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

FAX: **Exempt: #:** 5301

To: Hewes, John
NCI
EPS - Executive Plaza South, 450

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
The Technology Transfer Center (TTC) of the National Cancer Institute (NCI) negotiates and manages research collaborations for the NCI Intramural Research Program and nine other Institutes and Centers of the National Institutes of Health (NIH). (The NCI TTC does not negotiate licenses, s this activity is relegated solely to the centralized NIH Office of Technology Transfer.) The research activity is a Program Assessment of the NCI TTC funded primarily through the NIH Evaluation Office Evaluation Set-Aside program The

Original Request Received in OHSR on: 6/25/2010

Responsible NIH Research Investigator(s): John Hewes, PhD NCI

OHSR review of your request dated Thu, Jun 10, 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:
Submit to OHSR the final survey instruments, interview guides, and consent form or script for inviting subjects to participate as amendments once they are developed. These can be submitted as an e-mail attachment requesting an amendment to OHSR #5301.

Charlotte Holden, JD — Signature
Acting Director, OHSR — Title
7/21/2010 — Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: No

OHSR Use Only
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

#5301

REQUEST FOR REVIEW OF RESEARCH ACTIVITY INVOLVING HUMAN SUBJECTS

INSTRUCTIONS: Please type directly on this form. You can expand the document if you need more space. If your research involves a survey or questionnaire, please attach it to this completed form.

Completed forms (with all required signatures) may be sent to OHSR by FAX (301-402-3443), email to ohsr_nih_ddir@od.nih.gov, or by mail (2C146). If you have any questions, call OHSR at (301) 402-3444.

Date: June 10, 2010

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146

From: John D Hewes 06/11/2010
(John D. Hewes, Technology Transfer Specialist, Technology Transfer Center, National Cancer Institute)

Through: Karen Maurey
(Karen Maurey, Director, Technology Transfer Center, National Cancer Institute)

Protocol Title: Technology Transfer Center External Customer Satisfaction Survey

Name of NIH Principal Investigator(s): John D. Hewes, Ph.D.

IC: NCI
Laboratory/Branch: Technology Transfer Center
Building & Room No.: EPN 450
Tel. No. 301-4965-0477
FAX No. 301-402-2117

Is the Principal investigator an NIH employee? X **Yes** _____ **No**

If no, please explain: _____

1. What is the proposed research activity that you intend to perform at NIH (please use lay terms):
The Technology Transfer Center (TTC) of the National Cancer Institute (NCI) negotiates and manages research collaborations for the NCI Intramural Research Program and nine other Institutes and Centers of the National Institutes of Health (NIH). (The NCI TTC does not negotiate licenses, as this activity is relegated solely to the centralized NIH Office of Technology Transfer.)

The research activity is a Program Assessment of the NCI TTC funded primarily through

the NIH Evaluation Office, Evaluation Set-Aside program. The objectives of this Assessment are to evaluate three components that are critical to the performance of the NCI TTC:

(1) Satisfaction of TTC's external customers with its services;
(2) Preferred and expected communications channels of TTC's external customers; and
(3) Strategic direction of companies engaging in research-related partnerships with the NIH.

The program assessment will have direct usefulness to the NCI TTC and provide valuable information to the NIH technology transfer community. The results of the external customer survey will be used to achieve the following goals:

(1) improvement of the TTC workflow process;
(2) more focused marketing of NIH discoveries to TTC's external customers; and
(3) better communication of industry needs to NIH scientists.

The assessment will consist of an online Customer Satisfaction Survey of external customers, that is, those in the for-profit biotechnology and pharmaceutical sectors who interact with the TTC. The proposed research methodology is a brief web-based survey conducted in two phases:

(1) a pre-test of 9 or fewer subjects; and
(2) a full-scale web-based survey.

The research participants are past, current, and potential TTC external customers (i.e. industrial biotechnology, pharmaceutical and medical device executives). For mid-sized to large companies, the respondents will be at the level of Manager, Director or Vice President for Business Development. At smaller companies, the respondents will be individuals at the Chief Executive Officer, Chief Medical Officer, Chief Technology Officer, or Chief Science Officer level.

2. If applicable, list your non-NIH Collaborating Investigator(s).

Name Institution Address Tel. # FAX #
(Not Applicable)

3. Proposed start date of your research
June 21, 2010 for pretest;
April-May 2011 (pending OMB clearance) for the full-scale survey

Proposed completion date
July 2010 for pretest; July 2011 for completion of full-scale survey data collection

4. Will you be _____these samples or data?

Collecting No
Receiving No*
Sending No

* For the pre-test (aka "pilot survey"), we will receiving a report and revised survey design from the contractor, but no raw data. For the full survey, which will probably require an amendment to this application, we will have the option of receiving the anonymous/aggregated data.

5. Do the samples or data:

(a) Already exist? ___Yes __X_ No

(b) Or are they being collected for the express purpose of this study?
_X_ Yes ____No
If "yes," please describe:

The results of the external customer survey will be used to achieve the following goals: (1) improvement of the TTC workflow process; (2) more focused marketing of NIH discoveries to TTC's external customers; and (3) better communication of industry needs to NIH scientists.

(c) Or a combination of (a) and (b)? ____Yes __X__ No

6. What role will you have in this research project? (Check all that apply)

___ Analyze samples/data only.

__ Consultant/advisor to collaborator(s) listed above.

___ Author of the protocol that is being implemented by your collaborating investigator (identified in question #2).

__X_ Co-authorship on publication(s)/manuscript(s) pertaining to this research.

___ You or NIH hold an IND for this research.

_X__ Decisional authority over the design or implementation of the research at the IRB approved site? If so, please explain.

NCI TTC created the design for the survey and questionnaire and is responsible for the implementation of this research.

___Other (If necessary, use this space to describe your role in this research).

7. Where are the subjects of this research activity located?

Internet respondents worldwide

8. If human subjects are located elsewhere (not at NIH), will you have direct contact or intervention with them? (Examples: as subject's physician; in obtaining samples directly from the subject; by interviewing the subject?) __X_ Yes ____No

Pre-test and Survey participants will not have personal contact by Project Officer.

Pre-test participants will be recruited by mailed invitation signed by TTC Director, followed by email instructions on how to participate sent by outside contractor.

Full survey participants will be sent an invitation to participate, signed by TTC Director, sent by outside contractor via two emails instructing participants that they can voluntarily respond to survey via a secure, online questionnaire.

In both Pre-test and Survey, NCI personnel will have no direct contact with participants and will not have an opportunity to obtain or view raw data submitted by the respondents. Data will be aggregated and analyzed by the outside contractor and submitted to NCI TTC as anonymous data.

9. What kind of human samples (e.g., tissue, blood) or data (e.g., private information, responses to questionnaires) will be involved in your research?

Respondents will be asked to answer questions about company experiences in three areas: (1) general respondent company information (e.g. Is your company Public or Private?); (2) strategic directions (e.g. Does your company develop strategic technology partnerships (research collaborations, licensing, etc.) with outside organizations?); and (3) experience with NIH TTC services (e.g. How did you first learn about the NCI Technology Transfer Center?).

No personal information will be asked. Respondents will be asked for a corporate telephone number. (The survey instrument states **"The survey administrator is a contractor to the NIH. They may follow up by telephone with some participants to clarify answers. If you are available for follow-up, please provide a contact number where you can be reached.")** Survey respondents will be given the opportunity at the end of the survey to follow a link to the NCI TTC website to sign up for listserv announcements open to the general public.

10. If the samples, data do not come from an IRB approved protocol, do they come from:

(a) Repository ____Yes _x_ No

(b) Pathological waste ___ Yes _x_No

(c) Autopsy material ___ Yes _x_ No

(d) Publicly available source ___Yes _x_ No

(e) Other_____N/A_____

11. Please check the box(es) that apply(ies) to the samples/data that you will receive.

(a) _X_ Samples and/or data will be anonymized/unlinked. (The samples/data cannot be linked to individual subjects by you or your collaborators at other sites.)

(b) ___ Samples and/or data will be coded, however that code cannot be used by either the sender or the receiver to identify specific individuals.

(c) ___ Samples and/or data will be coded so that the provider of the samples/data can link them to specific individuals but the receiver will not be able to do so.

12. Will you send results back to the provider(s) (listed in question 2 of this form)?

(a) _X_ No, I will not send results back to the provider(s).

(b) ___ Yes, I will send aggregate results to the provider(s).

(c) ___ Yes, I will send results to the provider(s) that are linked to identifiable individuals.

If yes, does the provider intend to link your data to identifiable individuals?

_____Yes _____No

13. Has the research activity <u>that you are proposing in this form</u> been approved by an Institutional Review Board (IRB) elsewhere?

_____ Yes, the NIH research activity has been reviewed by the following IRB (s) (Please provide the following information for **each** IRB):

_____ Name of institution that provided the review

_____ Address of reviewing institution

_____ Name of PI for the IRB approved protocol

_____ Title of IRB approved protocol and protocol #

_____ Federal Wide Assurance (FWA) number**

___X___ No IRB review of the research activity described in question #1 above has taken place

(**An FWA is a contract between the U.S. Department of Health and Human Services (DHHS) and an entity receiving DHHS funds to conduct clinical research that the latter will follow ethical guidelines and federal regulations for the protection of human subjects. For a list of domestic and international institutions go to http://ohrp.cit.nih.gov/search/asearch.asp#ASUR

14. Per NIH guidance***, have conflicts of interest by NIH employees, if any, been resolved?
___X__ Yes _____No

If your answer is no, please see your Clinical Director about this matter before proceeding with this research.

***The January 5, 2005 NIH Guide to Preventing Conflict of Interest applies to all research conducted at NIH, http://ohsr.od.nih.gov/New/mpafwa_docs.html

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Monday, June 28, 2010 11:42 AM
To: Hewes, John (NIH/NCI) [E]
Subject: Request for Review Rec'd-OHSR 5301

Good morning Dr. Hewes,

This email is to verify that OHSR has received your Request for Review of Research and it is currently being processed as **OHSR #5301.** Please use this number in any future correspondence regarding this study. We will contact you via email if any additional information is needed. If you have not heard from OHSR within 7 business days, please contact us.

Protocol Title: Technology Transfer Center External Customer Satisfaction Survey

Thank you.

Sincerely,

OHSR - 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.


Please consider the environment before printing this e-mail

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Friday, July 23, 2010 9:19 AM
To: Hewes, John (NIH/NCI) [E]
Subject: Request for Review Determination_OHSR 5301
Attachments: HewesJ_NCI_5301_CY2010.pdf

Good morning, Dr. Hewes.

Attached, please find OHSR's determination of your Request for Review of Research, OHSR #5301.

Please contact OHSR with any questions.

Thank you.

Sincerely,
OHSR - 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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