INSTITUTIONAL REVIEW BOARD

APPLICATION FOR EXEMPT AND NON-EXEMPT PROJECT APPROVAL INSTRUCTIONS

What you need to submit for non-exempt and exempt studies:

Prepare the following documents in separate files.

1. CITI training (Social and Behavioral Research Module, Basic Course/Refresher) completion certificate for all researchers listed in the application, including the faculty supervising the student research.
2. Application Form (Save the file as "Your Name_Application" in one file.)
3. Appendices (Appendices should be saved as "Your Name_Appendices" in one file. We do not accept a zip file).

Distinctions between non-exempt and exempt categories:

- Non-Exempt: Unless your study can be classified in one of the exemption categories, it should be reviewed as a non-exempt study.

- Exempt: If your study meets one of the following criteria, it can be reviewed as an exempt study.

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.

1. **Project Identification**

    1.1 Provide a descriptive title for your research project.

    1.2 Provide the starting date and duration of your research project. Note that for 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. For any project continuing for more than 24 months, you will need to re-submit your IRB application for re-approval.

    1.3 Provide location of research project. If the location is external to SMC, you need to provide written permission on official letterhead with original signatures from that site to recruit participants and to collect data. If the data collection is at a school site, check with the school and district if you need permission from the site principal or from the district superintendent.

    1.4 Provide relevant information for the principal investigator.

    1.5 Provide relevant information for other investigators (if any).

    1.6 For students only, provide the name of the faculty member supervising the research.

    1.7 If you have any financial conflicts of interest, state what it is and how you are going to mitigate it.

    1.8 By checking the box, you are certifying that the statement is true.

2. **Purpose of Study (500 word limit)**

    Provide background information (what your study is about, why you are conducting the study) that helps the IRB understand your research. Avoid discipline-specific jargon.

3. **Participants**

    3.1 Specify your proposed participant population(s). Make a list if there are several populations. For example, Children ages 12-16 in the XYZ School; Physicians in a the XYZ Maternal Health Clinic in the X District of Y City If you are using multiple methods of data collection (e.g., interviews, surveys, observations) specify the number of participants from each data collection group.

    3.2 Provide the expected maximum number of participants.

    3.3 Check the appropriate age range of research participants.

    3.4 Check whether or not these vulnerable subject populations, as defined by CITI, are included in your research project. Note that an in-depth risk assessment in Section 8 is required for the protection of vulnerable subject populations.

4. **Recruitment**

4.1 Check the appropriate sampling method(s) and describe your recruitment plan(s). For example, if your sampling method is convenience sampling, how do you plan to approach the potential participants? Do you plan to use your personal contacts, if so, how? Will you go to public settings, such as a town market and approach people, if so how? Are local teachers, leaders, or organization staff helping you identify potential participants, if so how?

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

4.3 Check the appropriate recruitment methods and include all materials in your appendices.

5. **Description of Activities**

5.1 Check the appropriate design(s) of your study. If your study is an experiment with a survey, check both experiment and survey. If your study involves observation and a survey, check both. Make sure all the selected design(s) are described in detail in the section below (5.2).

5.2 This section asks you to chronologically describe, in lay language, the experience or your participants throughout the course of the study. Make sure you submit the finalized procedures and instruments. Once your study is approved by the IRB, any revision of the procedures and/or instruments needs to be reapproved. This section should include:

- How the research will be conducted, providing information about all study procedures (e.g., all interventions/interactions with participants, data collection procedures, etc.), including follow-up procedures. If any interviews, surveys, or focus groups will be conducted for the study, attach the finalized instruments (survey questionnaires, interview questions, and/or other instruments) in your Appendices. If you plan on conducting semi-structured or unstructured interviews, provide a description of the specific type of questions.
- Who will conduct the procedures, where and when they will take place. Indicate frequency and duration of visits/sessions, as well as total time commitment.
- If the proposed research involves use of existing data, describe how data will be acquired.
- Any research procedures that are experimental/investigational. Experimental or investigational procedures are treatments or interventions that do not conform to commonly accepted practices as may occur in psychological or educational settings.
- If any type of deception or incomplete disclosure will be used, explain what it will entail, why it is justified, and what the plans are to debrief subjects. Any debriefing materials should be included in your Appendices.

6. **Images and Recordings**

6.1 Select the appropriate box(es) and describe which participants will be recorded and in which setting(s). If your participants are children, you need image release both from parents and children.

6.2 Justify why images and/or recordings are needed for your study.

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

6.4 Indicate the locations that you plan to display, present, or distribute the images outside of your research team.

6.5 Indicate what you plan on doing with the recorded materials.

6.6 If you have a third party involved in the recording, transcribing, or handling of the recorded materials, describe how you ensure to protect the confidentiality of your participants' responses.

7. **Risks and Discomforts**

7.1 Check all the potential risks involved in participating in your study. Risks are not limited to physical strain, but includes psychological stress, emotional and physiological burden, and social implications (e.g., stigmatization). The primary risk related to research procedures is causing participants distress due to the research topic (e.g., previous trauma), 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. In the text box, explain why the identified risks are inevitable and how the benefits of your study outweigh these identified risks.

7.2 Describe how you will minimize research procedure risks. 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.

7.3 Check which type(s) of identifier, if any, will be collected.

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 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. 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 general terms (e.g., use age ranges rather than specific ages; use a broader group identity such as "trades-people" rather than a carpenter, a roofer, etc.).

Sometimes a researcher needs to keep identifiers during the data collection phase, but can destroy the identifiers as soon as the data are collected. If this is the case, describe how you plan to store the identifiers during the data collection phase and dispose afterwards.

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

Collecting direct identifiers may increase the 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).

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.

7.5 Read the statement and check the box to indicate your agreement.

8. **Informed Consent Process**

8.1 Choose which type(s) of informed consent process you will be using. Be sure to include all materials in appendices. Informed consent is generally 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. If you are administering an online survey with adult participants, it is recommended that you allow participants to choose "agree to participate" and "decline to participate" in lieu of a signature. The latter choice should direct the participants to exit the survey.

If you are conducting a study with children (under 18 years of age), you need both parental consent and child assent/consent. Submit both texts in appendices.

If you will use an oral consent process, submit a script of what you will say. 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: the primary researcher and the in-country mentor (if any).

Refer to the sample consent form for the format and content. 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. 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?

8.2 Describe how you approach potential participants and obtain their agreement to participate in your study. Also explain what happens if the participants decides to withdraw from the study after they agree to participate or decides to skip answering some questions.

9. **Compensation**

Compensation includes gifts, extra credit, donations to charities, and other incentives. Describe any compensation participants will receive. Note that in some cultures, payment is not appropriate, but tokens of appreciation are. Describe any conditions under which participants will receive partial or no compensation.

10. **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).

10.1 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 that the opportunity to participate in research or to contribute to knowledge on the research topic is not a benefit. Compensation is not a benefit.

10.2 Indirect Benefits: Describe any indirect benefits, such as an increase in an area of knowledge that might ultimately benefit the participants' population.

11. **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*
- *With participants whose primary language is not English.*

11.1 Provide the relevant information.

11.2 Provide the information.

11.3 Provide the information.

11.4 If you plan to use the service of an interpreter, describe the level of involvement of the interpreter in your research and relationship to you and to the participants. Also explain how you ensure that the interpreter understands and maintains confidentiality of the participants. Finally, describe how the participants communicate with you if they have questions or concerns.

11.5 Provide the information. It is the researcher's responsibility to indicate the accurate age that is considered adult.

11.6 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.

Describe your cultural competency related/relevant to this research. Discuss your prior experience and expertise (e.g., training, relevant coursework) with this culture/community which prepares you to conduct research in this location and/or with this particular population. If you have been invited into the community, provide the name and relevant credentials of that person. Finally, if you have limited competency with this culture/community, provide the name(s) and relevant expertise of someone who will review your study materials.

12. Check all documents included in your appendices.

Submitting via the Moodle site, which requires your official SMC email account, is regarded the *original* signature of the primary investigator or the faculty supervising student researchers for the submitted study proposal.

Submission Checklist:

4. CITI training (Social and Behavioral Research Module, Basic Course/Refresher) completion certificate for all researchers listed in the application, including the faculty supervising the student research.
5. Application Form (Save the file as "Your Name_Application" in one file.)
6. Appendices (Appendices should be saved as "Your Name_Appendices" in one file. We do not accept a zip file).

Regarding release documents for 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.*