

## EXTERNAL REPORT

September 22, 2014

**<NOTE: If the report is an unanticipated problem involving risk to subjects or others unrelated to the local research context, reporting to OHRP and FDA is not required.**

**Send when one or more federal agencies listed below or in the cc list require reporting.>**

*<If the research is DHHS-regulated or subject to DHHS oversight by virtue of a federalwide assurance (FWA), send to the following address:><sup>1</sup>*

Kristina Borrer  
Director of the Division of Compliance Oversight  
Office for Human Research Protections  
The Department of Health and Human Services  
The Tower Building  
1101 Wootton Parkway, Suite 200  
Rockville, MD 20852  
Phone: 301-496-7005  
Phone: 866-447-4777 (toll free)  
Fax: 240-453-6909  
[IRPT.OS@hhs.gov](mailto:IRPT.OS@hhs.gov)

*<If the research is FDA-regulated and involves a drug, send to:><sup>2</sup>*

Ms. Dana Walters  
Dana.Walters@fda.hhs.gov  
Division of Scientific Investigations (HFD-45)  
Office of Compliance  
Center for Drug Evaluation and Research  
White Oak Campus  
10903 New Hampshire Ave.  
BLDG 51, Rm. 5341  
Silver Spring, MD 20993  
Phone: 301-796-3150  
Fax: 301-847-8748

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<sup>1</sup> See: [http://www.hhs.gov/ohrp/policy/incidreport\\_ohrp.html](http://www.hhs.gov/ohrp/policy/incidreport_ohrp.html)

<sup>2</sup> See:

<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ReportProblemstoFDA/ucm136102.htm>

<If the research is FDA-regulated and involves a biologic, send to:><sup>3</sup>

Ms. Patricia Holobaugh  
Patricia.Holobaugh@fda.hhs.gov  
Bioresearch Monitoring Branch (HFM-664)  
Division of Inspections and Surveillance  
Office of Compliance and Biologics Quality  
Center for Biologics Evaluation and Research/FDA  
1401 Rockville Pike, Room 400S  
Rockville, MD 20852-1448  
Phone: 301-827-6347  
Fax: 301-827-6748

<If the research is FDA-regulated and involves a device, send to:><sup>4</sup>

Ms. Sheila Brown  
Sheila.Brown@fda.hhs.gov  
Center for Devices and Radiological Health  
Food and Drug Administration  
10903 New Hampshire  
W066 RM 1651  
Silver Spring, MD 20993  
Phone (301) 796-6563  
Fax: (301) 847-8120

Dear Sir or Madam:

<Name of organization> is submitting this report in fulfillment of its regulatory requirement to follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and department or agency heads of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing non-compliance with the regulations or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval.

This is a report of: <delete all that do not apply>

- An unanticipated problem involving risks to subjects or others;
- Serious or continuing non-compliance with the regulations or the requirements or determinations of the IRB; and
- A suspension or termination of IRB approval.

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<sup>3</sup> See:

<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ReportProblemstoFDA/ucm136102.htm>

<sup>4</sup> See:

<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ReportProblemstoFDA/ucm136102.htm>

The institution conducting the research is:

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

This report 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:	

Description of the problem including the findings of the organization and the reasons for the IRB's decision:

*<Insert description.>*

Actions the organization is taking or plans to take to address the problem:

*<Describe actions. For example: Revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, or increase monitoring of subjects.>*

Follow-up Plans

*<Delete if none. Otherwise describe plans, if any, to send a follow-up or final report by the earlier of (1) a specific date or (2) when an investigation has been completed or a corrective action plan has been implemented.>*

Please let us know if you need additional information.

Sincerely,

Organizational Official *<or designee>*

cc: *<Convened IRB by inclusion in the agenda materials as an information item>*  
*<Protocol Contact>*  
*<Principal Investigator>*  
*<Sponsor. Delete if none.>*  
*<Contract Research Organization. Delete if none>*  
*<Chairman or Supervisor of the Principal Investigator>*  
*<Sponsored Projects Services (SPS)>*  
*<Legal Counsel>*  
*<Risk Management>*  
*<Others as deemed appropriate by the Organizational Official.>*  
*<For international or collaborative research, the local research ethics committee or equivalent, as applicable>*  
*<The Privacy Officer of an organization, if the report involves unauthorized use, loss, or disclosure of the organization's individually identifiable information>*  
*<The Information Security Officer of an organization, if the report involves violations of the organization's information security requirements.>*  
*<The following regulatory agencies when they conduct, fund, or oversee the research when they want reporting separate from OHRP>*  
Agency for International Development (22 CFR 225)  
Central Intelligence Agency (Executive order)  
Consumer Products Safety Commission (16 CFR 1028)  
The Department of Agriculture (7 CFR 1c)  
The Department of Commerce (15 CFR 27)  
The Department of Defense (DOD) (32 CFR 219)  
*<If the research is conducted or funded by the Department of the Army (DOD), attach associated minutes and send to:>*  
Director, Army Human Research Protections Office  
usarmy.ncr.hqda-otsg.mbx.usarmy-ncr-hqda-otsg-mailbox-otsg--ahrp@mail.mil  
*<If the research is conducted or funded by the Department of the Navy (DOD), attach associated minutes and send to:>*  
Director, Human Research Protection Program  
human.research@med.navy.mil  
*<If the research is conducted or funded by the Marine Corps (DON, DOD), attach associate minutes and send to Director of the Department of the Navy Human Research Protection Program (as above) and to:>*  
Leah Watson, Human Research Protection Official  
leah.watson@usmc.mil  
*<If the research is conducted or funded by the Department of the Air Force (DOD), attach associated minutes and send to:>*  
Director, Research Oversight and Compliance Division  
afmsa.sge.c@pentagon.af.mil  
The Department of Education (ED) (34 CFR 97)  
The Department of Energy (DOE) (10 CFR 745)

The Department of Homeland Security (Public law 108-458 Sec. 8306)

The Department of Justice (DOJ) (28 CFR 46)

The Department of Transportation (49 CFR 11)

The Environmental Protection Agency (EPA) (40 CFR 26)

*<send to:>*

The Environmental Protection Agency (EPA) Human Subjects Research  
Review official

Housing and Urban Development (24 CFR 60)

National Aeronautics and Space Administration (14 CFR 1230)

National Science Foundation (45 CFR 690)

Office of Science and Technology Policy (Adoption of policy)

Social Security Administration (Public law 7.5.26)