**College of Saint Benedict and Saint John’s University**

**Institutional Review Board (IRB)**

**IRB Form 1: Expedited or Full Review**

**Directions for Submission:**
Please answer all questions completely. Do not delete or modify any questions. Responding to each question on this form fulfills one of the requirements for the ethical conduct of research. If a question does not pertain to your study, indicate NA (not applicable) following the question.

1. **Project Title**: Click here to enter text.
2. **Principal Investigator’s Name**: Click here to enter text.
3. **Department or Affiliation**: Click here to enter text.
4. **Email Address**: Click here to enter text.
5. **Anticipated Start Date for the Research**: Click here to enter text.
Note: IRB approval expires after one year. If the research extends beyond one year, a renewal form [(IRB Form 3](https://www.csbsju.edu/institutional-review-board/forms)) must be submitted.
6. **Is the Principal Investigator a Student?**

[ ]  No

[ ]  Yes (see below)

**If you answered “Yes” above:**

If the Principal Investigator is a student, a Faculty Advisor must be listed below and the IRB application must be submitted to the IRB chair (irb@csbsju.edu) by the Faculty Advisor.

**Faculty Advisor’s Name**: Click here to enter text. **Department**: Click here to enter text. **Email Address**: Click here to enter text.

1. **List All Co-Investigators**:

Name Email Address Student, Faculty, or Other

Click here to enter text.

**IMPORTANT NOTE FOR STUDENT RESEARCHERS:** All students working on this project must complete the CITI (Collaborative Institutional Training Initiative) “Students in Research” online ethics course before they can be involved in data collection. See the [“CITI Training” section of the IRB website](https://www.csbsju.edu/institutional-review-board/citi-training), or contact the IRB chair at irb@csbsju.edu for more information.

**Part I: Discerning the Type of Review: Expedited Review or Full Review?**

1. **Is Your Research Exempt?**Before completing the section below, check to make sure your research is not *exempt* from formal IRB review. Consult the [IRB’s list of categories of research that may be exempt](https://www.csbsju.edu/institutional-review-board/exempt-categories). If you believe your research is exempt from formal IRB review, submit [Form 2](https://www.csbsju.edu/institutional-review-board/forms) rather than this form (Form 1) to the IRB chair at irb@csbsju.edu.

**NOTE: Please review the IRB’s COVID-19 policies in order to determine any safety measures that must be included in your IRB form. You can find them on our website: https://www.csbsju.edu/institutional-review-board**

1. **Expedited or Full Review?**If your research does not qualify for exemption, check the box below next to the type of review (Expedited Review or Full Review) you believe is appropriate for your project.

One factor determining the type of review needed is whether the research presents *more than minimal risk* to participants. **Minimal risk means that “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”**

[ ]  **EXPEDITED REVIEW**

Research considered *minimal risk*, including research on individual or group behavior or characteristics where research does not cause stress to participants and confidentiality is maintained; research involving deception that poses no more than minimal risk; performance of non-invasive tests; collection of data using noninvasive procedures; collection of blood samples by finger stick or venipuncture by trained personnel; research using existing documents, records, pathological specimens, or diagnostic specimens.

[ ]  **FULL REVIEW**

Research with *greater than minimal risk*; research of a sensitive nature; research with vulnerable populations (children, prisoners, pregnant women, individuals with impaired decision-making ability, non-English or English as second language speakers, or economically/educationally disadvantaged individuals); research involving invasive procedures; and/or research inducing physical pain or potential injury.

Does your research involve any of the following? (check all that apply)

[ ]  Greater than minimal risk

[ ]  Research of a sensitive nature

[ ]  Research with vulnerable populations

[ ]  Research involving invasive procedures or inducing pain or potential injury

**Part II: Project Description**

Federal rules require that the IRB include individuals with varied backgrounds and education. Therefore, this section should be written in clear and simple language using terms understandable across disciplines.

1. **Research Questions.**List your research question(s).
2. **Literature Review.**
Citing previous research, describe the relevant literature and/or theory that supports your research question and design. This section should be approximately one page in length.

**Part III: Study Population and Sample Characteristics**

1. **Subjects.**How many subjects will participate in the research?
2. **Ages.**What are the ages of the potential participants? (check all that apply)

[ ] 0-7 years [ ] 8-17 years [ ] 18-65 years [ ] >65 years

*Note: Ages 0-7 typically requires full review and a legal guardian informed consent; ages 8-17 typically requires full review and a child assent form along with the legal guardian informed consent form; ages 18 and older require an adult informed consent form unless a waiver is indicated.*

1. **Vulnerable Populations.**

**NOTE: Under the IRB’s current COVID-19 policies, in addition to the populations listed below, researchers conducting in-person studies must indicate if they will intentionally recruit participants who may be at increased risk for complications due to COVID-19** ([CDC List of People at Increased Risk](https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html)).  **If you are intentionally recruiting such participants, check the box marked “other (please describe)” below and describe the participants.**

Some populations are considered “vulnerable” to coercion or require special protections. Will any of these populations be invited to participate in the research? (check all that apply)

[ ]  children (under age 18)

[ ]  prisoners

[ ]  pregnant women

[ ]  individuals with impaired decision-making ability

[ ]  non-English speakers

[ ]  economically/educationally disadvantaged individuals

[ ]  other (please describe):

**If you checked any of the boxes above:**

Provide your rationale for using these vulnerable populations and detail the safeguards that will be included in the research to protect their rights and welfare:

**Part IV: Participant Identification and Recruitment**

1. **Recruitment Plan.**How will potential participants be identified and recruited? (check all that apply)

[ ]  PRIA (psychology signup pool)

[ ]  Email or social media

[ ]  Physical flyers

[ ]  Personal requests

[ ]  Other (explain)

1. **Recruitment Materials.**Include below or in an addendum the text of any email or PRIA announcements, and/or electronic files of advertisements, bulletin board notices, telephone scripts, and other recruitment materials.

**NOTE: Under the IRB’s current COVID-19 policies, recruitment materials for in-person research must include possible COVID-19 exposure when describing the risks of participation. Further, the recruitment materials must describe how risk of exposure will be mitigated for participants (cleaning computers, wearing masks, social distancing, etc.).**

1. **Compensation.**Will compensation be provided to participants?

[ ]  No

[ ]  Yes (see below)

**If you answered “Yes” above:**

Describe the form of compensation. Note that incentives (payment or gifts for participation) are taxable and require adherence to CSB/SJU Business Office guidelines, so indicate how you will address the taxability of incentives:

1. **Letters of Agreement.**
Are you working with an individual (athletic director, coach, supervisor, etc.) or group to access potential participants for this study?

[ ]  No

[ ]  Yes (see below)

**If you answered “Yes” above:**

List the individuals or groups below. Note that aletter of agreement must be submitted to the IRB chair from the cooperating individual or organization; [a simple online form is available here](https://www.csbsju.edu/forms/UUR08HNO2P.aspx).

**Part V: Methods, Materials, and Procedures**

The purpose of this section is to give the IRB a complete understanding of the processes involved in conducting this research. This helps to ensure that the rights of study participants are protected.

1. **Description of Research Procedures.**

**NOTE: Under the IRB’s current COVID-19 policies, when describing the research procedures below, researchers conducting in-person studies must indicate how they will follow CSB/SJU current COVID-19 protocols to reduce risk of virus transmission. Please read the IRB’s COVID-19 policies carefully. You can find them on our website: https://www.csbsju.edu/institutional-review-board**

Describe the research procedures in the space below. What will participants do while participating in this study?

* List tasks or activities that participants will be asked to complete in a step-by-step manner and explain how each task or activity will help to answer your research questions. You may use a numbered list or bullets to help describe your procedures.
* Include all materials and equipment you will use for data collection (audio recording, video recording, surveys, lab equipment, etc.).
* Estimate the time it will take participants to complete each task or activity, as well as the total time commitment for participants to complete the study.
1. **Supporting Materials.**

If you will be using survey or interview methods in your research, please submit copies of your surveys, interview questions, or handouts with your application. These files must be emailed to the IRB chair at irb@csbsju.edu. A link to your survey or other materials is not sufficient.

**Part VI: Data Collection and Anonymity**

**NOTE: Under the IRB’s current COVID-19 policies, in cases where contact tracing is possible and provides safety benefits for researchers and research participants, researchers should collect participant names to allow for contact tracing. If the study requires contract tracing, identification codes should be assigned to participants, and a coding key should be created connecting the participants’ names with their assigned codes. The coding key should be kept in password-protected file or other secure location. This will allow contact tracing, if necessary, without directly associating participants’ names with their data. The coding key must be kept for at least 2 weeks after the last in-person session of the study.**

1. **Identifiers.**
Will any of the data collected (including audio or video recordings of the participants) include names or other identifiers that indicate who is in the study?

[ ]  No (see below)

[ ]  Yes (see below)

**If you answered “No” above:**

The raw data is anonymous and can normally be kept indefinitely. If you plan to destroy the data, please explain why here. Otherwise, proceed to the next section.

**If you answered “Yes” above:**

Please explain why these identifiers are necessary:

1. **Data Collection and Storage.**
How will non-anonymous data (including names, photos, and audio or video recordings) be collected and stored? Describe in detail the procedure and how participants’ identities will be protected throughout.
2. **Codes.**
If you plan to use codes as a substitute for participant names, provide the following information below:
* Your rationale for using codes(e.g., codes will be used to links two sets of data, such as survey data about an individual and that individual’s lab data)
* A description of your process for assigning the codes
* Who will have access to the codes
* Who will secure and maintain the code list
1. **Destruction of Data.**
While any anonymous data can normally be kept indefinitely, all data containing participant identifiers should be destroyed in as timely a manner as possible. When will all data containing participant identifiers be destroyed?

[ ]  when the study is complete

[ ]  within three years

[ ]  other:

Provide your rationale for the length of time selected above:

**Part VII: Risks and Benefits**

An important ethical principle is that research must balance risk and benefits to participants and society.

**NOTE: Under the IRB’s current COVID-19 policies, researchers conducting in-person research must include possible COVID-19 exposure when describing the risks of participation below. Further, under the Precautions section (question #3 below), researchers must describe how risk of COVID-19 exposure will be mitigated for participants (cleaning computers, wearing masks, social distancing, etc.).**

1. **Risks.**
Will the research present any risks to participants?

[ ]  No

[ ]  Yes (see below)

**If you answered “Yes” above:**

Please describe the actual and potential risks, discomforts, and inconveniences for the participants:

1. **More than Minimal Risk?**In your opinion, do the risks you have identified constitute more than *minimal risk*? Minimal risk is defined as that in which the harm or discomfort anticipated in the research is no greater than that encountered in daily life or during routine physical/psychological examinations or tests.

[ ]  No

[ ]  Yes

1. **Precautions.**
List precautions that will be taken to minimize or prevent potential risks, inconveniences, and discomforts (anonymous data collection, emergency response, etc.).
2. **Deception.**
Will deceptive techniques be used in the study?

[ ]  No

[ ]  Yes (see below)

**If you answered “Yes” above:**

Explain why the deception is necessary and when and how the deception will be revealed to participants. Provide the debriefing statement that will be used either as a separate attachment or as part of the description of your research procedures in Part V.1 above.

1. **Benefits to Participants.**

List the potential benefits (if any) *research participants* may experience as a result of participating in the research. If no direct benefits are likely, put “NA”.

1. **Benefits to Society.**
List the potential benefits (if any) *to society* that may be expected from this research beyond the direct knowledge gained from the results of study.

**Part VIII: Informed Consent**

**NOTE: Under the** **IRB’s current COVID-19 policies, informed consent documents for in-person studies must include possible COVID-19 exposure when describing the risks of participation, as well as how risk of exposure will be mitigated for participants (cleaning computers, wearing masks, social distancing, etc.).**

**In addition, if researchers will be collecting participants’ names and contact information to allow for contact tracing, this has to be explained in the informed consent documents. Information about how identification codes and a coding key will be created and used to maintain confidentiality must be included in the informed consent so participants understand the purpose of collecting their names and contact information (to assist with contact tracing, not to connect participants to their data). This section of the informed consent document should also describe when the coding key and any other identifying information will be destroyed.**

**If needed, the consent form should ask research participants to wear a mask if they are not vaccinated, but may not ask the vaccination status of the research participants.**

Informed consent is a process that typically involves:

* Presenting information that enables individuals to knowledgeably and voluntarily decide whether or not to participate in the research;
* Responding to the participant's concerns/questions during the research and communicating any new findings that may affect the participant's willingness to continue participating; and
* documenting consent with a written form signed by the participant (secured and maintained for three years unless otherwise stipulated by the IRB).
1. **Consent Documents.**

Indicate which consent documents will be used. Check all that apply. Email a copy of each consent form as a Word document to the IRB chair at irb@csbsju.edu. A [Consent Form template](https://www.csbsju.edu/institutional-review-board/forms) is located on the IRB website.

[ ]  A cover letter or page accompanying a confidential or anonymous survey that is not explicitly signed by the participant, but where continuation and subsequent participation in the research is deemed consent.

[ ]  An informed consent form to be signed by adult participants (ages 18 and older).

[ ]  An informed consent form to be signed by participants’ parents, guardians, or legally authorized representatives (for participants under 18 or participants who cannot legally consent for themselves)

[ ]  An assent form to be signed by participants under 18 or participants who cannot legally consent for themselves

[ ]  Other (please explain):

1. **Consent Procedures.**
Unless you checked only the first option above, describe the procedures that will be used to obtain informed consent (and child assent, if applicable).

**Part IX: Outside Collaborations (non-CSB/SJU) and Funding**

1. **IRB Approval and Collaboration Letters.**
If you are collaborating with an individual from another institution, the research must be submitted to their institution’s IRB as well, and a copy of the approval letter must be submitted. Check one of the following:

[ ]  Collaboration letter not applicable

[ ]  Collaboration letter submitted

[ ]  Collaboration letter has been solicited

Please list the institution(s) or organization(s) with whom are you collaborating:

1. **Funding sources.**
Are there any potential or confirmed funding sources for this research project?
[ ]  No

[ ]  Yes

**If you answered “Yes” above:**

Provide name(s) of funding source(s):

**If you answered “Yes” above:**

Will the funding source(s) regulate recruitment, data collection, analysis, or reporting of this study in any way?

[ ]  No

[ ]  Yes (explain):

**Part X: Certification Statement**

By electronically signing below, I certify/agree that:

* I have read and will comply with the Policies and Procedures of the IRB, including those designated under the Ethical Conduct of Research.
* The information in this application is correct.
* I will conduct the research in accordance with all submitted statements, except when changes are needed to eliminate an immediate, apparent hazard to participants.
* I will obtain written approval from the IRB before making significant amendments or alterations to the originally approved research protocol or consent document(s).
* I will promptly report to the IRB unexpected or otherwise significant adverse events that occur in the course of the research. I will make reasonable effort to alleviate the effects of adverse events.
* I will report to the IRB and the participants any significant new findings that develop during the course of the study that may affect the risks and benefits to participants.
* I will use an informed consent process when required that ensures that potential research participants fully understand the purpose of the research study, the nature of the procedures they are asked to undergo, the potential risks of these procedures, and their rights as a study volunteer. I will ensure that co-investigators and others assisting with the research are fully informed of these procedures.
* I will not begin any part of the research until final written approval is granted.
* Approval is in effect for one year unless otherwise indicated. The research is subject to continuing review and approval. I will comply promptly with IRB requests to report on the status of the study.
* I will keep records of this research, data, outcomes, and adverse effects to permit ongoing assessment of risks and benefits to participants.
* **In accordance with the IRB’s current COVID-19 policies, if I learn that a participant has been exposed to COVID-19 during the research process, I will immediately report the incident to the IRB and to the appropriate CSB/SJU COVID response personnel in order to initiate contact tracing procedures where possible.**

Principal Investigator’s Name: Click here to sign electronically.

Date: Click here to enter text.

Co-Investigator Name(s): Click here to enter text.

**PROCEED TO THE NEXT PAGE TO COMPLETE THE SUBMISSION CHECKLIST**

**Part XI: IRB Submission Checklist**

The checklist below should be completed by the Principal Investigator, **unless the Principal Investigator is a student, in which case the Faculty Advisor should complete the checklist before submitting the IRB form.**

For each item, use the drop-down menu to select **YES** if the item has been verified or **NA** if the item is not applicable to this study. Respond to all items before submitting this form.

Select one All questions on the IRB form answered completely and accurately

Select one Faculty Advisor listed

Select one Collaboration letter submitted

Select one Agreement letter for recruitment submitted

Select one Electronic copies of marketing and recruitment materials submitted

Select one Electronic copy of surveys or questionnaires submitted

Select one Electronic copy of informed consent submitted

Select one The consent form is completely free of grammatical and spelling errors

Select one Pages of the consent form are numbered properly (1 of 2; 2 of 2; etc.)

Select one The Principal Investigator and Co-Investigators have read, understood, and placed their names on the certification statement to indicate their agreement with its contents

Select one All student researchers working on this project have completed (or will complete) the CITI training course “Students in Research”

**IMPORTANT NOTE ON CITI TRAINING**:
When the Principal Investigator is a student, verification that all student researchers have completed the CITI training is required *before IRB approval can be granted*. Completion Reports for each student should be submitted with this IRB form.

When the Principal Investigator is not a student, the Principal Investigator assumes responsibility to ensure that all student researchers working on the project complete the CITI training *before they are involved in data collection*. See the [“CITI Training” section of the IRB website](https://www.csbsju.edu/institutional-review-board/citi-training), or contact the IRB chair at irb@csbsju.edu for more information.