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# Certificate of Approval

03-Aug-2025

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|---|---|
| **Title:** | Comparison of Weight Loss Generated by AM vs PM Exercise: A 13 Month Randomized Trial |
| **COMIRB#:** | 21-3094 |
| **Investigator:** | Victoria Catenacci |
| **Subject:** | Continuing Review |
| **Funding Source(s):** | National Institute of Diabetes and Digestive and Kidney Diseases/NIH/DHHS~ |
| **Panel:** | UCD Panel A |
| **Effective Date:** | 18-Jul-2025 |
| **Expiration Date:** | 17-Jul-2026 |

**Submission ID:** CRV005-1

**SUBMISSION DESCRIPTION:**

Active; enrollment is complete, but participants are still receiving research related interventions. PAM032-1 reviewed concurrently.

This study was reviewed and approved under the “2018 Requirements” of the Federal Policy for the Protection of Human Subjects.

If continuing review is required for your research, your submission is APPROVED until the expiration date listed above. The investigator will need to submit this research for Continuing Review at least 30 days prior to the expiration date. If a study's approval expires, investigators must stop all research activities immediately (including data analysis) and contact the COMIRB office for guidance

If your study has not been assigned an expiration date continuing review is not required for your research.
Regardless of continuing review, your research is under IRB oversight. You will receive annual notices from COMIRB about this study until it is closed. You are required to submit changes to your research for approval prior to implementing those changes. You are required to report unanticipated problems and serious or continuing noncompliance to COMIRB. When your research is complete you must report the study closure to COMIRB.
Your responsibilities as Principal Investigator are posted here:
https://research.cuanschutz.edu/docs/librariesprovider148/comirb_documents/guidance/investigator-responsibilities-guidance.pdf?sfvrsn=ba172fb9_2

**REVIEW DETAILS-**

All information required for continuing review and re-approval of the protocol and consent form was included and found to be satisfactory

The committee determination was: APPROVED

Conflict of Interest: No conflict declared.

Protocol and application form: The committee reviewed all the documents provided for the continuing review.

Previous changes: All previous changes have been reviewed and determined to be appropriate and incorporated into the

submitted documents.

There have been no changes that impact the regulatory and ethical conduct since the last review.

Requested changes from last review: All changes previously requested have been reviewed and determined to be appropriate and incorporated into the submitted documents.

Sites: COMIRB is acting as the IRB of record for the following sites: University of North Carolina at Chapel Hill.

Sites: The committee noted that one of our affiliated institutions is the coordinating site for this study.

The committee noted that no issues relating to coordination with other sites has been reported.

Status: Enrollment is complete, but participants are still receiving research-related interventions.

Number approved locally: 300
Number signed consent: 196
Number of screen failures: 26
Number of withdrawals: 62

The committee reviewed the reasons for withdrawals and had no concerns.

Subject enrollment: The committee determined that the selection of subjects is equitable.

Consent process: The committee noted that this study is closed to enrollment and therefore, the consent process described in the protocol is not applicable at this time.

FDA Regulated Research (Drugs/Devices): This research study is not subject to FDA regulations.

Safety information: The committee reviewed all the safety information provided and requested no changes to the protocol or consent form at this time.

No unanticipated problems were reported during the current review period.

Risks: The committee determined that the risks were appropriately minimized as outlined. The committee made the following risk assessment for the populations to be enrolled:

Adults: The committee determined that this research continues to involve greater than minimal risk.

The risks continue to be minimized by using procedures that are consistent with sound research design and which do not unnecessarily expose participants to risk, and by using procedures already being performed on subjects for diagnostic or treatment purposes. Investigators are qualified. The inclusion/exclusion criteria continue to be appropriate, as do monitoring of the subjects, and oversight of the study.

Risk/Benefit Ratio: Risks to participants continue to be reasonable in relation to anticipated benefits to participants and the importance of the knowledge that may reasonably be expected to result.

Continuing Review Frequency: The committee determined that a continuing review frequency of 12 months is appropriate.

All submitted documents were reviewed and approved or noted, except as detailed below.

The personnel form was reviewed with this continuing review. The new version of this document is approved with the associated amendment PAM032-1.

Committee comments:

1) The IRB commends the study team for the evidence of hard work and attention to detail that went toward this Continuing Review submission.

The continuing review form was submitted.

Protocol submitted: Does When You Exercise Matter? A Randomized Trial Comparing the Effect of Morning versus Evening Aerobic Exercise on Weight Loss and Compensatory Behaviors, Version Date: 4/3/2025.

Application form submitted: Application form, Version Date: Apr 15, 2025.

Other materials submitted:
1. Cover letter, 7/9/2025.
2. Personnel form: 03-Jul-2025.
3. Protocol Annual Noncompliance/Deviation Summary Report, no date.
4. NIH Inclusion Enrollment Report as of 7.3.2025.
5. Data Safety Monitoring Report, March 14, 2025 (signed by Safety Officer, March 19, 2025).

Consent form submitted: Consent with HIPAA authorization form, Version Date: 4/15/2025.

The consent form was reviewed but is not approved for use at this time because the study is closed to enrollment. The IRB approved the consent form for ongoing re-consenting purposes at the study team's request.

HIPAA Compliance: The COMIRB committee, acting as the COMIRB Privacy Board, acknowledged the submitted combined consent and HIPAA Authorization B form, and the information in the application form.

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