CALIFORNIA STATE UNIVERSITY, FULLERTON
INSTITUTIONAL REVIEW BOARD

APPLICATION FOR USE OF HUMAN SUBJECTS IN RESEARCH

The aim of the CSUF IRB is to protect the dignity, rights and welfare of human subjects in research conducted by faculty, staff, students and others as required in accordance with the federal regulations (45 CFR 46) and CSUF's University Policy Statement (UPS 420.103). The following information must be provided regardless of funding status. Research in which data are collected through the involvement of human subject participation may not be conducted in the absence of CSUF IRB approval**.**

Your completed application should be submitted along with copies of supporting documents which should include consent forms, surveys, questionnaires, etc.) to the CSUF IRB located in the Office of Grants & Contracts (MH-112.) Determination of how your protocol will be reviewed (e.g., Exempt, Expedited or Full Committee) is made by the CSUF IRB after you have submitted your application. Please also submit a copy of your Certification of Completion of CSUF IRB tutorial. (www.ogc.fullerton.edu/tutorial/humanIntro.asp)

While the CSUF IRB reserves the right to review any protocol at a full committee review, those studies which typically require such review are indicated below. Please visit the CSUF IRB webpage for full committee/submission deadlines and/or additional information as needed at www.ogc.fullerton.edu. When approval is issued, a stamped/approved consent form, if applicable will be returned to you for use in your study. **Please do not collect data until you receive the approval notice and stamped/approved consent form.**

APPLICANT INFORMATION

Principal Investigator:		Phone:		Email:	
Position at CSUF (faculty/student): (if student, please indicate Faculty Advisor below)		Dept.: Campus mail code (or other mailing address if needed):			
CSUF Faculty Advisor:		Dept.:		Email:	
Co-Investigator(s) (if applicable):		Dept.:		Email:	
		Dept.:		Email:	
		Dept.:		Email:	

Project Type: ○ Research ○ Thesis Publication ○ Teaching ○ Class Project ○ Other (specify):

Project Period: From: To:

Location of Research:

Project Title:

FUNDING INFORMATION:

Project is: unfunded ○ funded ○ *(if funded, please complete the following):* ○ to be funded (pending)

Funding Agency Name: 1. 2.

Sponsor program name: *Contract/Grant No. (If applicable):*

Are other institutions involved in this research? (If yes, please identify):		Yes ○ No ○
Has Another IRB reviewed and approved this protocol? (If yes, please identify):		Yes ○ No ○

FOR EVALUATION PURPOSES, PLEASE CHECK ANY OF THE FOLLOWING THAT APPLY TO YOUR PROTOCOL.

☐	Questionnaires or Survey(s) to be Administered	☐	Filming, Video or Audio Recording of Subjects
☐	Review of Data Banks, Archives or Medical Records	☐	Oral History
☐	Subjects Major Language is not English	☐	CSUF Students as Subjects
☐	Subjects to be Studied at CSUF	☐	Subjects to be Studied at Non-CSUF Location(s)
☐	Exclusion of Women or Children Subjects (must explanation reason for exclusion)	☐	Employees as Subjects (CSUF or otherwise)

APPLICATIONS WHICH TYPICALLY REQUIRE FULL COMMITTEE REVIEW ARE INDICATED BELOW.
If you check one or more of the below-listed categories, please submit an original plus 15 copies of this application.

☐	Participants with Disabilities	☐	Protocol is of a Sensitive or Controversial Nature
☐	Children or Minor Subjects (under 18 yrs. Old) – Assent Form Req'd	☐	Exposes Subject to Possibility of Physical or Mental Injury/Harm
☐	Prisoners, Parolees or Incarcerated Subjects	☐	Alcohol, Smoking or Drug Related Participation
☐	Suicidal Questionnaires and/or Evaluations	☐	Involves Attachment of Any Apparatus to the Subjects
☐	Pregnant Subjects	☐	Physical Exercise Studies
☐	Fetal, Placental or Surgical Pathology Tissue(s)	☐	Involves Collection of Blood Samples (fingerpricks/venipuncture)
☐	Involves Deception or Manipulation of Subjects Behavior or Response	☐	Therapist/Client Relationship

FOR CSUF IRB USE ONLY: DATE RECEIVED: IRB APPLICATION NO.:

DATA COLLECTION

Please check category wherein research will be conducted in one or more of the following methods, only:

☐	Normal educational practices in commonly accepted educational settings		
☐	Educational tests (cognitive, diagnostic, aptitude, achievement) – wherein subjects' responses are not manipulated		
☐	Collection or study of existing data, documents, records or specimens		
	Survey, Interview or Observational Procedures (if checked please answer the following):	**YES**	**NO**
	Data will be collected so that responses cannot be identified by persons other than the researcher (either directly or indirectly)	○	○
	Subjects' responses if known outside of research could increase risk of civil/criminal liability or damage subject's financial standing or employability	○	○
	Research involves collection of sensitive aspects of subject's own behavior, such as illegal conduct, drug use, sexual behavior or use of alcohol	○	○

MINIMAL RISK

Does Research Involve More than Minimal Risk to Subjects? If yes, please explain fully in Benefit & Risk section of this application	○	○

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [45 CFR 46.102(i)]

DESCRIPTION OF PROJECT

Please provide complete answers to the following questions as they relate to your use of human subject participants. Avoid the use of jargon, abbreviations or scientific terms, unless those items are defined in your procedures. If applicable, you should include copies of any tests, surveys or questionnaires along with your completed application. Use Additional Sheets for answering, if needed.

Purpose & Significance: Explain the purpose of your research. Include any scientific need or rational as well as significance of knowledge.

Participant Population & Recruitment: Include the number of participants, gender and age(s). Explain rational for any participant exclusion. Describe how potential participants will be identified and recruited. (If applicable, submit copies of recruitment advertisements, flyers, newspaper ads, etc., along with completed application.)

Methods: This description should include instructions given to participants, activities in which subjects will be asked to participate or engage in, special incentives, and experimental procedures.

Benefit & Risk: Have the risks involved been minimized and are they reasonable in relation to the anticipated benefits of research? If more than minimal risk is involved, please explain what additional measures will be taken to ensure participant safety. Explain importance of knowledge that may reasonably be expected regarding risk.

Informed Consent or Assent* (Attach a copy of the consent and/or assent form(s) you will use to obtain informed consent from participants. Describe procedures for obtaining informed consent and answer the following:

a) Who will be obtaining informed consent?
b) When will subjects be asked to participate and sign the consent form (or given the opportunity to agree to consent)?
c) If applicable, how will minors assent be obtained?

Anonymity* & Confidentiality: Describe how either anonymity or confidentiality of subjects will be maintained (Note: if a subject signs a consent form and/or identifiers are obtained by researcher, anonymity cannot be promised. Confidentiality should always be promised "to the extent allowed by law.") For studies involving internet surveys, researcher should clarify how email addresses will be disassociated from submitted responses in order to maintain confidentiality.

Audio/Video Taping: If audio or video taping of subjects is included in your protocol please explain the disposition of the recordings and/or any other pictures or personal documentation collected during and after completion of your data collection. You should state how long these items will be kept, where stored, and a data destruction date, etc.

Compensation: If subjects will be compensated for their participation, provide detailed information about the amount and the method/terms of payment. If non-monetary compensation (e.g., course credit, services) will be offered, explain how it will be provided. If no compensation will be provided, please state such.

Subject Matter: Is the research controversial? Is there a possibility your research will generate public concern? If so, please explain.

Debriefing: If applicable to your protocol, please explain your method for debriefing participants at the end of your data collection. If you do not intend to provide a debriefing please explain.

By signing below I certify that I am knowledgeable and agree to comply with all regulations and policies governing research with human subjects. I have completed the required CSUF IRB Tutorial (and attached a copy of the certification of completion for same to this application.) I acknowledge that I am responsible for requesting any proposed modifications to this protocol for review and approval by the CSUF IRB prior to implementation. I further agree to report any adverse events immediately to the CSUF IRB and to comply with all requests to report on the status of a study if so requested.

(Faculty Advisors hereby also agree to have read and be responsible for guidance and assuring ethical standards during collection of data regarding this protocol).

Principal Investigator (Faculty Researcher or Graduate Student):	Date:
Faculty Advisor (if applicable):	Date:
Co-Investigator (if applicable):	Date:
Co-Investigator (if applicable):	Date:
Co-Investigator (if applicable):	Date:

* Assent is an additional requirement whenever minors are asked to participant as research subjects (i.e., in addition to gaining parental consent, a researcher is required to gain "assent" from participants who are under the age of 18 years old.) Please see the CSUF IRB webpage at www.ogc.fullerton.edu for additional information regarding this requirement.

* A cover letter consent is typically used for survey research wherein researcher in lieu of having potential participants sign a consent form will use a cover letter which states "by completing the attached survey you are agreeing to participate in this research study."

NOTE: DO NOT START DATA COLLECTION UNTIL YOU HAVE RECEIVED APPROVAL AND/OR STAMPED/APPROVED CONSENT FORMS (FOR USE IN YOUR STUDY) FROM THE CSUF IRB. IF REVISIONS OR OTHER INFORMATION ARE NEEDED IN ORDER TO APPROVE YOUR PROTOCOL, YOU WILL BE ADVISED AND GIVEN AN OPPORTUNITY TO SUBMIT ANY REQUESTED ITEMS FOR FURTHER REVIEW TOWARDS APPROVAL. APPROVAL IS NOT OFFICIAL UNTIL YOU ARE IN RECEIPT OF THE CSUF IRB APPROVAL NOTICE, AND APPROVED CONSENT FORMS (IF APPLICABLE) FOR YOUR STUDY.