Institutional Review Board (IRB)
EXPEDITED OR FULL BOARD APPLICATION

COLORADO MOUNTAIN COLLEGE

Project Title: _____

Principal Investigator: _____

Is the principal investigator a student? Yes ☐ **No** ☐

Note: If the student is the primary investigator, the faculty supervisor must be indicated as a co-investigator*. Also, if you collaborate with an individual from another institution, you must confirm that the research has been submitted to that institution's IRB as well, and a copy of the approval letter must be filed with the IRB at CMC.* **Insert Form**

Department: _____ **Correspondence Address:** _____

Telephone: _____ **Email:** _____

Co-Investigators: _____ **Co-Investigators Telephone:** _____

Co-Investigators Email: _____

Anticipated Start Date for the Research: _____ **Ending Date:** _____

Describe potential or confirmed funding sources for this research project, if any.

Will the funding source regulate recruitment, data collection, analysis, or reporting of this study in any way? No ☐ **Yes (explain):** ☐

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Discerning the Type of Review: Expedited or Full Board?

The expedited subset or full committee will be asked to review your application, depending upon the nature and circumstances of your research. CHECK all of those that apply to your research.

EXPEDITED REVIEW

- ☐ Surveys or interviews that are considered minimal risk; these would include data collection strategies where identifiers may initially be required but are separated from the data and remain confidential in the analysis and report.
- ☐ Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to the subjects and confidentiality is maintained.
- ☐ Deception that does not involve more than minimal risk to subjects; this means that the deception is predicted to cause no more than minimal discomfort after debriefing; the deception is designed to distract but does not significantly misrepresent the research.
- ☐ Performance of non-invasive tests or procedures or recording of data from subjects 18 years of age or older using noninvasive procedures.
- ☐ Collection of blood samples by finger stick or venipuncture by trained personnel, in amounts not exceeding 450 ml in an 8-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.
- ☐ Performance of moderate exercise by health volunteers or vigorous activity by physically trained individuals if appropriately screened by a physician or nurse practitioner prior to participation.
- ☐ Research using existing data, documents, records, pathological specimens, or diagnostic specimens.
- ☐ Other (specify):

FULL REVIEW

- ☐ Research involving data collection methods where the subject matter or circumstances could place subjects at risk of civil/criminal liability or damage their financial status, employability, insurability, or reputation if data was disclosed to others (for example, studying alcohol intake by minors).
- ☐ Research considered sensitive in nature, such as that involving sexuality, sexually transmitted disease, HIV, pregnancy, drug/alcohol abuse, and physical/sexual abuse.
- ☐ Research involving vulnerable populations including children (defined as those less than 18 years of age), pregnant women, economically disadvantaged persons, and mentally disabled persons.
- ☐ Research that involves invasive procedures, deception placing subjects at greater than minimal risk (such as instilling the belief that there will be a potential harm to self or others), or stress greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations.
- ☐ Research inducing physical pain, discomfort, or potential injury from procedures or drugs.
- ☐ Other (specify):

Project Description

Note: *Federal rules require that the IRB include individuals with varied backgrounds and education. Therefore, this section is to be written in clear and simple language using terms understandable across disciplines.*

1. Briefly summarize the proposed research and its significance. Include explanations of the following:
   - Research questions/hypothesis
   - Research design, including independent/dependent variables, if appropriate
   - Relevant theory

Subject Population

Note: *Applications should include, where feasible and appropriate, women as well as men and minorities in the study of populations for all clinical and research efforts. If women and minorities are not to be included, a clear rationale for their exclusion should be provided below.*

2. How many subjects will participate in the research? Who will the subjects be?

3. What are the ages of the potential subjects? (Check all that apply)
   - ☐ 0-7 (requires legally authorized representative, i.e. parent/guardian informed consent form)
   - ☐ 8-17 (requires minor assent form and legally authorized representative informed consent form)
   - ☐ 18+ (requires informed consent form)

4. Some populations are considered "vulnerable" to coercion or undue influence. Will any of these populations be invited to participate in the research? (Check all that apply.)
   - ☐ Children (under age 18)
   - ☐ Prisoners
   - ☐ Pregnant women
   - ☐ Mentally disabled individuals
   - ☐ Elderly individuals (over age 65)
   - ☐ Non-English speakers
   - ☐ Economically/educationally disadvantaged individuals
   - ☐ No vulnerable populations

5. Provide rationale for using these vulnerable populations and detail the safeguards that will be included in the research to protect their rights and welfare.

Subject Identification and Recruitment

6. How will potential subjects be identified? (Such as college classes, directories, clubs, etc.)

7. How will potential subjects be recruited? Attach a copy of advertisements, bulletin board notices, telephone scripts, and other recruitment materials. List these and provide attachments below. **Insert Documentation**

8. Provide written documentation of cooperation/permission from any individual or organization that assists you in identifying or recruiting subjects. List these and provide attachments below: **Insert Documentation**

9. Will subjects be compensated for participating in the research? Yes ☐ No ☐
   If so, what kind of reward will be given and when will the subjects receive compensation?

Methods and Procedures

10. Describe the research procedures and list tasks/activities that subjects will be asked to complete.

11. Describe the various materials and equipment (videotape, audiotape, etc.) that will be used. Attach a copy of surveys, interview questions, handouts, etc. to your application. List these and provide attachments below. **Insert Documentation**

12. How will data be collected, recorded, and stored? Describe in detail the program/software/ survey technology if using a web-based survey and how subject identity will be protected.

13. Will the data include names or other identifiers? Yes ☐ No ☐
    If yes, how will it be secured and who will have access to it?

    If codes are assigned to data, who will secure and maintain the code list?

14. The raw data and coding key from this research will be destroyed
    - ☐ When the study is complete
    - ☐ Within three (3) years
    - ☐ Other:

    Provide rationale for length of time:

Risks and Benefits

Note: *Minimal risk is defined as that in which the harm or discomfort anticipated in the research is no greater than that encountered in daily life or during routine physical/psychological examinations or tests.*

15. Will the research present more than minimal risk to subjects? Yes ☐ No ☐

16. Describe the actual and potential risks, discomforts and inconveniences for the subjects.

17. What precautions will be taken to minimize or prevent potential risks, inconveniences, and discomforts (anonymous data collection, emergency response, etc.)?

18. What potential benefits, if any, may subjects receive as a result of participating in the research? Compensation, monetary or otherwise, should not be listed as a benefit.

19. What potential benefits to society may be expected from this research?

Informed Consent

Note: *Informed consent is a process that begins when you are planning your research and continues throughout the project. Typically, it involves:*

- Presenting information that enables an individual to knowledgeably and voluntarily decide whether or not to participate in the research
- Documenting consent with a written form signed by the subject *secured and maintained for three (3) years unless otherwise stipulated by the IRB.*
- Responding to the subject's questions/concerns during the research and communicating any new findings that may affect the subject's willingness to continue participating.

20. See the Sample Consent Form to use as a template. Indicate which consent documents will be used and attach a copy of each. **Insert Form**

☐ A signed informed consent form.
☐ A signed legally authorized representative informed consent form.
☐ A signed child assent form.

21. Describe the procedures that will be used to obtain informed consent and child assent, if applicable.

22. If deceptive techniques will be used in the study, how will subjects be misled during the informed consent process (what information will be withheld or what false information will be provided)? Describe when and how this deception will be revealed to subjects and provide a copy of the oral or written debriefing statement. **Insert Form**

☐ Not applicable.

Training Documentation: Please provide a copy of your Certificate of Completion from CITI (Collaborative Institutional Training Initiative) for the required ethics training: https://www.citiprogram.org/members/index.cfm?pageID=50.

Certification Statement By signing below, I certify/agree:

- I have read and will comply with the CMC IRB Policies and Procedures Manual.
- I will conduct the research in accordance with the highest ethical and professional standard.
- I will conduct the research in accordance with all submitted statements, except when changes are needed to eliminate an immediate, apparent hazard to subjects.
- I will obtain written approval of significant deviations from the originally approved protocol or consent document(s) prior to making any changes.
- I will promptly report to the IRB unexpected or otherwise significant adverse events that occur in the course of the research. I will make reasonable effort to alleviate the effects of adverse events.
- I will not enroll any individual into this research study until I obtain appropriate written informed consent.
- I will report to the IRB and the subjects any significant new findings that develop during the course of the study that may affect the risks and benefits to subjects.
- I will use an informed consent process when required that ensures that potential research subjects fully understand the purpose of the research study, the nature of the procedures they are asked to undergo, the potential risks of these procedures, and their rights as a study volunteer. I will ensure that co-investigators and other assisting with the research are fully informed of these procedures.
- I will not begin any part of the research until final written approval is granted.
- Approval is in effect for one year unless otherwise indicated. The research is subject to continuing review and approval. I will comply promptly with IRB requests to report on the status of the study.
- I will keep records of this research, data, outcomes, and adverse effects to permit ongoing assessment of risks and benefits to participants.
- The information in this application is correct.

Principal Investigator's Signature_____Date: _____

Co-Investigator Signature(s)_____Date:_____

Submit **Completed Application to Department of Institutional Research: vkinion@coloradomtn.edu**