Cal Poly Pomona - Human Research Protections Program
Institutional Review Board (IRB)
Protocol Approval Application (version: September 25, 2006)

IRB principles: respect for persons, beneficence, justice

Cal Poly Pomona (CPP) is committed both to research in advancement of teaching and science and to the protection of the individuals involved. As part of the assurance filed with regulatory agencies including the Department of Health and Human Services, the University has designated a human subjects' committee, called the Institutional Review Board or IRB, to review proposals for research involving living persons. This application, when submitted to the IRB, is evaluated in terms of its compliance with ethical standards regarding the treatment of subjects. While individual researchers are ultimately responsible for their practices, the IRB's review is designed to provide objective input as additional protection for the subjects. Further, it is of benefit to those who could be held accountable for the research practices – the researchers and the University.

Hints and help:

- This form is electronically protected. Complete it by 'tabbing' through the highlighted sections to enter information (the fields will expand to accommodate; links and spell check will activate by 'unlocking' the document) and responses pertaining to your research proposal. Then print, sign, and mail this front page to the Office of Research and Sponsored Programs (ORSP).
- Submit your completed application to ORSP. Electronically: E-mail the application and attachments such as surveys and recruiting flyers to bkennedy@csupomona.edu. To facilitate tracking, please include in the file name 1) the faculty member's last name and 2) one or two key words describing its subject. Campus mail: send to ORSP, building 1, room 229.
- Training in the conduct of human subject research is critical and investigators must demonstrate their knowledge and awareness through the completion of appropriate coursework. Through 2005, the IRB accepted the NIH on-line course. In early 2006, the IRB adopted the CITI "Course in The Protection of Human Research Subjects" (https://www.citiprogram.org). Please provide documentation of your training; you may be asked to pursue additional training appropriate to your proposal.
- Information about the IRB at CPP is available at the ORSP web page, http://www.csupomona.edu/~research/irb/.
- For other assistance, contact the Compliance Associate within ORSP, Bruce W. Kennedy MS RLATG, at x4215 and bkennedy@csupomona.edu or the IRB Chair, Dr. David Adams, at x3574 and dmadams@csupomona.edu.

Investigator information

Faculty member: Dr. Principal Investigator	Student, as applicable:
Affiliation (college/dept): CLASS, Psychology & Sociology	
Phone contact (office or home or cell):	
Email contact:	
Other investigators, as applicable:	
Title of protocol: Cold Pressor Task	
Date submitted: 11/30/2006 ☒ new ☐ amendment ☐ renewal; previous number:	
Vulnerable subjects? (risks): ☐ minors ☐ pregnant women ☐ medically sensitive ☐ other:	

DECLARATION BY THE RESPONSIBLE INVESTIGATOR(S): This proposal is guided by the ethical principles regarding research involving human subjects as set forth in the Belmont Report. I/We agree to abide by the policies and procedures of the IRB at CPP, including obtaining appropriate training in human subject research for myself and those involved in its conduct. I/We will not initiate any research associated with this proposal on or off campus until authorized by the IRB. I/We will inform the IRB of any adverse events that occur or of a need to modify the study design. I/We understand that approval, when granted, is valid for up to one year and will submit a renewal for its continuation.

	Signature	Date	Training (NIH, CITI, other-specify)
Faculty Member:			CITI
Student(s):			

IRB office use review type: full IRB (risk involved) expedited/designated review (minimum risk/harm) exempt		
Date rc'd:	Assigned to:	Training:
Protocol #:	copies: chair file	Renewal date:

This protocol has been reviewed and approved by the IRB, California State Polytechnic University, Pomona.

David Adams PhD
Chair, IRB

This protocol was approved for conduct by the IRB in late 2006. It is posted as a prototype written up with participant protections for an invasive project.

I. DESCRIPTION OF THE RESEARCH PROJECT

Research is defined as "a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." (45 CFR 46.102(d))

A. Purpose -- State the relationship of the proposed research to previous scientific investigations in the field. What are the objective(s) and goal(s)?

The purpose of this study is to compare responses to pain, induced using a cold pressor task, across four ethnic/racial groups, to identify cultural differences that may relate to the systematic undertreatment of pain among minority clients in medical settings. This is the first of a two-part study. IRB approval of the second part of the study will be submitted next year. The proposed project will explore differences in pain facial expression and self-report to determine whether membership in an ethnic or racial subculture influences: (1) expression and self report of pain; (2) beliefs about appropriate display of pain; and (3) evaluation of observed pain in another person of the same or different subculture. During the first part of the study (described in this IRB request), a cold-pressor task will be used to elicit pain in subjects who will be videotaped during the experience. During the second part of the study, their expressions will later be presented as stimuli to observers. The following healthy groups of male and female university students will be compared: (1) African-American students; (2) Hispanic students (Mexican-American, Mexican and Latin American immigrants); (3) Asian students (Asian-American and Asian immigrants, predominantly Chinese, Vietnamese, Japanese, Korean); (4) European-American students. An additional group of trained health care providers will be compared to untrained students as observers of pain expressions. The cold pressor study will examine whether members of different U.S. subcultures present pain expressions differentiable by their constituent facial movements, whether they rate pain and pain-related anxiety differently on standard measures, and whether they share similar beliefs about the appropriate expression of pain by males and females in their own and other subcultures. The relationship between pain facial expression and self report will also be measured and compared. We hope to better understand reasons for undertreatment of pain in minority clients, and ultimately propose suggestions for improved pain assessment and training of medical personnel.

B. Methods -- Summarize the study design. Describe in detail all procedures to be performed with human subjects. Include when and where the research will occur and who will conduct it.

All subjects will experience the same set of conditions and measures. The independent variable is membership in one of the four ethnic/racial groups tested. Initially, subjects will be asked to visit the restroom and wash their hands thoroughly. Upon their return, they will be screened using self-report demographic questions to ensure that they are members of one of the four groups that are the focus of this study. They will also be asked about medications they may have taken (e.g., Advil or cold medicines) and chronic conditions known to interfere with pain sensitivity (e.g., hypertension) or facial reactivity (e.g., depression). An initial blood pressure reading will be made and baseline facial expression and autonomic response measures will be made with the subject sitting quietly. The cold pressor task consists of the subject placing the right hand up to the wrist or forearm into circulating cold water maintained at a very low temperature (< 5 degrees centigrade). The subject may remove the hand at any time and the duration of exposure to the water is recorded. Subjects will be videorecorded during this task and their autonomic responses (heart rate, change in blood pressure, galvanic skin response on the hand not in the water) will be continuously recorded. These measures are non-invasive and have no effect on the subject's health or well-being. Following the task, subjects will be asked to rate the quality of the discomfort experienced, using the McGill Pain Inventory, and also complete an acculturation survey measuring association with an ethnic subculture, and a pain attitudes questionnaire asking about cultural beliefs about appropriate expression of pain (being developed specifrically for this study). No deception is involved in this study and no results will be made available to subjects (due to lengthy analysis needed). Subjects will be offered the opportunity to review, erase or destroy the videorecording at the end of the session, if they wish. If they state their desire to do so, all data will be deleted immediately. Debriefing will consist of explaining the purpose of the study and answering questions about it.

C. Funding and collaboration -- Is the project associated with any other entity (school, community group, government agency, etc.)? Is it sponsored through a grant? Describe as appropriate.

This cold pressor task is part of the grant-funded project:

D. Students -- Is the project part of a classroom experience or a graduate program? Describe as appropriate.

N/A

II. DATA COLLECTION

Collection methodologies include, but are not limited to: surveys, interviews, focus groups, oral histories, participant observation, observations of public behavior, research in public schools, and the analysis of existing data. Data include: survey sheets and questionnaires, biological samples, audio and video tapes, transcripts, paper and electronic records, previously collected (existing) information, etc.

A. What data will be collected? How will it be identified; will social security numbers be used? What will become of the data at the end of the study (returned, destroyed, archived)?

Data will consist of: (1) videorecordings of the subject during the entire task and associated facial action coding of the period while the hand is in cold water and a suitable baseline period for comparison; (2) measures of autonomic response during the task and baseline period and computer analysis of changes in such measures; (3) self-reported subjective experience during the task using rating scales and invenstoriies; (4) self-reported cultural attitudes measured by acculturation inventories; (5) self-reported pain attitudes measured by a pain attitudes questionnaire, (6) responses to demographic questions and screening questions used to determine eligibility for the study. Each subject's name will appear only on the informed consent form, Experimetrix appointment records (for assigning extra credit to participants), and in a lab journal. A code number will immediately be assigned to each subject and will appear on the informed consent and in the lab log book. The code number will identify all other data and records, including computer files, and the subject's name will never be associated with any data or records beyond those described above. No social security numbers or Bronco IDs will be used. Subjects will be given the opportunity to review videorecordings and immediately erase or delte them if desired. At that point, all data except informed consent forms and the lab journal will be destroyed. Subjects who are screened but do not continue in the study will also be deleted from any data files and no records will be maintained for them except their Experimetrix participation credit and lab journal entry. During the course of this research, access will be limited to those performing data entry or analysis. All data will be stored in the locked lab facilities or in the PI's locked office. Data will be destroyed as soon as possible after completion and publication of the research, consistent with APA mandated rules about keeping data for verification after publication of journal articles. When subjects give specific permission, some facial expressions may be presented as examples in posters, articles, classroom training, or conference presentations. In all cases, specific permission will be obtained for all such anticipated uses. Existence of such prior permission will be checked by looking at the consent forms immediately prior to each use. A subet of subject videorecordings will be used as stimuli during the second part of this study (IRB approval will be sought separately next year). Explicit informed consent for that later intended use will be obtained from subjects and no such use will be made without specific consent.

B. If applicable, have you submitted a copy of the survey or questionnaire to the IRB?

☐ yes ☒ in development comment: There are numerous questionnaires intended for use in this study. All are widely used in the literature except the pain attitudes questionnaire that we are developing. No sensitive questions will be asked about individuals. The questions are focused on what is true in a larger community or what the subject believes about cultural practices, not the subject's own behavior or experience. A copy will be provided as soon as it has been developed, but it is the product of a focus group study that is still in progress.

C. Who will have access to the data? To whom will the raw data be disclosed? How will the data be kept protected and secure?

Data will be stored in locked rooms and files and on password-protected computers. Only the researchers and student research assistants will have access to the data, and only as needed to complete assigned data collection or analysis tasks.

D. Does the research project have provisions or plans for the ongoing monitoring of data collection to ensure safety of subjects? If so, describe the plan.

Written protocols will be developed for conducting data collection. All researchers will be trained to conduct data collection according to protocol. Pilot sessions practicing the established procedures will be observed by the PI and errors will be corrected. Data collection will be video recorded and video sessions will be observed by the PI on an ongoing basis to ensure conformance to established procedures. Problems will be discussed during weekly lab meetings attended by all involved with this project.

E. For studies involving medical records, explain compliance with the HIPAA privacy rule (Health Insurance Portability and Accountability Act) and disclosure of protected health information (PHI). (see http://www.csupomona.edu/~research/irb/Hints_help_examples.htm for the "Experimental subject's bill of rights – Medical research" consent form if invasive procedures are to be performed)

☒ not applicable comment:

III. SUBJECTS

A human subject is a "living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information." (Dept. of Health and Human Services)

A. How many subjects are intended to be involved in the research project?

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B. Briefly describe the subject group(s).

Four groups will be recruited from the Cal Poly Pomona student body: (1) African Americans; (2) Asian Americans and Asian immigrants; (3) Hispanic Americans and Hispanic immigrants; (4) European Americans. Equal numbers of male and female subjects will be recruited within each ethnic group.

C. Will the subjects be compensated? If yes, how (money, gift, cash card, course credit, etc.)?

Subjects will be recruited from the Dept. of Psychology & Sociology human subjects pool via Experimetrix. They will receive course credit or extra credit, if available. No other compensation is planned for most groups. If we encounter difficulty recruiting any particular group, payment of $10 per session may be offered to subjects recruited via flyers on campus.

D. Describe the control and/or comparison group(s), if any.

The four ethnic groups listed above will be compared with each other. Additionally, within subject comparisons between different measures are planned. There is no control group, but individual baseline measures will be used as a control for some comparisons.

IV. VULNERABLE SUBJECTS

When a subject has limitations, is coerced or manipulated, there is a loss of capability to volunteer, and the subject may be vulnerable. Research conducted with vulnerable subjects may require demonstration of training with the population.

A. Minors – Will children, minors, or wards be recruited for this research? If so, explain in what way. How will their assent to participate be obtained? *Children in most circumstances are those less than 18 years of age. Research with children involving no greater than minimal risk requires the permission of one parent and the assent of the child (45 CFR 46.404).*

No children, minors or wards will be recruited for this research.

B. Others – Explain research involving other vulnerable subjects such as prisoners, pregnant women, or culturally or medically vulnerable groups?

No vulnerable groups will be recruited.

V. POTENTIAL RISKS

Risks include legal, social, emotional, or psychological issues, physical or biological hazards, revealing an identity, damage to reputation, exposure of behavior or medical character, illness, injury, etc.

A. Discuss the risks, if any, to the subjects.

No physical, psychological or confidentiality risks are anticipated in this study. The cold pressor task is widely used, especially in behavioral medicine, and is known to present no risks. The PI and a consultant have conducted a cold pressor task in the past, with 84 subjects, without averse incident or difficulties of any kind. The experience of cold is unpleasant but not upsetting, especially since subjects can remove their hand from the water at any time. Questionnaires about demographic information, cultural identity, and rating scales have also been widely used and shown to have no associated risks. The pain attitudes questionnaire being developed does not invite subjects to recall previous pain experiences, but may evoke memories. It is expected that the risks associated with this are no greater than any other stimulus in everyday life that might evoke such memories. They are not the focus of the questionnaire or the task.

B. Discuss your procedures for protecting against or minimizing potential risks.

Equipment that closely controls water temperature (to within .2 degrees C) will be used for immersion of the hand. Subjects will be required to remove the hand from the water after 3 minutes, if they have not already done so voluntarily. Most studies use 5 minutes as the maximum exposure time, so our maximum duration of 3 minutes is well within the commonly used time limit to prevent tissue damage. Further, subjects will be removing their hands whenever they wish and most do so after 1-2 minutes of exposure. The commercial JeioTech refrigerated circulating bath includes safety features to prevent hazard due to spillage or other fault. Subjects will be observed at all times via video camera and the experimenter will intervene immediately if distress or problems occur. Subjects will be reminded at key points in the experiment that they can quit at any time. To protect against evocation of unpleasant memories, subjects will be directed to seek counseling via CAPS if they are upset following the end of the session. Placement of biological sensors will be made so that subjects are not required to remove any clothing (beyond rolling up a sleeve), to prevent embarrassment. All sensors are non-invasive and present no risks to subjects. No individual biological data will be made available to subjects.

C. Are the risks reasonable in relation to the anticipated benefits, if any to the subjects, and the importance of the knowledge that may reasonably be expected to risk confidentiality?

This study has the potential to discover reasons for undertreatment of pain in medical settings. Thus, it can result in improved pain assessment and medication for members of minority groups. Because no risks are anticipated, these benefits far outweigh risks.

D. Describe in detail all procedures to assure the confidentiality or anonymity of subject information. *(See the CPP IRB web page for a discussion of what is confidential and what is anonymous.)*

Confidentiality will be protected by assigning code identifiers to every subject and using only those codes to refer to all data collected. However, because videorecording is part of this study, there is some risk that individuals may be recognized visually. This risk will be part of the informed consent. Specific uses of videorecordings will each be accompanied by a separate consent. The specific uses consented to

will be verified before any use of such recordings. Only researchers affiliated with this study will have access to data for analysis and only group results, not individual results will be presented publically, unless specific consent is given by the subject. Because it is anticipated that the videorecordings obtained in this study will provide stimuli for a later judgment study, subjects in this study will be fully informed of that future use and their explicit consent will be obtained. Subsequent use of videorecordings as stimuli will be submitted to the IRB for approval next year, when that phase of the study is planned. However, such recordings will be treated as confidential in all respects separate from their use as stimuli, and their presentation as stimuli in the planned follow-on study will be strictly limited to the uses required to obtain pain assessment and judgment data. The follow-on task will consist of presentation of individuals experiencing the cold pressor task, followed by ratings of their assessed pain. Those ratings will be compared to the actual self-reported pain ratings of the individuals shown in the video. At no time will any names or other identifying information be presented and all identifying data will be kept confidential, as described above.

VI. RECRUITMENT

As applicable, attach copies of flyers, e-mail text, etc., to be used for the recruitment of subjects in order to facilitate review by the IRB. Include the statement as follows: The Cal Poly Pomona Institutional Review Board has reviewed and approved this research involving human subjects.

Describe procedures for the recruitment of a racially and ethnically representative sample of the population. If this will not be the case, discuss the reasons for not having such a balanced sample, such as the research is focused on a certain subject group.

Ethnic and racial differences are the focus of this study. Four defined ethnic/racial groups will be recruited. Subjects who do not fit these definitions will be excluded because they are not the focus of the research.

VII. INFORMED CONSENT

Complete the accompanying consent form(s) as appropriate.

A. How will informed consent (adults) or assent (children) be obtained and documented*?*

Informed consent will be presented as a written document that is signed by both the subjects and the experimenter. A copy will be kept in our files and another copy will be provided to the subject to keep. In addition asking the subject to read the informed consent, the experimenter will point out key information verbally, to be sure the subject has noticed important information. The subjects will be additionally asked whether they wish to continue at key points during the experiment, such as immediately before the subject is asked to place his or her hand in water, and subjects will be reminded of their right to quit at any time.

B. Will there be recruitment of subjects who cannot themselves provide informed consent? If so, how will informed consent be documented for this population?

No

VIII. TRAINING

Formal training and practical experience in research with human subjects is critical for the protection of the participants and minimization of risk that might be associated with the conduct of the study. Federal regulations require that investigators possess training. The Cal Poly IRB adopted the following policy in early 2006: the on-line CITI program is required for training in human subjects research. All investigators submitting applications to the IRB must complete appropriate modules of CITI as a condition of approval of a protocol. Other formal training will be considered by the IRB on an individual basis. This policy will apply to protocols being renewed as of January 1, 2007.

Describe the training each principal investigator (faculty member, student, and individuals collecting data) on this study possesses. Include when it was obtained and provisions for any additional training relating to this proposal.

A. Faculty member:

CITI, IRB Module

B. Student(s) and others:

IX. CONSENT FORM

The IRB requests the following header on all Cal Poly Pomona approved protocols. It is reproduced on the next page followed by a write-in block for your Informed Consent Form to be included. Alternatively, you can

send it as an attachment, but it must have this informational header.

California State Polytechnic University, Pomona
Informed Consent Form for Research Involving Human Subjects

You are being invited to participate in a research study, which the Cal Poly Pomona Institutional Review Board (IRB) has reviewed and approved. This form is designed to provide you - as a human subject - with information about this study. The Principal Investigator or his/her representative will describe this study to you and answer any of your questions. If you have any questions or complaints about the informed consent process of this research study, please contact the Compliance Office within Cal Poly Pomona's Office of Research and Sponsored Programs at (909) 869-4215.

A properly written Informed Consent Form will include the following elements. Address each when writing your consent and/or assent form.

- A telephone number and/or e-mail address of all primary investigator(s) of this proposal, including faculty members and graduate students, who would be the point(s) of contact for the subjects
- Clarification of the contacts in research projects involving multiple sites
- Title of the protocol
- A statement that the study involves research
- An explanation of the purposes of the research
- The expected duration of the subject's participation
- A description of the procedures to be followed in layman's terms (at the 5th grade reading level)
- Identification of any procedures which are experimental
- A description of any reasonable and foreseeable risks or discomforts to the subject
- Changes of pronoun as appropriate to the subjects
- A description of any benefits to the subject or others which may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments would be available if injury occurs and, if so, what that would consist of or where further information may be obtained
- An explanation of whom to contact for answers to pertinent questions about the research and research subject's right, and whom to contact in the case of a research-related injury to the subject
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled
- Printed name and signature lines for the subject and the primary principal investigators (e.g., faculty member or the graduate student conducting the research)

California State Polytechnic University, Pomona
Informed Consent Form for Research Involving Human Subjects

You are being invited to participate in a research study, which the Cal Poly Pomona Institutional Review Board (IRB) has reviewed and approved. This form is designed to provide you - as a human subject - with information about this study. The Principal Investigator or his/her representative will describe this study to you and answer any of your questions. If you have any questions or complaints about the informed consent process of this research study, please contact the Compliance Office within Cal Poly Pomona's Office of Research and Sponsored Programs at (909) 869-4215.

(Name of PI) and colleagues are conducting a research study exploring the influence of culture on certain emotional and non-emotional states. You have been asked to participate to help us learn more about the expressions and subjective feelings associated with these various phenomena.

If you agree to be in this study, the following will happen:

1. You will be asked to put your hand and arm in a container of cold water. You may remove your hand from the water at any point.

3. Your physical responses (heart rate, blood pressure, skin conductance) will be measured during this task. This will be done using sensors of various kinds placed on the surface of your skin. There is no discomfort associated with such measurement. You may ask to have this stop at any point.

2. Before and after your task, you will be asked to complete some rating scales and questionnaires that include questions about your general background and your reactions to the task. You will also be asked to complete a questionnaire about your cultural background and about the attitudes and beliefs about medical practices held by members of your culture. There is no need for you to recall or describe personal experiences. However, because of the questions asked, such experiences may come to mind. If this would be distressing for you, you may decide not to participate. If you experience unpleasant emotions after participating in this study, the Cal Poly Pomona Counseling Center (869-3220) provides therapists who can help you explore and resolve your feelings.

3. Your session may be videotaped. You may request that taping be stopped at any time and erased.

The experiment will take less than an hour, and you will receive one hour of experimental credit for your participation.

The only risk or discomfort to you is that you may experience an unpleasant sensation while you are putting your hand in cold water. This will be of brief duration and you have the right to stop at any point. No other risks are associated with this study.

There will be no direct benefit to you from these procedures, but the knowledge gained by the investigators may help others in the future.

Participation in research is entirely voluntary. You may refuse to participate or withdraw at anytime without penalty.

Research records will be kept confidential to the extent provided by law. Because the results are analyzed by computer at the end of the study for the entire group, you will not be told your individual results. Although we prefer that you answer all of the questions, you are not required to and may skip questions that you do not wish to answer. Your name will not be associated with any of this information and it will be kept confidential.

You have received a copy of this consent form to keep. You attest that you are 18 years of age (or older) and agree to participate.

_____

Signature Date

_____

Witness Date

Video Recording Release Consent Form

As part of this project, a video recording may be made of you during your participation in this research project. You have the right to stop the video recording at any time and the entire tape or any portion of the tape may be erased at your request. Please indicate below the uses of these videotapes to which you are willing to consent (to do so, write your initials next to each line to which you consent). This is completely voluntary and up to you. In any use of the videotapes, you name will not be identified.

_____1. The videotapes can be studied by the research team for use in the research project.
Initials

_____2. The videotapes can be used for scientific publications.
Initials

_____3. The videotapes can be shown to subjects in other experiments.
Initials

_____4. The videotapes can be shown at meetings of scientists interested in the study
Initials of subjective states (emotion, pain).

_____5. The videotapes can be shown in classrooms to students.
Initials

_____6. The videotapes can be in public presentations to non-scientific groups.
Initials

_____7. The videotape can be used on television and radio.
Initials

You have read the above description and give your consent for the use of videotapes as indicated above.

_____

Signature Date

_____

Witness Date