**Institutional Review Board**

**Application For Exempt and Non-Exempt Project Approval**

**Choose the type of application (check one):**

[ ]  Non-Exempt

[ ]  Exempt (Choose an exemption category below)

Based on 45 CFR 46.401(b), the below exemption category applies to research with children as follows:

* The use of educational tests is exempt, but survey or interview procedures are **not** exempt
* Observations of public behavior is exempt **only when** the investigator does not participate in the observed activities

[ ]  Category 1

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

(i) research on regular and special education instructional strategies; OR

(ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

[ ]  Category 2

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, observation of public behavior, IF:

(i) the information obtained is recorded in such a manner that subjects CANNOT be identified, directly or through identifiers linked to the subjects; OR

(ii) any disclosure of the subject's responses outside of the research could NOT reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

\*This exemption does not apply to children except for research involving observation of public behavior when the investigator does not interact with the children. Workplace meetings and activities, as well as classroom activities, are not considered "public behavior".

[ ]  Category 3

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, or observation of public behavior that is not exempt under Category 2, IF:

(i) the subjects are elected or appointed public officials or candidates for public office; OR

(ii) federal statute requires confidentiality of identifiable information to be maintained permanently.

\*In most cases, managers and staff in public agencies are not "public officials".

[ ]  Category 4 (Fill out a Secondary Data Analysis Form instead of this Non-Exempt/Exempt Form)

Existing data: Research involving collection or study of existing data, documents, records, or specimens, IF:

(i) these sources are publicly available; OR

(ii) the information is recorded by the researcher in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

[ ]  Category 5

Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) public benefit or service programs;

(ii) procedures for obtaining benefits or services under those programs; OR

(iii) possible changes in or alternatives to those programs, OR

(iv) changes in methods of payment for benefits under those programs.

[ ]  Category 6

Taste and food quality evaluation and consumer acceptance studies, IF:

(i) wholesome foods without additives are consumed, OR

(ii) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service (FSIS) of the US Department of Agriculture (USDA); OR

(iii) a food is consumed that contains an agricultural chemical or environmental contaminant at or below the level found to be safe by the FDA or approved by the EPA or the FSIS of the USDA.

**CONTENTS OF APPLICATION FORM**

1. Project Identification
2. Purpose of Study
3. Participant Population
4. Recruitment
5. Description of Activities
6. Images and Recordings
7. Risks and Discomforts
8. Informed Consent Process
9. Compensation
10. Benefits
11. Research Abroad or With Participants Whose Primary Language is Not English
12. Putting Together Your Appendices File

**Need more help with this application?**

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

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

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* 1. **Anticipated Data Collection Dates:**

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

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

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* 1. **Principal Investigator:**

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

|  |  |
| --- | --- |
| 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.*

1. **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:*

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

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1. **PARTICIPANTS**
	1. **Specify your proposed participant population(s):**

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**3.2 Expected maximum number of participants:**

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**3.3 Check the expected 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)

1. **RECRUITMENT**
	1. **Check the appropriate sampling methods below (all that apply):**

[ ]  Convenience sampling

[ ]  Snowball (chain-referral) sampling

[ ]  Random sampling

[ ]  Other; please describe:

*Describe your recruitment plan(s) in detail:*

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* 1. **If your recruiting plan includes people who are in a position of authority over your potential subjects (e.g., a school principal recruiting his/her teachers), describe how you will address the issue of this influence.**

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* 1. **Check the documents or oral scripts you will use to recruit potential participants (all that apply):**

[ ]  Introductory letter or email

[ ]  Flyers/posters

[ ]  Oral script(s) for personal contact

[ ]  Other; please describe:

1. **DESCRIPTION OF ACTIVITIES**

**5.1. Check the appropriate research design(s) for your study (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:

**5.2. Describe exactly what research participants will do as part of the study. List the activities in a chronological order:**

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1. **IMAGES AND RECORDINGS**

**6.1 Will you photograph or record your participants? Check YES/NO for all:**

 **YES NO**

 [ ]  [ ]  Photograph images

 [ ]  [ ]  Video recordings

 [ ]  [ ]  Audio recordings

*If yes, describe which of your participants you will photograph and/or record (video or audio) and in what setting:*

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**Fill out sections 6.2-6.6, ONLY if you are collecting any images or recordings.**

**6.2 Justify why the images and/or recordings are necessary for your study:**

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**6.3 If some participants have not consented to be recorded/photographed, describe how you will exclude these participants from being recorded/photographed.**

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**6.4 Do you plan to display, present, or distribute the images outside of your research team (which includes your advisor)? Check all that apply:**

[ ]  I do not plan to share the images outside of my research team.

[ ]  In class

[ ]  On campus, outside of class (including poster sessions)

[ ]  A restricted public archive (restricted entry, password protected)

[ ]  An unrestricted public archive, (e.g., the SMC Library)

[ ]  A journal article or book chapter

[ ]  A conference presentation

[ ]  Online/on the Web

[ ]  Other; please describe:

**6.5 Disposition of audio-recordings, video-recordings, or photos**

[ ]  Destroy the recordings/photos after I have made transcripts.

[ ]  Archive\* the recordings/photos for further research and education. \**Archive*: Store in a physical or electronic collection or repository that is accessible to the public and/or to other scholars outside of your immediate program.

[ ]  Other; please describe:

**6.6 If you are using a videographer or sound engineer, please describe your process for ensuring the confidentiality of your subjects’ responses.**

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1. **RISKS AND DISCOMFORTS**

**7.1 Check the risks and discomforts that may result from research procedures (all that apply):**

[ ]  Presenting materials to participants that they might consider sensitive, offensive, threatening, or degrading

[ ]  Distress resulting from the topic of the study (such as surviving political violence or natural disaster)

[ ]  Any probing for personal or sensitive information in surveys or interviews, which might be experienced as an invasion of privacy

[ ]  Deception (lying to the participants—includes both withholding and misinforming)

[ ]  Administering drugs

[ ]  Taking tissue samples

[ ]  Administering nutritional supplements

[ ]  Drawing blood

[ ]  Administering alcohol

[ ]  Giving injections

[ ]  Other risks and discomforts; please describe:

*For above identified risk(s) and discomfort(s), provide justification (i.e., why is it essential for you to collect the information despite the risks?):*

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**7.2 How will you minimize *research procedure risks and discomforts*, and protect participants’ welfare?**

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**7.3 Do you plan to collect and record identifiers that will be associated with your research data?**

 *Refer to the instructions for the definitions and distinctions between direct and indirect identifiers.*

**YES NO**

 [ ]  [ ]  Direct identifiers

 [ ]  [ ]  Indirect identifiers

*If yes for direct identifiers, (1) describe the direct identifiers and explain why individuals or individual responses need to be identifiable; (2) explain how long you plan to keep the identifiers; and (3) state whether participants will be identified by name in your report.*

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*If yes for indirect identifiers, discuss how you will manage the participants’ information in such a way as to ensure that no one can be indirectly identified outside the research team.*

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**7.4 Protecting against a risk of inadvertent disclosure of individually identifiable information**

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**7.5 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.*

1. **INFORMED CONSENT PROCESS**

**8.1 Check the informed consent process(es) you will use in your study (all that apply):**

 *Include all materials in your appendices.*

[ ]  Written consent

[ ]  Oral consent\*

[ ]  Parental consent

[ ]  Child consent (ages 12-17)

[ ]  Child assent (ages 0-11)

*\* If an oral consent process is being used, one of the following must be true. Check all that apply:*

[ ]  The participants do not read and write. (If there is risk of harm, you may need a witness.)

[ ]  Your research methods include surveys, questionnaires, or anonymous focus groups, and you will not collect any individually identifying information.

[ ]  The primary risk is a breach of confidentiality and a consent form would be the only documented link between an individual and participation in the study. (Example: People with HIV/AIDS.)

[ ]  The study data are collected through a telephone or video conferencing interview.

[ ]  The research will take place in settings where written consent is considered disrespectful or in settings in which asking people to sign a document would cause distress.

**8.2 Describe your informed consent process:**

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1. **COMPENSATION**

**Will participants be compensated for participating in your study?**

*Compensation may include gifts, extra credit, donations to charities, and other incentives.*

[ ]  Yes

 [ ]  No

*If yes, describe the compensation amount and criteria, and under what conditions participants will receive partial or no compensation:*

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1. **BENEFITS**

*Please review the definitions and distinctions between direct and indirect benefits in the instruction. Note: The opportunity to participate in research is not a benefit, and compensation is not a benefit.*

**10.1 Describe any direct benefits that participants may receive:**

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**10.2 Describe any indirect benefits that may result from the study:**

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**RESEARCH ABROAD OR WITH PARTICIPANTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH**

*You need to fill out this section if:*

* *Your research will take place abroad, or*
* *Your research will take place in the United States with participants whose primary language is not English.*

**11.1 Site and Contact Information:**

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| Research Site:      | Contact person in country where research will be conducted:           |
| Agency or institutional affiliation of the contact:       | E-mail, phone, and/or other means to reach contact person:        |
| Describe how you will be able to maintain contact with the IRB while abroad:      |

**11.2 What is/are the language(s) spoken by your participants?**

**[ ]** English

**[ ]** Spanish

**[ ]** Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

**11.3 How well do you speak/write the language(s)?**

 [ ]  Native speaker [ ]  Fluent [ ]  Moderately fluent [ ]  Not well or at all

**11.4 Will you require the services of an interpreter?**

**[ ]** Yes

**[ ]** No *(If no, skip to 11.5)*

*How will you obtain the services of an interpreter (for recruitment, consent, etc)?*

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*How will you ensure that the interpreter(s) maintain confidentiality, if necessary?*

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*How will your participants be able to reach you if they have questions or concerns during or after participating in the study?*

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**11.5 Age of Consent**

At what age are persons considered adult in the setting where your research will take place?

**11.6 Cultural Competence**

*Please review the definitions cultural competence in the instruction.*

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1. **PUTTING TOGETHER YOUR APPENDICES**

*Do not send these as separate documents. Put all of your appendices into a single Word or PDF file and save as “Your Name\_Appendices”. Be sure to clearly label each item (e.g., Appendix A: Introductory Letter/Email) within the file. Submit your appendices as one attachment and this application as another attachment to the IRB Application site in Moodle. We do not accept zip files.*

*Check all the materials that you will include in your appendices.*

 *Recruitment materials:*

[ ]  Introductory letter or email

[ ]  Flyers/posters

[ ]  Personal contact script/text (oral and/or written)

[ ]  Letter of invitation for data collection, if outside of SMC, with the original signature from the appropriate authority on letterhead. It is the researcher’s responsibility to determine the appropriate level of authority (e.g., school site principal or district superintendent).

[ ]  Other:

 *Research instruments:*

[ ]  Surveys/questionnaires, interview questions and/or other instruments you will use

[ ]  If you plan on conducting life history or other open-ended or unstructured interviews, provide a description of the type and range of questions

[ ]  Justification for deception as well as debriefing materials.

 *Consent materials:*

 [ ]  Consent form for adult participants

 [ ]  Parental consent form

 [ ]  Child assent or consent form

 [ ]  Oral consent script for adult participants

 [ ]  Contact information cards to give participants, when appropriate, in oral consent process

[ ]  Focus group confidentiality agreement form

 *Releases:*

 [ ]  Photograph and video releases

 [ ]  Audio-recording release