

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

FAX: Exempt #: 4741

To: Taubenheim, Ann
NHLBI
Building 31 - Claude D Pepper Building, 4A10

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

The NHLBI seeks to collect data from NHLBI Health Information Center (HIC) customers who contact the HIC by telephone and e-mail to assess customer perception of the quality of services provided by the HIC.

Original Request Received in OHSR on: 6/16/2009

Responsible NIH Research Investigator(s): Ann Taubenheim, NHLBI

OHSR review of your request dated Wed, May 13, 2009 has determined that:

- Federal regulations for the protection of human subjects do not apply to above named activity. No further action is necessary.
- 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

Note: Office Person SPC Admin Assist. CB


Charlotte Holden, JD
Signature


Acting Director, OHSR
Title

6/19/2009
Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: No

OHSR Use Only
 1 2 3 4 5 6

#4741

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) or by mail (2C146). If you have any questions, call OHSR at (301) 402-3444.

Date: May 13, 2009

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

From: Ann Taubenheim, Ph.D., M.S.N. *Ann Taubenheim*
(Signature)

Through: Susan Shurin, M.D. *Susan Shurin*
(Signature of appropriate Official for IC, e.g., Lab/Branch Chief)

Name of NIH Principal Investigator(s): Ann Taubenheim, Ph.D., M.S.N.

IC NHLBI Laboratory/Branch Office of Communications and Legislative Activities
Building & Room No. Bldg 31, R 4A10 Tel. No. 301-496-4236 FAX No. 301-480-4907

Is the Principal investigator an NIH employee? 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 NHLBI seeks to collect data from NHLBI Health Information Center (HIC)

customers who contact the HIC by telephone and e-mail to assess customer perception of the quality of services provided by the HIC.

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

Name	Institution	Address	Tel. #	FAX #

3. Proposed start date of your research 11/2009
Proposed completion date 12/2009

4. Will you be collecting these samples or data?

Collecting Yes/No
Receiving Yes/No
Sending Yes/No

5. Do the samples or data:

(a) Already exist? ___ Yes No

(b) Or are they being collected for the express purpose of this study? Yes ___ No
If "yes," please describe: We are collecting responses to assess customer perception of the quality of services provided.

(c) Or a combination of (a) and (b)? ___ Yes 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).

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

___ You or NIH hold an IND for this research.

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

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

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

Primarily in the United States, with some international respondents

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?) ___ Yes No

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?

Data will be responses to questionnaires

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

- (a) Repository ___ Yes No
- (b) Pathological waste ___ Yes No
- (c) Autopsy material ___ Yes No
- (d) Publicly available source ___ Yes No
- (e) Other Electronic survey

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

- (a) 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) 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 that you are proposing in this form 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**

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?**

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

Attachment A. Revolving Customer Satisfaction Online and Telephone Surveys

NHLBI Health Information Center (HIC) Customer Satisfaction Survey Questions—Online Survey

*OMB No. 0925-XXXX
Exp. Date xx/xx/20xx*

*Public reporting burden for this collection of information is estimated to average 3 minutes or less per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-xxxx*). Do not return the completed form to this address.*

Evaluation Categories

- Timely response
- Knowledge of NHLBI health information
- Professionalism of response
- Meeting the requestor's needs
- Overall service

Introduction

Thank you for helping to rate the performance of the NHLBI Health Information Center. Please click the appropriate button to record your rating.

Questions

Please Rate:

- 1. The amount of time it took the NHLBI Health Information Center to respond to your request.**
 1 Poor 2 Fair 3 Good 4 Very Good 5 Excellent
- 2. The information specialist's knowledge of your topic.**
 1 Poor 2 Fair 3 Good 4 Very Good 5 Excellent
- 3. The information specialist's professionalism.**
 1 Poor 2 Fair 3 Good 4 Very Good 5 Excellent

4. **How well the information specialist met your information needs.**

1 Poor 2 Fair 3 Good 4 Very Good 5 Excellent

5. **The overall customer service you received.**

1 Poor 2 Fair 3 Good 4 Very Good 5 Excellent

6. **Are there other comments or suggestions you would like to make about the NHLBI Health Information Center? If so, please type here:**

NHLBI Health Information Center (HIC)
Customer Satisfaction Survey Questions—Telephone Survey

OMB No. 0925-XXXX
Exp. Date xx/xx/20xx

*Public reporting burden for this collection of information is estimated to average 3 minutes or less per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-xxxx*). Do not return the completed form to this address.*

Evaluation Categories

- Timely handling of call
- Knowledge of NHLBI health information
- Professionalism of call handling
- Meeting the caller's needs
- Overall service

Script

Thank you for agreeing to rate the service that you received today from the NHLBI Health Information Center. There are six questions. After each question, please press or say the number for your response. To repeat a question, press the pound sign.

1. **Please rate the amount of time it took the NHLBI Health Information Center to respond to your request.** If it was poor, say or press 1. If it was fair, say or press 2. If it was good, say or press 3. If it was very good, say or press 4. If it was excellent, say or press 5.
2. **Please rate the Information Specialist's knowledge of your topic.** If it was poor, say or press 1. If it was fair, say or press 2. If it was good, say or press 3. If it was very good, say or press 4. If it was excellent, say or press 5.
3. **Please rate the Information Specialist's professionalism.** If it was poor, say or press 1. If it was fair, say or press 2. If it was good, say or press 3. If it was very good, say or press 4. If it was excellent, say or press 5.
4. **Please rate how well the Information Specialist met your information needs.** If it was poor, say or press 1. If it was fair, say or press 2. If it was good, say or press 3. If it was very good, say or press 4. If it was excellent, say or press 5.
5. **Please rate the overall customer service you received.** If it was poor, say or press 1. If it was fair, say or press 2. If it was good, say or press 3. If it was very good, say or press 4. If it was excellent, say or press 5.
6. **Are there other comments or suggestions you would like to make about the NHLBI Health Information Center?** If so, please provide them after the tone. Thanks!

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Wednesday, June 17, 2009 9:53 AM
To: Taubenheim, Ann (NIH/NHLBI) [E]
Cc: McConnell, Patrick (NIH/NHLBI) [C]
Subject: Request for Review Rec'd-OHSR

Good morning Dr. Taubenheim,

This email is to verify that OHSR has received your Request for Review of Research and it is currently being processed as OHSR #4741. 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.

OHSR #4741: Study involving data from HIC

OHSR:
Ph: 301.402.3444
Fax: 301.402.3443

Thank you.

Sincerely,

Chris Brentin

Program Support Assistant

OD/OHSR/NIH

10 Center Drive, Rm. 2C-146

Bethesda, MD 20892

301-402-8631 (Direct)

301-402-3443 (Fax)