Colorado State University-Pueblo

Application to the Institutional Review Board for the Protection of Human Subjects

Section A

Principal Investigator _____

Department _____

PI Phone Number _____

Title of Project _____

If Sponsored agreement, agency to which it will be submitted _____

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

_____ _____

Signature of Principal Investigator | Date

_____ _____

Signature of Co-Investigator | Date

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 following 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.

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 & 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 and withdrawal of approval.

Signature of Principal Investigator	Date

Human subjects are involved in a project if it utilizes data derived from human responses, observations of human beings or human materials, whether such data is obtained directly from the human source or utilizes secondary data.

Are human subjects involved in this project? Yes ◯ No ◯

If the answer to the above is yes, complete the following:

Section B

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 which 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

	Choose One	
1. With respect to the above criteria the human subjects are at risk	Yes ◯	No ◯
2. Students will be used as subjects	Yes ◯	No ◯
3. Experimental drugs will be used	Yes ◯	No ◯
4. Experimental devices will be used	Yes ◯	No ◯
5. Non-English speaking subjects will be used	Yes ◯	No ◯
6. Minors will be used (less than 18 years)	Yes ◯	No ◯

7. Developmentally disabled subjects will be used Yes ◯ No ◯

8. Prisoners and/or incarcerated subjects will be used Yes ◯ No ◯

9. If you have answered YES to any of Section B items 1 through 8, a <u>Consent Form</u> must be included as a part of this application.

a. Please review the information available at: http://ricro.colostate.edu/IRB/forms.htm.

b. Please see the form called "Elements of Consent", and use the form called "Consent Form template" to develop a consent form.

c. Note: Informed consent must be given by either the research subject or by his/her legally authorized representative, such as a parent or guardian.

10. Subjects will be compensated Yes ◯ No ◯

If yes, clarify in what form: _____

11. If you are using one of the protected class subjects (minors, developmentally disabled, prisoners, etc.) how will you insure that they be able to give voluntary and informed consent?

12. Describe the provisions made for any services that may be required as a result of participation of the subject in the experiment?

13. Please explain your process for recruiting subjects and attach any recruitment advertising or recruitment statement you will use.
    a. The advertisement/statement should be limited to:
        i. The name of the investigator
        ii. The general purpose of the study
        iii. The eligibility criteria for participation
        iv. A phone number for further information

14. Describe the following:
    a. Basic procedures or research protocol used on your subjects.
    b. The dependent variable(s) including operational definitions.
    c. The independent variable(s).

THE FOLLOWING TO BE COMPLETED BY THE REVIEWER(s)

Date:_____ **Signature:** _____

Type of IRB review: ◯ **Exempt** ◯ **Expedited** ◯ **Full Board**

Action:

◯ **Approved**

◯ **Approved with revisions**

◯ **Deferred for extensive revisions**

◯ **Disapproved**

Reviewer Comments:

(Please submit your comments below on page 8)

Insert your comments here: