**

**Exemption Request for Research with Human Participants**

*Instructions:* ***Complete and send the request form electronically to irb@western.edu****.*

***Note:*** *Text boxes will expand to provide space needed. Checkboxes can be checked by putting an “x” in the box.*

Research activities are not exempt if prisoners, fetuses, or pregnant women are **targeted** for participation; if participants will be exposed to more than minimal risk; or if the research involves deception of the participant.

**Section I: Study Description**

**1.** Study Title:

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**2.** Principal Investigator (PI) and responsible faculty member if student is the PI:

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| Department(s): |

**3. Purpose of research**: *Please describe briefly the purpose of the research, and research question.*

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**4. Procedures of the research as they relate to participants:** *include a summary of recruitment, type of data collected, how data will be stored and destroyed.*

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**5.** By submitting this request, the PI (and responsible faculty member if PI is a student) accepts responsibility for ensuring that all members of the research team: 1) complete the required CITI training and any other necessary training to fulfill their study responsibilities, 2) follow the study procedures as described in the IRB approved application and comply with [*Western State Colorado University’s Guidelines for the Review of Research Involving Human Subjects*](http://www.orsp.appstate.edu/sites/default/files/documents/compliance/irb_policy.pdf) and all IRB communication and 3) uphold the rights and welfare of all study participants.

The parties (i.e., the IRB and the PI and responsible faculty member if PI is a student) have agreed to conduct this application process by electronic means, and this application is signed electronically by the Principal Investigator and by the responsible faculty member if a student is the PI.

My name and email address together constitute the symbol and/or process I have adopted with the intent to sign this application, and my name and email address, set out below, thus constitute my electronic signature to this application.

PI Name PI Email address

Faculty Advisor Name if PI is a student Faculty Advisor Email address if PI is a student

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Date

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| **6.** Dissemination of Results | |
|  | I plan to publish (thesis, dissertation, journal, book, etc.) |
|  | I plan to present off campus (conferences, etc.) |
|  | I plan to present on campus (Celebration of Student Research, Capstone, etc.) |
|  | I will not publish or present outside of class assignment |
|  | Other: describe   |  | | --- | |  | |

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| **7**. Type of research, check all that apply: | |  | Faculty Research |  | Dissertation/Thesis |
|  |  |  | Product of Learning/ Capstone Research | | |
|  |  |  | Class Project – Course Number:   |  | | --- | |  | | | |
|  |  |  | Other: describe (e.g., Honor’s Thesis)   |  | | --- | |  | | | |

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| **8.** Source of Funding: |  | Not Funded |  | Funds Awarded |  | Funds Pending |
|  |  | Federally Funded |  | University Funded: describe   |  | | --- | |  | | | |

If funds awarded/pending, provide sponsor name, Sponsored Programs number:

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*Attach a copy of the contract/grant/agreement.*

**9.** What, if any, relationship exists between the researcher(s) and agencies (e.g., schools, hospitals, homes) involved in the research? *Attach appropriate approvals (e.g., letter of agreement) from agencies involved in the research.*

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**Section II: Research Personnel**

**1.** Enter each team member (including PI) in the table below. All members of the team must complete the [Research, Ethics, and Compliance Training | CITI Program](https://about.citiprogram.org/).

**(Note:** Changes in personnel must be sent to the IRB. Changes can be submitted via email with the information below. If you need additional room, add rows by: right click, insert, and then insert rows below)

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| **Name** | **Role** (e.g., PI, co-I, Research Assistant, Research Coord., Faculty Advisor, etc.) | **Receive IRB Correspondence** (Y/N)?  If yes, provide preferred email address. |
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**2.** Are there any known or potential conflicts of interest related to this research?

*Conflict of interest relates to situations in which financial or other personal considerations may compromise or have the appearance of compromising an employee’s objectivity in meeting University responsibilities.*

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|  | No |  | Yes If yes, describe and explain how participants will be protected from  the influence of competing interests:   |  | | --- | |  | |
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**Section III: Participant Population and Recruitment**

**1.** Number of participants sought:

**2.** Targeted Participant Population (check all that apply):

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|  | Adults (>= 18 yrs old) |  | College Students (only 18 or older) |
|  | Minors (<18 yrs old) Age range: |  | College Students (<18 may participate) |
|  | Minorities |  | Cognitively or emotionally impaired |
|  | Inpatient participants |  | Non-English speaking |
|  | Outpatient participants |  | Employees of a profit or non-profit organization |
|  | International research |  |  |

**Section IV: Risk**

*Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

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| Assessment of level of risk: | |
|  | This study contains no more than minimal risk. |
|  | This study contains risks that are more than minimal. |

**Section V: Exempt Categories**

Please select the category or categories most applicable to your research and answer the question(s) associated with any selected categories:

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|  | **Normal Educational Practices and Settings (1)** |
| Research conducted in established or commonly accepted educational settings, involving normal education practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.  1a. Explain why the research procedures are normal educational practices in a commonly accepted educational setting:   |  | | --- | |  | | |

1b. If research includes accessing identifiable educational records, how will the records be protected from unauthorized access?

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1c. If research includes accessing identifiable educational records, when will access to the records for research purposes be terminated? Or, if identifiable educational records are copied for research purposes, when will the identifiable information be destroyed?

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|  | **Educational Tests, Surveys, Interviews, or Observations (2)** | | | | | | | | | |
| Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews or observation of public behavior, unless: (i) information obtained is recorded in such a manner that participants can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of an individual’s response(s) outside of the research setting could reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. [**Note:** Surveys or interviews which include minors as subjects are not included in this exempt category.] | | | | | | | | | | |
| 2a. Can the information collected be linked (directly or indirectly) to participants? | | | | | |  | Yes |  | No |
| 2b. If the answer to 2a is yes, would an accidental disclosure of the information damage a participant’s | | | | | | | | | | |
| reputation, employability or financial standing? | |  | Yes |  | No | | | | |

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|  | **Identifiable Subjects in Special Circumstances (Public Officials or Federal Statutes) (3)** |
| Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observations of public behavior that are not exempt under (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personal identifiable information will be maintained throughout the research and thereafter.  3a. Explain why the research applies to this category:   |  | | --- | |  | | |

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|  | **Collection or Study of Existing Data (4)** | | | | | | | | | |
| Research involving the collection or analysis of existing data, documents, records, pathological specimens, or diagnostic specimens, if such sources are a matter of public record or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. | | | | | | | | | | |
| 4a. All of the data/specimens involved in the study have already been collected: | | | | | |  | Yes |  | No | |
| 4b. The investigators will not record any information that can be linked directly or indirectly to participants: | | | | | | | | | | |
|  | |  | True |  | False | | | | | |
|  | | 4c. The data/specimens are considered Protected Health Information and are subject to HIPAA Privacy Policy: | | | | | | | |
|  | |  | True |  | False | | | | | |

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|  | **Public Benefit or Service Programs (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 such programs; (iii) possible changes in or alternatives to such programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under such programs.  5a. Explain why the research applies to this category:   |  | | --- | |  | | |

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|  | **Taste and Food Evaluation and Acceptance Studies (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.  6a. Explain why the research applies to this category:   |  | | --- | |  | | |

**Section VI: Informed Consent**

**1.**  Consent to participate in the research will be sought by providing (please check allthat apply):

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|  | A statement of the purpose of the research. |
|  | An explanation of the procedures of the study. |
|  | If there are foreseeable risks, benefits to the participant, or compensation, they are explained. |
|  | An explanation that participation is voluntary and there are no consequences if the subject refuses to participate or decide to discontinue participation (at any time). |
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|  | Contact information for the investigator and faculty advisor if the investigator is a student. |

If any of the consent items above are not checked, please explain why it is impractical to explain this information to participants:

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| **2.** Will participants sign an informed consent? |  | Yes |  | No |

Please **send an electronic PDF file (not scanned) of this application and any accompanying materials (e.g., informed consent, surveys, interview questions) and CITI Training Certificate of Completion to** [**irb@western.edu**](mailto:irb@western.edu)

Thank you for promoting ethical human participant research at Western Colorado University!