**CSUP IRB Application Form**

Submission of a human subjects research project for review by the Colorado State University –Pueblo Institutional Review Board (CSUP IRB) requires the following steps.

Step 1. Determine if your activity requires IRB review and if you are eligible to conduct the project as Principal Investigator (PI). This is determined by completing the questions in Step 1 of the application form and may lead to a variety of outcomes as noted in the process.

Step 2. If IRB review is determined to be required, basic requirements to do so have been met, and the PI is eligible for submission, then the research project must be further described in the application relative to federal human subjects regulations. This step provides the information about the study necessary for the CSUP IRB Chair to classify it for review as either exempt, expedited or full board. Once the IRB Chair establishes the review category the project application is then further reviewed and approved/disapproved by the CSUP IRB procedures, as dictated by the review category. This is accomplished by completing the questions in Step 2 of the application and the required written materials for submission.

Step 3. Once Step 2 is completed, Step 3 involves the electronic submission of the signed research application and the required supporting materials to the IRB Chair by email.

Step 4. The CSUP IRB Chair will then classify the project for review as either Exempt, Expedited or Full Board Review and will proceed to conduct the review. This step may take days to several weeks depending on review classification.

Step 5. The project disposition will then be determined as either: 1) approved, 2) tentatively approved subsequent to minor revisions, 3) in need of major revision for re-review or 4) not approved.

Step 6. Once a project disposition is decided the CSUP IRB chair will send a letter to the PI indicating the project status.

***Note: Humans subject research may only commence once IRB approval is obtained. In addition, human research project approvals are for one year. It is the responsibility of the PI to seek a renewal to extend the project for an additional year, or the project will be considered complete. Completed projects may not be continued. Further, it is the PI’s responsibility to submit any revisions to the project methodology for approval prior to implementing them. Both revisions and renewals are submitted by emailing the CSUP IRB chair directly.***

1. Step One - Preliminary Questions

1. Are you proposing to perform human subjects research?

If this is unclear then please refer to the following OHRP decision making chart and/or contact the CSUP IRB Chair for clarification prior to submitting an application.

<https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c1>

Yes No

***Note: Please note that the definition of human subjects research includes both systematic data collection from humans as well as the intent to generalize the information obtained. If you are not performing human subject research as defined in this way by the Office of Human Research Protections (OHRP) you do not require CSUP IRB review and oversight for your activities.***

2. Have you completed human subjects protection training (most typically CITI training)?

Yes No

***Note: Please note that you will need to submit evidence of your training with your human subjects research application. If you have not completed this training you are not eligible to be a Principal Investigator under CSUP IRB oversight and should not proceed until you have done so. CITI training can be completed for free by registering as a CSUP faculty member or student user at:*** [***https://about.citiprogram.org/en/homepage/***](https://about.citiprogram.org/en/homepage/)

3. Are you affiliated with Colorado State University – Pueblo as a full or part time faculty member, staff member or student?

Yes No

***Note: Please note that CSUP students applying as Principal Investigators must be performing a project to meet final degree completion requirements (dissertation, thesis or undergraduate degree final project) and have a CSU Pueblo faculty member acting as Co-Principal Investigator.***

4. Are you completing research which is independent of any other research project already approved by another IRB?

Yes No

***Note: In some cases researchers are extending a project which has been previously approved by another institution’s IRB. Typical examples are when a CSUP employee completes dissertation or thesis requirements from another school with a CSUP subject population/resources or when a CSUP faculty or staff member wants to contribute to a broader human research project with CSUP as a data collection site. In such cases (if you answer No to this question) you should contact the CSU IRB Chair directly for clarification as to how to proceed.***

5. Have you developed consent forms and recruitment materials for your using subjects using current CSU templates found here: <https://www.research.colostate.edu/ricro/irb/templates/> ?

Yes No

***Note: The development of effective consent forms, which address a myriad of federal, state and institutional requirements, is both complex to develop for PIs and challenging to review for the IRB. The use of our CSU system templates makes this process far more efficient. Please note the need to adjust IRB contact information accordingly. The CSUP IRB contact information is: George Dallam, CSUP IRB Chair, 719-549-2619,*** ***George.Dallam@CSUPueblo.edu***

6. Are you willing to abide by the following definition of misconduct?

Yes No

***Note: Submission of a proposal to the institutional review board for the protection of human subjects requires that the PI sign this application which includes the following definition of “misconduct” and implies that the PI understands the definitions and will not commit acts of misconduct in this research as defined below.***

DEFINITION OF MISCONDUCT

“Misconduct” shall be considered to include the following:

1. Fabrication, falsification, plagiarism of language or concepts, deception or other practices that seriously deviate from those that are commonly accepted within a research community for proposing, conducting or reporting research;

2. Material failure to comply with Federal requirements for protection of researchers, human subjects or the public;

3. Failure to meet other material legal requirements governing research;

4. Failure to comply with established standards regarding author names on publications; or

5. Failure to disclose any conflicts of interest or potential conflicts of interest between the PI (and his/her co-investigators, if any) and the involved funding source or drug or device provider.

The IRB reviews all research involving human subjects, regardless of funding source, to ascertain that the rights and welfare of subjects are being protected. The University’s Assurance with the Department of Health and Human Services applies to all research involving human subjects, whether funded or not. The Assurance specifically states that involvement of human subjects in research will not be permitted until the protocol and informed consent procedures have been approved by the IRB. In addition, the IRB is responsible for assuring that recruitment advertising is not misleading or coercive to the research subject. All projects using human subjects are to be reviewed no less than annually. Anyone who conducts and/or supervises studies or experiments involving human subjects without such approval may be personally responsible for legal or other liabilities that my consequently arise. In addition, the researcher may be subject to disciplinary action by the University. Failure to comply with IRB guidelines or procedures for an approved research protocol or consent form will be cause for immediate suspension of the project and withdrawal of approval.

If you have answered Yes to all of the previous questions you should then proceed to submit a completed research application in Step 2 by answering the following questions. If you answered No to any of the questions you should then proceed as indicated in the ***Notes*** for each.

2. Step Two - Project Description

1. Please list invest5igation title, investigator names and contact information as indicated.

Investigation Title \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Department\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Co-Principal investigator (if applicable)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Additional Co-Investigators (if applicable)

Name Institution

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***Note: The identified Principal Investigator (PI) is normally expected to act as the primary contact with the IRB in regards to the proposed human subjects research project and ultimately carries the primary responsibility for human subject safety in the project.***

2. Are you seeking external funding for the project?

Yes No

If Yes, please indicate the funding source here:

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***Note: Externally funded projects have a variety of requirements regarding IRB review status. Please be sure to clarify compliance within agency/grant requirements and proceed accordingly.***

3. Will your subjects be placed at risk beyond that encountered in their normal lives?

 Yes No

***Note: An individual is considered to be at risk if he/she may be exposed to the possibility of harm-physical, psychological, sociological or other—as a consequence of any activity that goes beyond the application of those established and accepted methods necessary to meet his/her needs. The most obvious examples of placing subjects at risk include the experimental use of medical procedures. There is however a wide range of social and behavioral projects in which, although there may be no immediate physical risk, procedures are introduced which involve discomfort, anxiety, harassment, invasion of privacy, or constitute a threat to the subject’s dignity though the imposition of demeaning of dehumanizing procedures. Finally, the risk element will be examined for those studies dependent upon stored data, or information, which have been obtained for a different purpose. If an activity will expose an individual to risk, then the committee will wish to assure itself that the rights and welfare of the individual are adequately protected, the methods used to obtain informed consent are adequate and appropriate, and the risks to the individual are out-weighed by the importance of the knowledge gained.***

If you answered Yes to this question meaning that your subjects will be at risk (psychologically, emotionally, physically, legally or otherwise), please describe the procedures you will use to manage or mitigate that risk here.

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***Note: Such procedures typically involve the use of informed consent, adequate medical screening and emergency response in the case of physical interventions, and the use of appropriate psychological screening and helping resources in the case of emotional/psychological interventions.***

4. Will you include subjects who are part of a protected class?

Yes No

If Yes which classes will be represented?

Students? Yes No

Minors (under 18)? Yes No

Non-English Speaking? Yes No

Developmentally disabled? Yes No

Incarcerated (prisoners)? Yes No

Native Americans? Yes No

Individuals likely to be engaged in illegal behavior? Yes No

Please indicate here your anticipated minimal sample size.

\_\_\_\_\_\_\_\_\_\_\_\_\_subjects.

If you answered Yes to any of the previous questions, please describe how you will obtain **voluntary** and **informed** consent in a way that is specific to the protections of the class?

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***Note: Your consent/assent language must be submitted with your application and reflect CSU templates found here:*** [***https://www.research.colostate.edu/ricro/irb/templates/***](https://www.research.colostate.edu/ricro/irb/templates/)

***Accessing subject populations associated with other institutions (schools, prisons, Native American tribal groups, workplace employees, etc.) requires that permissions be obtained from those institutions as well. In some cases this process also involves their own institutional IRB or a community IRB as well. Please also consider that sample size impacts the ability to potentially identify a subject using other descriptors such as age, gender, ethnicity, etc.***

5. Will your project involve a descriptive or experimental research design?

Descriptive Experimental

***Note: Comparisons of pre-existing groups which differ on a variable/s do not constitute experimental studies (i.e. comparing people who exercise to people who do not exercise). Experiments occur only when an independent variable is directly manipulated and differences resulting from that manipulation are observed across conditions and/or groups formed for that purpose (i.e. a group is formed who exercise and compared to a group formed that does not exercise).***

Please describe your basic research design (nature of comparisons/groups, basic analytic techniques) and the use of blinding and subject randomization if the design is experimental here:

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***Note: Answer following question 5 or 6 depending on the nature of your design.***

6. If an experimental design will be used which of the following forms of intervention (independent variable manipulation) will be used?

Use of a drug? Yes No

Use of food substances? Yes No

Use of a device? Yes No

Use of physical training? Yes No

Use of mental training? Yes No

Use of visual stimuli? Yes No

Use of deception? Yes No

Use of educational methods? Yes No

Other (please describe) Yes No

If Yes to any of the above please provide a detailed description of how the intervention will be employed?

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***Note: Describe both how the active treatment and any control group placebo/sham to be used will be employed.***

7. If a descriptive design will be used please describe any groupings to be used, the variables to be assessed and measurement procedures you will employ here:

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***Note: If surveys are to be used these must also be submitted with your application. In the case of online surveys please specifically describe the specific software tool to be used as well as whether or not you will employ software modifications to make the survey anonymous versus confidential. Your choice of approach should also be reflected in your consent language.***

8. How will the data be stored and kept confidential and eventually destroyed? Please describe your procedures and time frames here:

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9. Will your subjects benefit directly through participation in your project?

Yes No

If Yes please describe how they will benefit directly?

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***Note: The use of subject participation/completion incentives also potentially increases the opportunity for subject manipulation. If applicable, please address how this will be avoided or minimized.***

10. Will your research contribute to the body of knowledge in your field?

Yes No

If Yes, please describe how here:

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***Note: Please briefly describe how your research will contribute to what is already known or not known in the scientific literature. Please be as concise as possible.***

11. Please describe your subject recruitment process here:

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***Note: Any written materials used for subject recruitment must be submitted with your application. This should also include a script if verbal recruitment is to be used with groups such as classes. You can refer to worksheets for completion of recruitment materials here:*** <https://www.research.colostate.edu/ricro/irb/templates/recruitment/>

12. Optional - If you feel you project should be classified as Exempt for the purpose of IRB review you may indicate your reasoning here:

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***Note: This response is optional as the IRB Chair will proceed to classify your project for review based on your previous responses, whether you choose to provide justification here or not.***

Once you have completed these questions you can proceed to submit your signed application in Step Three. Be sure to include your human subjects training evidence, consent forms, recruitment materials, any required institutional permissions, subject screening materials and any surveys with your application submission.

3. Step Three - Application Completion and Submission

If you have answered yes to all of the previous questions please provide the following information and electronic signatures and then submit your application.

Signatures

I have read the attached DEFINITION OF MISCONDUCT and the requirements for informed consent and will abide by them.

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Signature of Principal Investigator

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Signature of Co-Principal Investigator (as needed for student led projects)

***Note: Submission of a proposal to the institutional review board for the protection of human subjects requires that the PI sign this page which includes the definition of “misconduct” and implies that the PI understands the definitions and will conduct this research in such a manner that acts of misconduct will not be committed.***