MONTGOMERY COLLEGE

INSTITUTIONAL REVIEW BOARD (IRB)

APPLICATION TO CONDUCT RESEARCH INVOLVING HUMAN SUBJECTS

The Montgomery College IRB reviews requests to conduct research involving human subjects. The principal investigator is responsible for providing detailed information describing the research procedures and the informed consent process. If the principal investigator is a Montgomery College student, the applicant's faculty sponsor and the department chair must approve and sign the application.

After completing the application and obtaining the required signatures, the principal investigator must email the original application and all supporting materials to **irb@montgomerycollege.edu.**

The IRB will notify each applicant of the IRB's decision. If you have any questions, please contact the IRB Coordinator, Daphne Alfelor, at **daphne.alfelor@montgomerycollege.edu**.

As part of the IRB process, the Principal Investigator must supply the following in paper or electronic documentation listed below:

- Data collection instruments (surveys, interview questions, etc.)
- Informed consent document(s) or minor assent document(s)
- Recruitment materials (if applicable)
- Letter of IRB approval from cooperating institutions (if applicable)
- Evidence of human subjects protection training within the last two years
- All required signatures and responses to items 1-10 in this application

PLEASE TYPE ALL RESPONSES

APPLICANT:

TITLE OF STUDY/PROJECT:

TYPE OF PROJECT:

SUBMISSION DATE: Click or tap to enter a date.

PROPOSED BEGIN AND END DATES FOR THE RESEARCH PROJECT:
(*The proposed start date must be at least four weeks from the submission date.)*

FROM: Click or tap to enter a date. **TO:** Click or tap to enter a date.

Note: The IRB must approve the proposed research study with human participants before the research begins, regardless of the requested start date indicated in the application. If the principal investigator's requested start date is before the research is approved or authorized, the IRB will automatically adjust the start date to the date of approval.

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PRINCIPAL INVESTIGATOR INFORMATION

Name of Principal Investigator (P.I.):			
If applicable, P.I.'s position at MC:			
Department/Organization:		**Phone**	
Email address:			

If applicable, Name of Co-Principal Investigator (P.I.):			
If applicable, Co-P.I.'s position at MC:			
Department/Organization:		**Phone**	
Email address:			

If you are a student at Montgomery College:

Faculty Sponsor Name:	
Faculty Sponsor Phone Number:	
Department Chair Name:	
Department Chair Phone Number:	

KEY RESEARCH TEAM MEMBER(S)

Provide the name(s) of other Research Team Member(s) and their role(s) for this study.

NAME	DEPARTMENT/INSTITUTION	ROLE

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TYPE OF FUNDING SUPPORT

A. Is this project part of a proposal for external support or funding?	**YES** ☐	**NO** ☐
Agency or Sponsor:		
B. Is this research part of a degree program at another institution?	**YES** ☐	**NO** ☐
Name of Institution:		

Note: If "yes" to either A or B, please submit a copy of the "methodology" section of the grant request or research proposal with this application.

IRB STATUS

A. Is this a continuation of a previously approved IRB project?	**YES** ☐	**NO** ☐
If YES, provide the previous IRB submission number:		
B. Is this submission intended as a replacement for a previously submitted IRB application?	**YES** ☐	**NO** ☐
If YES, provide the previous IRB submission number:		
C. Is this a project performed in collaboration with another organization?	**YES** ☐	**NO** ☐
If YES, attach the IRB approval letter.	**YES** ☐	**NO** ☐

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PROVIDE RESPONSES TO EACH OF THE FOLLOWING SECTIONS

1. BACKGROUND, RATIONALE, AND PURPOSE

Provide a brief, non-technical description of the proposed research. (What is the research question that this study will address? Describe why it makes sense to do this research or any other relevant information to justify it. What is the importance or value of the information gained from this research and its contribution to existing knowledge?) Use and maintain consistent terminology and keep the explanation concise for easy comprehension by education non-experts. If you use acronyms, spell them out upon their first usage. Double-check your grammar for accuracy. **Do not include your Master's or Doctoral Thesis.**

2. PARTICIPATION POPULATION AND RECRUITMENT PROCEDURES

Who is your targeted population? How many people will be used in this study? Explain in detail how and where you will recruit. Provide recruitment materials as applicable (emails, mailings, sign-up sheets, social media, flyers, etc.).

3. METHODS AND RESEARCH PROCEDURES

What do you plan to do? Discuss or outline the sequence and the timing of all study activities. Discuss the data collection methods, procedures, and tools/instruments you will employ in this study (e.g., survey, cognitive assessments, interview process, use of focus groups, etc.) Briefly describe (1) the instrument(s) you will use to collect data (2) how will you distribute the data collection method to study participants? and (3) how will you collect the data from participants? Does the data collection involve audio or audiovisual recordings? If recording, include permission to record in the consent script. The IRB must confirm the use of a reliable tool for data acquisition and review anything provided to the participant. **Do not include your Master's or Doctoral Thesis.**

4. TIME

How long will it take a participant to complete the study? If this study has multiple components, include the time it takes to complete each component and the approximate time it will take to complete the entire study. The time entered here should match what you write on any recruitment material and the Informed Consent Form. (Do **NOT** include the time needed to read the Informed Consent Form.)

5. RISKS OR DISCOMFORTS

Describe any potential risks to the participants' dignity, rights, health, welfare, or loss of confidentiality, and discuss the steps you will take to mitigate them. Risks may be physical, psychological, social, legal, economic, or reputational. Examine all possible options to minimize risks to study participants.

6. BENEFITS

Discuss any potential benefits of this study to the participants. If the study does not directly benefit participants, describe the importance of the knowledge that may result from the study. The benefits described in this section must match what you write on the consent form; here, you are writing to the IRB reviewer, and on the consent form, you will write then directly to the participants.

7. INFORMED CONSENT

Describe the procedure you will use to obtain informed consent from the participants. How and where will you get consent? **Attach a copy of all consent and/or assent documents.**

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8. CONFIDENTIALITY OF RECORDS, DATA STORAGE, AND DATA RETENTION

Describe procedures for maintaining participant confidentiality for data and plans for sharing data. Describe how and where the data will be stored, managed, and secured. Specify the length of time data will be retained and when it will be destroyed.

A. Will participant information be ANONYMOUS or CONFIDENTIAL?

B. Justify the classification and describe the safeguards you will employ to protect participant privacy in securing, sharing, and maintaining data during the study:

The research is anonymous if you do not ask for a participant's name or other identifying information. Explain how you will keep participant information private. If you collect participants' names or any additional identifying information, the study will be considered 'confidential'; you need to explain how you will keep participants' private information confidential.

C. Indicate what will happen to data collected from participants who choose to "opt out" during the research process.

Explain what you will do if a participant starts the study but does not complete the study.

D. Where and how long will participant data be kept? Include the plan for storage or destruction of data upon study completion.

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9. COMPENSATION/INCENTIVES

A. Will participants be paid for their participation, or are you providing other incentives, including extra credit?

B. What will be the compensation or incentive?
If you are compensating participants, explain what the compensation will be.

C. Describe your policy for dealing with participants who start but fail to complete the research.
Explain whether or not those who begin the study but don't finish the study will be compensated (even if partially compensated).

10. EXEMPTION SCREENING QUESTIONS

Research activities in which the only involvement of human subjects will be in one of the categories under 45CFR 46.104(d) qualify as "exempt" and subject only to "administrative review." Even if your study may qualify as exempt, you must complete items **A through I** below. The exemption determination may only be made by the IRC chair or designee, **not** the researcher. Exempt studies do not require continued IRB monitoring. If any substantive changes are made to exempt research, the newly proposed study must be submitted to and approved by the IRB.

IF THE QUESTION DOES NOT APPLY, MARK "NO"

A. GENERAL EXEMPTION – FOR RESEARCH INVOLVING SPECIAL POPULATIONS, INTERVENTIONS OR MANIPULATION

1. Does your research involve prisoners?	**YES** ☐	**NO** ☐
2. Does your study involve the deception of subjects?	**YES** ☐	**NO** ☐
3. Does your research involve survey or interview procedures with children as subjects?	**YES** ☐	**NO** ☐
4. Does your research involve observing children in settings where the investigator(s) will participate in the observed activities?	**YES** ☐	**NO** ☐

B. EXEMPTION 1 – FOR RESEARCH IN AN EDUCATIONAL SETTING		
1. Does the proposed research occur in an established educational setting?	**YES ☐**	**NO ☐**
2. Does the proposed research involve normal educational practices?	**YES ☐**	**NO ☐**
3. Does the proposed research take time or attention away from normal instruction in a way that might negatively affect student achievement (e.g., navigate impact on standardized test scores, GPA, grades)?	**YES ☐**	**NO ☐**
4. Does the proposed research impact individual instructors in a way that could adversely affect the assessment of their practice or performance?	**YES ☐**	**NO ☐**
5. Does the research involve access to student education records under the Family Educational Rights and Privacy Act (FERPA)?	**YES ☐**	**NO ☐**
C. EXEMPTION 2 – FOR RESEARCH USING SURVEY, INTERVIEW OR OBSERVATIONAL PROCEDURES		
1. Does the proposed research collect data using one or more of the following research methods ONLY?		
a. Surveys	**YES ☐**	**NO ☐**
b. Interviews (including cognitive interviews)	**YES ☐**	**NO ☐**
c. Focus groups	**YES ☐**	**NO ☐**
d. Observation of public behavior (i.e., behavior that occurs in a public place without expectation of privacy and where no special permission is required to observe others, such as a public street or park).	**YES ☐**	**NO ☐**
2. Is the data collected anonymously?	**YES ☐**	**NO ☐**
3. Does the research collect sensitive information about subjects that could place them at risk if inadvertently disclosed outside the research?	**YES ☐**	**NO ☐**
D. EXEMPTION 3 – FOR RESEARCH INVOLVING BENIGN BEHAVIORAL INTERVENTIONS		
1. Does the research involve benign behavioral intervention and collecting information from an adult subject? ***AND*** **Is the information obtained collected in such a manner that the identity of the human subjects cannot be ascertained?**	**YES ☐** **YES ☐**	**NO ☐** **NO ☐**
2. Would disclosure of the human subjects' responses outside the research place the subjects at risk of criminal or civil liability or damage the subjects' financial standing, employability, educational advancement, or reputation?	**YES ☐**	**NO ☐**
3. Is the information obtained 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?	**YES ☐**	**NO ☐**

D. EXEMPTION 3 CONTINUED – FOR RESEARCH INVOLVING BENIGN BEHAVIORAL INTERVENTIONS	
4. Does the research involve deception?	**YES ☐ NO☐**
5. If the research involves deception, has the subject authorized the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that they will be unaware of or misled regarding the nature or purposes of the research?	**YES ☐ NO☐**
E. EXEMPTION 4 – FOR SECONDARY RESEARCH USES OF IDENTIFIABLE DATA	
1. Does the research use identifiable private information or identifiable information? ***AND*** **Are the identifiable private information or identifiable biospecimens publicly available?**	**YES ☐ NO☐** **YES ☐ NO☐**
2. Is the information, which may include information about biospecimens, recorded by the investigators 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?	**YES ☐ NO☐**
3. Does the research involve only information collection and analysis involving the investigator's use of identifiable health information for "health care operations" or "research" (as defined by 45CFR 164.501) or for "public health activities and purposes" (as defined by 45 CFR 164.512(b))?	**YES ☐ NO☐**
F. EXEMPTION 5 (NOT APPLICABLE)	
Does the research apply only to research and demonstration projects *conducted by a federal department* using government-generated data?	**YES ☐ NO☐**
G. EXEMPTION 6 – (NOT APPLICABLE)	
Does the research apply only to taste and food quality evaluation and consumer acceptance studies?	**YES ☐ NO☐**
H. EXEMPTION 7 – (NOT APPLICABLE)	
Does the proposed research apply to storing and maintaining of identifiable data and/or biospecimens for future research collected under *broad consent (i.e., creating a repository)*?	**YES ☐ NO☐**
I. EXEMPTION 8 – (NOT APPLICABLE)	
Does the proposed research apply to data or biospecimen collected under broad consent?	**YES ☐ NO☐**

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RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

Any changes to this research project must be re-submitted to the IRB with all supporting documents for written approval before implementation.

Once the project has begun, the IRB must be notified of any issues related to using human subjects.

The principal investigator and their designee are responsible for retaining Informed Consent documents for **three years** after the completion of the project.

The principal investigator may only initiate research involving human subjects once written notification of IRB approval or compliance with all contingencies made with said approval has been received.

Failure to provide all required information will result in the return of your IRB application for correction before an IRB review.

SIGNATURES

By submitting this application, you are certifying that the Principal Investigator(s) and any other research team members acknowledge the following:

1. The information in this application is accurate and complete.
2. All procedures performed during this project will be conducted by individuals responsibly entitled to do so.
3. I/We will comply with all federal, state, and institutional policies and procedures regarding the protection of human subjects in research.
4. I/We will ensure that every participant follows the consent process and research procedures described in the research.
5. Any significant systematic deviation from the submitted protocol (for example, a change in the principal investigator, sponsorship, research purposes, participant recruitment procedures, research methodology, data collection and analysis, risks, benefits, or consent procedures) will be submitted to the IRB for approval before its implementation.
6. I/We will promptly report any adverse events to the IRB.

Approval by Principal Investigator	
	Click or tap to enter a date.
PRINCIPAL INVESTIGATOR SIGNATURE	**DATE**
Approval by faculty sponsor (required for all Montgomery College students): *I confirm the accuracy of this application, and I accept responsibility for the conduct of this research, the supervision of human subjects, and the maintenance of informed consent documentation as required by the IRB.*	
	Click or tap to enter a date.
FACULTY SPONSOR SIGNATURE	**DATE**
Approval by Department Chair (required for all Montgomery College students): *I confirm the accuracy of the information stated in this application. I am familiar with and approve of the procedures that involve human subjects.*	
	Click or tap to enter a date.
DEPARTMENT CHAIR SIGNATURE	**DATE**