Policies and Procedures: Institutional Review Board (IRB)
Revised 1/21/2019, 9/10/2019 and 8/19/20

College of Saint Benedict and Saint John’s University
Institutional Review Board (IRB)
IRB Form 2: Exempt

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

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: If this project is granted exemption from IRB review, the exemption is good for three years. If the research extends beyond three years, a renewal form (IRB Form 3) 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.

7. **List All Co-Investigators:**
<table>
<thead>
<tr>
<th>Name</th>
<th>Email Address</th>
<th>Student, Faculty, or Other</th>
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   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, or contact the IRB chair at irb@csbsju.edu for more information.
Part I: Exemption Certification

1. Exempt Categories of Research
   Consult the IRB’s list of exempt categories of research. Identify which category applies to your research by typing the exempt category number here (identify all categories that apply): Click here to enter text.

If you have questions, contact the IRB Chair at irb@csbsju.edu.

Exempt categories 2c, 3c, 7, and 8 require a limited IRB review. If one of those categories applies to your research, be sure to complete the Part III: Limited Review section below.

Part II: Project Description
This section is required for all projects.

NOTE: Under the IRB’s current COVID-19 policies:
- Recruitment materials for in-person studies 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.).
- When describing the research procedures, researchers conducting in-person studies must indicate how they will follow CSB/SJU current COVID-19 protocols to reduce risk of virus transmission.
- 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.
- 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.).
- 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.
- 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.
- Please read the IRB’s COVID-19 policies carefully. You can find them on our website: https://www.csbsju.edu/institutional-review-board
1. **Description of Your Research.**
   Describe your research in the space below. Include the following information:
   - Recruitment of participants
   - The consent process
   - Methods and procedures used for data collection
   - Data storage, how the data will be protected, and who will have access to the data

2. **Supporting Materials.**
   When submitting this form, please submit copies of the following (if applicable):
   - Recruitment documents
   - Approvals from other institutions
   - Consent forms
   - Survey, interview, or focus group questions

3. **Letter of Agreement.**
   If access to potential participants for this study requires approval from an individual (e.g., athletic director, coach, supervisor, etc.) or an organization, a letter of agreement must be submitted from the cooperating individual or organization. A simple online form for obtaining letters of agreement is available here.

**Part III: Limited Review**
If limited review is a condition of exemption for this study (under exempt categories 2c, 3c, 7, or 8) or if your data will contain identifiers or codes, describe how participants’ identities will be protected by addressing the following concerns.

1. **Data Collection and Storage.**
   How will non-anonymous data (including participant 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
Part IV: 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 accept responsibility for the ethical conduct of this research study.
- 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.
- 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 IV: 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 exemption 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, or contact the IRB chair at irb@csbsju.edu for more information.