Montgomery College
Institutional Review Board (IRB)

APPLICATION FOR THE CONDUCT OF RESEARCH INVOLVING HUMAN SUBJECTS

The Montgomery College IRB reviews all requests to conduct research involving human subjects. It is the Investigator's responsibility to give complete information regarding procedures and the informed consent process. If the principal investigator is a student, the application must be approved and signed by the applicant's faculty sponsor and the department chair.

After completing the application and obtaining required signatures, one original of the application and all supporting materials must be forwarded to: **MC IRB, c/o Office of Institutional Research & Effectiveness, 9221 Corporate Blvd., Rockville, MD 20855, or fax: 240-567-9129 or e-mail to: irb@montgomerycollege.edu**

The IRB will notify each applicant of the IRB's decision. If you have questions, please contact the IRB Coordinator, Daphne Alfelor at daphne.alfelor@montgomerycollege.edu or 240-567-7316.

The Principal Investigator must supply the paper or electronic documentation listed below:

- A copy of all questionnaires or survey instruments
- Informed consent document(s) or minor assent document(s)
- Letters of IRB approval from cooperating institutions (if appropriate)
- All required signatures and responses to Items 1 – 11 in this application

Please Type or Print all responses

1. TITLE OF STUDY / PROJECT:

2. PRINCIPAL INVESTIGATOR INFORMATION *(If more than one principal investigator, provide supplementary page with contact information.)*				
Name of Principal Investigator(P.I.):				
Department:			**Phone:**	
Mailing Address:	Street 1			
	Street 2			
	City		State	
E-mail address:				
If you are a student at MC:	**Faculty Sponsor Name:**		**Faculty Sponsor phone #:**	

3. FUNDING	
A. Is the project part of a proposal for external support or funding?	**yes** ☐ **no** ☐
Agency or Sponsor:	
B. Is the research part of a degree program at another institution?	**yes** ☐ **no** ☐
Agency or Sponsor:	
If "yes" to either 3-A or 3-B, please submit a copy of the "methodology" section of the grant request or research proposal with this application.	

4. IRB Status **A. Is this a continuation of a previously approved IRB project?**	**yes** ☐ **no** ☐
If yes, **provide previous IRB case number:**	
B. Is this a project performed in collaboration with another organization?	**yes** ☐ **no** ☐
If yes, did the collaborating organization's IRB review and approve the project? If yes, please attach the IRB approval letter.	**yes** ☐ **no** ☐

5. PROJECT DESCRIPTION

The IRB must have sufficient information about what will happen to the subjects in order to evaluate and estimate possible risks. Assurance from the investigator, no matter how strong, will not substitute for a description of the transactions between the investigator and subject. Provide a brief, non-technical summary of the proposed research. Address objectives, treatments, or *activities; who the subjects/participants will be – how they are recruited and selected – how many there will be; what data will be collected and how; how the data will be recorded and maintained securely; what analyses will be conducted; and how the results will be reported.*

Proposed Beginning and Ending dates for the research project:	From To:

6. RESEARCH PARTICIPANTS

*Who else will participate in the research project (**not subjects, but participants** in the implementation or conduct of the study)? What will their roles be?*

NAME	ROLE

7. INFORMED CONSENT

Describe here the informed consent process and attach a copy of all consent and/or assent documents. (See Appendix A for "Guidelines for Informed Consent and sample Consent forms.")

8. CONFIDENTIALITY AND ANONYMITY

1. How will subjects' privacy be maintained and confidentiality guaranteed?

2. How will the data be recorded and stored securely?

9. RISKS

Describe all known and anticipated risks to the subject including declining to participate, side effects, risks of placebo, risks of normal treatment delay, etc.

10. BENEFITS

Describe the anticipated benefits to the subjects, the College, other postsecondary students or institutions, etc.

EXEMPTION SCREENING QUESTIONS

Research activities in which the *only* involvement of human subjects will be in one or more of the categories under 45CFR46.104(d) qualify as "exempt" and subject only to "administrative review." Even if your study may qualify as exempt, you must complete the items A through I below. The determination of exemption may only be made by the IRB chair or designee, not the researcher. Exempt studies do not require continued IRB monitoring. If there are any substantive changes made to exempt research, the new proposed study must be submitted to and approved by the IRB.

If the question does not apply, mark 'NO'

General Exemption - For research involving special populations, interventions or manipulation		
1. Does your research involve prisoners?	**Yes ☐**	**No ☐**
2. Does your study involve 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 observation of children in settings where investigator(s) will participate in the activities being observed?	**Yes ☐**	**No ☐**

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 attentional away from normal instruction in a way that might negatively affect student achievement (e.g. negative impact on standardizes test scores)?	**Yes ☐**	**No ☐**
4. Does the proposed research impact individual instructors in a way that could adversely affect 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 ☐**

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:		
• **Surveys**	**Yes ☐**	**No ☐**
• **Interviews (including cognitive interviews)**	**Yes ☐**	**No ☐**
• **Focus groups**	**Yes ☐**	**No ☐**
• **Observation of public behavior (i.e., behavior that occurs in a public place where there is no 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 ☐**

Exemption 3 - For research involving benign behavioral interventions		
1. Does the research involve benign behavioral interventions in conjunction with the collection of information from an adult subject? AND **Is the information obtained collected in such a manner that the identity of the human subjects cannot readily 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 be damaging to 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 ☐**
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 he or she will be unaware of or misled regarding the nature or purposes of the research?	**Yes ☐**	**No ☐**

Exemption 4 - For secondary research uses of identifiable data		
1. Does the research use identifiable private information or identifiable biospecimens? AND **Are the identifiable private information or identifiable biospecimens publicly available?**	**Yes ☐** **Yes ☐**	**No ☐** **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 the purposes of "health care operations" or "research" (as defined by 45 CFR 164.501) or for "public health activities and purposes" (as defined by 45 CRF 164.512(b))?	**Yes ☐**	**No ☐**

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 ☐**

Exemption 6 (NOT APPLICABLE)		
Does the research apply only to taste and food quality evaluation and consumer acceptance studies?	**Yes ☐**	**No ☐**

Exemption 7 (NOT APPLICABLE)		
Does the proposed research apply to *storage and maintenance* of identifiable data and/or biospecimens for future research collected under *broad consent (i.e., creation of a repository)*?	**Yes ☐**	**No ☐**

Exemption 8 (NOT APPLICABLE)		
Does the proposed research apply to the *use* of data or biospecimens collected under broad consent?	**Yes ☐**	**No ☐**

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

- Any additions or changes in procedures in the protocol will be submitted to the IRB for written approval prior to these changes being put into practice.
- Any problems connected with the use of human subjects once the project has begun must be brought to the attention of the IRB.
- The principal investigator and his or her designee are responsible for retaining Informed Consent Documents for a period of three years after the completion of the project.

The principal investigator may not initiate any research involving human subjects until written notification of IRB approval or compliance with any and all contingencies made in connection with said approval has been received.

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

SIGNATURES:

Approval by Principal Investigator: *I certify to the best of my knowledge the information presented is an accurate reflection of the proposed research project and that I intend to comply with the letter and spirit of the MC Policy on the Protection of Human Subjects in Research.*

A.	**Principal Investigator(s) signature**	**Date**

Approval by faculty sponsor (required for all MC students): *I confirm the accuracy of this application, and I accept responsibility for the conduct of this research, the supervision of human subjects, and maintenance of informed consent documentation as required by the IRB.*

B.	**Faculty Sponsor signature**	**Date**

Approval by Department Chair (required for all MC 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.

C.	**Department Chair signature**	**Date**

Submit this Application and the following additional documents to the:

MC IRB, c/o Office of Institutional Research & Effectiveness

9221 Corporate Blvd., Rockville, MD 20855

or by Fax: 240-567-9129 or electronically to irb@montgomerycollege.edu

- Methodology chapter or section of research or grant proposal
- Proposed Informed Consent Statements for human subjects
- Survey, Questionnaire, Interview, or Testing items or questions
- Letters of IRB approval from cooperating institutions (if applicable)