

Smithsonian Institution

Human Subjects Institutional Review Board FWA #0005809

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MEMORANDUM

TO: Laura Koehly

SUBJECT: Research Protocol Involving Human Subjects

DETERMINATION DATE: March 6, 2013

TITLE: Genomics and Society Surveys in Conjunction with Smithsonian Museum of Natural History Genome Exhibit

PROTOCOL NUMBER: HS13023

This is to advise you that the Institutional Review Board for Human Subjects Research has determined that your research protocol submitted March 4, 2013 is exempt under paragraph 7 of the Exemption section of Smithsonian Directive 606. Provided there are no changes to your research project or key personnel, you do not need to submit your project for continuing review and you do not need to submit progress reports to the IRB.

Changes or Amendments: If you plan to make changes in your protocol or in the personnel involved in the project, please submit these changes immediately to the IRB for further review. The proposed changes may not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to research subjects. The currently approved project personnel are Laura Koehly, Barbara Biesecker, Vence Bonham, Gillian Hooker, Christopher Marcum, Colleen McBride, Susan Persky, Philip Shaw, Tyra Wolsburg, David Kanney, Andy Baxevanis and William Klein.

Adverse Events: Any injuries or other unanticipated problems involving risks to research subjects or others resulting from this study must be reported promptly to the Office of Sponsored Projects (ospmail@si.edu). If the problem is serious, approval may be withdrawn pending further review by the committee.

Completion of Study and Record Retention: Please notify the Office of Sponsored Projects (OSP) as soon as the research has been completed. Study records, including full protocols and any signed consent forms (originals) for each subject, must be kept in a secured location by the investigator for 3 years following the study's completion.

If you have any questions, please contact OSP by phone or email at the address below. All forms referred to herein are available from OSP.

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

FAX: 301-480-3108

Exempt#: 11817

To: Persky, Susan

NHGRI

Building 31- Claude D Pepper Bldg, B1B54D

Front Office of Human Subjects Research (OHSR)

Nature of Research Activity:

Within the upcoming Genome exhibit at the Smithsonian Museum of Natural History, we will have a display inviting visitors to text their responses to questions related to genomics and genomic information (Appendix B). Displays will also contain a word cloud based on the aggregated, anonymous responses that visitors text to these questions. Text message content will be collected via Poll Everywhere, a short code texting service. The resulting text messages will be downloaded and stored in a secure database. The information will be used for research purposes only and will be de-identified. The information will not be used for any other purpose.

Original Request Received in OHSR on: 2/19/2013

Responsible NIH Research Investigator(s): Susan Persky, NHGRI

OHSR review of your request dated Fri. Feb 15, 2013 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.
- 181 ☐ 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:
3/1/2013: Smithsonian Exhibit and Surveys

Office Person HB

Admin Assist. CB


Lynnette Nieman, MD
Signature

Director, OHSRP
Title

3/1/2013
Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: No

OHSR Use Only
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