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

FAX: **Exempt: #:** 5260

To: McMullen, Susan
NCI
Building 82 - R A Bloch International Cancer Center, 101

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
The purpose of this research is to gain understanding of the awareness level and knowledge of NCI, including the services NCI provides, the activities it conducts, and its location. The survey also asks about clinical trial referral practices and how these physicians find out about clinical research opportunities for their patients.

Original Request Received in OHSR on: 6/2/2010

Responsible NIH Research Investigator(s): Susan McMullen, NCI

OHSR review of your request dated Thu, Apr 1, 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

Note: Office Person SPC Admin Assist. CB

Charlotte Holden, JD — Signature
Acting Director, OHSR — Title
6/15/2010 — Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: No

OHSR Use Only
☐ 1 ☒ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

#5206

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: April 1, 2010

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

From: Susan McMullen
(Signature)

Through: _____
(Signature of appropriate Official for IC, e.g., Lab/Branch Chief)

Protocol Title: The Survey of Health Care Professionals' Awareness and Perceptions of the National Cancer Institute's Intramural Clinical Trials (NCI)

Name of NIH Principal Investigator(s):
Susan McMullen, RN, Director, Office of Patient Outreach and Recruitment
Center for Cancer Research,
NCI
Bloch Building 82, Room 101, MSC 8200,
9030 Old Georgetown Road, Bethesda, Maryland 20892
mcmulles@mail.nih.gov
Tel. No: (301) 402-5931 **FAX No:** (301) 480-0278

Is the Principal investigator an NIH employee? Yes

If no, please explain: _____

1. **What is the proposed research activity that you intend to perform at NIH (please use lay terms):**
   The purpose of this research is to gain understanding of the awareness level and knowledge of NCI, including the services NCI provides, the activities it conducts, and its location. The survey also asks about clinical trial referral practices and how these physicians find out about clinical research opportunities for their patients.

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

Jean Walmsley
MMG
600 Kings Farm Boulevard
5th Floor
Rockville MD 20850
jwalmsley@mmgct.com
Phone: 301-348-1627
Fax: 301-921-4405

3. Proposed start date of your research _____September 2010__
Proposed completion date __October 2010_ and then yearly for 3 years

4. Will you be _____these samples or data?

Collecting **Yes**
Receiving No
Sending No

5. Do the samples or data:
(a) Already exist? No

(b) Or are they being collected for the express purpose of this study? Yes
If "yes," please describe: The purpose of this research is to gain understanding of the awareness level and knowledge of NCI, including the services NCI provides, the activities it conducts, and its location. The survey also asks about clinical trial referral practices and how these physicians find out about clinical research opportunities for their patients. The survey results are collected anew each time the survey is sent out.

(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?

E-mail survey sent out nationwide by AMA to members who have opted in to receive e-mails

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?) 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?

No human samples will be involved. Respondents will be asked to answer questions about their experience and opinions on NCI and the services the institute provides.

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

(a) Repository No - N/A

(b) Pathological waste No - N/A

(c) Autopsy material No - N/A

(d) Publicly available source No - N/A

(e) Other___

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 <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**

_____√____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?
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

National Cancer Institute

Fax

To: OHSR

From: Susan McMullen
Office of Patient Outreach and Recruitment
CCR

Fax: 301-402-3443

Pages: 6 (including cover)

Phone:

Date: 6/2/2010

Re: Request for review

CC:

☐ **Urgent** ☐ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

• **Comments:**

OHSR (NIH/DDIR)

From: Walmsley, Jean [jwalmsley@mmgct.com]
Sent: Monday, June 14, 2010 12:27 PM
To: OHSR (NIH/DDIR)
Cc: McMullen, Susan (NIH/NCI) [E]; Goldfarb, Jeff (MMG); Badillo, Veronica; Carrigan, Angela
Subject: McMullenS_NCI_5260_CY2010
Attachments: Attachment 1_ Email Survey 2010 v2 2010.03.15.doc; Attachment 4 - NIH Privacy Act Memo.pdf

Good Morning,

I am replying on behalf of Susan McMullen. The Email survey "The Survey of Health Care Professionals' Awareness and Perceptions of the National Cancer Institute's Intramural Clinical Trials." is attached. While a consent form is not included in the e-mail to the respondents, a brief introduction included on the survey describes the purpose and use of the questions. Respondents imply consent in the completion and return of the survey.

This is an e-mail survey sent out by the AMA to members who have opted in to receive e-mails and has been reviewed by the NIH privacy act officer, I have attached the privacy act memo.

We are currently working on OMB clearance through Vivian Horovitch-Kelley; PRA/OMB Project Clearance Liaison.

The original survey that was disseminated in 2007 and received IRB exemption approval # 3772.

Please let me know if you need anything further.

Best Regards,

Jean

Jean Walmsley
Senior Account Executive
Direct 301.348.1627
jwalmsley@mmgct.com

700 King Farm Boulevard
5th Floor
Rockville, MD 20850

Main 301.984.7191
Fax 301.921.4405
wegetpatients.com

From: OHSR (NIH/DDIR)
Sent: Thursday, June 10, 2010 11:22 AM
To: McMullen, Susan (NIH/NCI) [E]
Subject: McMullenS_NCI_5260_CY2010

Good Morning Ms. McMullen:

Thank you for the opportunity to review your research project entitled "The Survey of Health Care Professionals' Awareness and Perceptions of the National Cancer Institute's Intramural Clinical Trials." Based on the information you have provided, OHSR needs to review both the questionnaire and the informed consent, information sheet, and/or script you will use to invite participants into the study. We have attached an example for your convenience.

We also need to remind you that you need to contact Mikia Currie in the Office of Policy for Extramural Research Administration (OPERA) to determine whether you will need OMB Clearance for this survey.

Best regards,

Office of Human Subjects Research
Office of Intramural Research
National Institutes of Health

Bldg 10 Room 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

OMB #: 0925-xxxx
Expiry Date: xx/xx/20xx

NCI's Center for Cancer Research
Survey to Assess Health Care Professionals' Awareness of NCI Intramural Clinical Trials

The National Cancer Institute's (NCI) Center for Cancer Research is surveying physicians and nurses in order to gain a deeper understanding of the perception that health professionals have of NCI and the services the Institute provides. The results from this survey will be used to evaluate the level of awareness and understanding of NCI's Center for Cancer Research and to develop new programs to educate and inform healthcare professionals of their activities.

Your participation in this survey is completely voluntary. Please be assured that your responses will be kept confidential and will not be disclosed to anyone outside NCI or its contractor, Matthews Media Group (MMG), except as otherwise required by law. Data will be provided to NCI in aggregate form only, with any potentially identifying information removed. You may skip any questions that you prefer not to answer. This survey should take approximately 5 minutes to complete.

If you have any questions or would like to know the results of the survey, please contact Angela Carrigan at acarrigan@mmgct.com or 301-348-1694.

1. Before beginning this survey, were you aware of the National Cancer Institute (NCI)? ❑ Yes ❑ No	If yes, continue; if no, skip to #4
2. How familiar are you with NCI? ❑ Very Familiar ❑ Somewhat familiar ❑ Not too familiar ❑ Not familiar at all	Record and proceed to #3
3. What activities do you think NCI conducts or provides? *(Check all that apply.)* ❑ Defines standards of care for cancer patients ❑ Distributes cancer information to patients ❑ Distributes cancer information to physicians ❑ Sponsors clinical trials ❑ Conducts clinical trials ❑ Provides information about ongoing clinical trials ❑ Provides physicians and patients with access to thought leaders in cancer research	Record and proceed to #4

❑ Publishes journal articles
❑ Maintains regulatory oversight over pharmaceutical and biotechnology companies
❑ Collaborates with the private sector on cancer-related clinical research
❑ Conducts research for rare cancers typically not investigated by the private sector
❑ Other_____

4. For each of the attributes listed below, please rank the following medical institutions in order from 1 to 6 for each characteristic. .

Record and proceed to #5

	Dana-Farber Cancer Institute	Fred Hutchinson Cancer Center	Kimmel Cancer Center at Johns Hopkins	M. D. Anderson Cancer Center	Memorial Sloan Kettering Cancer Center	NCI on the NIH campus in Bethesda, Md.
Cutting-edge research	❒	❒	❒	❒	❒	❒
State-of-the-art technology	❒	❒	❒	❒	❒	❒
Reputable	❒	❒	❒	❒	❒	❒
Oncology expertise	❒	❒	❒	❒	❒	❒
Industry leader	❒	❒	❒	❒	❒	❒
Quality medical professionals	❒	❒	❒	❒	❒	❒
Ethical	❒	❒	❒	❒	❒	❒

5. Have you ever referred a patient to a cancer clinical trial (regardless of whether the patient was eligible and/or participated)? ❑ Yes ❑ No

If yes, continue; if no, skip to #11

6. In the past year, approximately how many patients have you referred to a cancer clinical trial (regardless of whether the patient was eligible and/or participated)?
❑ None ❑ 1-5 ❑ 6-10 ❑ 11-15 ❑ 16-20 ❑ 21 or more

Record and proceed to #7

7. Please select the name(s) of the medical institutions to which you have ever referred a patient to a cancer clinical trial (regardless of whether the patient was eligible and/or participated)?
❑ Dana-Farber Cancer Institute
❑ Fred Hutchinson Cancer Center
❑ Kimmel Cancer Center at Johns Hopkins
❑ M. D. Anderson Cancer Center
❑ Memorial Sloan Kettering Cancer Center
❑ NCI on the NIH campus in Bethesda, Md.
❑ Other _____

If NCI is selected, record and proceed; if NCI is not selected, skip to #10

8. In the past year, approximately how many cancer patients have you referred to a clinical trial at NCI in Bethesda, Md. (regardless of whether the patient was eligible and/or participated)?

Record and

❑ None ❑ 1–2 ❑ 3–5 ❑ 6–10 ❑ 11 or more	proceed to #10
9. Have you ever referred a cancer patient to an **NCI-sponsored clinical trial** that was conducted at an institution or site other than NCI in Bethesda, Md. (regardless of whether the patient was eligible and/or participated)? ❑ Yes ❑ No ❑ Don't know	Record and proceed to #11
10. How do you learn about clinical research opportunities for your patients? *(Check all that apply.)* ❑ Brochures/Flyers ❑ Colleagues ❑ Conferences/Seminars ❑ E-mail ❑ Grand Rounds ❑ Interdepartmental meetings ❑ Internet ❑ Journal articles ❑ Mail ❑ Newsletters ❑ Patients ❑ None/Don't learn about clinical trials ❑ Other_____	Record and proceed to #12
11. How do you **prefer** to learn about clinical research opportunities for your patients? *(Check all that apply.)* ❑ Brochures/Flyers ❑ Colleagues ❑ Conferences/Seminars ❑ E-mail ❑ Grand Rounds ❑ Interdepartmental meetings ❑ Internet ❑ Journal articles ❑ Mail ❑ Newsletters ❑ Patients ❑ None ❑ Other_____	Record and proceed to #13
12. Which of these communications have you seen from NCI? *(Check all that apply.)* ❑ Brochures/Flyers ❑ E-mail ❑ On-line ❑ Journal articles\News releases ❑ Journal ads ❑ Mail ❑ Newsletters ❑ Patients ❑ None ❑ Other_____	If "None", record and proceed to #14. Otherwise record and proceed to #13
13. What was the overall quality of these communications from NCI? ❑ Poor ❑ Fair ❑ Good ❑ Very good ❑ Excellent	
Please tell us about yourself.	
14. What is your professional status? ❑ RN ❑ RD ❑ NP ❑ PharmD ❑ RPh ❑ MD ❑ Other_____	Record and proceed to #14
15. What is your area of specialization? *(Check the one that most applies.)* ❑ Hematology ❑ Oncology ❑ Radiation Oncology ❑ Surgical Oncology ❑ Other_____	Record and proceed to #15
16. Approximately how many cancer patients do you treat each month?	Record

❑ None ❑ 1-5 ❑ 6-10 ❑ 11-20 ❑ 21-30 ❑ 31 or more	and proceed to #16
17. Where do you primarily practice? City:_____ State:_____ ❑ Outside the United States	Record and proceed to #17
18. How many years have you been working with cancer patients? ❑ Less than 1 year ❑ 1-2 years ❑ 3-5 years ❑ 6-10 years ❑ 11-20 years ❑ More than 20 years	Record and proceed to #18
19. What is your current practice setting? *(Check the one that most applies.)* ❑ Hospital inpatient ❑ Hospital-based outpatient ❑ Hospital-based clinic ❑ University ❑ Private practice ❑ Other_____	Record and proceed to #19
Thank you for taking the time to complete the survey. Your answers have been submitted. If you have any questions or would like to know the results of this survey, please contact Marita Lynott at 301-348-1639 or mlynott@mmgct.com. NCI's Center for Cancer Research distributes a free quarterly e-newsletter, *BethesdaTrials News,* which helps community physicians stay informed of investigational approaches to treating, diagnosing, and preventing cancer. Each issue features one or more clinical trials in process at NCI on the NIH campus in Bethesda, Md. 20. Would you like to receive this e-newsletter? ❑ Yes ❑ No *(Check only one.)* ❑ I currently receive this e-newsletter	If yes, continue; if no or I currently receive, skip to closing
To sign up for *BethesdaTrials News,* please click on the link below to be redirected to NCI's Center for Cancer Research Web site. The contact information you provide will not be linked to this questionnaire. Note that the National Cancer Institute's Center for Cancer Research does not sell or share its mailing list. http://bethesdatrials.cancer.gov/health-care-professionals/mailinglist.asp Thank you again for completing this survey.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

DATE: May 7, 2010

TO: Susan McMullen
Director, Office of Patient Outreach and Recruitment
Center for Cancer Research, NCI

FROM: NIH Privacy Act Officer

SUBJECT: Applicability of the Privacy Act: The Survey of Health Care Professionals' Awareness and Perceptions of the National Cancer Institute's Intramural Clinical Trials (NCI)

I have reviewed the NCI submission to OMB entitled, "The Survey of Health Care Professionals' Awareness and Perceptions of the National Cancer Center Institute's Intramural Clinical Trials (NCI)". The project involves the collection of personally identifiable information via an email survey to medical professionals who treat cancer patients to gain a deeper understanding of their perception of NCI and the services the Institute provides.

I have determined that the Privacy Act will not apply to the data collection, which includes the collection of work email address, professional status, area of specialization and geographic location of practice. The responses are being collected electronically and will be automatically stored on a secured server. The survey data cannot be tracked to individual respondents and will be provided to NCI through its contractor, Matthews Media Group (MMG), in aggregate form only.

If you have any questions, please contact my office at (301) 496-2832

Karen M. Plá

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Thursday, June 10, 2010 11:22 AM
To: McMullen, Susan (NIH/NCI) [E]
Subject: McMullenS_NCI_5260_CY2010
Attachments: Consent form for Usability Testing.doc

Good Morning Ms. McMullen:

Thank you for the opportunity to review your research project entitled "The Survey of Health Care Professionals' Awareness and Perceptions of the National Cancer Institute's Intramural Clinical Trials." Based on the information you have provided, OHSR needs to review both the questionnaire and the informed consent, information sheet, and/or script you will use to invite participants into the study. We have attached an example for your convenience.

We also need to remind you that you need to contact Mikia Currie in the Office of Policy for Extramural Research Administration (OPERA) to determine whether you will need OMB Clearance for this survey.

Best regards,

Office of Human Subjects Research
Office of Intramural Research
National Institutes of Health
Bldg 10 Room 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

Informed Consent Form for Usability Testing

Identification of Project Statement of Age of Subject	**Advanced Medical Imaging Tools** I state that I am at least 18 years of age, in good physical health, and wish to participate in a program of research being conducted by (your information).
Purpose	The purpose of this research is to ….
Procedures	Participants will be asked questions about their data needs and their expectations _____.The total time involved, including instructions, will be no more than ___ minutes.
Confidentiality	All information collected in this study is confidential. I understand that the data I provide will be grouped with data others provide for the purpose of reporting and presentation and that my name will not be used. I understand that this usability study will be audio taped and that my onscreen movements will be recorded, but my voice will not be played or shown to others besides the research team without my written permission (or whatever is specific for this study).
Risks	I understand that the risks of my participation are expected to be minimal in nature.
Benefits, Freedom to Withdraw, & Ability to Ask Questions	I understand that this study is not designed to help me personally but that the investigators hope to update and redesign the _____ (type of technology) in order to make the experience better. I am free to ask questions or withdraw from participation at any time and without penalty.
Contact Information of Investigators	Name: Position: Telephone: Email: FAX to:

Printed Name of Research Participant _____

Signature of Research Participant _____

Date_____

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Thursday, June 10, 2010 9:37 AM
To: McMullen, Susan (NIH/NCI) [E]
Subject: Request for Review Rec'd-OHSR 5260

Good morning Ms. McMullen,

This email is to verify that OHSR has received your Request for Review of Research and it is currently being processed as **OHSR #5260.** 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: The Survey of Health Care Professionals' Awareness and Perceptions of the National Cancer Institute's Intramural Clinical Trials (NCI)

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