



**SOUTH DAKOTA
STATE UNIVERSITY**

Tutorial for Submitting an Application for review
by the SDSU IRB in Cayuse

Opening screen after logging in with SSO credentials.

To submit a new application for review, ensure the role selected is that of Researcher.

To submit a new application, or if you are unsure if your study needs reviewed select **+ New Study**

The Human Ethics dashboard allows you to check on the status of your application from submission to acceptance and post—review.

The screenshot shows the Cayuse Human Ethics dashboard. At the top, the logo and navigation tabs (Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, More) are visible. The user's role is set to 'Researcher' and the name is 'Matthew Vukovich'. The dashboard features several key sections:

- Status Cards:** Five cards representing application stages: In-Draft, Awaiting Authorization, Pre-Review, Under Review, and Post Review. A '+ New Study' button is located in the top right of this section.
- My Studies:** A table listing two studies: 'Example NHSR Study 11.29.23' and 'Test Expedited Review 11.29.23'. A 'View All' button is at the bottom.
- My Tasks:** A section indicating 'All Tasks Complete' with a checkmark icon.
- Submissions by Type:** A table showing counts for various submission types.
- Approved Studies:** A section showing 'No Approved Studies' with a sad face icon.
- Studies Expiring In 30 days:** A section showing 'No Expiring Studies' with a happy face icon.
- Expired Studies:** A section showing 'No Expired Studies' with a happy face icon.

Type	Count
Renewal	0
Initial	2
Modification	0
Incident	0
Withdrawal	0
Closure	0
Legacy	0

Study Details Submissions

Enter study title here

PDF Delete

Approval Date: N/A	Expiration Date: N/A	Organization: N/A	Active Submissions:	Population Flags:	Additional Flags:
Admin Check-In Date: N/A	Closed Date: N/A	Current Policy	Sponsors: N/A		

Enter the title of the study.
Click checkmark.

Studies / Study Details

Study Details

Unsubmitted

IRB-FY2024-18 Impact of physical activity on health and well being

PDF Delete

Approval Date: N/A	Expiration Date: N/A	Organization: N/A	Active Submissions: N/A	Population Flags:	Additional Flags:
Admin Check-In Date: N/A	Closed Date: N/A	Current Policy Post-2018 Rule	Sponsors: N/A		

Key Contacts (i) Attachments Flags

Team Member	Role	Number	Email
No Key Study Contacts.			

Select the [+New Submission] button.
Then select [Initial] from the drop-down menu.



Unsubmitted

Initial

IRB-FY2024-18 - Impact of physical activity on health and well being

[Edit](#) [Delete](#)

PI: N/A Current Analyst: N/A Decision: N/A Policy: Post-2018 Rule Required Tasks: [Assign PI](#)
Review Type: N/A Review Board: N/A Meeting Date: N/A [Assign PE](#)
[Complete Submission](#)

Approvals Task History Attachments

Research Team

Name	Role	Result	Date
No entries.			

Select the [Edit] button to begin entering the information about your study.

IRB NUMBER: IRB-FY2024-18

Impact of physical activity on health and well being - Initial

CREATE PDF COMPARE SAVE

- Sections <
- Welcome ✓
- Project Personnel
- Project Description
- Participant Information
- Recruitment Process
- Consent Process
- Venue
- Risk, Privacy, Confidential...
- Compliance

Welcome

Any research project in which university faculty, staff or students will collect and analyze data on human subjects must be reviewed and approved by the IRB before data collection begins. Although some research activities may be determined by the IRB to be exempt from continued IRB oversight (per Federal regulations), such research is not exempt from state laws and institutional policies. Regardless of exemption status, the gathering of data from human subjects through direct or indirect interaction must be done with the highest level of regard for the rights and welfare of research participants, and in accord with disciplinary ethical standards.

Please complete the application with as much detail as possible. If you need assistance, contact the office at 605-688-5642 or SDSU.IRB@sdstate.edu.

Program Director of Research Integrity and Compliance: Keiji Horikoshi 605-688-5642, email: keiji.horikoshi@sdstate.edu.
IRB Chair: Matt Vukovich 605-688-6580, email: matt.vukovich@sdstate.edu.

Researcher Training

The Human Subjects Committee (also known as the Institutional Review Board or IRB) assures that risks to human research subjects are minimized, consent is voluntary and informed, and confidentiality is protected. The Committee upholds the principles articulated in the [Belmont Report](#) and applies the regulations articulated in the [Common Rule](#).

If you have not completed the [CITI](#) Training, please do so.

< >

Some of the sections will be informational while others will request information about your study. When a section is completed, select the arrow button to move to the next section. Or you can click on the section heading in the left menu.

As you enter the information requested, the application uses built in logic to walk you through the necessary sections.

Sections <
Welcome ✓
Determination ✓
Routing Send to PI for certification? ▾
COMPLETE SUBMISSION >

Determination

Would you like the IRB staff to determine whether your project needs IRB approval?
If you are unsure if your project requires IRB review or need documentation of a determination that no IRB review is needed, please select "Yes" and fill out the form. If you know your project needs IRB approval, please select "No".

Yes
 No

Sections <
Welcome ✓
Determination ✓
Project Personnel

Would you like the IRB staff to determine whether your project needs IRB approval?
If you are unsure if your project requires IRB review or need documentation of a determination that no IRB review is needed, please select "Yes" and fill out the form. If you know your project needs IRB approval, please select "No".

Yes
 No

- 1. Do you have or are you applying for external (non-SDSU) funding?
 Yes
 No

2. Please provide a non-technical description of the proposed project.
Please include a brief general description of the purpose of your project and the methodology you plan to use.


B I U [List Bullets] [List Numbered] [Link] [Image]

[Empty text area]

- 3. Is your project a systematic investigation?
*Research is defined as "a systematic investigation designed to develop or contribute to generalizable knowledge."
Are you taking a methodical approach to your project? For example, do you have a hypothesis or research question and a formulated plan to gather or analyze data that might support the hypothesis or answer the research question?*
 - Quality assessment and quality improvement projects.
 - Quality improvement and quality assessment projects are systematic investigations that aim to measure and/or improve something specific within a certain program or organization. The results are often not generalized or shared outside the program; instead the results are used to make improvements or guide decision making locally. By contrast, "human subjects research" is conducted with the intent to generalize study findings
 - 4. Is your goal limited to evaluating or improving clinical care or some other part of a specific program?
 Yes
 No
 - 5. Is the activity primarily designed to generate data limited to your specific study population?
 Yes
 No
 - 6. Will the knowledge you gain in this project be applied to other similar programs or populations?
 Yes
 No
 - 7. Are you trying to create or contribute to generalizable knowledge with this project?
Generalizable knowledge is information that will contribute to the field or area being studied, and may be of interest or applicable to people outside of your study population. If you plan to present or publish your findings as a test or application of a scientific theory you expect you or others may make recommendations for practice or policy based on your results, that probably means you are trying to create or contribute to generalizable knowledge.
- Yes
 No

If you are unsure if your study requires IRB review, select [Yes] and answer the questions. You will also need to complete the Project Personnel Page.

If you select [No], the Project Personnel Page will be the first section to complete.


Role: Researcher | Products | Matthew Vukovich

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

SUBMISSION DETAILS | IRB NUMBER: IRB-FY2024-27 | **Impact of physical activity on health and well-being - Initial** | CREATE PDF | COMPARE | SAVE

Project Personnel

If you are unable to locate a person, they may not have an account set up, please request an account by contacting Program Director of Research Integrity and Compliance: Keiji Horikoshi 605-688-5642, email: keiji.horikoshi@sdstate.edu.

* Please indicate if the PI is a faculty or a student

Faculty
 Student

* Please select the Principal Investigator

Note: If a student is the Principal Investigator, the faculty advisor will also be listed as Principal Investigator and has the ultimate responsibility for the project and the conduct of the student(s) involved in the research project.

Name	Organization	Address	Phone	Email	Trainings	
Matthew Vukovich	South Dakota State University 3E0000	, Brookings, SD 57007	605-688-6580	MATT.VUKOVICH@SDSTATE.EDU	View	✕

Please select a Co-Principal Investigator if required.


* Please select the Primary Contact.

This person will be the main point of contact for the IRB reviewers

Name	Organization	Address	Phone	Email	Trainings	
Matthew Vukovich	South Dakota State University 3E0000	, Brookings, SD 57007	605-688-6580	MATT.VUKOVICH@SDSTATE.EDU	View	✕

Please select the Co-Investigators.

If you originally selected [Yes] to on the Determination screen:
 Once the Project Personnel section has been completed, select Complete Submission.


Role: Researcher | Products | Matthew Vukovich

[Dashboard](#) | [Studies](#) | [Submissions](#) | [Tasks](#) | [Meetings](#) | [Reporting](#) | [More](#)

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

✔ **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

Awaiting Certification

Initial
IRB-FY2024-27 - Impact of physical activity on health and well-being

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	Role	Result	Date
Matthew Vukovich	Principal Investigator	Pending Certification	

Once submission is completed, the next screen will ask you to Certify the project.



Certify



I confirm that I have the proper training, expertise and resources to conduct this study. I understand and accept my responsibilities as the Principal Investigator, Co-Principal Investigator, and/or Primary Contact for this study. I confirm that I have no significant financial conflict of interest in this project or have disclosed a conflict per institutional policies and federal requirements. I confirm that the information provided in this application is true, complete, and accurate to the best of my knowledge; that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties; and agree to accept responsibility for the oversight and scientific conduct of the project.

Cancel | Confirm

After selecting [Confirm], the application will be sent to the IRB to review and determine if the project is human subject research and if it requires review.

You will be able to track the progress of the application on this screen.

- Sections <
- Welcome ✓
- Determination ✓
- Project Personnel ✓
- Project Description ✓
- Routing Send to PI for certification? v
- COMPLETE SUBMISSION >

Project Personnel

If you are unable to locate a person, they may not have an account set up, please request an account by contacting Program Director of Research Integrity and Compliance: Keiji Horikoshi 605-688-5642, email: keiji.horikoshi@sdstate.edu.

* Please indicate if the PI is a faculty or a student

Faculty
 Student

* Please select the Principal Investigator

Note: If a student is the Principal Investigator, the faculty advisor will also be listed as Principal Investigator and has the ultimate responsibility for the project and the conduct of the student(s) involved in the research project.

Name	Organization	Address	Phone	Email	Trainings	
Matthew Vukovich	South Dakota State University 3E0000	, Brookings, SD 57007	605-688-6580	MATTVUKOVICH@SDSTATE.EDU	View	x

Please select a Co-Principal Investigator if required.

FIND PEOPLE

* Please select the Primary Contact.

If you selected [No] in the Determination section, you will be directed to complete the Project Personnel Information, followed by questions specific to the project [Project Description].

- Sections
- Welcome
- Determination
- Project Personnel
- Project Description

Project Description

Is this study part of an application for external funding?

- No
- Yes

* Please provide the Cayuse Sponsored Projects Proposal or Award number.

Rich text editor toolbar with icons for Bold, Italic, Underline, Text Color, Background Color, Bulleted List, Numbered List, Indent, Outdent, Undo, and Redo.

Attach a copy of the abstract or proposal summary.

ATTACH

Will parts of the research project take place at another location or an institution with an IRB (e.g., universities, hospitals, reservation, etc.) and/or will researchers from other institutions be involved in this project?

- No
- Yes

Project Description

As you answer questions there will be additional popup questions based on your answers.

Questions will address study purpose, methodology, data analysis, if external IRBs are involved, etc.

If the application is part of an externally funded project, provide the routing number from the SDSU Routing document or the Cayuse Proposal Number.

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

- Sections <
- Welcome ✓
- Determination ✓
- Project Personnel ✓
- Project Description ***
- Participant Information
- Recruitment Process
- Consent Process
- Risk, Privacy, Confidential...
- Compliance

Attach a copy of the abstract or proposal summary.

ATTACH

Will parts of the research project take place at another location or an institution with an IRB (e.g., universities, hospitals, reservation, etc.) and/or will researchers from other institutions be involved in this project?

No
 Yes

Is this a student-led project? (class project, honors project, thesis, dissertation, or independent study?)

No
 Yes

Does this project involve the secondary use of data or samples?

Were the data / bio-specimens you wish to analyze initially collected for research purposes other than purpose(s) stated above or from non-research purposes?

No
 Yes

If you select [No] to the question, “Does the project involve the secondary use of data or samples?”, you will see additional sections appear on the left menu.

As sections are completed, a checkmark will appear. If a red asterisk (*) appears, there is a required question that needs to be completed.

IRB NUMBER: IRB-FY2024-28
SUBMISSION DETAILS Impact of Physical Activity on Wellness - Initial CREATE PDF COMPARE SAVE

- Sections
- Welcome
- Determination
- Project Personnel
- Project Description
- Secondary Data
- Compliance

Empty text area for the project description.

Attach a copy of the abstract or proposal summary.

ATTACH

Will parts of the research project take place at another location or an institution with an IRB (e.g., universities, hospitals, reservation, etc.) and/or will researchers from other institutions be involved in this project?

- No
- Yes

Is this a student-led project? (class project, honors project, thesis, dissertation, or independent study?)

- No
- Yes

Does this project involve the secondary use of data or samples?

Were the data / bio-specimens you wish to analyze initially collected for research purposes other than purpose(s) stated above or from non-research purposes?

- No
- Yes

Provide name and location of where initial data/sample collection occurred and upload a copy of the IRB approval letter.

Rich text editor with a toolbar containing icons for Bold, Italic, Underline, Text Color, Background Color, Bulleted List, Numbered List, Indent, and Link.

If you select [Yes] to the question, “Does the project involve the secondary use of data or samples?”, questions specific to the acquisition and use of secondary data will appear.

Participant Information

Maximum number of participants you plan to enroll.

- You may estimate; however, the number of participants consented cannot exceed this number.
- Once a person has been consented they are considered a participant, even if they withdraw, do not complete the study, or the data is not used. We suggest you estimate more than your target sample size to account for this.
- Potential participants that are screened but not consented because they do not meet your enrollment criteria are not included in this number

Describe study population.

B I U S i i o

Protected and/or Special Subject Populations.

Check all populations you plan to focus on.

- N/A
- Pregnant women
- Children
- Prisoners
- Your Employees
- Your Students
- Emancipated Minors
- Fetuses/Neonates
- Those with limited decision-making capacity
- Individuals with limited English proficiency.
- Economically/educationally disadvantaged persons.
- American Indian or Alaskan Native

For any of the special populations checked, provide rationale, and describe all special considerations and/or steps that will be taken to ensure their protection from undue influence or coercion to participate.

B I U S i i o

Participant Information

In this section you will describe the study population and identify if any special populations will be recruited to participate. Questions about offering extra credit for students and/or compensation for participants is included.

Recruitment Process

How will you recruit participants?

Check all that apply.

- In-person
- E-mail
- Phone/text message
- Web-post
- Flyer
- Letter
- Research pool
- Snowball Sampling
- Word of mouth
- Social Media
- Other

Please attach your recruitment materials including emails, social media posts, flyers, etc.

Recruitment materials should include:

- Purpose & topic of the research
- What participants will do in the study (including how long it will take)
- Simple eligibility criteria (over 18, USD student, etc.)
- Location of the research (e.g., online, on-campus, specific off-campus location, etc.)
- Researcher name and contact information (email address, phone number, etc. lab contact information is OK instead of personal)

ATTACH

Describe the recruitment process, including where and when it will take place.

B I U ↺ ☰ ☷ ↻

Recruitment Process.

Describe the recruitment process and the methods used. You will need to upload the recruiting materials. Select [ATTACH], a popup will allow you to attach the recruitment materials.

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

Indicate how you will obtain consent from participants.

Check all that apply. (Contact the IRB for assistance or questions at sdsu.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 detail description of the consent process including who will obtain consent/assent and timing, providing participants sufficient time for adequate consideration.

B I U ↺ ☰ ☷ ↻

Consent Process

Attach your consent/assent documents and answer the questions specific to the consent process.

Risk, Privacy, Confidentiality, and Data Protection

Are there potential risks to the research participants in any of the following areas?

- Physical (i.e., discomfort, pain, injury, illness, or disease; may result from administration of stimuli, controlled substances, or devices. Engaging a subject in a social situation which could involve violence may also create a physical risk).
- Psychological (includes the production of anxiety, depression, guilt, shock, and loss of self-esteem. Sensory deprivation, sleep deprivation, use of hypnosis, deception or mental stresses are examples of psychological risks.)
- Economic (such as direct costs; loss of wages or income for participating; or breach of confidentiality that may result in loss of employment or damage to a subject's employability).
- Social (i.e., embarrassment, loss of respect, negative labeling, or harming relationships within a subject's business or social group; breach of confidentiality regarding drug and alcohol use, mental illness, and sexual behavior).
- Legal (requiring activities for which the subject may be criminally or civilly liable; or disclosing illegal activity or information that would be reportable to authorities or might render the subject prosecutable under the law, such as child abuse, alcohol abuse, alcohol abuse by a pregnant woman, danger to self or others).

Will the research involve incomplete disclosure (deception) to subjects?

- No
- Yes

Identify all sources of data you plan to collect.

Check all that apply.

- Survey
- Interview or Focus Groups
- Records
- Databases
- Observations
- Biological specimens
- Sensor
- Measurements
- Other

Role: Researcher Products Matthew Vukovich

Dashboard Studies Submissions Tasks Meetings Reporting More

IRB NUMBER: IRB-FY2024-28

Impact of Physical Activity on Wellness - Initial

CREATE PDF COMPARE SAVE

Sections

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

Routing Send to PI for certification? COMPLETE SUBMISSION

Compliance

The Principal Investigator Agrees to

- Report all serious or unexpected adverse events.
- Obtain informed consent/assent from each subject (unless a waiver of the consent process is granted) and the consent form is signed, dated and retained in the PI's files (if a consent form is required).
- Study procedures are not initiated until the PI receives IRB approval.
- Important information regarding retention of informed consent forms and research records.
- 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 regulations. Click [here](#) first, to review SD BOR retention 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 State University policies governing human subject research. (type name)

Matt Vukovich

I Agree

After completing the compliance section, select [Complete Submission] and confirm submission.

Role: Researcher Products Matthew Vukovich

Dashboard Studies Submissions Tasks Meetings Reporting More

Studies / Study Details / Submission Details

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

Awaiting Certification

Initial

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	Role	Result
Matthew Vukovich	Principal Investigator	Pending Cert

Once submission is completed, the next screen will ask you to Certify the project.

After selecting [Confirm], the application will be sent to the IRB. Your supervisor will also be asked to certify the project.

You will be able to track the progress of the application on this screen.

Certify

I confirm that I have the proper training, expertise and resources to conduct this study, understand and accept my responsibilities as the Principal Investigator, Co-Principal Investigator, and/or Primary Contact for this study. I confirm that I have no significant financial conflict of interest in this project or have disclosed a conflict per Institutional policies and Federal requirements. I confirm that the information provided in this application is true, complete, and accurate to the best of my knowledge; that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties; and agree to accept responsibility for the oversight and scientific conduct of the project.

Cancel Confirm

+ 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

☹️
No Approved Studies

Studies Expiring in 30 days

😊
No Expiring Studies

Expired Studies

😊
No Expired Studies

The dashboard allows you to track your submissions and to see if the IRB has any tasks, issues, or questions for you to address.