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 If the problem is serious, approval may be withdrawn pending further review by the committee.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. <u>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.</u>

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 BIdg, B1B54D				
Fror	nt Office of Human Subjects Resea	rch (OHSR)			
Witinvi B). to t	re of Research Activity: chin the upcoming Genome exhibit at iting visitors to text their responses to Displays will also contain a word clou hese questions. Text message conte e re!\e:m-:h te::m will downlord visitor!\f	o questions related to ger ud based on the aggregat nt will be collected via Po	nomics and ge ed,anonymou oll Everywhere,	nomic informat s responses th a short code to	ion (Appendix at visitors text exting service.
Origi	nal Request Received in OHSR on:	2/19/2013			
Resp	oonsible NIH Research InvestIgator(s)	: Susan Persky, NHGI	RI		
OHS	SR review of your request dated Fri. Fo	eb 15,2013 has determine	ed that:		
	Federalregulations 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 ANE-MAIL AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESEARCH ACTIVITY. The activity is designated fXfMe!. 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.				
О	<u>NOT EXEMPT</u> . OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additionalinformation In order to determine whether expedited or full review is acorooriate.				
O	Confidentiality Agreement				
Ο	Reliance				
Ο	Amendment				
O	Other				
No: 3/1/	te: /2013: Smithsonian Exhibit and Surve		Person HB	Admin As	esist. CB
Sig	(5.rc.lce J7r- nnette Nieman,MD' gnature neslicIInternational:	Director, OHSRP Title		3/1/20 Date	13
Do	mestic		OHSR Use	e Only	
	nan Subjects Data: Yes			03 04	Os 06
Biol	ogic Material: No				