

# SOUTH DAKOTA STATE UNIVERSITY

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



cayuse Human Ethics Role: Researcher 🚄 🔷 Products 💌 Matthew Vukovich Dashboard Studie Meetings More Submission Tasks Reporting + New Study Awaiting Authorization E In-Draft 🔶 Pre-Review -> Under Review 🔶 Post Review 🔶 My Tasks Submissions by Type My Studies Example NHSR Study 11.29.23 Renewal IRB-FY2024-13 0 IRB-FY2024-12 Test Expedited Review 11.29.23 Initial 2 Modification 0 Incident 0 Withdrawal 0 All Tasks Complete Closure 0 Legacy 0 View All Approved Studies Studies Expiring in 30 days Expired Studies  $\bigcirc$  $\odot$  $\odot$ No Approved Studies No Expired Studies No Expiring Studies

Opening screen after logging in with SSO credentials.

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

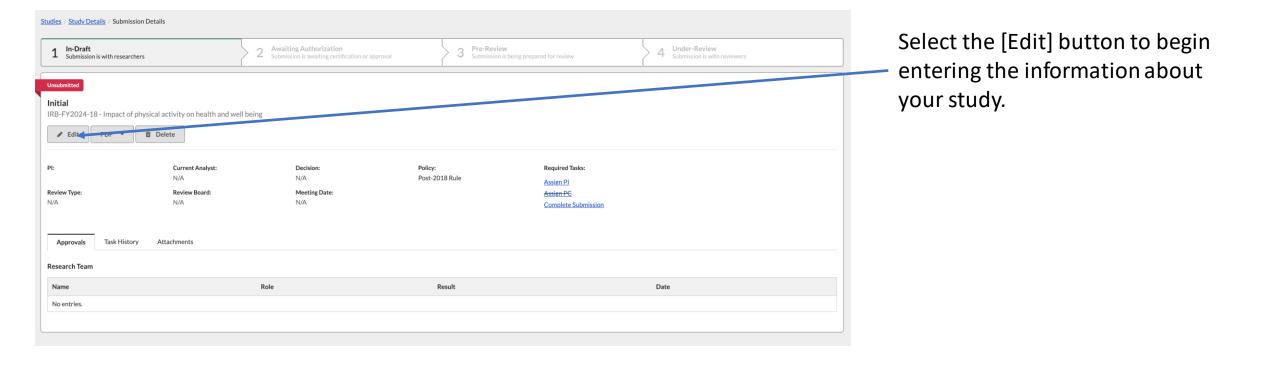
To submit a new application, or if you are unsure if your study needs reviewed select + New Study

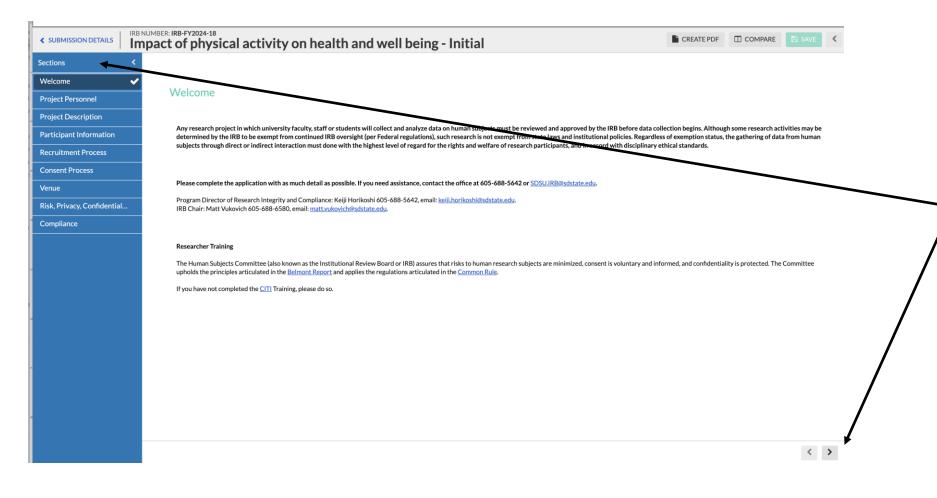
The Human Ethics dashboard allows you to check on the status of your application from submission to acceptance and post—review.

|  | S  | itudy Details                          |  |                   | Submissions       | Enter the title of the study. |                  |
|--|--|--|--|-------------------|-------------------|-------------------------------|------------------|
| Enter study title here                               |  |  |  |                   |                   |                               | Click checkmark. |
| Approval Date:<br>N/A<br>Admin Check-In Date:<br>N/A | Expiration Date:<br>N/A<br>Closed Date:<br>N/A | Organization:<br>N/A<br>Current Policy | Active<br>Submissions:<br>Sponsors:<br>N/A | Population Flags: | Additional Flags: |                               |                  |

| Studies / Study Details                                       |  |  |   |                   |                                | + New Submission |
|---|--|--|---|-------------------|--------------------------------|------------------|
|   | 2  | Begin Initial Submission<br>You've created a study! Click here to begin your |   |                   |                                |                  |
| Unsubmitted<br>IRB-FY2024-18 Impac                            | ct of physical activity on health a            | nd well being  |   |                   | initial submission to the IRB. |                  |
| Approval Date:<br>N/A<br>Admin Check-In Date:<br>N/A          | Expiration Date:<br>N/A<br>Closed Date:<br>N/A | Organization:<br>Current Policy<br>Post-2018 Rule                            | Active<br>Submissions:<br>N/A<br>Sponsors:<br>N/A | Population Flags: | Additional Flags:              |                  |
| Key Contacts Attachm<br>Team Member<br>No Key Study Contacts. | nents Flags                                    |  | Role  | Number            | Email                          |                  |

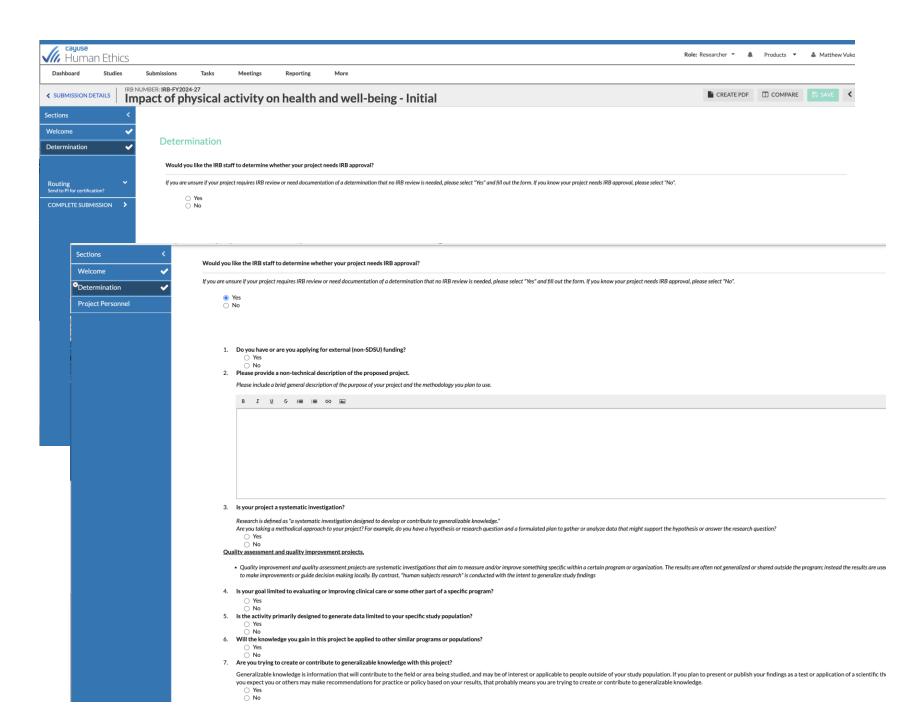
Select the [+New Submission] button. Then select [Initial] from the dropdown menu.





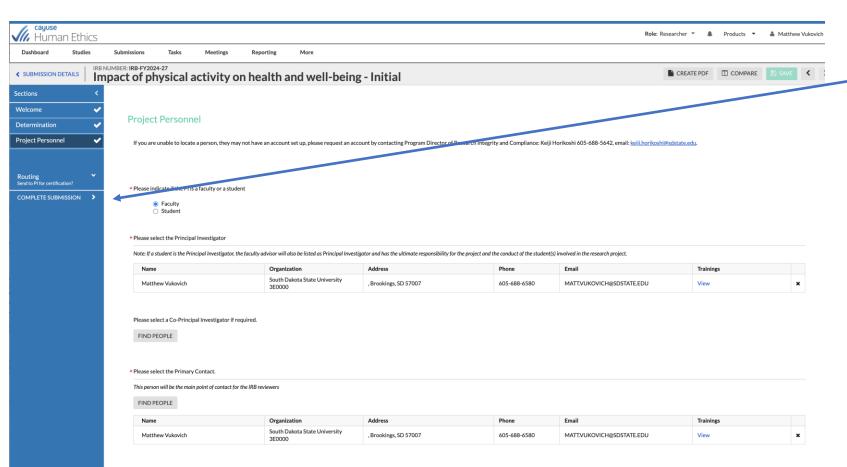
Some of the sections will be informational while others will request information about your study. When a section is completed, select the arrow button to move to the next section. Or you can click on the section heading in the left menu.

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



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.



If you originally selected [Yes] to on the Determination screen:

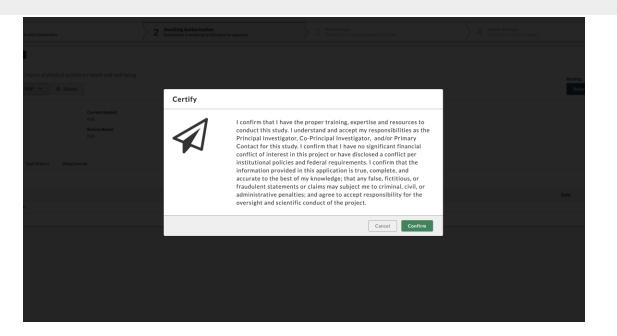
Once the Project Personnel section has been completed, select Complete Submission.

Please select the Co-Investigators.

FIND PEOPLE

| Human Ethics   |  |                           |                                       | Role: Researcher 👻 📌 Products 👻 🎍 Matthew Vukovi |
|--|--|---------------------------|---------------------------------------|--|
| Dashboard Studies Submissions Tasks Meetings   | Reporting More   |                           |                                       |  |
| Studies / Study Details / Submission Details   |  |                           |                                       |  |
| V In-Draft<br>Submission is with researchers   | 2 Awaiting Authorization<br>Submission is awaiting certification or approval | 3 Pre-Revi<br>Submissio   | iew<br>n is being prepared for review | 4 Under-Review<br>Submission is with reviewers   |
| Awsiting Certification Initial IRB-FY2024-27 - Impact of physical activity on health and well-being          IRB-FY2024-27 - Impact of physical activity on health and well-being         Image: Contract of the second seco | Decision:<br>N/A<br>Meeting Date:<br>N/A                                     | Policy:<br>Post-2018 Rule | Required Tasks:<br>N/A                | Routing:<br>Return Certify                       |
| 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.



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.

| 着 Matthew | Products • | : Researcher 🝷 🛛 🞜 | Role   |                               |   |  |                              |  |                  | thics                     | <del>ayuse</del><br>Human Eth |                     |
|-----------|------------|--------------------|--|-------------------------------|---|--|------------------------------|--|------------------|---------------------------|-------------------------------|---------------------|
|           |            |                    |  |                               |   | ng More                                      | Meetings Report              | Tasks  | Submissions      | udies                     | oard Stud                     | Dashbo              |
| 🖺 SAVE    | COMPARE    | CREATE PDF         |  |                               |   | Iness - Initial                              | ctivity on We                | 24-28<br>hysical A                           | NUMBER: IRB-FY20 | s In                      | ISSION DETAILS                |                     |
|           |            |                    |  |                               |   |  |                              |  |                  | <                         |                               | ections             |
|           |            |                    |  |                               |   |  | I                            | t Personne                                   | Projec           | *<br>•                    |                               | Welcome<br>Determir |
|           |            | :hi@sdstate.edu.   | lorikoshi 605-688-5642, email: <u>keiji,horiko</u> | grity and Compliance: Keiji   | ount by contacting Program Director of Research Inte        | account set up, please request an acco       | person, they may not have an | e unable to locate a                         | lf you ar        | *<br>*                    | Personnel                     | Project P           |
|           |            |                    |  |                               |   |  | faculty or a student         | ndicate if the PI is a<br>Faculty<br>Student |                  | <b>~</b><br>N <b>&gt;</b> | for certification?            |                     |
|           |            |                    | involved in the research project.                  | d the conduct of the student( | ator and has the ultimate responsibility for the project an | or will also be listed as Principal Investig |                              | elect the Principal<br>student is the Princ  |                  |                           |                               |                     |
|           | ngs        | Training           | Email  | Phone                         | Address   | Organization                                 |                              | e  | Nam              |                           |                               |                     |
| ×         |            | View               | MATT.VUKOVICH@SDSTATE.EDU                          | 605-688-6580                  | , Brookings, SD 57007                                       | outh Dakota State University<br>E0000        |                              | hew Vukovich                                 | Mat              |                           |                               |                     |
|           |            | View               | MATT/VUKOVICH@SDSTATE.EDU                          | 605-688-6580                  | , Brookings, SD 57007                                       |  |                              |  | Please s         |                           |                               |                     |

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].

\* Please select the Primary Contact.

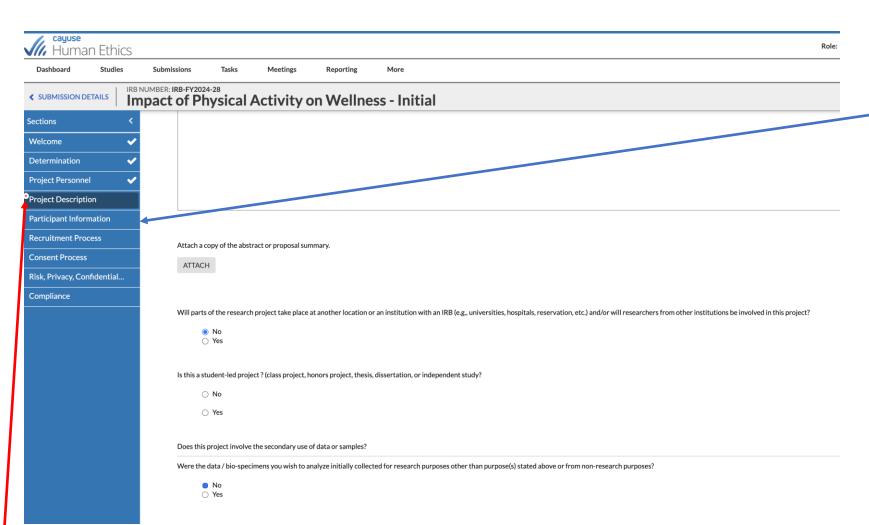
| Cayuse<br>Hum  | e<br>nan Ethics       |                  |                               |                     |                        |                  |             |                   |                  |                |                 |               |                |              |                 |                  |              | Role: Res | earcher 🔻 | P  | Products 💌 | 🛔 Mat | thew Vukovich |
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| Dashboard      | Studies               | Submissions      | Tasks                         | Meetings            | Reporting              | More             |             |                   |                  |                |                 |               |                |              |                 |                  |              |           |           |    |            |       |               |
|                |                       | NUMBER: IRB-FY20 | <sup>24-28</sup><br>hysical / | Activity            | on Wellne              | ss - Ini         | nitial      |                   |                  |                |                 |               |                |              |                 |                  |              |           | CREATE PI | DF | COMPARE    | 🖹 SA  | E             |
| Sections       |                       |                  |                               |                     |                        |                  |             |                   |                  |                |                 |               |                |              |                 |                  |              |           |           |    |            |       |               |
| Velcome        | <ul> <li>✓</li> </ul> | Durlin           |                               |                     |                        |                  |             |                   |                  |                |                 |               |                |              |                 |                  |              |           |           |    |            |       |               |
| Determinatior  | n 🗸                   | Projec           | t Descript                    | ion                 |                        |                  |             |                   |                  |                |                 |               |                |              |                 |                  |              |           |           |    |            |       |               |
| Project Person | nnel 🗸                | Is this st       | udy part of an app            | lication for extern | nal funding?           |                  |             |                   |                  |                |                 |               |                |              |                 |                  |              |           |           |    |            |       |               |
| Project Descri | iption                |                  | ○ No<br>● Yes                 |                     |                        |                  |             |                   |                  |                |                 |               |                |              |                 |                  |              |           |           |    |            |       |               |
|                |                       |                  | 105                           |                     |                        |                  |             |                   |                  |                |                 |               |                |              |                 |                  |              |           |           |    |            |       |               |
|                |                       | * Please p       | rovide the Cayus              | e Sponsored Proje   | ects Proposal or Award | I number.        |             |                   |                  |                |                 |               |                |              |                 |                  |              |           |           |    |            |       |               |
|                |                       | в                | । ग २ः ।≣                     |                     |                        |                  |             |                   |                  |                |                 |               |                |              |                 |                  |              |           |           |    |            |       |               |
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|                |                       |                  |                               |                     |                        |                  |             |                   |                  |                |                 |               |                |              |                 |                  |              |           |           |    |            |       |               |
|                |                       |                  |                               |                     |                        |                  |             |                   |                  |                |                 |               |                |              |                 |                  |              |           |           |    |            |       |               |
|                |                       |                  |                               |                     |                        |                  |             |                   |                  |                |                 |               |                |              |                 |                  |              |           |           |    |            |       |               |
|                |                       |                  |                               |                     |                        |                  |             |                   |                  |                |                 |               |                |              |                 |                  |              |           |           |    |            |       |               |
|                |                       | Attach a         | copy of the abstr             | act or proposal su  | mmary.                 |                  |             |                   |                  |                |                 |               |                |              |                 |                  |              |           |           |    |            |       |               |
|                |                       | ATTAC            | сн                            |                     |                        |                  |             |                   |                  |                |                 |               |                |              |                 |                  |              |           |           |    |            |       |               |
|                |                       |                  |                               |                     |                        |                  |             |                   |                  |                |                 |               |                |              |                 |                  |              |           |           |    |            |       |               |
|                |                       |                  |                               |                     |                        |                  |             |                   |                  |                |                 |               |                |              |                 |                  |              |           |           |    |            |       |               |
|                |                       |                  |                               | project take place  | at another location o  | r an institutior | ion with an | n IRB (e.g., univ | niversities, hos | ospitals, rese | eservation, etc | c.) and/or wi | ill researcher | rs from othe | er institutions | be involved in t | his project? |           |           |    |            |       |               |
|                |                       |                  | No<br>Ves                     |                     |                        |                  |             |                   |                  |                |                 |               |                |              |                 |                  |              |           |           |    |            |       |               |
|                |                       |                  |                               |                     |                        |                  |             |                   |                  |                |                 |               |                |              |                 |                  |              |           |           |    |            |       |               |

# **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.



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.

| Gayuse<br>Human Ethics   | Role: Researcher * | Products 🔻 | 🛔 Matthew V |
|--|--------------------|------------|-------------|
| Dashboard Studies Submissions Tasks Meetings Reporting More  |                    |            |             |
| < SUBMISSION DETAILS IRB NUMBER IRB-FY2024-28<br>Impact of Physical Activity on Wellness - Initial   | CREATE PI          | DF COMPARE | 🖺 SAVE      |
| Sections <   |                    |            |             |
| Welcome 🗸  |                    |            |             |
| Determination 🗸  |                    |            |             |
| Project Personnel  |                    |            |             |
| •Project Description   |                    |            |             |
| Secondary Data   |                    |            |             |
| Compliance Attach a copy of the abstract or proposal summary.  |                    |            |             |
| АТТАСН   |                    |            |             |
|  |                    |            |             |
|  |                    |            |             |
| 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 proje | ct?                |            |             |
| 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<br>● Yes  |                    |            |             |
| Provide name and location of where initial data/sample collection occurred and upload a copy of the IRB approval letter.   |                    |            |             |
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|  |                    |            |             |
|  |                    |            |             |
|  |                    |            |             |

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. 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.

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#### 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.
- Economically/educationally disadvantaged pers
- 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.

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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.

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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.   | <u>Consent Process</u>           |
|--|----------------------------------|
| **If your study is registered on clinicaltrials.gov, your consent form <u>must</u> include the following statement: A description of this clinical trial will be available on <u>clinicaltrials.gov</u> , 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 <u>clinicaltrials.gov</u> , at any time | Attach your                      |
| ATTACH   | consent/assent                   |
| Indicate how you will obtain consent from participants.  | documents and                    |
| Check all that apply. (Contact the IRB for assistance or questions at sdsu.irb@sdstate.edu)  | answer the questions             |
| <ul> <li>Signed informed consent.</li> <li>Electronic signature. (Note: a checkbox does not count as an electronic signature.)</li> <li>Implied consent.</li> <li>Child assessment and parental consent</li> <li>Obtaining consent using a short form with oral explanation and witness.</li> <li>Other</li> </ul>   | specific to the consent process. |

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

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# **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.)
- C 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 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

| // Humar  | 1 Ethics   | 5   |  |                         |  |  |                          |                          |                                |                              |                         | Role: Researcher *  |                 | cts 🔻       |               |          |
|---|--|---|--|-------------------------|--|--|--------------------------|--------------------------|--------------------------------|------------------------------|-------------------------|---|-----------------|-------------|---------------|----------|
| Dashboard   | Studies  | Submission  |  | Meetings                | Reporting  | More   |                          |                          |                                |                              |                         |   |                 |             |               |          |
| SUBMISSION DE   |  | RB NUMBER: IRB-F  | Physical                                       | Activity o              | on Wellne  | ss - Initial   |                          |                          |                                |                              |                         | CREATE P  |                 | MPARE       | 🖹 SAVE        | <        |
| ctions  |  | <   |  |                         |  |  |                          |                          |                                |                              |                         |   |                 |             |               |          |
| /elcome   | •  | -   |  |                         |  |  |                          |                          |                                |                              |                         |   |                 |             |               |          |
| etermination  |  | Cor   | npliance                                       |                         |  |  |                          |                          |                                |                              |                         |   |                 |             |               |          |
| roject Personnel  |  |   | Principal Investigat                           |                         |  |  |                          |                          |                                |                              |                         |   |                 |             |               |          |
| oject Descriptio  | n 🔹  |   | Obtain informed                                |                         | n each subject (unles  | s a waiver of the consent proce  | ss is granted) and the   | e consent form is signed | dated and retained             | in the PI's files (if a cons | ent form is required).  |   |                 |             |               |          |
| articipant Inform   | a 🔇  |   | <ul> <li>Important inform</li> </ul>           | ation regarding rete    | til the PI receives IRI<br>ntion of informed co<br>to review and adher | B approval.<br>Insent forms and research reco<br>re to the SD BOR policy for mai | rds:                     | ciated with research a   | d those that may fal           | under HIPAA regulatio        | ns Click here first to  | eview SD BOR retention rec  | wirements for r | research da | ta: REG 202 1 |          |
| ecruitment Proce  | ess 🔹  | <ul> <li>Image: A set of the set of the</li></ul> | and REG 202.2 he                               | re.                     | to review and adner  | e to the 3D BOK policy for mar   | intaining records asso   | clated with research a   | u those that may fai           | under HIPAA Tegulatio        | inst, to                | eview 3D BOK retention ret  | unements for f  | esearchua   | na. REG 202.1 |          |
| onsent Process  | <u> </u>   | <ul> <li>Image: A set of the set of the</li></ul> |  |                         |  |  |                          |                          |                                |                              |                         |   |                 |             |               |          |
| sk, Privacy, Conf   | i 🔨  | * Inv   | stigator Statement                             | of Compliance           |  |  |                          |                          |                                |                              |                         |   |                 |             |               |          |
| mpliance  | •  | By:   | ubmitting this form,                           | l certify all informati | on provided is accura  | ate and that procedures involve  | d in this project are co | onducted according to fe | deral regulations and          | I South Dakota State Un      | iversity policies gover | ing human subject research.   | (type name)     |             |               |          |
|   |  | м   | att Vukovich                                   |                         |  |  |                          |                          |                                |                              |                         |   |                 |             |               | 1        |
| outing<br>nd to PI for certificati  |  |   |  |                         |  |  |                          |                          |                                |                              |                         |   |                 |             |               |          |
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| COMPLETE SUBMIS   |  |   | * 💿 l Agr                                      | ree                     |  |  |                          |                          |                                |                              |                         |   |                 |             |               |          |
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|   | ision >  | :S<br>Submissio   |  | Meetings                | Reporting  | More   |                          |                          |                                |                              |                         | Role: Researcher 👻  | Produ           | ucts 💌      | 着 Matthev     | v Vukovi |
| omplete submis<br>cayuse<br>Huma  | n Ethic  | Submissio   |  |                         | Reporting  | More   |                          |                          |                                |                              |                         | Role: Researcher *  | Produ           | ucts 💌      | ≜ Matthev     | v Vukovi |
| Cayuse<br>Huma<br>Dashboard<br>Studies / Study]   | n Ethic<br>studies<br>Details / Sut  | Submission<br>Details   |  | Meetings                | <ul> <li>Awaiting Auti</li> </ul>                                      |  |                          | 3 Pre-R                  | view<br>ion is being prepared  | or review                    |                         | Role: Researcher        Role: Researcher       Value       Under-Review       Submission is with rr |                 | ucts 💌      | A Matthew     | v Vukov. |
| Cayuse<br>Huma<br>Dashboard<br>Studies / Study  | n Ethic<br>studies<br>Details / Sut  | Submission<br>Details   |  | Meetings                | <ul> <li>Awaiting Auti</li> </ul>                                      | norization   |                          | 3 Pre-R                  | view<br>ion is being prepared  | or review                    |                         |   |                 | ucts 💌      | â Matthev     | v Vukov  |
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Certify

4

Confirm

Result Pending Certi

Task History

Approvals

Research Team

Matthew Vukovich

Name

Attachment

Role

Principal Investigator

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

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.

| Cayuse         Human Ethics         Dashboard       Studies         Studies       Submissions         Tasks       Meetings         Rep         In-Draft + | uthorization >                | Role: Researcher * Products * & Matthew Vukovich    New Study  Under Review   Post Review   Post Review | you to track your<br>submissions and to<br>see if the IRB has any<br>tasks, issues, or |
|---|-------------------------------|---|--|
| My Studies  | My Tasks                      | Submissions by Type   | questions for you to   |
| IRB-FY2024-28 Impact of Physical Activity on Wellness   |                               | Renewal 0   | address.   |
| IRB-FY2024-27 Impact of physical activity on health and well-being  |                               | Initial 4   |  |
| IRB-FY2024-13         Example NHSR Study 11.29.23           IRB-FY2024-12         Test Expedited Review 11.29.23  | _                             | Modification 0 Incident 0   |  |
| INDELEVENTED REVIEW 11.27.23  | All Tasks Complete            | Withdrawal 0  |  |
|   |                               | Closure 0   |  |
|   |                               | Legacy 0  |  |
| View All  |                               |   |  |
| Approved Studies  | Studies Expiring in 30 days 👻 | Expired Studies   |  |
|   |                               |   |  |
| No Approved Studies   | No Expiring Studies           | No Expired Studies  |  |