

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

FAX: 301-480-7558  
To: Sampson, Annie  
NCI  
10/A28D

Exempt #: 12414

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

Central to OAR's identity is both matching qualified research advocates to engage in research activities within NCI and engaging with a variety of advocacy organizations at the organization level. These activities rely on a robust database to store and retrieve information about the advocates, organizations and research activities. A custom OAR application for these purposes was developed by CBIIT (accessible at <http://oar.nci.nih.gov/oar>). The purpose of the database as it long has been is to track interactions between both

Original Request Received in OHSR on: 4/10/2014

Responsible NIH Research Investigator(s): Annie Sampson, MS NCI

OHSR review of your request dated Tue, Apr 29, 2014 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 TM

Admin Assist. CB

Note:  
Program evaluation

  
Takunda Matose

Program Analyst, OHSRP

5/20/2014

Signature

Title

Date

Domestic/International:

Domestic

Human Subjects Data: Yes

Biologic Material: No

OHSR Use Only

1  2  3  4  5  6

## Matose, Takunda (NIH/OD) [C]

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**From:** OHSR (NIH/DDIR)  
**To:** Sampson, Annie (NIH/NCI) [E]  
**Cc:** Grant, Nicole (NIH/NCI) [E]  
**Subject:** Determination for OHSRP 12414  
**Attachments:** Request for Amendment OHSRP #\_\_\_\_

Dear Dr. Sampson,

Attached is the OHSRP determination of **Excluded from IRB Review** per 45 CFR 46 and NIH policy for your project *NCI Advocate Database*. **You may proceed with the project.**

Please retain this documentation as you would other research records. Amendments and or changes to the research must be submitted to OHSRP for review as changes may affect the determination. Please refer to **OHSRP #12414** for future amendments to this activity. To request future amendments, please use the attached email template modified to meet the specific changes needed for your project. If you have any questions or need further assistance, please feel free to contact us.

Best,

Takunda Matose  
OHSRP - National Institutes of Health  
Bldg 10, Suite 2C146  
Bethesda, MD 20892  
Office Telephone: 301-402-3444  
Office Fax: 301-402-3443

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**From:** OHSR (NIH/DDIR)  
**Sent:** Friday, May 09, 2014 12:51 PM  
**To:** Sampson, Annie (NIH/NCI) [E]  
**Subject:** Req for Determination Rec'd\_OHSRP 12414

Good afternoon Ms. Sampson,

This email is to verify that OHSR has received your Request for Determination and it is currently being processed as **OHSRP #12414**. Please use this number in any future correspondence regarding this study. We will contact you via email if any additional information is needed. Please note that due to ongoing project deadlines, determinations are taking longer than normal to process.

**Protocol Title:** NCI Advocate Database

Thank you.  
Sincerely,  
Chris Brentin  
OHSRP - National Institutes of Health  
Bldg 10, Suite 2C146  
Bethesda, MD 20892  
Office Telephone: 301-402-3444

**REQUEST FORM: OHSRP DETERMINATION FOR SURVEYS, INTERVIEW PROCEDURES,  
PROGRAM EVALUATION, EDUCATIONAL TESTING AND RESEARCH**

**Date of Request:** 4/29/2013

**Requestor's name:** Nichole Sorhaindo      **e-mail:** nichole.sorhaindo@nih.gov

**Role:**  Administrative support    Investigator    Other, explain: \_\_\_\_\_

**Name of NIH Senior Investigator:** Annie Sampson  
(The investigator must be an NIH employee)

**IC:** National Cancer Institute   **Laboratory/Branch:** Office of Advocacy Relations

**Building & Room No.** 10A28D    **Tel. No.** 301-594-6831    **FAX No.** 301-480-7558

**Is the NIH Senior Investigator an NIH employee(FTE)?**  Yes    No

**Senior Investigator Signature:** \_\_\_\_\_  
(Signature of Investigator who will conduct research)

**Supervisor Signature:** \_\_\_\_\_  
(Signature of official for IC, e.g., Lab/Branch Chief)

**Name of NIH investigator conducting research if not the NIH Senior Investigator:** (i.e., junior investigator, contractor investigator, fellow, student)

**Please provide the name and e-mail of any others who should receive a copy of the OHSRP determination:** Kelley Landy [kelley.landy@nih.gov](mailto:kelley.landy@nih.gov); Kelli Marciel [kelli.marciel@nih.gov](mailto:kelli.marciel@nih.gov); Annie Sampson [annie.sampson@nih.gov](mailto:annie.sampson@nih.gov)

**1. What role will the NIH investigator(s) have in this research project?** (check all that apply)

- Conduct research activity
- Analyze samples/data only
- Consultant/advisor to collaborator(s)
- Author on publication(s)/manuscript(s) pertaining to this research
- Other, please describe: Pull information from database

**2. Title:** NCI Advocate Database  
(Provide a short title to distinguish this activity from other projects that you may have)

**3. Describe in lay terms the research activity that will be performed:**  
Central to OAR's identity is both *matching qualified research advocates* to engage in research activities within NCI and *engaging with a variety of advocacy organizations* at the organization level. These activities rely on a robust database to store and retrieve

**REQUEST FORM: OHSRP DETERMINATION FOR SURVEYS, INTERVIEW PROCEDURES,  
PROGRAM EVALUATION, EDUCATIONAL TESTING AND RESEARCH**

information about the advocates, organizations and research activities. A custom OAR application for these purposes was developed by CBIIT (accessible at <http://oar.nci.nih.gov/oar>).

The purpose of the database, as it long has been, is to track interactions between both individual volunteer research advocates and NCI's Office of Advocacy Relations, and advocacy organizations and OAR. Another purpose for this database is tracking and evaluating the process and outcomes of engaging advocates in research in support of the NCI mission. The database is programmatic in nature.

The NCI Advocate Database stores and retrieves information about advocates, organizations and NIH research activities in which research advocates have participated. All information is entered into the database by OAR staff, with two exceptions; requests for research advocate activity participation from may be submitted via online form by an investigator and individual research advocates may edit their profiles through an online form. The use to which this information will be put is for OAR staff to be able to respond to internal requests from investigators to identify and match qualified research advocates with research advocacy opportunities at NCI and across NIH.

The NCI Advocate Database is being slightly revised from its previous iteration, architected in 2005; this revision includes updates to fields where information is collected from participants and it also includes functionality and design changes to the backside dashboard where OAR staff can view and search for records.

**4. Proposed start date 7/1/2013    Proposed completion date: n/a**

**5. Specify the nature of the data: (select all that apply)**

Interview procedure

Survey

Educational Testing

Educational Research

Research on public benefit or service programs

*Other, describe: Research advocate profile information for potential involvement in NCI research activities*

**6. What kind of human data (e.g., private information, responses to questionnaires, test results, recordings) will be collected in your research?**

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**7. Will human data be? (select all that apply)**

Collected    Yes\_\_ No **X**

Received    Yes\_\_ No **X**

Sent    Yes\_\_ No **X**

**REQUEST FORM: OHSRP DETERMINATION FOR SURVEYS, INTERVIEW PROCEDURES,  
PROGRAM EVALUATION, EDUCATIONAL TESTING AND RESEARCH**

**8. If receiving or sending, list the collaborating investigator(s):**

Name	Institution/IC	Address/e-mail	FWA number*
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**9. Where are the subjects of this research activity located?** *(Provide a general description or complete the institutional information below)*

*Nationwide*

Institution: n/a      Contact Name: n/a

Address: n/a      Phone: n/a

**10. Will NIH investigator(s) have direct contact or intervention with the subjects of the study?** *(For example, by interviewing, surveying or recording the subjects?)*

Yes  No

If yes, what is the age range of subjects involved in the research?

Children aged < 18 years

Adults aged ≥ 18 years

**11. Who will collect the data or information?**

(a)  NIH Investigator

(b)  non-NIH Collaborator

(c)  NIH Contractor

(d)  Other, specify: respondents input information onto online database themselves

If b or c, will an Honest Broker or data use agreement be used? Yes  No

If yes, complete and attach the Honest Broker Assurance or data-use agreement to this submission; e-mail [ohsr\\_nih\\_ddir@od.nih.gov](mailto:ohsr_nih_ddir@od.nih.gov) to request a form.

**12. Select the best description that applies to the human data or information:**

Data or information will not contain any identifiable information, nor can it be linked to individual subjects by you or your collaborators.

Data or information will be recorded in such a manner that subjects can be identified directly or through identifiers linked to the subjects

**13. Per NIH guidance, are all conflicts of interest by NIH employees (sender or receiver), if any, resolved?**  Yes  No\*\*

## OHSR (NIH/DDIR)

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**From:** Bridge, Heather (NIH/OD) [E]  
**Sent:** Friday, April 11, 2014 7:08 AM  
**To:** Sampson, Annie (NIH/NCI) [E]; Matose, Takunda (NIH/OD) [C]; Brentin, Christine (NIH/OD) [E]; Brown, Kristan (NIH/OD) [E]  
**Subject:** FW: Office of Advocacy Relations  
**Attachments:** 1833\_001.pdf

**Importance:** High

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

**Categories:** Red Category, Yellow Category

Hi Annie,

I no longer process these requests but have cc'd my colleagues for you. We had some technical issues w/our inbox that may have caused a delay.

Folks please make sure this determination request is processed.

Best,

Heather Bridge

Office of Human Subjects Research Protections

Office of Intramural Research

National Institutes of Health

10 Center Drive,

Bldg. 10, Room 2C146

Bethesda, MD 20892

Direct line: 301-402-4504

BB: 240-281-9015

Office Main: 301-402-3444

Fax: 301-402-3443

E-mail: [bridgeh@od.nih.gov](mailto:bridgeh@od.nih.gov)

OHSRP website: <https://federation.nih.gov/ohsr/nih/index.php> (NIH login required)

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**From:** Sampson, Annie (NIH/NCI) [E]  
**Sent:** Thursday, April 10, 2014 4:03 PM  
**To:** Bridge, Heather (NIH/OD) [E]  
**Subject:** Office of Advocacy Relations

Hi Heather,

I put this request in awhile ago, you have probably reviewed it and made a recommendation, however I do not have the final signature page. Can you please send me your final determination?

Thank you,  
Annie

*Annie Sampson, MSc*

NIH/National Cancer Institute  
Office of Advocacy Relations

31 Center Drive, MSC 2580  
Bethesda, MD 20892  
Phone: (301) 594.6831  
[sampsona@mail.nih.gov](mailto:sampsona@mail.nih.gov)

## OHSR (NIH/DDIR)

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**From:** OHSR (NIH/DDIR)  
**Sent:** Friday, June 21, 2013 10:43 AM  
**To:** OHSR (NIH/DDIR); Sampson, Annie (NIH/NCI) [E]  
**Subject:** FW: Cannot Process RE: OAR Advocate Database -- Request for Determination

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

**Categories:** Red Category, Yellow Category

Hi Annie,  
I am forwarding your question to Takunda Matose, who reviews the requests.

Chris

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**From:** Sampson, Annie (NIH/NCI) [E]  
**Sent:** Friday, June 21, 2013 10:31 AM  
**To:** OHSR (NIH/DDIR)  
**Subject:** RE: Cannot Process RE: OAR Advocate Database -- Request for Determination

Honestly, I'm not sure what this is. should I check with our Administrative Office?

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**From:** OHSR (NIH/DDIR)  
**Sent:** Friday, June 21, 2013 10:30 AM  
**To:** Sampson, Annie (NIH/NCI) [E]  
**Subject:** RE: Cannot Process RE: OAR Advocate Database -- Request for Determination

Hi Annie,  
Will an Honest Broker or data use agreement be used?

Thank you.  
Chris

Sincerely,  
OHSRP - 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

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**From:** Sampson, Annie (NIH/NCI) [E]  
**Sent:** Thursday, June 20, 2013 9:17 AM



**To:** OHSR (NIH/DDIR)

**Subject:** RE: Cannot Process RE: OAR Advocate Database -- Request for Determination

I apologize, I thought I had responded. The answer is A. I will be the NIH investigator.

Does that answer the outstanding question?

Please let me know if you need anything else.

Thank you,  
Annie

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**From:** OHSR (NIH/DDIR)

**Sent:** Thursday, June 20, 2013 9:14 AM

**To:** Sampson, Annie (NIH/NCI) [E]

**Subject:** Cannot Process RE: OAR Advocate Database -- Request for Determination

**Importance:** High

Hi Annie,

I wanted to follow up with this request. OHSRP has not yet received your response to the email below. Please let me know if you would like to continue this request.

Thanks very much.

Sincerely,  
Chris Brentin  
OHSRP

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**From:** OHSR (NIH/DDIR)

**Sent:** Monday, May 20, 2013 2:10 PM

**To:** Sampson, Annie (NIH/NCI) [E]

**Subject:** Cannot Process RE: OAR Advocate Database -- Request for Determination

**Importance:** High

Hi Annie,

I apologize that we omitted a correction that OHSRP needs in order to process your request. The current form has a typo in #11. It should read: "*if **A** or c, will an Honest Broker or data use agreement be used?*"

11. Who will collect the data or information?

(a) *X NIH Investigator*

(b) *\_ non-NIH Collaborator*

(c) *\_ NIH Contractor*

(d) *X Other, specify: respondents input information onto online database themselves*

**If b(A) or c, will an Honest Broker or data use agreement be used? Yes\_ No\_**

*If yes, complete and attach the Honest Broker Assurance or data-use agreement*

Please answer this question in a response email. You do not have to resend the form. I have attached an Honest Broker form if you do need it. Once I receive your response, I will enter it into our system for review.

Please contact OHSRP with any questions.

Thank you.

Sincerely,  
Chris Brentin

OHSRP - 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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**From:** Sampson, Annie (NIH/NCI) [E]  
**Sent:** Thursday, May 16, 2013 9:12 AM  
**To:** OHSR (NIH/DDIR)  
**Cc:** Sorhaindo, Nichole (NIH/NCI) [C]; Sampson, Annie (NIH/NCI) [E]  
**Subject:** RE: OAR Advocate Database -- Request for Determination

Good morning,

I have attached the adjusted form here.

Thank you,  
Annie

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**From:** OHSR (NIH/DDIR)  
**Sent:** Monday, May 06, 2013 4:31 PM  
**To:** Sampson, Annie (NIH/NCI) [E]  
**Cc:** Sorhaindo, Nichole (NIH/NCI) [C]  
**Subject:** RE: OAR Advocate Database -- Request for Determination

Good afternoon Dr. Sampson.

While reviewing this request I found that question #4 – Proposed completion dates was not completed. If you expect the study to continue past 5 years, enter 7/1/2018 as the proposed date. Send an amendment request via email to extend the date as it gets closer to 2018. Question #7 – Will human data be collected, received or sent (check all that apply) was answered no. I assume you will be collecting? Question #13 – Are all conflicts resolved was answered no. This question has to be answered Yes before we can process your submission.

Please let me know if you have any questions.

Kristan Brown  
OHSRP - 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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**From:** Sorhaindo, Nichole (NIH/NCI) [C]  
**Sent:** Monday, May 06, 2013 11:52 AM  
**To:** OHSR (NIH/DDIR)  
**Cc:** Bridge, Heather (NIH/OD) [E]; Sampson, Annie (NIH/NCI) [E]; Landy, Kelley (NIH/NCI) [E]  
**Subject:** OAR Advocate Database -- Request for Determination  
**Importance:** High

Hello,

I would like to submit the attached OHSRP Determination Request Form on behalf of the NCI's Office of Advocacy Relations (OAR) for OAR's Advocate Database. If you have any questions, please feel free to contact me at [nichole.sorhaindo@nih.gov](mailto:nichole.sorhaindo@nih.gov) or the PI, Annie Sampson, at [annie.sampson@nih.gov](mailto:annie.sampson@nih.gov).

Thanks,

*Nichole Sorhaindo, MPH*

Contractor  
Paldian Partners, Inc.  
Office of Advocacy Relations (OAR)  
National Cancer Institute (NIH)  
Building 31, Room 10A28E  
31 Center Drive, MSC 2580, Bethesda, MD 20892-2580  
**Phone:** 301-594-3194  
**Email:** [sorhaindond@mail.nih.gov](mailto:sorhaindond@mail.nih.gov)

## OHSR (NIH/DDIR)

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**From:** OHSR (NIH/DDIR)  
**Sent:** Friday, May 09, 2014 12:51 PM  
**To:** Sampson, Annie (NIH/NCI) [E]  
**Subject:** Req for Determination Rec'd\_OHSRP 12414

Good afternoon Ms. Sampson,

This email is to verify that OHSR has received your Request for Determination and it is currently being processed as **OHSRP #12414**. Please use this number in any future correspondence regarding this study. We will contact you via email if any additional information is needed. Please note that due to ongoing project deadlines, determinations are taking longer than normal to process.

**Protocol Title:** NCI Advocate Database

Thank you.

Sincerely,

Chris Brentin

OHSRP - 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