UNIVERSITY OF MINNESOTA

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APPROVAL OF CONTINUING REVIEW

November 16, 2018

Danni Li
612-626-0299
dannili@umn.edu

Dear Danni Li:

On 11/16/2018, the IRB reviewed the following submission:

Type of Review:	Continuing Review
Title of Study:	Blood Biomarkers as Surrogate Endpoints of Treatment Responses to Aerobic Exercise and/or Cognitive Training in Amnestic Mild Cognitive Impairment
Title of Submission:	Continuing Review for Study The ACT Trial Blood Biomarker Study
Investigator:	Danni Li
IRB ID:	STUDY00001835
Submission ID:	CR00003024
Sponsored Funding:	Sponsor Name: NIH NAT'L INSTITUTE ON AGING (NIA), Grant Title: Blood Biomarkers as Surrogate Endpoints of Treatment Res
Grant ID/Con Number:	CON000000070057;
Internal UMN Funding:	Departmental funding : PI's department fund
Fund Management Outside University:	None
IND, IDE, or HDE:	None
Documents Reviewed with this Submission:	None

The IRB determined that the criteria for approval continue to be met and that this study continues to involve No greater than minimal risk.

This study was re-approved under Expedited Category(ies):

• (7) Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

• (2)(a) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, non-pregnant adults who weigh > 110 pounds where the amount drawn is <550 ml/8 week period and collection occurs at most 2 times/week.

The IRB approved the study from 11/16/2018 to **10/25/2019** inclusive. You will be sent a reminder from ETHOS to submit a Continuing Review submission for this study. You must submit your Continuing Review no later than 30 days prior to the last day of approval in order for your study to be reviewed and approved for another Continuing Review period. If Continuing Review approval is not granted before 10/25/2019 approval of this protocol expires immediately after that date.

You must also submit a Modification in ETHOS for review and approval prior to making any changes to this study.

Previously approved consent forms or recruitment materials are located under the Final column in the Documents tab in the ETHOS study workspace.

The previously approved HIPAA Authorization is also available there; however, this document will not receive an approval watermark from ETHOS.

In conducting this study, you are required to follow the requirements listed in the Investigator Manual (HRP-103), which can be found by navigating to the HRPP Toolkit Library on the IRB website.

For grant certification purposes, you will need the approval and last day of approval dates listed above and the Assurance of Compliance number which is FWA00000312 (Fairview Health Systems Research FWA00000325, Gillette Children's Specialty Healthcare FWA00004003).

Sincerely,
Tricia A Carstedt

IRB Analyst

We value feedback from the research community and would like to hear about your experience. The link below will take you to a brief survey that will take a minute or two to complete. The questions are basic, but your responses will help us better understand what we are doing well and areas that may require improvement. Thank you in advance for completing the survey.

Even if you have provided feedback in the past, we want and welcome your evaluation.

http://z.umn.edu/irbsurvey