# STUDENT APPLICATION FOR EXEMPT HUMAN SUBJECTS RESEARCH PROJECTS MCCCD Institutional Review Board

#### Rationale

This form is required for students conducting <u>human subjects research</u> under the direction of faculty. It ensures compliance with ethical standards and institutional policies, safeguarding the rights and well-being of research participants.

#### Instructions

Students should complete this application if their project involves gathering data from individuals through interviews, surveys, experiments, or other methods. It is particularly important for class projects or independent research that might be presented, published, or shared outside the classroom. Before submitting, consult your faculty sponsor to review the form and ensure all required attachments (e.g., consent forms, surveys) are included. Submit the completed application and materials to your <u>College's IRB Member</u> for review by the College Research Review Committee prior to starting data collection.

#### Date: 🖻 Date

# Project Information Project Title Student Investigator(s) Faculty Sponsor(s) Affiliated College Select College Affiliation Project Status

	Revision to previously approved project	
Project Start Date	Date	
Project End Date	🛱 Date	
Project Location	Select Site of Research	

Project Type. Check the one that applies.

- Project is part of a class requirement, including research, internship, special project, and/or honors classes (specify class):
- Project is part of a cocurricular activity, including research conducted as part of a student organization (specify activity):
- Other (please specify):

Project Checklist. Check as appropriate	Proje	ect Che	cklist.	Check	as a	appro	opriate
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	Vee	Na	
	Yes	No	
1.			Does this research involve collecting data that identifies individuals (e.g., cohort databases including SSN# data on individuals, surveys, or interviews identifiable by name or student number)?
2.			If you answered Yes to (1), will identifiable data be shared with anyone (such as in a performance report for a funding source, conference presentations, published articles and reports)? If you answered No to (1), leave blank.
3.			Are data sources clearly identified (such as interviews, surveys, and existing data, including services received, reports, grades, school records)?
4.			Will participation in this research be voluntary?
5.			Will participants be offered an incentive to participate?
6.			Will participants' privacy and personal information be protected?
7.			Will participants be videotaped or audiotaped during the research?
8.			Will participants provide informed consent before the research begins?
9.			Will participants be fully informed about the benefits and any risks?
10.			Will participants be debriefed following the completion of the research?
11.			If this research is funded, will the funding source benefit financially or professionally from the outcome? If there is no funding source, leave blank.

# **Participant Characteristics**

**Research Participants.** Identify the intended research participants and include an estimate of the total number of individual participants in each relevant category.

- Students:
- □ Faculty:
- Staff:
- General public:
- Other (please specify category and estimate):

**Vulnerable Populations.** If your project specifically targets participants from any vulnerable populations, identify the group(s) and describe the steps you will take to ensure ethical protections and minimize risks.

- □ No vulnerable populations are targeted for participation in this project
- Educationally disadvantaged individuals:
- Economically disadvantaged individuals:
- □ Individuals with physical disabilities:
- □ Children and youth under 18 years of age:
- Pregnant women:
- Prisoners:

# Inclusion/Exclusion Criteria.

Inclusion criteria are proactive—they define the specific characteristics of the desired participant profile, helping to target the population you intend to study. Exclusion criteria are reactive—they serve as safeguards to eliminate individuals who might otherwise meet the inclusion criteria but possess characteristics that could compromise the project, create risks, or otherwise make participation unsuitable.

- A. Provide the *inclusion* criteria for your project (e.g., age range, enrollment in a specific course, or certain professional roles).
- B. Provide the *exclusion* criteria for your project (e.g., prior experience, insufficient proficiency in the language used in the project materials, or inability to provide informed consent.)
- C. Explain how these criteria will guide your recruitment process to ensure only eligible participants are recruited while minimizing unintentional inclusion of ineligible individuals.

Answer here.

# Project Description

#### I. Abstract Describing Project and Purpose

Provide a concise overview of your research project, focusing on the following:

- A. The research question or objective and the overall purpose of the project.
- B. A high-level summary of what participants will experience (e.g., types of activities, duration).
- C. The broader significance or expected outcomes of the research, such as how it contributes to knowledge or addresses a specific issue.

Answer here.

#### II. Methodology

Provide detailed information about the procedures and logistics of your research:

- A. Procedures: Describe the specific steps participants will complete during the study, including activities, timelines, and data collection methods (e.g., surveys, interviews, experiments).
- B. Recruitment: Explain how participants will be identified, approached, and recruited. Specify the settings (e.g., classrooms, online) and recruitment tools (e.g., emails, flyers). Focus on the implementation of the inclusion/exclusion criteria noted in the Participant Characteristics section.
- C. Existing Data/Specimens (if applicable): If using pre-existing data or specimens, describe their source and how they will be accessed, handled, and analyzed.

Answer here.

# III. Voluntary Participation

Specify the steps that will be taken to ensure that each individual's participation is voluntary. State what, if any, inducements will be offered for their participation.

Answer here.

## IV. Confidentiality of Data and Privacy Protection

Describe the methods to be used to safeguard the privacy of your participants and ensure the confidentiality of data obtained, including plans for publication, disposition, and destruction of data, including that of computer, print, videotape, and audio materials. Include a security plan for web-based or online survey data.

Answer here.

#### V. Informed Consent

Include with your submission a copy of all consent forms to be signed by the participants and/or any statements to be read to or provided to the participants. See the Related Resources section of the MCCCD Institutional Review Board page for consent form instructions and templates.

Answer here.

#### VI. Risks to Participants

- A. Describe any potential risks to participating individuals physical, psychological, social, legal, or other.
- B. Include all known and anticipated risks to the participants, such as side effects and risks of placebo treatments.
- C. In research that proposes substantial risk to human participants, list emergency backup procedures that are in place, such as counseling interventions.

Answer here.

#### VII. Benefits

- A. Describe the benefits or any compensation that the participating individuals can expect.
- B. Describe the gains in knowledge that may result from the project or research study.

Answer here.

#### VIII. Conflict of Interest

Do you, members of your immediate family, or the research personnel have any interests or relationships (including volunteer services) that might constitute a conflict of interest or create an appearance of conflict of interest in connection with the research project? If yes, please explain.

Answer here.

#### **Exemption Categories**

#### Human Subjects Research Protection Exemption Categories

Federal law 45 CFR 46.104(d) identifies eight (8) Exempt categories of research. These categories are called "Exempt" not because they are exempt from IRB review but because the research may be determined to involve minimal risk and fall within these specific regulatory categories.

Special Note: Exempt research falling under categories 2 and 3 below may still require limited IRB review. This review ensures that adequate provisions are in place to protect the privacy of subjects and maintain the confidentiality of data.

# *Instructions:* Review the categories carefully and check all that apply to your project. If you're uncertain whether your research qualifies under these exemptions, consult your faculty sponsor or the IRB.

#### (1) Research In Commonly Accepted Educational Settings

Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

#### (2) Interactions Involving Educational Tests

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

#### (3) Benign Behavioral Interventions

(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

#### (4) Secondary Research for Which Consent Is Not Required

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

#### (5) Federal Department or Agency Projects

Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(ii) [Reserved]

#### (6) Taste and Food Quality Evaluation and Consumer Acceptance Studies

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

#### (7) Storage or Maintenance for Secondary Research Requiring Broad Consent

Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

#### (8) Secondary Research Requiring Broad Consent

Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

## Attachments

**Attachments.** Check the ones you've included with your proposal. The information should be in sufficient detail to allow the IRB to make a determination under Federal Regulations 45 CFR 46.

- □ Informed consent document(s)
- Research methods (research design, data source, sampling strategy, etc.)
- Questionnaires, surveys, or other data-gathering forms
- Letters, flyers, or other recruitment materials
- Current CITI Social-Behavioral-Educational Researchers certificates for all researchers
- External support proposal or award letter

# **Certifications and Signatures**

### In making this application, we certify that:

We have successfully completed the <i>Social-Behavioral-Educational Researchers</i> certificate through the CITI Program (requires an 80% pass rate on each section).
We have read and understand the protocol and method of obtaining informed consent, as outlined by the MCCCD IRB, and will follow it during the period covered by this research project.
We intend to comply with the letter and spirit of MCCCD IRB policies and regulations.
We agree to comply with federal, state, and local laws regarding the protection of human participants in research.
We will submit any future changes to the research project to the MCCCD IRB for review and approval prior to implementation, as these may alter the status of the project.
We agree that any new findings that develop during this project that may affect the risks and benefits to participants will be promptly reported to the MCCCD IRB in writing.
We agree that any adverse events that occur in the course of this study will be promptly reported to the MCCCD IRB in writing.
We also agree and understand that records of the participants will be kept for at least three (3) years after the completion of the research.
We may begin data collection when the MCCCD IRB gives notice of its approval.

#### Student Investigator(s). I confirm the accuracy of this application.

Signature	Email (MEID@maricopa.edu)	Date
FirstLast		🛱 Date
FirstLast		🛱 Date
FirstLast		🛱 Date
FirstLast		🗇 Date
FirstLast		🛱 Date
FirstLast		🛱 Date

**Faculty Sponsor(s).** I confirm the accuracy of this application. I accept responsibility for the conduct of this research, the supervision of human participants, and the maintenance of informed consent documentation as required by the MCCCD IRB.

Signature	Email	Date
First Last		🛱 Date
First Last		🛱 Date