APPLICATION FOR PROTOCOL APPROVAL—UPDATED 7/14
ADAPTED FROM MATERIALS FROM DUKE UNIVERSITY

This form is to be used for all **non-exempt** undergraduate and graduate **student** research.

### Instructions

**How does the IRB review process work?**

There are two steps in the review process: (1) drafting and reviewing this application with your advisor; (2) review by members of the IRB. Each step is likely to have **more than one** round of feedback and revision.

**How to submit this form and begin the IRB review process:**

1. **Work with your faculty advisor** for mentoring, drafting, and other assistance. Your faculty advisor is considered the responsible investigator for your research protocol.

2. **Fill out this form and submit it via the IRB Application site in Moodle.**
   (If there are questions about using the text form fields or checkboxes with this form, please contact the IRB chair or IRB@stmarys-ca.edu).

   *Make sure to include the e-mail addresses of all investigators (including the faculty advisor who is serving as Responsible Investigator for a student research project).*

3. **Make one file (pdf or Word) for additional file(s)** that contain all your protocol documents (e.g., recruitment texts, consent forms, assent forms, survey instruments, interview questions and **data collecting site permission**), and **send it via the IRB Application site in Moodle**.

   - After your faculty advisor’s supervision, your proposal and appendices will be submitted to the IRB committee by your supervisor via the Institutional Review Board Application site on Moodle.
   - Submitting via the Moodle site, which requires your official SMC email account, is regarded the **original** signature of the primary investigator or the faculty mentor of student researchers for the submitted study proposal. Please note that unsigned proposals (i.e., the proposals not submitted via the Moodle site) will **not** be reviewed.
Need more help with this application?

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

Contents of Application Form

1. Project Identification and Signatures
2. Research Abroad or In Non-English-Speaking Communities
3. Purpose of Study
4. Participant Population
5. Recruitment
6. Description of Activities
7. Compensation
8. Benefits
9. Risk: A Primer
10. Risks in Your Study
11. Images and Recordings
12. Informed Consent Process
13. Putting Together Your Appendices File(s)

...Yes, it looks long at first glance. But you'll notice there is a lot of explanation and instruction to help you prepare your application. The actual amount of text you write will be relatively short.
APPLICATION FOR PROTOCOL APPROVAL
FOR UNDERGRADUATE AND GRADUATE STUDENT RESEARCH

1. Project Identification and Signatures

1.1 Project Title

1.2 Anticipated Date Your Research Project Will Start and Duration of Your Research Project*
(*Please note that any project continuing for more than 12 months from your original IRB approval date, you will need to fill out an Interim Application for Continuing Research and for any project continuing for more than 24 months, you will need to re-submit your IRB application for re-approval.)

1.3 Research site? (Note: if this is external to St. Mary’s, you need to provide written permission on official letterhead with original signature(s) from that site to recruit participants and to collect data.)

1.4 Principal Student Investigator (Note: A faculty member must agree to be the responsible investigator for the project.)

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<thead>
<tr>
<th>Name (Last name, First name):</th>
<th>Department or School:</th>
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<tbody>
<tr>
<td>E-mail Address:</td>
<td>Phone Number:</td>
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<tr>
<td></td>
<td>Program Providing Funding:</td>
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<tr>
<td>Student role:</td>
<td></td>
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<tr>
<td>Graduate</td>
<td>Undergraduate</td>
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<tr>
<td>Post-Doctoral Fellow</td>
<td>Other Fellow/Scholar</td>
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As Student Investigator of this study, I certify to the following:
1. The research will not be initiated until written approval is secured from the IRB.
2. I will conduct this study as described in the approved protocol. If any changes are anticipated, I will contact the IRB staff and receive IRB approval prior to implementing the changes. I will contact the IRB staff immediately if any of the following events occur: unanticipated risks or problems, and findings during the study that would affect the risks or benefits.

| Original Signature of Student Investigator | Date |

1.5 Other Student Investigators (if any), certifying as in 1.3, above

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<tr>
<th>Name (Last name, First name):</th>
<th>Original Signature</th>
<th>Email:</th>
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1.6 Responsible Investigator(s)

The Responsible Investigator is an SMC faculty member who assumes responsibility for the content of this application and the conduct of the research.

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<th>Name (Last name, First name):</th>
<th>Department or School:</th>
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<tr>
<td>E-mail Address:</td>
<td>Phone Number:</td>
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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 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.

<table>
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<tr>
<th>Original Signature of Responsible Investigator</th>
<th>Date</th>
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IRB USE ONLY

1.7 Human Subjects Administration

This section is to be completed by IRB staff or members only.

<table>
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<tr>
<th>APPROVED as ☐ Category 1 or ☐ Category 2 Research</th>
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<table>
<thead>
<tr>
<th>Original Signatures of one IRB member and the IRB chair</th>
<th>Date</th>
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</thead>
</table>
2. Research Abroad or in Non-English-Speaking Communities

You need to fill out this section if:
1. Your research will take place abroad, or
2. Your research will take place in the United States with a non-English-speaking community.
Otherwise, skip to Section 3.

2.1 Site and Contact Information

<table>
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<tr>
<th>Research Site:</th>
<th>Contact person in country where research will be conducted:</th>
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</thead>
<tbody>
<tr>
<td>Agency or institutional affiliation of the contact:</td>
<td>E-mail, phone, and/or other means to reach contact person:</td>
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</table>

Describe how you will be able to maintain contact with the IRB and your advisor while abroad:

2.2 Language

Is the primary language of your participants English? □ Yes □ No

If yes, skip to 2.3

What is/are the primary language(s) of your participants, if not English? ______

How well do you speak/write the language(s)?
□ Native speaker □ Very fluent □ Moderately fluent □ Not well or at all

Will you require the services of an interpreter? □ Yes □ No

If yes, how will you obtain the services of an interpreter (for recruitment, consent, etc)?

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

If you do not speak the language well, how will your participants be able to reach you if they have questions or concerns during or after participating in the study?

2.3 Cultural Competence

Cultural competence includes an understanding of a culture or sub-culture’s beliefs, norms, and values that may have an effect on how individuals within that culture understand the proposed research.

What prior experience, if any, do you have in this community?
If you have no or limited experience in the community how will you become conversant in its cultural norms and the differences from your own culture?

Were you invited into the community, and if so, by whom?

Will someone review your research study materials (e.g., interview questions, consent process) to make sure they are culturally appropriate? Please tell us who and briefly explain his/her or their qualifications to know what is culturally appropriate.

Please provide the name, e-mail, and telephone number of an SMC faculty member who is familiar with the culture in which you be conducting your research. This might be your advisor.
3. Purpose of Study

3.1 Purpose of Study: What is the purpose of the study? Provide background information that would help the reviewer understand your research. Avoid discipline-specific jargon, because your reviewer’s area of expertise may be in a different field.

4. Participants

4.1 Describe your proposed participant population(s). Be specific. Make a list if there are several populations.

(Examples: Children ages 12-16 in XYZ school; Physicians in XYZ Maternal Health Clinic in the X District of Y City)

4.2 Expected number of participants in each population: ____

4.3 Expected Age Range(s)

Check all that apply:

☐ 0-12 (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
☐ 65 and older

*Assent, permission, consent? See Section 12 on Informed Consent and/or the document The Process of Informed Consent.

4.4. Other Potentially Vulnerable Subject Populations: Please check all that apply (if any).

☐ Psychology Participant Pool
☐ Students or employees of the researcher
☐ Adults who are not legally or mentally competent
☐ Prisoners
☐ Other _____

Comments:
5. Recruitment

Recruitment is part of the informed consent process. It is usually the first way that potential participants get any information about your research. We will need to know how you plan to recruit and what you plan to use to recruit. We also need to know what steps you are taking to make sure subjects do not feel compelled to complete your study.

5.1 How do you plan to find potential participants? For example, do you plan to use your personal contacts? Will you go to public settings, such as a town market and approach people? Are local teachers, leaders, or organization staff helping you identify potential participants?

5.2 What documents or oral scripts will you use to recruit potential participants?
Check all the recruitment methods that apply:
- Introductory letter or e-mail
- Flyers/posters
- Newspaper ads
- Script(s) for personal contact
- Other; please describe:

Important: Save the text(s) or script(s) of your recruitment method(s) as Word file(s). That will be the start of the Word file(s) that contain all your appendices.

5.3 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.

6. Description of Activities

The main concern of the Institutional Review Board (IRB) is the experience of your research participants throughout the course of the study. Use everyday, easy to understand language.

6.1 What are the activities that you will ask participants to do? How long will each activity take, and what is the estimated duration of the study? If the study involves observation, describe the setting and events that you will observe.

Tip: First imagine, then give the reviewer the step-by-step experience that a participant will have.

6.2 List or describe here and attach as appendices (in the Word file(s) you are creating) the 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 specific type of questions.

7. Compensation (including gifts, extra credit, donations to charities, and other incentives.)

7.1 Will you give participants gifts or payments?
Note that in some cultures, payment is not appropriate, but tokens of appreciation are.

☐ Yes
☐ No

If yes, please explain:

7.2 If you plan to compensate, under what conditions will participants receive partial or no compensation?

8. Benefits

Benefits from participating in the research may be direct and/or indirect. Direct benefits are not as common in social sciences as in medical science (where participants may benefit from an experimental treatment).

8.1 Direct Benefits:
Describe any anticipated direct benefits of this research for individual participants in each participant group. Lots of social and behavioral science and humanities research does not provide a benefit directly to participants, and that’s fine. If none, state “None.”

Note: The opportunity to participate in research is not a benefit.
Note: Compensation is not a benefit.

8.2 Indirect Benefits:
Describe any indirect benefits, such as an increase in an area of knowledge that might ultimately benefit the participants’ population.
9. Risks: A Primer

When your protocol is reviewed, the IRB is required to assess the risks presented by the research, to examine the balance between risks and benefits, and to ensure that risks are minimized.

This section will provide a very basic primer about risk. Section 10 will ask you to assess the risks in your study and describe how you will minimize them.

There are two broad types of risk of harm to participants in research in the social and behavioral sciences and the humanities. They are:

1) Risks that result from research procedures.
2) The risk of an inadvertent disclosure of identifiable, potentially damaging, or private information.

9.1 Risks that result from research procedures:

The primary risk related to research procedures is causing participants distress due to the research topic (previous trauma, for example), or research methods such as probing about sensitive topics, or the risk of social embarrassment when a participant is unable to answer a question, or the fear that responses will affect a student’s grade.

Examples of procedures to minimize distress include:

- Ensuring that participants know the nature of the questions they will be asked.
- Clarifying in the consent process and during the study that participants may choose not to answer particular questions and that they may stop being in a study at any time.
- Ensuring that interviews about private issues will be conducted in a setting that protects privacy.
- Establishing relationships with participants before asking probing questions that participants might perceive as intrusive.
- Minimizing any deception and fully debriefing (explaining the reason for deception, minimizing any negative effects from deception) subjects after any deception.

9.2 Risks of inadvertent disclosure of identifiable, potentially damaging (to self or others), or private information:

What constitutes potentially harmful information will vary from culture to culture, but can include illegal activities, infidelity, sexual orientation, political activism, and so forth. It may also include harmful information about other persons named or unnamed, though potentially identifiable by position or other descriptive information. Private information includes information that may be potentially harmful, but also includes information that would
probably not be harmful, but which the participants expect will not be shared with anyone outside the research setting (e.g., income, academic performance, class rank or test scores).

Harms that could result from an inadvertent disclosure of identifiable information include damage to participants’ insurability, employability, reputation, status, or family relationships and include exposing participants to legal or physical harm (e.g., disclosing information about illegal or stigmatized activities).

The best way to protect participants is to not connect any identifying information with individual responses (e.g., survey or questionnaire responses, or research notes from participant observation). Please note that pseudonyms can be used in research data and reports.

Examples of procedures to manage the risk of inadvertent disclosure of potentially damaging or private information include:

- Removing identifiers as soon as possible.
- Creating a key with unique numbers that can connect identifiers with research data.
- Storing identifiable data in a locked, secure setting.
- Keeping any keys that could link participants’ names to data in a separate location from the data. If you are doing international research on a highly sensitive topic, you could send the key in a password protected file to a site in the U.S.

Protection is not needed if the participant specifically wants the information to be disclosed.

Consent forms are not considered research data and are usually kept in a separate location from your research data.

9.3 Identifying Information:

There are two types of identifying information: direct and indirect.

Direct Identifiers:
Direct identifiers include names, addresses, phone numbers, images, and other obvious identifiers. Direct identification can occur when identifiers are written on survey instruments, participants’ addresses are put in your notes, or when the researcher creates a key that can be used to link surveys to individuals.

Indirect Identifiers:
Indirect identifiers are bits of information that could be combined by someone outside the research team to identify participants. For example, if a researcher described a participant as a freshman forward from Oregon on the SMC men’s basketball team, someone who knew the team could identify the participant.

If you are going to use names, the question of indirect identifiers is irrelevant. Indirect identifiers are of concern when you prepare a report: will others be able to deduce who your participants were? This can be a problem especially in a small population. You may need to create misleading identifiers, report data in aggregate only, or depict identifiers in more
10. Risks: Your Research

Please refer to Section 9 as you complete this section. If you have more than one participant population, complete Section 10 for each population. For example, you may be interviewing school officials, parents, and children. You might survey a large number of people and conduct focus groups with just a few.

10.1 Risks that result from research procedures (see 9.1). Please check 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 uninforming and misinforming)
- Administering drugs
- Taking tissue samples
- Administering nutritional supplements
- Drawing blood
- Administering alcohol
- Giving injections
- Other risks, specify: _____
- None

10.2 Provide your thoughts about how you will minimize research procedure risks, and protect participants’ welfare (see 9.1). Your thoughts are likely to be the first step in a conversation with your advisor.

10.3 The risk of an inadvertent disclosure of identifiable, potentially harmful (to self or others), or private information (see 9.2):

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

- Yes
- No

If yes, please (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.

*Sometimes a researcher needs to keep identifiers during the data collection phase, but can destroy the identifiers as soon as the data are collected. Again, it is better to simply not collect them.
10.4 Protecting against a risk of inadvertent disclosure of individually identifiable information:

Please describe how you plan to protect information that might damage participants if it were inadvertently released.

10.5 Indirect identifiers (see 9.3):

Have you analyzed the information about your participants that you will include in your data and present in your reports in such a way as to ensure that no one can be indirectly identified outside the research team? Please discuss.

10.6 Report of inadvertent or adverse effects:

In the case of unanticipated inadvertent or adverse effects, the researcher is required to submit to the IRB a description of the event or series of events that led to these adverse effects, what those effects are, and what the researcher has done to respond to them (including referral to outside support services, notification of appropriate campus or public officials, etc.).

11. Images and Recordings

11.1 Collecting and Releasing Identifiable Photographs and Videos

*If you make photographs or videos of people in public settings (festivals, marketplaces, activities of daily living, etc.) you do not have to obtain releases.*

*If you make photographs or videos of people in a private setting, you need to get releases. If you take your research participants into a public setting and they can be identified as your participants, you need releases.*

*Sample releases, both incorporated into a consent form and as separate forms, are available through links in the document The Process of Informed Consent.*

*Releases must explain all the ways you hope to use the images and give individuals the option to approve or not approve potential uses.*

Will you photograph or video-record your participants?

- [ ] Yes
- [ ] No
If yes, describe which of your participants you will record and in what setting.


Explain why the images (photos or videos) are needed for your study.


Where do you plan to display, present, or distribute the images, outside of your research team (which includes your advisor)? Check as many as apply:

☐ Nowhere else; only 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

11.2 Audio-recording

If you plan to interview participants (either individuals or in groups, such as a focus group) do you plan to audio-record the interview?

☐ Yes
☐ No

11.3 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:

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


12. Informed Consent Process

The informed consent process is at the heart of research with human participants. It is the process through which we communicate respect for people’s autonomous choices. We do this by giving them enough information to make a free choice, and by letting them know that if they choose to participate, they can skip portions or stop if they wish.

Application For Protocol Approval: Undergraduate and Graduate Student Research
Because it is so important, you should count on devoting some time and effort to developing your consent processes.

Developing your informed consent processes requires that you put yourself in the shoes of your research participants. What would you want to know before you decide to participate? What would make the information truly understandable?

You will be incorporating much of what you have written in this application, such as who you are, what your research is about, what you are asking the participants to do, and how you will protect confidentiality. You will need to write this in a way that is understandable to your participants.

Informed consent generally is obtained using a written document that the participants sign. However, under some circumstances an oral consent process may be used. If you will use a written consent process, you must submit the text of your consent form(s) as one of your appendices. Similarly, if you will use an oral consent process, submit a script of what you will say.

12.1 You might be able to use an oral process if one or more of the following is true.
   Check any that you think might apply to your research:
   - 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 interview.
   - None of the above apply, but 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.

In many cases where the consent process is oral, researchers should give a card with contact information to participants in case they have any questions later. A card is usually not useful if the participant is illiterate, unless that person has easy and comfortable access to someone who is literate. Sometimes oral directions to your residence or the mentoring organization’s office are more useful.

The card should have the name and contact information that is practical to that population for the following: you, your SMC advisor, and your in-country mentor (if any).

12.2 Age of Consent

   Adults provide consent for themselves. Minors must first have an adult (parent, guardian, or culturally appropriate responsible person) provide permission, and then the minors may be asked for assent.

   Tip: See SAMPLES, linked through the document The Process of Informed Consent.

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

12.3 Develop your recruitment, consent, and release materials, using the document The Process of Informed Consent. And include them as appendices in the Word file(s) you are creating.

12.3.1 Written consent be sometimes be waived in educational (or similar) research that is not exempt. This can occur for a project:
1. with minimal/no risk and
2. when the potential educational benefit outweighs any risk and
3. when the design necessitates the use of intact groups or other features that make written consent unwieldy and
4. there is no audio or video taping and
5. no identifiers are collected or data will be held in strict confidence.

If you feel these apply to your project, please explain here and the committee will consider your request for a waiver of written consent.

13. Putting Together Your Appendices File(s)

Here is a checklist of possible items you might have in the Word file(s) that contain your appendices. Check all that you will include:

Recruitment materials:

☐ Introductory letter or e-mail
☐ Flyers/posters
☐ Newspaper ads
☐ Personal contact script
☐ Other, please describe

Research instruments:

☐ Justification for deception and debriefing materials
☐ 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

Consent materials:

☐ Oral consent script(s)
☐ Written consent text(s)
☐ Parental permission process (oral and/or written)
☐ Child assent process (oral and/or written)
☐ Combined adult consent (to participate) and parental permission (for child to participate)
Contact information cards to give participants, when appropriate, in oral consent process
Consent scripts or texts for non-participants (e.g. community leaders, in certain cultures)

Releases:

Photograph and video releases
Audio-recording release

Again, do not send these as separate documents. Put all of these appendices into the Word or PDF file, or make a Zip holder. Please be sure to clearly label each item. Thank you!

You have reached the end of this form. Congratulations!