

OHRP NOTIFICATION OF A WAIVER OF THE CONSENT PROCESS FOR  
PLANNED EMERGENCY RESEARCH

June 26, 2012

*<Send when the research is subject to OHRP oversight.>*

Division of Policy and Assurances  
Office for Human Research Protections  
The Department of Health and Human Services  
1101 Wootton Parkway, Suite 200  
Rockville, MD 20852  
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(301) 496-7005  
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Dear Sir or Madam:

On *<Date of IRB Meeting>* the IRB approved a protocol involving a 45 CFR §46  
WAIVER OF INFORMED CONSENT REQUIREMENTS IN CERTAIN  
EMERGENCY RESEARCH (Federal Register Wednesday, October 2, 1996,  
61(192):51531-51533):

The institution conducting the research is:

Organization:	
FWA:	
IRB Registration:	
Address:	
Contact Name:	
Contact Title:	
Contact Phone:	
Contact Fax:	
Contact Email:	

This notification is in regard to:

Type of Review:	<Indicate Initial, Continuing, or Modification>
Title:	
Investigator:	
IRB ID:	
Funding:	<Indicate "None" if there is none.>
Grant Title:	<Indicate "None" if there is none.>
Grant ID:	<Indicate "None" if there is none.>
IND, IDE or HDE:	<Indicate "None" if there is none.>
Documents Reviewed:	
IRB Review Date:	

Attached are the following documents in hard copy and on the enclosed CD-ROM in PDF format:

- a. Relevant IRB minutes that document the findings required by the notification in the Federal Register Wednesday, October 2, 1996, 61(192):51531-51533.
- b. The IRB application form.
- c. Other information requested or required by the IRB to be considered during initial IRB review.
- d. Most current version of protocol and grant application submitted to and reviewed by the IRB and modified by the principal investigator if required by the IRB.
- e. Most current version of consent documents submitted to and reviewed by the IRB and modified by the principal investigator if required by the IRB.
- f. Relevant DHHS grant application or proposal. *(delete if not applicable)*
- g. Other relevant IRB minutes. *(delete if not applicable)*
- h. Relevant IRB correspondence. *(delete if not applicable)*

Sincerely,

IRB Manager

cc: <Protocol Contact>  
<Investigator>  
<Sponsored Projects Services (SPS)>