**Institutional Review Board**

**Category 4 Exemption**

**Application For Secondary Data Analysis Project Approval**

**Category 4** exemption studies must meet one of the following criteria. Mark which condition is met in your study.

[ ]  The information in the data (i.e., existing data, documents, records, or specimens) is publicly available.

[ ]  The information in the data is recorded by the researcher in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

**CONTENTS OF APPLICATION FORM**

1. Project Identification
2. Purpose of Study
3. Participants in the Data
4. Information on the Data
5. Images and Recordings
6. Reporting of Inadvertent or Adverse Effects

**Need more help with this application?**

Contact the IRB staff: IRB@stmarys-ca.edu



1. **PROJECT IDENTIFICATION**
	1. **Project Title:**

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* 1. **Data Collection Dates**

**Start Date (MM/DD/YYYY) End Date (MM/DD/YYYY)**

* 1. **Research Site(s):**

*If off campus, attach a letter of invitation for data collection signed by the appropriate level of authority on a letterhead.*

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* 1. **Research Site Compliance Requirement**

[ ]  My research site(s) require(s) me to submit an IRB protocol to their site-specific compliance function, and I have already done or will do so.

[ ]  My research site(s) do(es) not have their own research compliance review function, but I have obtained a letter of approval from the site(s). - *Letter must be attached in the appendix to this application*.

[ ]  I am conducting my research on SMC campus.

* 1. **Principal Investigator:**

*Submitting this application to Moodle will serve as the electronic signature.*

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| Name (Last name, First name): | Department or School: |
| E-mail Address:  | Phone Number:  | Program Providing Funding: |
| Investigator role: [ ] Faculty [ ] Staff [ ] Administrator[ ] Graduate Student [ ] Undergraduate Student [ ] Other:       |

* 1. **Other Investigators (if any):**

|  |  |  |
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| Name (Last name, First name):              | Department or School:           | Email:             |
| Investigator role: [ ] Faculty [ ] Staff [ ] Administrator[ ] Graduate Student [ ] Undergraduate Student [ ] Other:        |
| Name (Last name, First name):           | Department or School:           | Email:           |
| Investigator role: [ ] Faculty [ ] Staff [ ] Administrator[ ] Graduate Student [ ] Undergraduate Student [ ] Other:       |
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| Name (Last name, First name):              | Department or School:           | Email:             |
| Investigator role: [ ] Faculty [ ] Staff [ ] Administrator[ ] Graduate Student [ ] Undergraduate Student [ ] Other:       |

**1.6 Responsible Faculty Supervising Student Research (if applicable):**

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| Name (Last name, First name):           | Department or School:                 |
| E-mail Address:                 | Phone Number:           |

**1.7 Potential Financial Conflicts of Interest:**

[ ]  Yes, I declare a financial conflict of interest.

[ ]  No, I declare no financial conflict of interest.

*If yes, describe the potential financial conflict of interest and how you will mitigate it:*

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**1.8 Assurance**

 As Responsible Investigator of this study, I assure the IRB that the following statements are true:

I certify that the protocol accurately describes the research procedures and incorporates human subjects protections, including the assessment and management of potential risks and an appropriate informed consent process. To the best of my understanding, I believe the protocol meets the requirements of the Institutional Review Board and applicable regulations for protecting research subjects. I assume responsibility for 1) ensuring that any student researchers are aware of their responsibilities as investigators, and 2) that the IRB will be immediately informed in the event of research-related unanticipated risks or problems, or findings during the study that would affect the risks or benefits of participation.

[ ]  *Check this box if you have read the statement above, acknowledge, and agree to abide by the assurance.*

**2. PURPOSE OF STUDY**

*Describe the purpose of your study and background information (NOT the procedures) in lay terms that will help the IRB understand your research (500 word limit):*

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*List citations, if any, referenced in the purpose statement above, following your disciplinary citation style (e.g., APA, MLA, Chicago):*

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 *List the question(s) your research is attempting to answer and/or your hypotheses:*

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**3. PARTICIPANTS IN THE DATA**

* 1. **Specify the number of participants in the data:**

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**3.2 Check the age range (all that apply):**

[ ]  0-11 (You will need to create a child’s **assent** process and a parental permission process)

[ ]  12-17 (You will need to create a child’s **consent** process and a parental permission process)

[ ]  18-65

[ ]  66 and older

**3.4. Will vulnerable subject populations be purposively included in your study? Check YES to all categories that are targeted in your study, otherwise check NO:**

 **YES NO**

 [ ]  [ ]  Children (<18 yrs)

 [ ]  [ ]  Pregnant women

 [ ]  [ ]  Human fetuses or neonates

 [ ]  [ ]  Individuals who are terminally ill or very sick

 [ ]  [ ]  Individuals with physical disabilities

 [ ]  [ ]  Individuals with mental disabilities or cognitive impairments

 [ ]  [ ]  Socioeconomically disadvantaged

 [ ]  [ ]  Racial or ethnic minorities

 [ ]  [ ]  Prisoners

 [ ]  [ ]  Institutionalized persons (e.g. persons in correctional facilities, nursing homes,

 or mental health facilities)

 [ ]  [ ]  Other (i.e. any vulnerable subject population(s) not specified above): Please

describe:

**3.5. Check the informed consent process(es) used in the data collection (all that apply):**

[ ]  Written consent

[ ]  Oral consent

[ ]  Parental consent

[ ]  Child consent (ages 12-17)

[ ]  Child assent (ages 0-11)

[ ]  No informed consent was obtained

[ ]  Unknown

**4. INFORMATION ON THE DATA**

* 1. **Check the source(s) of the data (all that apply):**

[ ]  Publicly available on the internet without a password protected function

[ ]  Publicly available in the library or museum archive

[ ]  My own students’ course work (I am the instructor of record for these students’ work.)

[ ]  Institutional data available to its employees

[ ]  Institutional data available in my supervision

[ ]  Other; please describe:

* 1. **Check the data collection method(s) (all that apply):**

[ ]  Experiment – Multiple group design

[ ]  Experiment – Single subject design

[ ]  Survey

[ ]  Interviews

[ ]  Focus Group

[ ]  Assessment (including educational tests and assignments)

[ ]  Observation

[ ]  Action Research

[ ]  Other: please describe:

* 1. **Report whether direct or indirect identifiers were collected. Check YES/NO for all:**

**YES NO**

 [ ]  [ ]  Direct identifiers

 [ ]  [ ]  Indirect identifiers

* 1. **Report whether direct or indirect identifiers will be disseminated. Check YES/NO for all:**

*Category 4 exemption must maintain anonymity.*

**YES NO**

 [ ]  [ ]  Direct identifiers

 [ ]  [ ]  Indirect identifiers

* 1. **If you have direct and/or indirect identifiers in the data, describe the process of how you de-identify the data before the analysis phase.**

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**4.6** **Describe how you will protect against the inadvertent disclosure of individually identifiable information.**

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**5. IMAGES AND RECORDINGS**

**5.1 Does your data have images and recordings? Check YES/NO for all:**

 **YES NO**

 [ ]  [ ]  Photograph or still images

  [ ]  [ ]  Video recordings

 [ ]  [ ]  Audio recordings

**5.2 If YES is selected above, describe the process of how you de-identify the images and recordings before the analysis and dissemination phases.**

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**6. REPORTING OF INADVERTENT OR ADVERSE EFFECTS**

I understand that in the case of unanticipated inadvertent or adverse effects, I (the researcher) am required to submit to the IRB within 10 days of learning of the inadvertent or adverse effects a description of the event or series of events that led to these adverse effects, what those effects are, and what I (the researcher) have done to respond to them promptly. Appropriate responses may include referral to outside support services, notification of appropriate campus or public officials, etc.

[ ]  *Check this box if you have read the statement above, acknowledge, and agree to abide by the statement.*