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

SUSPENSION OR TERMINATION

Today's Date: «getTodayMergeString()»

Investigator: «getInvestigatorMergeString(name)»

IRB ID: «parentStudy.ID»

Submission ID: «ID»

Study Title: «parentStudy.studyTeamDescription»

Determination Date: «determinationDate»

Determination: <Select All that Apply>
☐ A suspension of IRB approval
☐ A termination of IRB approval

The IRB/I reviewed the following information item(s) on the above referenced study:

- *Brief summary of the information/event*
- *<Auto-Pull Text from RNI Submission SmartForm, Question #6>*

<I/the convened IRB> *<suspended/terminated>* the above protocol(s).

Explanation of Suspension/Termination Determination
The IRB/I determined that the information provided requires a suspension/termination of IRB approval because <include the reasoning for the determination that was made>.

[If suspended outside the convened IRB, add this statement. Otherwise delete.] This action will be reviewed by the convened IRB at its meeting on *<Date and Time of Meeting>*.

Corrective Actions are Required *<Delete this section if no action plan is required.>*
The IRB requires that you take the following corrective actions and should be submitted within 10 business days (see Guidance for developing a corrective and preventive action plan):

- *<Describe actions and the reasons for those 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.>*

Important information regarding the suspension/termination of IRB approval *<Delete this section if the study was not suspended or terminated.>*

- 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 identifiable 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>

Continuation of research activities without prior IRB review and approval is a violation of federal regulations.

If you believe that current research participants 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 with this information in ETHOS via "Add a Comment" and select "Notify IRB Coordinator"
- 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 overriding safety concern or ethical issue involved such that it is in the best interest of subjects to continue. Any granted continuation will be communicated to you in writing via ETHOS in a timely manner.

Please take the following actions to protect participants:*<Include statements below as needed or provide other actions that are necessary.>*

- Transferring research participants to another investigator.
- Making arrangements for clinical care outside the research.
- Allowing continuation of some research activities under the supervision of an independent monitor.
- Requiring or permitting follow-up of research participants for safety reasons.
- Requiring adverse events or outcomes to be reported to the IRB and the sponsor.
- Notification to current research participants.
- Notification to former research participants.

Single IRB – Communication Requirements *<Delete this section if the this is not a related to a Single IRB RNI.>*

As UMN IRB is serving as the single IRB (sIRB), additional communications are required.

- Please share this determination letter with the participating site (pSite) investigator. The pSite investigator may have additional reporting requirements at their institution.
- The UMN HRPP will share a copy of this determination letter with the relying institution's IRB.

How to Respond [Update if determination was made outside the convened IRB]

- Provide a summary of your response, including any changes you made (a separate document or by adding a comment). and how those changes address the IRB's questions or concerns.
- If you are required to make changes to study related documents, you will need to submit a modification. Include in your response, the modification submission ID.
- If a requested change or question is unclear, please add a comment with your questions and notify the IRB coordinator.
- More information on how to respond to an RNI can be found on the IRB website.

Important information regarding reports to federal agencies (OHRP/FDA) *<Delete this section if the this is not a reportable event to OHRP/FDA.>*
According to federal regulations at 45 CFR 46.103(b)(5) and 21 CFR 56.108(b), the IRB is mandated to report this determination to appropriate entities including regulatory authorities (OHRP/FDA), the study sponsor and institutional officials. The investigator is copied on these required notifications.

Appealing the IRB Determination [If suspension was made outside of the convened IRB meeting, remove "IRB" references from this section.]
Researchers may request that the IRB reconsider a decision by submitting a written response to the IRB in ETHOS within 5 business days. Documents can be included in the Supporting Documents section of the ETHOS SmartForm.

When submitting a request to reconsider, the researcher must provide rationale for the request, including any additional supporting documents.
Grounds for a request are limited to:
- New information not reasonably available during the IRB review/investigation
- Material failure by the IRB to follow IRB policies and procedures
- The sanction exceeds the severity of the non-compliance violations, if applicable
- The action is disproportionate to the risks to subjects safety/welfare

Additional Study Information and Documentation			
Sponsored Funding:	«parentProject.customAttributes.irbSubmis» <Indicate "None" if there is none.>	Proposal/ Award ID:	«parentProject.customAttributes.irbSubmis» <Indicate "None" if there is none.>
Internal UMN Funding:	«parentProject.customAttributes.irbSubmis»	Fund Management Outside University:	«parentProject.customAttributes.irbSubmis»
IND, IDE, or HDE:	«parentProject.getDeviceOrDrugNumbersMerg» <Add if this is an NSR study or delete>: This study is subject to abbreviated IDE requirements.		
Documents Reviewed with this	All documents that were reviewed are located in the Documents tab of this submission.		

Submission:	

Questions?
Please submit any questions via "Add a Comment" through ETHOS and select notify IRB Coordinator.

Questions?
Please submit any questions via "Add a Comment" through ETHOS and select notify IRB Coordinator.

On behalf of the University of Minnesota IRB,
<Analyst Name> OR
<Name and title of person who ordered the suspension or termination>

Institutional Review Board
200 Oak Street SE
Suite 280
Minneapolis, MN 55455
irb@umn.edu (612) 626-5654

cc:

<Protocol Primary Contact>
<Department leadership of the Principal Investigator>
<Others as deemed appropriate by the Institutional Official.>
<For international or collaborative research, the local research ethics committee or equivalent, as applicable>
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
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>