UNIVERSITY OF MINNESOTA

Twin Cities Campus

Human Research Protection Program
Office of the Vice President for Research

Room 350-2
McNamara Alumni Center
200 Oak Street S.E.
Minneapolis, MN 55455

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irb@umn.edu
https://research.umn.edu/units/irb

REVIEW OF NEW INFORMATION REPORT

«getTodayMergeString()»

«investigator.studyTeamMember.fullName()»
«getBusinessAddressMergeString(investigat»
«getPhoneFaxEmailMergeString(investigator»

Dear «investigator.studyTeamMember.honorific»
«investigator.studyTeamMember.fullName()»:

On «determinationDate», the IRB reviewed the following new information item(s):

- *<briefly describe items>*

This information is in regard to:

Type of Review:	«submissionType»
Title:	«name»
Submitted by:	«investigator.studyTeamMember.fullName()»
Responsible Party:	«reportableNewInformation.responsiblePart»
IRB ID:	«ID»

<Choose one of the 3 options below. Delete the other two options.>

<OPTION 1>

The IRB requests the following additional information before making a determination:

- <Insert description>

<OPTION 2>

<The Selection in ETHOS is *"None of the above"*-- The IRB has determined this information does NOT fall into the category of non-compliance, UPIRTSO, or requiring suspension or termination. No further action is required. >

OR

<OPTION 3>

The IRB determined that this information is:

<Delete all that do not apply>

- Non-compliance that is neither serious nor continuing

<Only include this note if the determination is non-compliance that is neither serious nor continuing> Please note that continued findings may result in a finding of Serious or Continuing non-compliance. The definitions of these findings can be found in HRP-001-SOP Definitions.

- Serious or continuing non-compliance with the regulations or the requirements or determinations of the IRB *<Specify whether "serious," "continuing," or both>*
- A non-local unanticipated problem involving risks to subjects or others (UPIRTSO)
- A local unanticipated problem involving risks to subjects or others (UPIRTSO)
- A suspension or termination of IRB approval *<Specify whether "suspension" or "termination" applies>*

The IRB requests the following additional information:

- *<Insert description. Delete this section if no information is required.>*

«getRNIActionPlanMergeString()»

<If the determination is a UPIRTSO, Serious non-compliance, and/or Continuing non-compliance, or Suspension or Termination include a) the definition of the determination and b) the reporting language. Be sure to send the letter to the Assistant Director and consult with her before sending the letter to the PI.>

<Definitions. *Delete the definitions that do not apply to the determination.>*
A UPIRTSO is defined HRP-001 as: (1) Any problem or event which was unexpected in nature, severity, or frequency; (2) is related or possibly related to participation in the research; and, (3) places subjects or others at greater risk of harm than was previously known or recognized.

Serious non-compliance is defined in HRP-001 as non-compliance that adversely affects the rights or welfare of subjects.

Continuing non-compliance is defined in HRP-001 as a pattern of non-compliance that suggests the likelihood that, without intervention, instances of non-compliance will recur, a repeated unwillingness to comply, or a persistent lack of knowledge of how to comply.

Suspension of IRB Approval is defined in HRP-001 as an action of the IRB, IRB designee, Institutional Official/Organizational Official, or designee of the Institutional

Official/Organizational Official to temporarily or permanently withdraw IRB approval of some or all research procedures short of a Termination of IRB Approval. Suspended studies remain open and are subject to continuing review.

Termination of IRB Approval is defined in HRP-001 as an action of the IRB, IRB designee, Institutional Official/Organizational Official, or designee of the Institutional Official/Organizational Official to permanently withdraw IRB approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review.

<Reporting Language>
Please note: According to federal regulations at 45 CFR 46.103(b)(5) and 21 CFR 56.108(b), when the IRB makes a [list specific IRB determination], it is mandated to report to appropriate entities including, regulatory authorities (e.g., FDA and OHRP) as applicable, and institutional officials. The investigator is copied on these required notifications.

<If research is suspended or terminated, add the text below. Delete if this section does not apply:>

- *As part of this <suspension/termination> the following research activities must stop: <select one>*
  - *All research activities must stop. This includes recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information. Advertisements currently running in the media must be pulled.*
  - *All recruitment, screening, enrollment, consent, interventions, and interactions must stop. Collection and analysis of private information may continue.*
  - *All recruitment, screening, enrollment, and consent must stop. Interventions, interactions, and collection and analysis of private identifiable information may continue.*
  - *<Other: Describe requirements>*
- *If you believe that current subjects are at risk of harm by stopping research procedures described above:*
  - *Identify the research procedures that need to continue.*
  - *Describe the reasons that these procedures need to continue.*
  - *Immediately provide the IRB Office with this information.*

  Your response, if any, will be evaluated by an IRB member, in consultation with others as necessary and a decision made as to whether there is an over-riding safety concern or ethical issues involved such that it is in the best interest of subjects to continue. Any granted continuation will be communicated to you in writing in a timely manner.

Should you wish to respond, or have been requested to do so, please submit a written response to the IRB within 10 business days. Please let us know if you need additional information.

Sincerely,

<IRB Manager>

cc: *<Protocol Contact>*
<Principal Investigator>

<Also copy the following individuals when the information item was determined to be a non-local or local UPIRTSO, Serious and/or Continuing non-compliance, or Suspension or Termination of IRB approval . Otherwise delete.>

<Institutional Official.>
<Research Partners (e.g., Fairview or Gillette).>
<Department leadership of the Principal Investigator.>
<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.>
In addition, for local UPIRTSOs, for Serious and/or Continuing Non-compliance, and Suspension/Termination, as applicable
<FDA>
<OHRP>
Only add SPA when study is being suspended or terminated
<Sponsored Projects Administration.>