#5720 - This is a test

Protocol Information

Submission Type New

Status

In Progress

General Information Principal Investigator -- search by name, CSU eID, or email address

Please note that Personnel and Department lists include information across the entire CSU System (excluding students). If you cannot find your name or department or need students to access your protocols, please submit a ticket using the VPR Service Desk.

Principal Investigator (start typing the last name or eID on the line below) BRETT-GREEN, BARBARA A Head Unit (CO for Fort Collins and PB for Pueblo) PSYCHOLOGY (PB-P216) Project Title This is a test

People

Additional Protocol Personnel -- search by name, CSU eID, or email address

Please note that Personnel and Department lists include information across the entire CSU System (excluding students). If you cannot find your name or department or need students to access your protocols, please submit a ticket using the VPR Service Desk.

Search for personnel by typing the last name on the line below BRETT-GREEN, BARBARA A Home Unit (CO for Fort Collins and PB for Pueblo) PSYCHOLOGY (PB-P216) Email Address barbara.brettgreen@csupueblo.edu Phone 719-549-2676 **CSU** Status **Researcher Role** Principal Investigator Please identify all the research roles or activities that this individual will have attributed to them: Contact Roles Admin Permissions **Full Access**

Training infoBARBARA BRETT-GREEN has no training courses on file.

COI status Status: Not Disclosed Disposition: No Disposition Personnel Attachments

By Colorado State University (CSU) policy and federal regulations, the Principal Investigator (PI) is the individual responsible for writing an accurate proposal to utilize human subjects, and for designing practices and implementing the approved use(s) of those subjects. Student researchers can be included as Co-Investigators but must list their advisor as the PI. 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.

General Questionnaire CSUP IRB Application Form

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

1. Determine if your activity requires IRB review and if you are eligible to conduct the project as Principal Investigator (PI).

2. If IRB review is required, the research project must be further described in the application submission. The project will be reviewed by the CSUP IRB.

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

4. Once a project is approved or not approved a letter will be forwarded to the PI indicating project status.

Note: Humans subject research may only commence once IRB approval is obtained. Preliminary Questions

Are you proposing to perform human subjects research?

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.

If you are unsure please refer to the OHRP decision making chart and/or contact the CSU Pueblo IRB Chair for clarification prior to submitting an application.

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

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

Please note that you will need to submit evidence of your training in the Person section later in the 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/

Yes

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

Please note that CSU Pueblo students typically cannot be the Principal Investigators and must have a CSU Pueblo faculty member acting as the Principal Investigator.

Yes

Are you proposing an original research project which is **NOT** an extension of a research project already approved by another IRB?

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 as a data collection site. In such cases (if you answer "No" to this question) you should contact the <u>CSUP</u> IRB Chair directly for clarification as to how to proceed.

Yes

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/

The development of effective consent forms which address a myriad of federal, state and institutional requirements is both complex to do as a PI and challenging to review as an IRB. The use of the CSU system templates makes this process far more efficient. Please contact the Pueblo IRB chair <u>Barbara Brett-Green</u> for more information.

Yes

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

Submission of a proposal to the institutional review board for the protection of human subjects requires that the PI certify this application. This 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.

Yes

You have answered "Yes" to all of the previous questions. Press Next and complete the research application.

Project Description

Are you seeking external funding for the project?

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

Which protected classes will be represented in your study?

Will your project involve a descriptive or experimental research design?

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

Will your subjects benefit directly through participation in your project?

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

Please describe your subject recruitment process here:

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

Procedures

List all research activity procedures in which a participant will be involved, including follow-up procedures. Each procedure can be added by clicking "Add Line." Add as many lines with the "Add Line" button as needed and provide details within the popup box for each entry. Once lines are added you can edit the details by clicking on the pencil icon.

Will any of these activities take place regardless of whether you are conducting the study?

Attachments

Be sure to include your humans subjects training evidence, consent forms, recruitment materials, any required institutional permissions, subject screening materials and any surveys with your application submission.

Certification and Submission

Note: Submission of a proposal to the institutional review board for the protection of human subjects requires that the PI certify to the statement below 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.

Administrative Details Form

Determinations Risk Determination Review Type Review Categories

Details

Subpart D: Children Does this study involve drugs Does this study involve devices Study Status

Notes