



**SOUTH DAKOTA
STATE UNIVERSITY**

Tutorial for Submitting a Modification for review
by the SDSU IRB in Cayuse

cayuse Human Ethics

Role: Researcher | Products | Matthew Vukovich

Dashboard | Studies | Submissions | Tasks | Meetings | Reporting | More

+ New Study

In-Draft →

Awaiting Authorization →

Pre-Review →

Under Review →

Post Review →

My Studies

IRB-FY2024-28	← Impact of Physical Activity on Wellness
IRB-FY2024-27	Impact of physical activity on health and well-being
IRB-FY2024-13	Example NHR Study 11.29.23
IRB-FY2024-12	Test Expedited Review 11.29.23

[View All](#)

My Tasks

All Tasks Complete

Submissions by Type

Renewal	0
Initial	4
Modification	0
Incident	0
Withdrawal	0
Closure	0
Legacy	0

Approved Studies

IRB-FY2024-28	Impact of Physical Activity on Wellness
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[View All](#)

Studies Expiring in 30 days

No Expiring Studies

Expired Studies

No Expired Studies

Dashboard view of Cayuse Human Ethics module. To modify an approved study, select the study from the **My Studies** menu

Studies / Study Details

[+ New Submission](#)

Study Details | Submissions

Approved

IRB-FY2024-28 Impact of Physical Activity on Wellness

PDF Delete

Approval Date: 02-09-2024 | Expiration Date: 02-07-2025 | Organization: South Dakota State University | Active Submissions: N/A | Population Flags: | Additional Flags:

Admin Ch: N/A

Select **+New Submission**
Select [Modification] from the pulldown menu.

Key C

Team M

Matthe

Matthe

Approved

IRB-FY2024-28 Impact of Physical Activity on Wellness

PDF Delete

Approval Date: 02-09-2024 | Expiration Date: 02-07-2025 | Admin Check-In Date: N/A | Closed Date: N/A

Key Contacts | Attachments | Flags

Team Member

Matthew Vukovich
Matthew Vukovich

[+ New Submission](#)

- Renewal
- Modification
- Incident
- Closure

Select Edit.

Studies / Study Details / Submission Details

1 In-Draft Submission is with researchers | 2 Awaiting Authorization Submission is awaiting certification or approval | 3 Pre-Review Submission is being prepared for review | 4 Under-Review Submission is with reviewers

Unsubmitted

Modification

IRB-FY2024-28 - Impact of Physical Activity on Wellness

Edit PDF Delete

PI: Matthew Vukovich | Current Analyst: N/A | Decision: N/A | Policy: Post-2018 Rule | Required Tasks: [Assign PI](#) [Assign PC](#) [Complete Submission](#)

Review Type: N/A | Review Board: N/A | Meeting Date: N/A

Approvals | Task History | Attachments

Research Team

Name	Role	Result	Date
No entries.			

cafuse
Human Ethics

Role: Researcher Products Matthew Vukovich

Dashboard Studies Submissions Tasks Meetings Reporting More

IRB NUMBER: IRB-FY2024-28
SUBMISSION DETAILS Impact of Physical Activity on Wellness - Modification

CREATE PDF COMPARE SAVE

Sections

- Amendments ✓
- Compliance
- Welcome ✓
- Determination ✓
- Project Personnel ✓
- Project Description ✓
- Participant Informa... ✓
- Recruitment Process ✓
- Consent Process ✓
- Risk, Privacy, Conf... ✓
- Compliance ✓

Amendments

Amendments

- Adding funding source.
- Removing a funding source.
- Recruitment materials - advertisement, text, script, social media messaging.
- Increasing participant numbers.
- Decreasing participant numbers.
- Inclusion/Exclusion criteria.
- Changes to study procedures.
- Changes to informed consent/assent.
- Compensation.
- Reopening enrollment
- Location change
- Other Amendment Request
- Survey
- Focus group questions or text.
- Do modifications affect risks to participants, the way data is coded, de-identified, analyzed, or stored?
- Add Personnel.
- Transfer study to new principal investigator.

Select which type of modification you would like to make. You can select more than one modification.

causer Human Ethics

Role: Researcher Products Matthew Vukovich

Dashboard Studies Submissions Tasks Meetings Reporting More

IRB NUMBER: IRB-FY2024-28

Submission Details: Impact of Physical Activity on Wellness - Modification

CREATE PDF COMPARE SAVE

Amendments

Amendments

- Adding funding source.
- Removing a funding source.
- Recruitment materials - advertisement, text, script, social media messaging.
- Increasing participant numbers.
- Decreasing participant numbers.
- Inclusion/Exclusion criteria.
- Changes to study procedures.
Provide justification.

Changes to study procedures.
Provide justification.

Changing the treadmill performance test protocol to accommodate participants different fitness levels. The new protocol will start at a slower speed.

- Changes to informed consent/assent.
Provide justification.

For each modification or amendment to the study, provide a justification. Select [Save] after each change.

- Sections <
- Amendments ✓
- Compliance ✓
- Welcome ✓
- Determination ✓
- Project Personnel ✓
- Project Description ✓
- Participant Informa... ✓
- Recruitment Process ✓
- Consent Process ✓
- Risk, Privacy, Conf... ✓
- Compliance ✓
- Routing Send to PI for certification? ▾
- COMPLETE SUBMISSION >

Compliance

* Did any unanticipated problems, including adverse events or subject complaints, occurred since the last IRB review.

No
 Yes

Important information regarding retention of informed consent forms and research records:

- Reported all serious or unexpected adverse events as required.
- Obtained informed consent from each subject (unless a waiver of the consent process was granted and that a consent form was signed, dated, and is retained in the PI's files).
- Not made any changes to the study procedures or consent form(s) without prior IRB approval.
- The principal investigator is expected to review and adhere to the SD BOR policy for maintaining records associated with research and those that may fall under HIPAA requirements for research data: REG 202.1 and REG 202.2 [here](#).

* Investigator Statement of Compliance

By submitting this form, I certify all information provided is accurate and that procedures involved in this project are conducted according to federal regulations and South Dakota subject research. (Type name)

Matt Vukovich

Once compliance statement is completed, select the menu that corresponds to the modification that was selected in the first screen. In that example, changes to study procedures and changes to informed consent were selected.

Role: Researcher | Products | Matthew Vukovich

Dashboard Studies Submissions Tasks Meetings Reporting More

< SUBMISSION DETAILS | IRB NUMBER: IRB-FY2024-28 **Impact of Physical Activity on Wellness - Modification**
CREATE PDF COMPARE SAVE < >

Sections <

- Amendments ✓
- Compliance ✓
- Welcome ✓
- Determination ✓
- Project Personnel ✓
- Project Description**
- Participant Informa... ✓
- Recruitment Process ✓
- Consent Process ✓
- Risk, Privacy, Confi... ✓
- Compliance ✓

* Design and Methodology
 Describe study design and data collection methodologies.

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Update the design and methodology.

Role: Researcher | Products | Matthew Vukovich

Dashboard Studies Submissions Tasks Meetings Reporting More

< SUBMISSION DETAILS | IRB NUMBER: IRB-FY2024-28 **Impact of Physical Activity on Wellness - Modification**
CREATE PDF COMPARE SAVE < >

Sections <

- Amendments ✓
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- Participant Informa... ✓
- Recruitment Process ✓
- Consent Process**
- Risk, Privacy, Confi... ✓
- Compliance ✓

Consent Process

Attach all consent/assent forms.

**If your study is registered on clinicaltrials.gov, your consent form must include the following information that can identify you. At most, the website will include a summary of results. You can search clinicaltrials.gov at any time

ATTACH

Consent form.docx ✕

Indicate how you will obtain consent from participants.

Check all that apply. (Contact the IRB for assistance if you are unsure.)

- Signed informed consent.
- Electronic signature. (Note: a checkmark is not sufficient.)
- Implied consent.
- Child assessment and parental consent.
- Obtaining consent using a short form.
- Other

Attach new consent form. Only one consent form can be attached. Delete the first one and then add new consent form.

Role: Researcher | Products | Matthew Vukovich

Dashboard Studies Submissions Tasks Meetings Reporting More

< SUBMISSION DETAILS | IRB NUMBER: IRB-FY2024-28 **Impact of Physical Activity on Wellness - Modification**
CREATE PDF COMPARE SAVE < >

Sections <

- Amendments ✓
- Compliance ✓
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- Participant Informa... ✓
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- Risk, Privacy, Confi... ✓
- Compliance ✓

Consent Process

Attach all consent/assent forms.

**If your study is registered on clinicaltrials.gov, your consent form must include the following information that can identify you. At most, the website will include a summary of results. You can search clinicaltrials.gov at any time

ATTACH

Consent form.docx ✕

DOCUMENTS ✕

Files

Consent form.docx ✕

* Single Attachment Only: Delete previous attachment to add another

- Sections <
- Amendments ✓
- Compliance ✓
- Welcome ✓
- Determination ✓
- Project Personnel ✓
- Project Description ✓
- Participant Informa... ✓
- Recruitment Process ✓
- Consent Process ✓
- Risk, Privacy, Conf... ✓
- Compliance ✓
- Routing
Send to PI for certification?
- COMPLETE SUBMISSION

Consent Process

Attach all consent/assent forms.

If your study is registered on clinicaltrials.gov, your consent form **must include the following statement: A description of this clinical trial will be available on clinicaltrials.gov, as required by U.S. law. This will not include information that can identify you. At most, the website will include a summary of results. You can search clinicaltrials.gov at any time

ATTACH

Consent form.docx

Indicate how you will obtain consent from participants.

Check all that apply. (Contact the IRB for assistance or questions at cau.irb@sdstate.edu)

- Signed informed consent.
- Electronic signature. (Note: a checkbox does not count as an electronic signature.)
- Implied consent
- Child assessment and parental consent
- Obtaining consent using a short form with oral explanation and witness.
- Other

Provide a detailed description of the consent process including who will obtain consent/assent and timing, providing participants sufficient time for adequate consideration.

Remember to select save.
When all modifications have
been made, select
[Complete Submission]



Studies / Study Details / Submission Details



Awaiting Certification

Modification

IRB-FY2024-28 - Impact of Physical Activity on Wellness

View PDF Delete

Routing: Return Certify

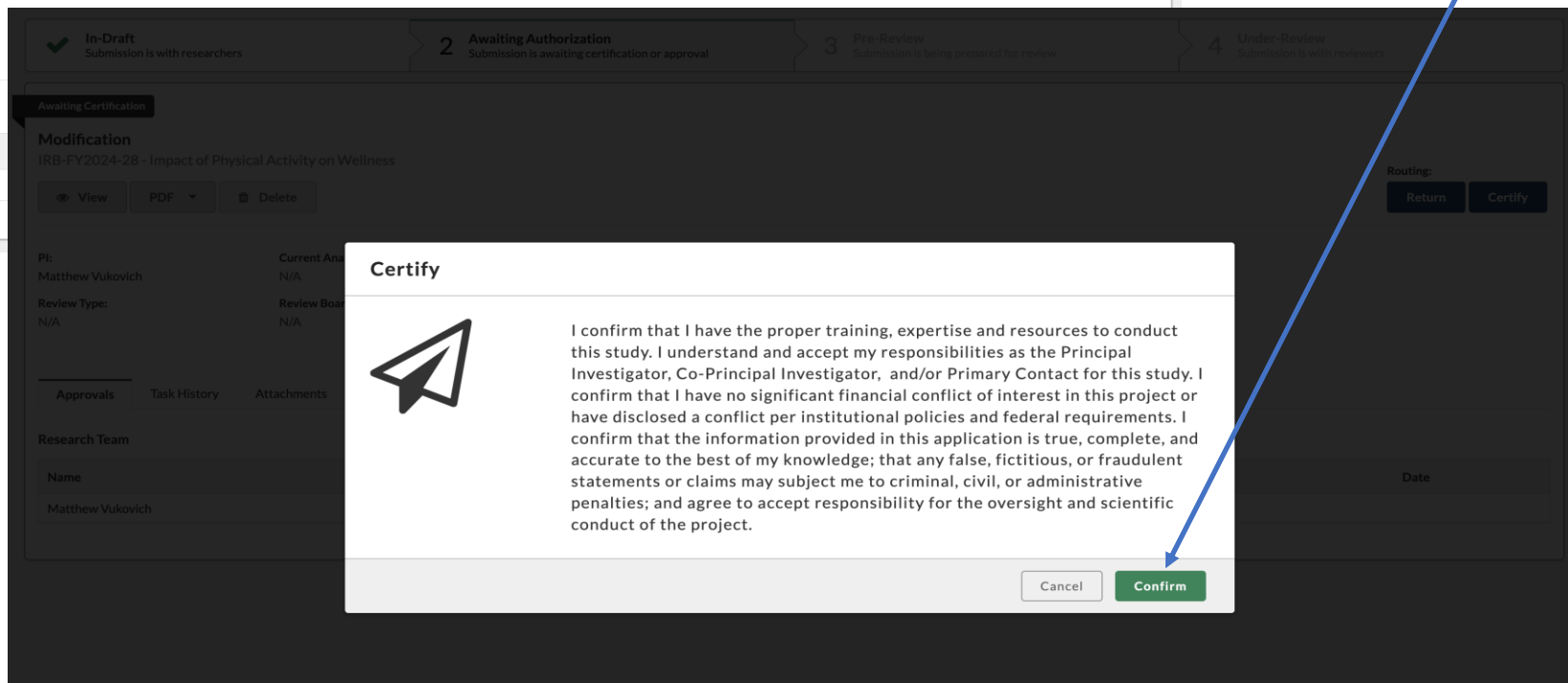
PI: Matthew Vukovich Current Analyst: N/A Decision: N/A Policy: Post-2018 Rule Required Tasks: N/A

Review Type: N/A Review Board: N/A Meeting Date: N/A

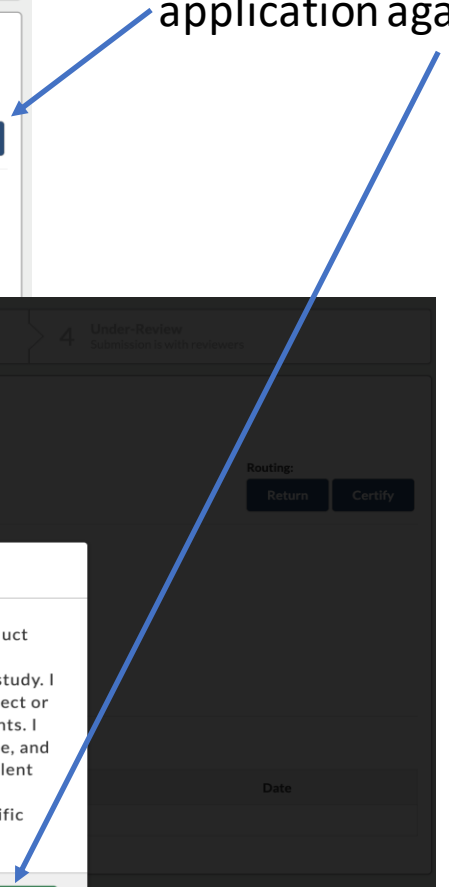
Approvals Task History Attachments

Research Team

Name Matthew Vukovich



You will need to [Certify] the application again.



Role: Researcher | Products | Matthew Vukovich

Dashboard | Studies | Submissions | Tasks | Meetings | Reporting | More

Studies / Study Details / Submission Details

In-Draft Submission is with researchers

Awaiting Authorization Submission is awaiting certification or approval

3 Pre-Review Submission is being prepared for review

4 Under-Review Submission is with reviewers

Under Pre-Review

Modification
IRB-FY2024-28 - Impact of Physical Activity on Wellness

Review | PDF | Delete

Routing: **Proceed**

PI: Matthew Vukovich | Current Analyst: N/A | Decision: N/A | Policy: Post-2018 Rule | Required Tasks: Assign Analyst

Review Type: N/A | Review Board: N/A | Meeting Date: N/A

Approvals | Task History | Attachments

Research Team

Name	Role	Result	Date
Matthew Vukovich	Principal Investigator	Certified	02-09-2024 10:36 AM

After certifying, the Submission Details screen appears. It is awaiting authorization.

If you select proceed, the following error message pops up indicating the IRB analyst needs to be assigned and application reviewed.

Your supervisor will also receive an email to certify/approve of the modification.

Role: Researcher | Products | Matthew Vukovich

Dashboard | Studies | Submissions | Tasks | Meetings

Studies / Study Details / Submission Details

In-Draft Submission is with researchers

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Under Pre-Review

Modification
IRB-FY2024-28 - Impact of Physical Activity on Wellness

Review | PDF | Delete

Routing: **Proceed**

PI: Matthew Vukovich | Current Analyst: N/A | Decision: N/A | Policy: Post-2018 Rule | Required Tasks: Assign Analyst

Review Type: N/A | Review Board: N/A | Meeting Date: N/A

Approvals | Task History | Attachments

Research Team

Name	Role	Result	Date
Matthew Vukovich	Principal Investigator	Certified	02-09-2024 10:36 AM

ERROR

The following required assignments must be made before proceeding:
Analyst.

Please contact your system administrator if this error continues to occur.
[Show Error Details](#)

CLOSE

Role: Researcher | Products | Matthew Vukovich

Dashboard | Studies | Submissions | Tasks | Meetings | Reporting | More

+ New Study

In-Draft → | Awaiting Authorization → | Pre-Review → | Under Review → | Post Review →

My Studies	My Tasks	Submissions by Type
IRB-FY2024-28 Impact of Physical Activity on Wellness IRB-FY2024-27 Impact of ph IRB-FY2024-13 Example NH IRB-FY2024-12 Test Expedi		Renewal 0

Main Dashboard.

Role: Researcher | Products | Matthew Vukovich

Dashboard | Studies | Submissions | Tasks | Meetings | Reporting | More

Studies / Study Details

+ New Submission

Study Details | Submissions

Study Details dashboard

Role: Researcher | Products | Matthew Vukovich

Dashboard | Studies | Submissions | Tasks | Meetings | Reporting | More

Studies / Study Details

+ New Submission

Study Details | Submissions

Approved

IRB-FY2024-28 Impact of Physical Activity on Wellness

PDF Delete

Approval Date: 02-09-2024 | Exp 02-09-2024
 Admin Check-In Date: N/A | Clo N/A

Key Contacts | Attachments

Team Member: Matthew Vukovich, Matthew Vukovich

Submission Type	Review Type	Status	Decision
Initial	Expedited	Review Complete	Approved 02-09-2024
Modification	Unassigned	Under Pre-Review	--

25 per page | 1-2 of 2 | 1

Submission Dashboard – shows study is under review by IRB.

Human Ethics

Role: Researcher Products Matthew Vukovich

Dashboard Studies Submissions Tasks Meetings Reporting More

Studies / Study Details [+ New Submission](#)

Submission Type	Review Type	Status	Decision
Initial	Expedited	● Review Complete	Approved 02-09-2024
Modification	Unassigned	● Under Pre-Review	--

25 per page 1-2 of 2

During the pre-review process, the IRB analyst will determine the level of review required. Since the initial application was an expedited review, the modification will more than likely require an expedited review.

Date: February 28, 2024
PI: Matthew Vukovich
Re: Modification - IRB-FY2024-28
Impact of Physical Activity on Wellness

The South Dakota State University Institutional Review Board has reviewed the above-referenced submission and rendered the decision below.

Decision: Exempt
Decision Date: February 28, 2024
Study Admin Check-in Date: --
Review Type: The reviewed modifications fall under 45 CFR 46.104. Category 2.(ii). Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

Findings:
Research Notes:

Key Principal Investigator Responsibilities:

- Submit any proposed changes to the Study prior to being implemented via a Modification submission for IRB review and approval.
- Promptly notify the IRB, via Incident submission, of any reportable events (adverse events/protocol deviations/unanticipated problems/subject complaints/etc.) that occur during the research, including any breach in confidentiality or data security that places participants or others at a greater risk of harm.
- Submit a Renewal Submission in advance month of Administrative Check-in or Study Expiration dates to allow for IRB review and approval to continue conducting study activities.

Once review is complete, you will receive an email notifying you of the determination. You can also see in the dashboard that the review has been completed.

The screenshot shows the Cayuse Human Ethics dashboard. The top navigation bar includes the logo, user role (Researcher), and name (Matthew Vukovich). The main content area is titled 'Studies / Study Details' and features a '+ New Submission' button. Below this is a table with two tabs: 'Study Details' and 'Submissions'. The 'Submissions' tab is active, displaying a table with the following data:

Submission Type	Review Type	Status	Decision
Initial	Expedited	● Review Complete	Approved 02-09-2024
Modification	Expedited	● Review Complete	Exempt 02-28-2024

At the bottom of the table, there is a '25 per page' dropdown menu, a '1-2 of 2' indicator, and a pagination control showing '1' with left and right arrows.