

**EXTERNAL REPORT
IN CONJUNCTION WITH REPORT TO OHRP**

DATE

<NOTE: If the report is an unanticipated problem involving risk to subjects or others for a multi-site study AND is unrelated to the local research context (e.g. protocol modification to include a new risk identified by the sponsor), reporting to OHRP and FDA is not required. However, if this is UPIRTSO for a pSite for a study where UMN IRB is serving as the sIRB, reporting is required.>

Send when the organization is notified by any Federal department, agency or national organization that any part of the HRPP is under investigation for cause involving a DoD-supported research protocol.¹

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

<If the research is regulated under any agency in conjunction with DHHS, complete this template and submit the completed OHRP Incident Report Form to the following as appropriate:>

<If the research is FDA-regulated and involves a drug, send to:>ⁱ

Office of Scientific Investigations
Email: CDER-OSI-GCFReferrals@fda.hhs.gov
Phone: (301) 796-3150

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

Bioresearch Monitoring Branch
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research/FDA
10903 New Hampshire Ave.
Building 71, Room 5126
Silver Spring, MD 20993
Email: CBERBIMONotification@fda.hhs.gov
eFax: (301) 480-9748

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

Phone (301) 796-5490

¹ See <https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf>

Fax: (301) 847-8136
Email: bimo@cdrh.fda.gov

Dear Sir or Madam:

The University of Minnesota 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.

This report is in regard to:

EXAMPLE

Type of Reportable Event:	<i><Include only those that apply.></i> An unanticipated problem involving risks to subjects or others; Serious non-compliance with the regulations or the requirements or determinations of the IRB; Continuing non-compliance with the regulations or the requirements or determinations of the IRB A suspension or termination of IRB approval.
Study Title:	
Investigator:	
IRB Submission ID:	
Sponsored Funding:	<i><Indicate "None" if there is none.></i>
Proposal/Award Title:	<i><Indicate "None" if there is none.></i>
Proposal/Award ID:	<i><Indicate "None" if there is none.></i>
IND, IDE or HDE:	<i><Indicate "None" if there is none.></i> <i><Add if this is an NSR study or delete.></i> This study is subject to abbreviated IDE requirements.
Participant Enrollment Status:	
Documents Reviewed:	
IRB Review Date(s):	

Please see the attached copy of the OHRP Incident Report Form email confirmation for full detailed information regarding the event.

Please let us know if you need additional information.

Sincerely,

Joanne Billings, MD
 Associate Vice President for Research Integrity and Compliance

cc:

- <Protocol Contact>*
- <Principal Investigator>*
- <Sponsor. Delete if none.>*
- <Contract Research Organization. Delete if none>*
- <Chairman or Supervisor of the Principal Investigator>*
- Debra Dykhuis, HRPP Executive Director*

Shashank Priya, PhD, Vice President for Research and Innovation, Institutional Official
<Research Partners (e.g. Fairview or Gillette, if applicable):

Jill Cordes, BSN RN CHRC, System Director, MHealth Fairview Research Administration

<Name>, Gillette Specialty Healthcare

Lauren Popp, JD CHRC, Chief Health Information Compliance Officer and Director <If the report involves unauthorized use, loss, or disclosure of the organization's individually identifiable information>

Pamela Webb, Associate Vice President for Research and Innovation Administration <ONLY for suspension, termination, lift of suspension>

Danielle Rintala, Director Research Integrity and Compliance <ONLY for suspension, termination, lift of suspension>

<Others as deemed appropriate by the Organizational Official.>

<For international or collaborative research, the local research ethics committee or equivalent, as applicable>

<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>

Contact information for the following agencies can be found at

<https://www.hhs.gov/ohrp/compliance-and-reporting/common-rule-agencies-contacts/index.html>:

- 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)
- *<Attach associated minutes and send to your institution's assigned point of contact (e.g. HRPO/HPA/EDO) for the specific branch that is supporting the research>*
- The Department of Education (ED) (34 CFR 97)
- The Department of Energy (DOE) (10 CFR 745)
- The Department of Homeland Security (6 CFR Part 46)
- The Department of Justice (DOJ) (28 CFR 46)
- The Department of Labor
- The Department of Transportation (49 CFR 11)
- The Environmental Protection Agency (EPA) (40 CFR 26)
- Department of Housing and Urban Development (24 CFR 60)
- National Aeronautics and Space Administration (14 CFR 1230)

- National Science Foundation (45 CFR 690)
- Office of the Director of National Intelligence
- Social Security Administration (Public law 7.5.26)

ⁱ See:

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

ⁱⁱ See:

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

ⁱⁱⁱ See:

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

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