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**St. John Fisher University Institutional Review Board**

**IRB Application Form**

**Instructions:**

It is recommended that you read through the entire application before starting. Each question is very specific; please respond ONLY to the question being asked. Mark any sections that do not apply to your protocol as N/A.

Save your document as a Word file. Include your last name and a description of the document in the title, e.g., Smith Application Form.

Your application is considered complete when you include all required supporting documents in a single pdf. The complete application (in a single pdf) should be submitted from your SJF email address to [irb@sjf.edu](mailto:irb@sjf.edu). The body of the email must include your full name (students should also include the name of their research supervisor), the title of your application, and a numbered list of all the supporting documents.

**Additional information that may be helpful as you complete the application form is available on the** [SJF IRB website](https://www.sjfc.edu/services/institutional-review-board/guidelines-for-irb-application/)**.**

**PLEASE NOTE: You may not begin any part of your project—including recruiting participants—until you receive notification of approval from the SJF IRB office***.*

# SECTION ONE: SUMMARY INFORMATION

1. **Investigator Information:**

|  |  |
| --- | --- |
| **Principal Investigator:** | Click or tap here to enter text. |
| **SJF Phone:** | Click or tap here to enter text. |
| **SJF Email:** | Click or tap here to enter text. |
| **CITI Training Expiration Date:** | Click or tap here to enter text. |
| **Status:** | **Undergraduate Student  Graduate Student  Faculty/Staff  Other** |
| **Department/ Program:** | Click or tap here to enter text. |

If there are multiple investigators, provide names, CITI information & status. If there is more than one, copy and paste the next three rows as many times as you need.

|  |  |
| --- | --- |
| **Co- Investigator Name, Department, & Institution (if not SJF):** | Click or tap here to enter text. |
| **CITI Training Expiration Date:** | Click or tap here to enter text. |
| **Status:** | **Undergraduate Student  Graduate Student  Faculty/Staff  Other** |

**If you are a student researcher,** you must provide information about your faculty research supervisor(s). Include dissertation chair, dissertation committee members, and undergraduate research mentors. If more than one, copy and paste the next three rows as many times as you need.

|  |  |
| --- | --- |
| **Faculty Supervisor Name & Department:** | Click or tap here to enter text. |
| **Faculty Supervisor’s Email:** | Click or tap here to enter text. |
| **Faculty Supervisor CITI Training Expiration Date:** | Click or tap here to enter text. |

1. **Project Title & Type of IRB Review:**

**Enter title in box below:**

Click or tap here to enter text.

**Identify level of IRB review** (review guidelines at: <https://www.sjf.edu/services/institutional-review-board/guidelines-for-irb-application/>)**:**

|  |  |
| --- | --- |
| **Level of Review:** | **Exempt  Expedited  Full Board Review** |

|  |
| --- |
| **If you indicated Exempt, identify the category (categories) that pertain to your research:**  Research in established or commonly accepted educational settings  Educational tests, surveys, interviews, observations of public behavior  Benign behavioral interventions in conjunction with the collection of information from adult subjects  Secondary research for which consent is not required  Research & demonstration projects that are conducted or supported by a federal department agency  Taste and food quality evaluation and consumer acceptance studies  Storage or maintenance for secondary use for which broad consent is required  Secondary research for which broad consent is required |

1. **How do you intend to use the information gathered? (check all that apply):**

|  |
| --- |
| **thesis  campus presentation  conference presentation**  **grant-related (provide details below)  submission for possible publication**  **other (provide details in box below):** |

Click or tap here to enter text.

1. **Study Timelines:**

|  |  |
| --- | --- |
| **Estimated start date:** | Click or tap here to enter text. |
| **Will this project be completed within one calendar year?** | **YES  NO** |

1. **Data Collection (click all that apply):**

**online Will IP addresses be collected?  YES  NO   
 Identify the online platform you will use:** Click or tap here to enter text.

**in-person If in-person, please describe the location(s). If your plan is to use a “mutually agreed upon site” indicate that here.**

Click or tap here to enter text.

***Please note, if participants are being recruited from an off-campus site, you must include a letter of support for your research from any cooperating agency/ business/ institution in the appendices of this application.***

# SECTION TWO: PROTOCOL NARRATIVE & MEASURES/INSTRUMENTS

1. **Describe the purpose, specific aims, or objectives of your research project such that it can be understood by a reviewer outside of your academic discipline. (not to exceed 2 paragraphs; 500 words or less)**

Click or tap here to enter text.

1. **State the research question(s) or the hypotheses to be tested.**

Click or tap here to enter text.

1. **Summarize relevant existing data, literature, past and ongoing studies, and how your study ties in with these.** **Use in-text citations where appropriate. (approximately 2-3 paragraphs)**

Click or tap here to enter text.

1. **Provide a list of any references cited above.**

Click or tap here to enter text.

1. **Research Design (check all that apply):  Quantitative  Qualitative  Mixed Methods**

**Specify the research design (e.g., experimental, correlational, case study, phenomenological, etc.):**

Click or tap here to enter text.

1. **Will deception procedures be used in this study?  Yes  No**
2. **Will data collection be audio-/video- recorded?  Audio  Video  No**

**If data will be recorded, what alternative data collection methods will be available to participants who do not consent to audio- or video-recording?**

Click or tap here to enter text.

1. **Measures/ study instruments to be used (check all that apply):**

**N/A (e.g., secondary analysis of existing data)**

**Created/ adapted by researcher**

**Existing measure**

1. **Please list each measure/ study instrument with a brief description and citation, if applicable. If permission is necessary, please provide evidence of permission(s) in the appendix.**

Click or tap here to enter text.

# SECTION THREE: PARTICIPANT SELECTION & RECRUITMENT

1. **Participant Information and Recruitment Process**

|  |  |
| --- | --- |
| **Indicate the approximate total number of participants that will be recruited or records that will be reviewed.** | Click or tap here to enter text. |
| **Age Range of Participants (check all that apply):** | **Under 18  18 or over** |

1. **Indicate whether you will specifically target any of the following vulnerable populations in your study:**

**No vulnerable populations**

**Students of principal investigator (PI) or staff/research team**

**Students (K-12) in an educational setting (in class or at school)**

**Employees supervised by PI, research member or research sponsor**

**Prisoners**

**Refugees**

**Non-English-speaking individuals**

**Limited or non-readers**

**Economically/educationally disadvantaged individuals**

**Wards of the state (e.g., foster children)**

**Institutionalized patients/residents**

**Individuals with impaired decision-making capacity**

**Other – Explain below:**

Click or tap here to enter text.

1. **If you checked any of the boxes above, describe the additional precautions that will be taken to protect these individuals from coercion or undue influence during the recruitment and/or consent process:**

Click or tap here to enter text.

1. **Describe any criteria that define who will be *included in* your study and provide a rationale:**

Click or tap here to enter text.

1. **Describe any criteria that define who will be *excluded from* your study and provide a rationale:**

Click or tap here to enter text.

1. **Describe *screening procedures* for determining participants’ eligibility, if applicable. Screening refers to determining if prospective participants meet the inclusion and exclusion criteria described above.**

Click or tap here to enter text.

1. **Check all recruitment methods/materials you plan to use. Attach all recruitment materials in the appendix.**

**N/A (e.g., secondary analysis of existing data)**

**Recruitment letter/ email**

**Flyer**

**Verbal script**

**Information kiosk at public venue**

**Social media posting (specify platform(s)) below:**

Click or tap here to enter text.

**Other materials/methods—explain below:**

Click or tap here to enter text.

1. **Describe when, where and how potential participants will be recruited, including how often an individual may be contacted. Be specific.**

Click or tap here to enter text.

# SECTION FOUR: INFORMED CONSENT/MINOR ASSENT

1. **For expedited and exempt studies, you may request to waive the requirement to have participants sign the consent form if one of the following options applies:**

**Option 1:** The only record linking the participant and the research is the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. The research is not subject to FDA regulations.

**Option 2:** The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

**Are you requesting that participants do not have to sign the consent form?  YES  NO**

* 1. **If YES, which of the above option applies?  1  2**

***Please note, you still need to provide the consent information. The waiver described above just omits the required signature of the participant, the informed consent process still must occur.***

1. **Informed Consent Process—Check all methods you plan to use:**

**N/A (e.g., secondary analysis of existing data)**

**Online consent (e.g., clicking to indicate consent and digital signature)**

**In person**

**By regular mail, including interoffice mail**

**By e-mail**

**By phone**

**Other method—explain below:**

Click or tap here to enter text.

1. **Describe in detail how, when and where you will seek informed consent from participants (or from participants’ legally authorized representatives), keeping in mind that exempt studies still require a statement of consent to be shared with prospective participants. Attach consent documents in appendix.**

Click or tap here to enter text.

1. **Minor Assent Process—If working with participants under the age of 18, describe in detail how, when and where you will seek minor assent, if applicable. Attach assent documents in the appendix.**

Click or tap here to enter text.

1. **In special cases, you may request to alter, or waive altogether, the informed consent process if ALL of the following apply:**

* **Research is no more than minimal risk;**
* **Research could not be carried out without requested waiver/alteration;**
* **Waiver/alteration will not adversely affect the rights and welfare of participants; AND**
* **When appropriate, additional information will be provided to participants after they have completed the study.**

**Is a waiver or alteration of informed consent requested?  YES  NO**

**If YES—explain below:**

Click or tap here to enter text.

# SECTION FIVE: METHODS & PROCEDURES

1. **Provide a detailed, step-by-step description of the methods and procedures for data collection and analysis, including the role(s) of all researchers. You are encouraged to provide a list of steps. Provide enough detail so that a reviewer outside of your discipline will understand the research. For research taking place in a classroom or educational setting only – also describe the activities planned for non-participating students and explain where both participants and non-participants will be during the research activities.**

**Depending on the nature of your research, response length may range from 1-2 paragraph to multiple pages.**

**There is no need to include detailed participant recruitment, screening or consent procedures in your response, as these have already been addressed earlier in this form.**

Click or tap here to enter text.

# SECTION SIX: COMPENSATION

1. **Is any compensation and/or incentives going to be used?  YES  NO**

**If yes to above, please indicate if any compensation/incentives are to be used & identify the form of compensation:**

**Cash**

**Check**

**Gift card/gift certificate**

**Voucher**

**Raffles/lotteries**

**Course/extra credit**

**Other – explain below:**

Click or tap here to enter text.

**Indicate compensation amount and describe how, when and where participants will be compensated. Include how you will document compensation.**

Click or tap here to enter text.

# SECTION SEVEN: RISK MANAGEMENT & BENEFITS

1. **Risk Management:**

Every study has the potential for risks, even if they are minimal. **Copy and paste the “Risks” section of your Consent Form in the space below.** It should detail possible risks for participants, including potential risks to privacy and confidentiality, and describe precautions to be taken to minimize or eliminate these risks. If there are no known risks, then use the following suggested statement in this section: “We believe this study has no more than minimal risk.”

Click or tap here to enter text.

* 1. **Benefits— Copy and paste the “Benefits” section of your Consent Form in the space below.**

State any direct personal benefits to participants, keeping in mind that most social and behavioral research does not offer any direct personal benefits. If participants are not expected to directly benefit, then use the following suggested statement in this section and complete it with information specific to your study: “You may not directly benefit from this research; however, we hope that your participation in the study may (add information here to describe the societal benefits).”

Click or tap here to enter text.

# SECTION EIGHT: PRIVACY & CONFIDENTIALITY

1. **Privacy and Confidentiality—List any identifying information (e.g., name, address, IP address, etc.) to be collected:**

Click or tap here to enter text.

1. **Coding—If using pseudonyms, numbering or another coding system, explain how a master list connecting codes to participant names will be protected (check as many as apply):**

**N/A Not using coding**

**N/A Using coding, but not maintaining master list connecting codes to names**

**In password-protected file on password-protected device (using different passwords)**

**Encrypted file**

**In locked drawer (separate from data storage)**

**Other—explain below:**

Click or tap here to enter text.

1. **Results will be reported (check all that apply):**

**Individually, using coding or pseudonyms  As aggregate data  Other—explain below:**

Click or tap here to enter text.

1. **Provide the *physical location* where the identifiable data and IRB documentation will be kept during the research and after the study has been closed. The repository should include, at minimum, copies of IRB correspondence as well as signed consent documents. This documentation should be maintained for a minimum of 3 years after the study has been closed.**

|  |  |
| --- | --- |
| **Document type:** | **Storage location (street address, building, room number, etc.):** |
| **Identifiable data & signed consent forms** | **N/A**  ***While study is active:***  Click or tap here to enter text.  ***After study has been closed:***  Click or tap here to enter text. |
| **Copies of IRB correspondence/documentation (approval letters, continuation/modification approvals, approved protocol with all attachments)** | ***While study is active:***  Click or tap here to enter text.  ***After study has been closed:***  Click or tap here to enter text. |

1. **Timeline for destroying identifiable data and IRB documentation:**

|  |  |
| --- | --- |
| **Identifiable data & signed consent forms** | **N/A**  **3 years   Other–explain below:** |
| **Copies of IRB correspondence/documentation (approval letters, continuation/modification approvals, approved protocol with all attachments)** | **3 years**  **Other–explain below:** |

1. **Method of destroying identifiable data and IRB documentation:**

|  |  |
| --- | --- |
| **Identifiable data & signed consent forms** | **N/A**  **Permanently delete files**  **Shred paper**  **Other–explain below:** |
| **Copies of IRB correspondence/documentation (approval letters, continuation/modification approvals, approved protocol with all attachments)** | **Permanently delete files**  **Shred paper**  **Other–explain below:** |

# SECTION NINE: SUPPORTING DOCUMENTS

**Please organize your supporting documents as appendices of your application and submit as a single pdf. Check the supporting documents you are including to complete your application:**

**Recruitment notices, letters, e-mails, fliers, scripts, etc.**

**Informed consent document(s), if applicable**

**Minor assent document, if applicable**

**documentation of CITI or NIH certification for any external collaborators**

**Any survey instruments, psychological tests, interview forms, interview protocols, etc.**

**Written permission to use survey instrument, if required**

**Instructions to participants for use of instrument**

**Letter, e-mail or verbal script used to solicit support from external institution or agency**

**Letter of Support from external institution or agency**

**Research Supervisor Form, if student is principal investigator**

**Other—explain below:**

Click or tap here to enter text.

# SECTION TEN: INVESTIGATOR’S PLEDGE

**By submitting this protocol and clicking the box below, you certify that you accept responsibility for and will follow the ethical guidelines set forth by the Belmont Report, Declaration of Helsinki, the Nuremberg Code and the Ethical Principles of the American Psychological Association (if applicable), as well as by St. John Fisher University. You have the requisite funding, credentials and training, if needed, to carry out all procedures involved in this protocol.**

**Submitting the protocol also affirms that the information you have provided concerning the procedures to be taken for the protection of human participants is correct; no other procedures will be used in this project; you will seek and obtain prior approval from the IRB for any modification in this project; and you will promptly report any unexpected or otherwise significant adverse effects encountered in the course of this study to the IRB.**

**By checking this box, I affirm the pledge above.**