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

FAX: 301-480-6641 **Exempt: #:** 4947

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 the National Cancer Institute's (NCI) Clinical Trials Reporting Program (CTRP) Database 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 CTRP Database 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

Original Request Received in OHSR on: 11/5/2009

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

OHSR review of your request dated Tue, Nov 3, 2009 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 Admin Assist.

for Charlotte Holden, JD — acting Dir. — 11/10/2009
Signature Title Date

Domestic/International:

Human Subjects Data:

Biologic Material:

OHSR Use Only
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

#4947

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: November 3, 2009

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

From: John Speakman
(Signature)

Through: George A. Komatsoulis Deputy Director, 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. 301-480-6641 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 the National Cancer Institute's (NCI) Clinical Trials Reporting Program (CTRP) Database 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 CTRP Database 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, and provide appropriate public access. Information

___ 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 NCI's receipt of information through the CTRP Database is not a research activity. NCI grantees and contractors that conduct clinical research will submit study subject accrual information as described below in response to question #10.

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: No research data will be submitted. Rather, NCI awardees will report information concerning study subject accruals. Specifically, awardees will be expected to submit the following data elements:

- Submission title
- Submission cut off date (MM/DD/YYYY)

(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

* NCI will not send results back to the provider. However, access to data in the NCI CTRP Database will be provided as follows:

- Access by program and administrative staff: Full access to the data within the CTRP Database will be provided to designated, appropriate NCI employee and contractor staff for purposes of portfolio management and compliance with regulatory and administrative reporting obligations. Access will be limited to those with a direct need to access the data. Access will be granted to non-Federal staff under a non-disclosure agreement and staff will be given mandatory privacy and security training.

- Access for submitters: Individual submitters will have full access to information they have submitted; institutions of individual submitters will have access to tools that gather and present the accumulated data submitted by their individual investigators.

- Public access: Consistent with the requirements and timelines of the Food and Drug Administration Amendments Act of 2007, P.L. 110-85 (FDAAA), open access to protocol registration information and summary level patient accrual information will be provided to all persons not described above, including NCI intramural researchers.

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**

OHSR (NIH/DDIR)

From: Patterson, Wendy (NIH/NCI) [E]
Sent: Wednesday, November 04, 2009 11:17 AM
To: OHSR (NIH/DDIR)
Cc: Horovitch-Kelley, Vivian (NIH/NCI) [E]; Speakman, John (NIH/NCI) [E]
Subject: NCI request for review of CTRP database
Attachments: NCI CTRP Request for Review 20091103 .pdf

To whom it may concern:

On behalf of the NCI Center for Biomedical Informatics and Information Technology (NCI CBIIT), attached please find the Request for Human Subjects Research Review in connection with the NCI's Clinical Trials Reporting Program Database. Please confirm receipt of this email and advise us of when we may expect a reply.

Thanks very much.

Wendy Ehrenkranz Patterson, Esq.
Senior Advisor
Technology Transfer Center
National Cancer Institute
Executive Plaza South, Suite 450
6120 Executive Blvd. MSC 7182
Rockville, MD 20852
Tel. 301-435-3110
Cell: 301-520-1561
Fax: 301-402-2117
Email: pattersw@mail.nih.gov

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Thursday, November 05, 2009 11:45 AM
To: Speakman, John (NIH/NCI) [E]
Cc: Horovitch-Kelley, Vivian (NIH/NCI) [E]
Subject: Request for Review Rec'd-OHSR 4947

Good afternoon Dr. Speakman

This email is to verify that OHSR has received your Request for Review of Research and it is currently being processed as OHSR #4947 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.

Please use our updated submission form for all future submissions.
Click the link below to access the updated form.
http://ohsr.od.nih.gov/info/pdf/requestforReview.doc

Thank you.

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)