**

**Request for Review of Human Participant Research**

Western Colorado University’s Human Research Protection Program

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

***Note:*** *checkboxes can be checked by putting an “x” in the box.*

**Section I: Study Description**

1. Study Title:
2. Study Description: Briefly describe any relevant background, the purpose of the research, any literature searches performed, the research question, and anticipated plans for disseminating results*.*
3. Principal Investigator(s) (PI) and faculty advisor if student is the PI:

Department(s):

1. By submitting this request, the PI (and faculty advisor if PI is a student) accept 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 Colorado University’s Guidelines for the Review of Research Involving Human Subjects* and all IRB communication; and 3) uphold the rights and welfare of all study participants.

*The parties (i.e., the IRB, the PI, and faculty advisor(s), if any) agree to conduct this application process by electronic means, and this application is signed electronically by the PI and faculty advisor(s), if applicable. 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.*

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| --- | --- |
|       |       |
| Name of the PI | PI Email Address |
| I certify that I have read and endorse the materials submitted. Date:       |
|       |       |
| Faculty Advisor name if PI is a student | Faculty Advisor email if PI is a student |

1. Type of Research, check all that apply:

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|  | Product of Learning  |
|  | Faculty Research |
|  | Dissertation/Master’s Thesis/Honors Thesis |
|  | Class Project – Course Number:       |
|  | Other: describe       |

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| --- | --- | --- | --- | --- | --- | --- |
| 1. Source of Funding
 |  | Not Funded |  | Funds Awarded |  | Funds Pending  |
|  |  | Federally Funded  |  | University Funded: describe       |

If external funds awarded/pending, provide the sponsor name       and Sponsored Programs number:       Attach a copy of the contract/grant/agreement.

1. Is another institution engaged in the research (i.e., an agent of another institution will obtain informed consent, interact with participants to obtain information, or access private identifiable information about participants)?

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| --- | --- | --- | --- | --- | --- |
|  |  | No |  | Yes | If yes, list institution(s) and whether that IRB will review or rely on the WCU IRB.        |
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1. What, if any, relationship exists between the researcher(s) and agencies (e.g., schools, hospitals, homes) involved in the research? *Attach statement of approval (e.g., letter of agreement) from any agencies that will need to approve the research.*

**Section II: Research Personnel**

Enter each team member (including PI) in the table below. (*A member of the research team is defined as one who will: 1) access participants’ private identifiable information; 2) obtain informed consent;* ***or*** *3)**interact with participants.)*

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Role** (e.g., PI, co-I, Research Assistant, Research Coord., Faculty Advisor, etc.) | **Responsibilities**: Select all that apply from the list of Responsibilities below (e.g., “a, b, c”). | **Receive IRB Correspondence** (Y/N)? If yes, provide preferred email address. |
|       |       |       |       |
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**(Note:** If you need additional room, you can add rows by a right click, insert, and then insert rows below. Changes in personnel must be sent to the IRB. Minor personnel changes can be sent via an email; non-minor personnel changes require a modification request).

**Responsibilities:**

|  |  |
| --- | --- |
| **a.** Screens potential participants | **h**. Conducts physical exams |
| **b.** Obtains Informed Consent | **i**. Collects biological specimens (e.g., blood samples)  |
| **c.** Has access to identifiable data | **j**. Conducts study procedures |
| **d.** Administers survey | **k**. Dispenses medications |
| **e**. Conducts interviews | **l.** Supervises exercise |
| **f.** Enters subject data into research records | **m.** Educates participants, families, or staff |
| **g**. Analyzes data with identifiable information | **n.** Other: describe |

**Note**: In some cases, expertise to perform study procedures (e.g., blood draws, interviewing participants about sensitive topics) must be documented to show that risks to participants is minimized. Complete the *Research Personnel Form* (download from on the HRC website) and include with this application to document expertise.

**Section III: Conflict of Interest**

1. Do any of the researchers responsible for the design, conduct, or reporting of this research have a known or potential conflict of interest related to this research?

*Conflict of interest relates to situations in which financial or other personal considerations, circumstances, or relationships may compromise, involve the potential for compromising, or have the appearance of compromising a researcher’s objectivity in fulfilling research responsibilities.*

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|  | No |  | Yes  |

If yes, explain who has the conflict, whether the conflict has been disclosed and/or managed and explain how participants will be protected from the influence of competing interests.

*Note: The IRB Chair will determine any institutional obligations in addressing the conflicts of interest in research.*

**Section IV: 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 (≥18 yrs.) |
|  | Children (<18 yrs. old) Age range:       |  | College Students (<18 yrs.) |
|  | Minorities |  | Prisoners |
|  | Institutionalized Participants |  | Cognitively or emotionally impaired  |
|  | Inpatient participants |  | Non-English speaking |
|  | Outpatient participants |  | Pregnant Participants |
|  | International research  |  | Employees of a profit or non-profit organization |

1. Federal regulations require the equitable selection of participants. Is the targeted population an appropriate group to bear the burdens of this research?

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| --- | --- | --- | --- | --- |
|  | Yes |  | No If no, please explain: |       |
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* Are participants a subset of the population most likely to receive the benefits of this research?

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| --- | --- | --- | --- | --- |
|  | Yes |  | No If no, please explain: |       |
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1. Explain any inclusion and exclusion criteria for the study:
2. Describe how subjects will be recruited. A copy of all recruitment materials must be submitted with this application.
3. Does the research include any compensation, or reimbursement for participation?

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| --- | --- | --- | --- | --- |
|  | Yes |  | No If yes, explain payment schedule:  |       |
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**Section V: Informed Consent Process**

1. Explain how informed consent will be obtained. Includeinformation about the setting, any time provided to consider participating in the research, and opportunity to ask questions.
2. If applicable, describe the safeguards in place to protect the rights and welfare of any vulnerable participants *(e.g., children, prisoners, pregnant persons, or any population that may be relatively or absolutely incapable of protecting their interests through the informed consent process).*
3. Select factors that might interfere with informed consent:

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| --- | --- |
|  | None known |
|  | Participants or their authorized representative (parent) may not speak and/or read English. |
|  | Research will involve current students in a course/program taught by member of research team. |
|  | Participants are employees whose supervisor is recruiting/requiring participation. |
|  | Participants have a close relationship to research team.  |
|  | Other (please specify/indicate any relationship that exists between research team and participants):       |
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For selected factors, describe any efforts to mitigate interference with informed consent:

1. Will participants sign a consent form?

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|  | Yes |  | No |

If no, participants must still be provided with a statement regarding the research and one of the following criteria must be met and selected and followed:

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The only record linking the participant and the research is the consent document and the principal risk is potential harm resulting from a breach of confidentiality, and the research is not FDA-regulated. Each participant will be asked whether he/she wants documentation linking the participant with the research and the participants wishes will govern; OR

The research presents no more than minimal risk of harm and involves no procedures for which written consent is normally required outside of the research context.

1. Are you requesting a modification to the required elements for informed consent?

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| --- | --- | --- | --- |
|  | Yes |  | No If yes, explain:  |

**Section VI: Study Procedures**

**1.** Describe research procedures as they relate to human participants. Information must be sufficiently detailed to explain what participants will be asked to do, duration of procedures, and frequency of procedures.

**2.**  Projected data collection dates:

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| 1. Check all locations of study procedures that apply:
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|  | N/A – online survey |
|  | High Altitude Exercise Physiology Laboratory, Western Colorado University. |
|  | Other Buildings on Western Colorado University’s campus, indicate building:       |
|  | School system(s):       |
|  | Off-campus location(s). List:       |

1. If your study does not involve biomedical procedures or accessing private health information, skip to question #5. Otherwise, select all data collection activities that apply:

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|  | Blood samples by finger-stick, heel-stick, ear-stick or standard venipuncture. Indicate the type of participants and how much blood will be drawn by checking the appropriate boxes below: |
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|  | From healthy, non-pregnant adults who weigh at least 110 pounds. |
|  | From other adults or children. |
|  | How many times per week will blood be drawn?       |
|  | How much blood will be drawn at one time?       |
|  | How much blood will be drawn in an 8-week period?       |
|  | How often will collection occur?       |
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|  | Obtaining private health information (PHI) from a HIPAA covered entity. |
|  | Test articles regulated by the FDA.  |
|  | *[The term “test article” is found in the FDA regulations on Protection of Human Subjects (21 CFR 50.3, Definitions (j)). The term includes drugs (including botanicals, biologicals, and gene therapy, and genetically derived products that meet the definition of a “drug”), and medical devices for human use. The FDA has statutory authority to regulate the development and marketing of these products.]* |
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|  | Other: describe       |

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| 1. Does the study involve deception of participants?
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|  |  |  | Yes |  | No  | If yes, please describe:       |

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| 1. Does the data to be collected relate to any illegal activities (e.g., immigration status, drug use, abuse)?
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|  |  | Yes |  | No  |  If yes, please describe:       |
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1. Will human subject data/specimens be used for future research that is not described in the research procedures? (Future use of data/specimens should be disclosed to the participant in the informed consent.)

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|  |  | Yes |  | No If yes, please explain:        |

**Section VII: Confidentiality and Safeguards**

1. Explain provisions to protect the privacy of subjects (if applicable):
2. Participants’ identification (check one):

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Anonymous: the identity of the subject cannot be matched to his/her responses at any time.

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Confidential: participants can be identified but identifying information will be kept confidential.

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Identifiable: participants can be identified and identifying information will be disclosed publicly.

1. Explain how the confidentiality of the data will be maintained by explaining: 1) where data will be stored; 2) any plans to de-identify or anonymize data; and 3) any plans to share identifiable data with personnel not listed on the application. **Note**: *The IRB expects researchers to access the minimal amount of data to conduct the study and comply with HIPAA and the Family Educational Rights and Privacy Act (FERPA):*
2. Data security for storage and transmission:

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| Electronic data: |
|  | Data anonymized by research team so source of data cannot be determined. |
|  | Secure network. |
|  | Password-protected access. |
|  | Encryption of all identifiable data transmitted (e.g., email). |
|  | Encryption of all identifiable data stored electronically. |
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|  | Using subject codes on all collected data with the key linking subject codes with the key to identifiable information stored in a separate location from data. |
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|  | Portable storage (e.g., laptop, flash drive)—private identifiable information stored on portable devices will be encrypted. |
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|  | Other, please describe:       |  |

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| Hard copy data and/or specimens: |
|  | Data anonymized by research team so source of data cannot be determined. |
|  | Locked suite or office.  |
|  | Locked cabinet. |
|  | Using subject codes on all collected data and maintaining the key linking subject codes with identifiable information in a separate location from data.  |
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|  | Other, please describe:       |

1. Secure Disposal: Note: consent forms should be stored for 3 years after study completion.

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| 1. How long will the data be stored?
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|  |       years after study completion |  | Indefinitely |
|  | Data without identifiers stored indefinitely |  | Other, please describe (e.g., sponsor requirements):       |
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| 1. How will data be destroyed?
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|  | Paper will be shredded by:        |
|  | Biological samples will be destroyed by:       |
|  | Destroy electronic files from computer/PDAs/removal media (CDs, diskettes) by:       |
|  | Other, please describe:       |

**Section VIII: Risk and Benefits of Study**

The risks (the probability and magnitude of harm) to participants must be reasonable in relation to any anticipated benefits for participants and the importance of the knowledge you are expecting to gain. When applicable, the research plan must include provisions for monitoring collected data to ensure the safety of subjects.

1. Describe the potential risks (e.g., psychological, legal, physical, social harm, loss of confidentiality):
2. Assessment of level of risk:

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Risks (including physical, emotional, social, legal or financial) are the same as encountered in daily life or during the performance of routine physical or psychological examinations or tests (minimal risk).

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Risks are more than minimal in that either: a) the probability of harm or discomfort anticipated, or b) the magnitude of harm or discomfort anticipated is greater than that encountered in daily life.

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Information to be collected could cause participants to be at risk of criminal or civil liability if responses are disclosed outside of the research setting.

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Information to be collected could be damaging to participant’s financial standing, employability, or reputation if disclosed outside of the research setting.

1. Describe procedures for protecting against, or minimizing, the potential risks; including (where applicable) how collected data will be monitored to protect the privacy and safety of subjects:
2. Describe the potential benefits of the study:

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Describe how participants of the study may directly benefit (compensation is not considered a benefit):

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Describe how society may benefit from the study:

**Please send a single electronic PDF attachment of this application and any accompanying materials (recruitment, consent form, data collection instruments including surveys, or interview questions, etc.) with all relevant CITI certifications for all researchers to** **irb@western.edu****.**

Thank you for taking time to promote ethical human subjects research at Western Colorado University!