCATIONAL TESTING AND RESEARCH

Date of Request: 07/29/2014

Requestor's name: Anthony Dickherber e-mail: dickherberaj@mail.nih.gov

Role: Administrative support Investigator Other, explain: _____

Name of NIH Senior Investigator: Anthony Dickherber

(The investigator must be an NIH employee)

IC NCI Laboratory/Branch Center for Strategic Scientific Initiatives

Building & Room No. 31/10A33 Tel. No. (301)547-9980 FAX No. (301)480-2889

Is the NIH Senior Investigator an NIH employee(FTE)? Yes No

Senior Investigator Signature: _____

(Signature of Investigator who will conduct research)

Supervisor Signature: _____

(Signature of official for IC, e.g., Lab/Branch Chief)

Name of NIH investigator conducting research if not the NIH Senior Investigator: *(i.e., junior investigator, contractor investigator, fellow, student)*

Please provide the name and e-mail of any others who should receive a copy of the OHSRP determination: _____

1. What role will the NIH investigator(s) have in this research project? *(check all that apply)*

- Conduct research activity
- Analyze samples/data only
- Consultant/advisor to collaborator(s)
- Author on publication(s)/manuscript(s) pertaining to this research
- Other, please describe: _____

2. Title: Outcome evaluation of the NCI Innovative Molecular Analysis Technologies (IMAT) extramural grant program

(Provide a short title to distinguish this activity from other projects that you may have)

3. Describe in lay terms the research activity that will be performed:

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.

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4. Proposed start date 03/01/2015 Proposed completion date 09/01/2015

5. Specify the nature of the data: (select all that apply)

- Interview procedure
 Survey
 Educational Testing
 Educational Research
 Research on public benefit or service programs
 Other, describe: _____

6. What kind of human data (e.g., private information, responses to questionnaires, test results, recordings) will be collected in your research?

Responses to a questionnaire regarding their views of the program in question, their research experience in developing a novel technology, and their reflections on the current state of the technology for applicable fields of research.

7. Will human data be? (select all that apply)

- Collected Yes No
Received Yes No
Sent Yes No

8. If receiving or sending, list the collaborating investigator(s):

Name	Institution/IC	Address/e-mail	FWA number*
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9. Where are the subjects of this research activity located? (Provide a general description or complete the institutional information below)

Survey responders are predominantly located at institutions across the United States of America with a small percentage of responders located at foreign institutions.

Institution: _____ Contact Name: _____

Address: _____ Phone: _____

10. Will NIH investigator(s) have direct contact or intervention with the subjects of the study? (For example, by interviewing, surveying or recording the subjects?)

Yes No

If yes, what is the age range of subjects involved in the research?

- Children aged < 18 years
 Adults aged ≥ 18 years

11. Who will collect the data or information?

**REQUEST FORM: OHSRP DETERMINATION FOR SURVEYS, INTERVIEW PROCEDURES,
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- (a) ___ NIH Investigator
(b) ___ non-NIH Collaborator
(c) X NIH Contractor
(d) ___ Other, specify _____

If b or c, will an Honest Broker or data use agreement be used? Yes ___ No X

If yes, complete and attach the Honest Broker Assurance or data-use agreement to this submission; e-mail ohsr_nih_ddir@od.nih.gov to request a form.

12. Select the best description that applies to the human data or information:

- ___ Data or information will not contain any identifiable information, nor can it be linked to individual subjects by you or your collaborators.
X Data or information will be recorded in such a manner that subjects can be identified directly or through identifiers linked to the subjects

13. Per NIH guidance, are all conflicts of interest by NIH employees (sender or receiver), if any, resolved? X Yes ___ No**

**A Federalwide Assurance (FWA) is issued by the U.S. Department of Health and Human Services (DHHS)/ Office of Human Research Protections (OHRP) to institutions which receive Federal funds/support to conduct human subjects research. To search for the FWA# for domestic or international institutions go to <http://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc>*

***If the answer is "No", note that OHSRP will be unable to make a determination and research may not proceed until all conflicts are resolved. For more information, see the October 2011, [A Guide to Preventing Financial and Non-Financial Conflict of Interest in Human Subjects Research at NIH](#). For assistance review the list of Ethics Coordinators and find the contact for your IC: <http://ethics.od.nih.gov/coord.pdf>*

OHSR (NIH/DDIR)

From: Dickherber, Tony (NIH/NCI) [E]
Sent: Thursday, October 16, 2014 10:41 AM
To: OHSR (NIH/DDIR)
Cc: Barnes, Dereck (NIH/OD) [E]; Matose, Takunda (NIH/OD) [C]
Subject: Request for OHSRP approval to survey program participants
Attachments: Attachment 7_OHSRP Exemption(PLACEHOLDER).pdf

To whom it may concern:

Please find attached a request for approval from OHSRP to issue surveys and interviews as part of an extramural program evaluation of the NCI Innovative Molecular Analysis Technologies (IMAT) program. This request was put together with guidance from Takunda Matose (cc'd) this past July, but mistakenly assumed that the submission seeking approval from the Office of Management and Budget for a waiver of the Paperwork Reduction Act was the appropriate mechanism for registering this request. It only recently became clear to me that this form should be submitted to this office.

For background, this request is for permission to obtain new information from extramural researchers regarding their experience with technology development research supported by NIH grant programs, especially associated with the NCI IMAT program. Please don't hesitate to contact me for any additional information.

Kind regards
Tony

Tony Dickherber, PhD
Program Director
Innovative Molecular Analysis Technologies
<http://innovation.cancer.gov>
National Cancer Institute
National Institutes of Health
Tel. (301)547-9980
Fax.(301)480-2889
anthony.dickherber@nih.gov

 *Please consider the environment before printing this message.*

Brentin, Christine (NIH/OD) [E]

From: OHSR (NIH/DDIR)
Sent: Monday, October 20, 2014 3:21 PM
To: Dickherber, Tony (NIH/NCI) [E]
Subject: Req for Determination Rec'd_OHSRP 12656

Good afternoon Dr. Dickherber,

This email is to verify that OHSR has received your Request for Determination and it is currently being processed as **OHSRP #12656**. Please use this number in any future correspondence regarding this study.

Protocol Title: Outcome evaluation of the NCI Innovative Molecular Analysis Technologies (IMAT) extramural grant program

Thank you.

Sincerely,

Chris Brentin

OHSRP - National Institutes of Health

Bldg 10, Suite 2C146

Bethesda, MD 20892

Office Telephone: 301-402-3444

Office Fax: 301-402-3443

The NIH is committed to maintaining the highest standards for the protection of human subjects.



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