

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

FAX: 301-402-0341

Exempt #: 5080

To: Gill, Michael

NLM

38A - Lister Hill Center, 10S1014

From: Office of Human Subjects Research (OHSR)


Nature of Research Activity:

The proposed research activity will evaluate the effectiveness of NLM's newly developed information technology tools to assist in reunifying family members in the wake of a disaster, in this case the January 2010 earthquakes in Haiti. The activity aims both to provide immediate assistance to people affected by the earthquakes in Haiti and to inform further development and refinement of information technology tools for family reunification

Original Request Received in OHSR on: 1/27/2010

Responsible NIH Research Investigator(s): Michael Gill, NLM

OHSR review of your request dated Wed, Jan 27, 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 8/31/2010 
- Other

Office Person SPC

Admin Assist. CB

Note:
AMENDED: 08/31/2010 to evaluate this technology at disasters throughout the world with no completion date. This project uses publicly available data to evaluate new technology.

Charlotte Holden, JD

Acting Director, OHSR

1/28/2010

Signature

Title

Date

Domestic/International:

Dom./Int.

Human Subjects Data: Yes

Biologic Material: No

OHSR Use Only

1 2 3 4 5 6

OHSR (NIH/DDIR)

From: Gill, Michael (NIH/NLM/LHC) [E]
Sent: Friday, August 27, 2010 1:37 PM
To: OHSR (NIH/DDIR); Pursley-Crotteau, Suzanne (NIH/OD) [E]
Cc: Thoma, George (NIH/NLM/LHC) [E]; Antani, Sameer (NIH/NLM/LHC) [E]; Goodwin, Rebecca (NIH/NLM/LHC) [E]
Subject: FW: please submit email request for amendment to Office of Human Subjects Research (Lost Person Finder)
 FW: GillIM_NLM_5080_CY2010
Attachments: GillIM_NLM_5080_CY2010.pdf; FW: ; IRB Exemption Request - Haiti - For Submission-8-27-10-amendmentVersion&Signed.pdf

Suzanne,
 Sorry for the delay ... here it is with requested changes.
 Mike

From: Goodwin, Rebecca (NIH/NLM/LHC) [E]
Sent: Thursday, August 26, 2010 3:57 PM
To: Thoma, George (NIH/NLM/LHC) [E]; Gill, Michael (NIH/NLM/LHC) [E]; Antani, Sameer (NIH/NLM/LHC) [E]
Subject: please submit email request for amendment to Office of Human Subjects Research (Lost Person Finder) FW: GillIM_NLM_5080_CY2010

Dr. McDonald and I met with Suzanne Pursley-Crotteau (Office of Human Subjects Research – OHSR) yesterday about a different project, but she inquired about the Lost Person Finder (Haiti Earthquake Person Locator) project.

She needs you to send an email to ohsr_nih_ddir@mail.nih.gov with the following request (and include the attached pdf and email message):

Please amend the Request for Review (GillIM_NLM_5080_CY2010) to expand the original project to an omnibus project for the use of this technology for all disasters.

Nature of Research Activity

The proposed research activity will evaluate the effectiveness of NLM's newly developed information technology tools to assist in reunifying family members in the wake of a disaster, ~~in this case the January 2010 earthquake in Haiti.~~ The activity aims both to provide immediate assistance to people affected by disasters ~~the earthquakes in Haiti~~ and to inform further development and refinement of information technology tools for family reunification.

Please also amend the project end date to be "indefinite."

Rebecca Marci (Brown) Goodwin, J.D.
 Project Manager & Advisor to the Director
 Foster Hill National Center for Biomedical Communications
 National Library of Medicine, National Institutes of Health, HHS
 Direct: (301) 451-4635
 .HC Main: (301) 496-4441
 Email: Rebecca.Goodwin@nih.gov

From: OHSR (NIH/DDIR)
Sent: Friday, August 13, 2010 11:04 AM
To: Miller, Karen (NIH/NLM) [E]; Goodwin, Rebecca (NIH/NLM/LHC) [E]

8/31/2010

Subject: GillM_NLM_5080_CY2010

Dear Karen,

Here is the protocol that needs an amendment from Dr. Gill. I have also attached a scanned copy of the e-mail traffic related to the need for an amendment.

Please let me know if you have any questions.

Best regards,
Suzanne

8/31/2010

OHSR RESPONSE TO REQUEST FOR REVIEW OF RESEARCH ACTIVITY
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FAX: 301-402-0341

Exempt #: 5080

To: Gill, Michael

NLM

38A - Lister Hill Center, 10S1014

From: Office of Human Subjects Research (OHSR)

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- Confidentiality Agreement
- Reliance
- Amendment
- Other

Office Person SPC

Admin Assist. CB

Note:

This project uses publicly available data to evaluate new technology.

Signature: 

Title: Acting Director, OHSR

Date: 1/28/2010

Signature

Title

Date

Domestic/International:

Dom./Int.

Human Subjects Data: Yes

Biologic Material: No

OHSR Use Only

1 2 3 4 5 6

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- Reliance
- Amendment
- Other

Office Person SPC

Admin Assist. CB

Note:

This project uses publicly available data to evaluate new technology.


Charlette Holden, JD

Acting Director, OHSR

1/28/2010

Signature

Title

Date

Domestic/International:

Dom./Int.

Human Subjects Data: Yes

Biologic Material: No

OHSR Use Only

1 2 3 4 5 6

#5080

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: January 27, 2010

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

From: Michael Gill, 

Sameer Antani, Ph.D.
(Signature) 

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

Protocol Title:

Investigation into use of information hosting and delivery for family unification in a disaster using the following tools: "Earthquake in Haiti People Locator" Notification Wall Web site and "Found in Haiti" iPhone app.

Name of NIH Principal Investigator(s): Michael Gill and Sameer Antani
IC NLM Laboratory/Branch Communications Engineering Branch (LHC)
Building & Room No. 38A, 10S1014, and 38A/10S1010
Tel. No. 301-435-3212 and 301-435-3218
FAX No. 301-402-0341

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 proposed research activity will evaluate the effectiveness of NLM's newly developed information technology tools to assist in reunifying family members in the wake of a disaster, in this case the January 2010 earthquakes in Haiti. The activity

aims both to provide immediate assistance to people affected by the earthquakes in Haiti and to inform further development and refinement of information technology tools for family reunification.

The NLM's "Earthquake in Haiti People Locator" Web site (henceforth, NLM People Locator) is an interactive Web-based system that will be used to provide information about people that are still missing or who have been found in Haiti after the devastating earthquake in January 2010. This Web site offers the public a tool for searching for people who have been found in Haiti (e.g., recovered by medical staff and other relief workers) and for voluntarily posting information about people who are still missing. Information on recovered individuals is gathered voluntarily from medical and relief personnel, such as medical staff aboard the USNS Comfort, who use the "Found in Haiti" application developed by NLM for the iPhone or who submit information by email via computer or cell phone. The iPhone application enables submission of photographs and descriptive information about recovered victims in a structured format, e.g., name (if available), age category, gender, general status (healthy, injured), location. In addition, the site will be populated daily with information downloaded from the Google Person Finder which is being widely used – including by US Government agencies – as a service for locating people involved in the Haiti earthquake. Information submitted directly to NLM People Locator will be transferred to the "Google Person Finder" to ensure that users of either system can search the complete set of available data for their family members and loved ones and to ensure that use of the NLM system in no way interrupts or distracts from the operation or use of other personal finder systems.

The tools NLM has developed for submitting information to the People Locator and for searching for matching offer several unique features that are not currently available in the Google Person Finder system or other systems currently used to assist in reuniting families and friends. These include the iPhone/iPod Touch application, which assists in the quick and easy submission of photos and other descriptive data in a standard format. In addition, the NLM People Locator can also accept information from any type of camera-equipped cell phone or computer. The NLM People Locator also provides search capabilities not yet available in other systems. Currently, Google and other tools require a user to enter part of a name. NLM's system will allow for other types of searches including retrieval of individuals whose name is not known, by age (adult or child), and gender. The NLM People Locator also includes a "notification wall" that provides a scrolling display of images of victims added in the last 1 or 24 hours. Finally, NLM is developing a federated system to provide one-stop searching across all known lost person finders, including Google.

The research will aim to examine the utility and effectiveness of the NLM People Locator system in reunifying family members, as well as to analyze technical parameters of the system. Specific technical considerations to be examined include the ability of the system to identify duplicate records, the effectiveness of the image processing software in analyzing content (e.g., person wearing a red shirt), in locating and improving the visibility of faces in submitted photographs, and in finding similar

faces. Lessons will also be drawn about data management approaches for crises and issues of data hosting, networking, and extensibility of the system to other emergencies. The research will make use of publicly available information about missing and recovered persons in Haiti. Results of this analysis will inform efforts to improve the People Finder System for deployment during other disasters, in particular in the context of the Bethesda Hospitals Emergency Preparedness Partnership (BHEPP, <http://www.bhepp.org>), of which NLM and NIH are participating organizations.

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

Name	Institution	Address Tel. # FAX #
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- 3. Proposed start date of your research** Jan 25, 2010
Proposed completion date: Cessation of U.S. Relief Effort in Haiti

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? Yes No

Data will be provided to the NLM People Locator from existing public sources of information, including the Google Person Finder Web site (which contained more than 40,000 records as of January 25, 2010), from members of the public who are searching for missing family members or loved ones, and from emergency responders and others who are assisting the relief efforts in Haiti as people are found (recovered). The NLM People Locator system will provide a means of structuring collected data in ways to make it more searchable and improve the ability to find matches. All of the data are being collected as part of the emergency response efforts in Haiti and will be made publicly available via the NLM People Locator, Google Person Finder, and other person finder systems that source information from Google. As indicated above, collected data will include the name (if available), estimated age (or age-group), general health status (alive & well, injured, deceased, unknown), picture and location information.

(b) Or are they being collected for the express purpose of this study? Yes No

(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.

The system to be studied in this project has been developed as part of NLM's disaster information management research mission within BHEPP and will be deployed by NLM. The system is intended to assist first responders by helping, organize, and structure relevant personal information so that the family members, relief workers, and other interested parties may be able to search and obtain information about loved ones affected in a disaster. To ensure that collection of information for this project does not detract from other ongoing efforts to reunify families and loved ones during the relief effort, collected information will be shared with lost person finder systems operated by other institutions and agencies (e.g., Google).

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

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

This research activity will make use of publicly available data about missing and found persons that is submitted to publicly accessible person locator systems, such as the system operated by Google, or directly to the NLM People Locator system by relief personnel or by members of the public who are who are searching for missing family members or loved ones in Haiti.

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?

The research will involve publicly available data about missing and recovered persons in Haiti. Information will include name (if available), gender, estimated age or age group, photograph, general health status (alive & well, injured, deceased, unknown), and location. Information on found individuals will be voluntarily submitted to the NLM system by emergency responders (medical and relief workers) in Haiti, and information on missing individuals will be submitted by family members and friends who are searching for them. All those who submit information to the system will be presented a Privacy Notice indicating that submitted information will be made publicly available/searchable on a Web site and shared with other person finder systems (such as the one operated by Google) that are also intended for public use.

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_

Will come from a publicly available source (the Google Person Finder), others will come from care provides and other relief workers located in
Haiti _____

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.

The data being gathered in this study is for the specific purpose of locating and reuniting affected parties in a disaster zone. Consistent with this objective, all information collected about the Victims will be made available to the public, as is being done via other person-finder tools, such as the tool developed by Google.

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?**

X **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

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Friday, January 29, 2010 12:43 PM
To: Gill, Michael (NIH/NLM/LHC) [E]
Cc: Antani, Sameer (NIH/NLM/LHC) [E]
Subject: Request for Review Determination_OHSR 5080
Attachments: GillIM_NLM_5080_CY2010.pdf

Good afternoon Dr. Gill,

Attached, please find OHSR's determination of your Request for Review of Research, OHSR #5080.

Please contact OHSR with any questions.

Sincerely,

Chris Brentin

Administrative Assistant

OD/OHSR/NIH

10 Center Drive, Rm. 2C-146

Bethesda, MD 20892

301-402-8631 (Direct)

301-402-3443 (Fax)