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

FAX: 301-480-6641 **Exempt: #:** 4722

To: Speakman, John
NCI
2115EJ - 2115 E Jefferson St, 6009

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
The reporting of information through this resource is not a research activity but rather an infrastructure development project that will be enabled by public funds expended pursuant to the American Recovery and Reinvestment Act of 2009, P.L. 111-5. The National Cancer Institute (NCI) is developing an electronic resource, the NCI Clinical Trials Reporting Program (CTRP) Database, which is intended to serve as a single, definitive source of information about all NCI-suported clinical research, thereby enabling the NCI to

Original Request Received in OHSR on: 6/5/2009

Responsible NIH Research Investigator(s): John Speakman, NCI

OHSR review of your request dated Thu, Jun 4, 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
6/8/2009 — Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: No

OHSR Use Only
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

#4722

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: June 4, 2009

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

From: John Speakman
(Signature)

Through: George A Komatsoulis Deputy Director NCI CBIIT
(Signature of appropriate Official for IC, e.g., Lab/Branch Chief)

Name of NIH Principal Investigator(s): John Speakman
IC NCI Laboratory/Branch Center for Biomedical Informatics and Information Technology (CBIIT), Office of the Director
Building & Room No. 2115 E. Jefferson, Suite 6000 Tel. No. 301-451-8786
FAX No. _____ E-MAIL: john.speakman@nih.gov

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 reporting of information through this resource is not a research activity but rather an infrastructure development project that will be enabled by public funds expended pursuant to the American Recovery and Reinvestment Act of 2009, P.L. 111-5.

The National Cancer Institute (NCI) is developing an electronic resource, the NCI Clinical Trials Reporting Program (CTRP) Database, which is intended to serve as a single, definitive source of information about all NCI-supported clinical research, thereby enabling the NCI to execute its mission to reduce the burden of cancer and to ensure an optimal return on the nation's investment in cancer clinical research. In addition, deployment of this resource will allow the NCI to consolidate program and regulatory reporting, aggregate information and reduce redundant submissions. Information will be submitted by clinical research administrators as designees of clinical investigators who conduct NCI-supported clinical research.

2. **If applicable, list your non-NIH Collaborating Investigator(s).** N/A

3. **Proposed start date of your research** July 1, 2009
   Proposed completion date ongoing

4. **Will you be _____these samples or data?**

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

5. **Do the samples or data:**
   (a) Already exist? _X_ Yes ____No

   (b) Or are they being collected for the express purpose of this study? ___Yes _X_No
   If "yes," please describe:_____

   (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.

_____

__X___Other (If necessary, use this space to describe your role in this research). This is not a research activity. I serve as the acting program manager for the NCI Clinical Trials Reporting Program and have been the project lead for the development of the CTRP Database.

7. **Where are the subjects of this research activity located?** There are no research subjects as the collection of information through the CTRP Database is not a research activity. Only clinical trials registration information, including information about trial

protocols, clinical investigators and template informed consent documents, is currently proposed for collection through this resource.

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?) N/A

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? NONE

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: Submissions will include the trial protocol document, the template informed consent document, and IRB approval documentation, if available, and the following data elements relating to trial registration:

- Lead organization
- Lead organization trial identifier
- NCT number
- Principal investigator
- Protocol title
- Trial type
- Trial phase
- Trial purpose
- Sponsor
- Responsible party's work email address
- Responsible party's work phone number
- Summary 4 funding type
- Summary 4 funding sponsor
- NIH grant funding mechanism
- NIH institute code
- Serial number
- NCI division/program code
- Current trial status

- Current trial status date
- Trial start date (actual or anticipated)
- Primary completion date (actual or anticipated)
- IND/IDE number
- IND/IDE grantor
- IND/IDE holder type
- Expanded access type (if applicable)

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.

Names, work telephone and work email information concerning clinical investigators, not research subjects or patients, will be submitted.

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?
a. _____Yes _____No

(d) __X___ Other Submitters will have full access to the CTRP Database with respect to information they have submitted. Further, the CTRP Database automatically generates, as a by-product of CTRP registration, trial summary files (in XML format) that are compatible with the requirements of ClinicalTrials.gov, After independently reviewing the trial summaries, NCI awardees can then choose to upload the XML files directly to ClinicalTrials.gov in lieu of registering their trials by manual entry through ClinicalTrials.gov's registration system.

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?**

_____Yes _____No

N/A – This is not a research activity.

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 08, 2009 10:59 AM
To: Speakman, John (NIH/NCI) [E]
Subject: Request for Review Rec'd-OHSR

Good morning Mr. Speakman,

This email is to verify that OHSR has received your Request for Review of Research and it is currently being processed as OHSR #4722. 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:
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)