UNIVERSITY OF MINNESOTA

Twin Cities Campus

Human Research Protection Program
Research and Innovation Office

350-2 McNamara Alumni Center
200 Oak St. SE
Minneapolis, MN 55455

612-626-5654
irb@umn.edu
https://research.umn.edu/units/irb

EXTERNAL REPORT

ALL AGENCIES NOT INCLUDING 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 the 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 FDA-regulated and involves a drug, send to:>[2]
Office of Scientific Investigations
Email: CDER-OSI-GCPReferrals@fda.hhs.gov
Phone: (301) 796-3150

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

[1] See https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf
[2] See: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ReportProblemstoFDA/ucm136102.htm
[3] See: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ReportProblemstoFDA/ucm136102.htm

<If the research is FDA-regulated and involves a device, send to:>[4]
Phone (301) 796-5490
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.

The institution conducting the research is:

Organization:	University of Minnesota (IORG0000261)
FWA:	FWA#00000312
IRB Registration:	IRB00010642
Address:	200 Oak St. SE, Suite 350-2 Minneapolis, MN 55455
Contact Name:	Debra Dykhuis
Contact Title:	Executive Director, HRPP
Contact Phone:	612-626-4851
Contact Fax:	612-626-6061
Contact Email:	dykhu001@umn.edu

[4] See: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ReportProblemstoFDA/ucm136102.htm

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This report is in regard to:

Type of Reportable Event:	<Include only those that apply.> 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:	*<Indicate "None" if there is none.>*
Proposal/Award Title:	*<Indicate "None" if there is none.>*
Proposal/Award ID:	*<Indicate "None" if there is none.>*
IND, IDE or HDE:	*<Indicate "None" if there is none.>* Instructional Text (Add if this is an NSR study or delete>: This study is subject to abbreviated IDE requirements.
Participant Enrollment Status:	
Documents Reviewed:	
IRB Review Date(s):	

Problem

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

<Insert description.>

Actions Taken

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,

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>

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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 (National Institute of Standards and Technology) (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)
- 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
- Office of Science and Technology Policy (Adoption of policy)
- Social Security Administration (Public law 7.5.26)