Institutional Review Board (IRB)
Application for Approval of Human Subjects Research

Please select the type of review* you are requesting:

☐ Exempt (minimal risk) ☐ Expedited (moderate risk) ☐ Full Review (high risk)

**For a description of each category, refer to the IRB Standard Operating Procedures. Please allow up to 30 days for processing Exempt and Expedited requests and 60 days for processing Full Review requests.*

A complete application packet should include all of the following. Submit the packet to arosenberg@saddleback.edu.

1. Application for Approval of Human Subjects Research
2. Bio-sketch
2. IRB Approval from External College/University
3. Recruitment Documents (Letter, Email, Flyer, and any other)
4. Informed Consent Form
5. Instruments (surveys, questionnaires, interview protocol, etc)
6. Evidence of Completion of Human Subjects Ethics Training in the form of a certificate from either the Collaborative Institutional Training Initiative (CITI) or the National Institutes of Health (NIH) Training (for Expedited or Full Review studies)

Part I: Principal Investigator (PI) Information

PI's Name: _____

Email Address: _____

Mailing Address: _____

Title of Research Project: _____

Please select the objective for you study:

☐ Saddleback College Student Project ☐ Personal Academic Interest

☐ Master's Thesis ☐ Grant Requirement

☐ Dissertation ☐ Other (please specify): _____

If conducting a student project, thesis or dissertation, please complete the following:

Name of Advisor: _____

College/University: _____

Department/Course: _____

Degree of Study: _____

Research Start Date: _____

Research End Date: _____

It is the PI's responsibility to secure a sponsor to assist with any human subjects' recruitment. If recruiting, please provide sample recruitment material.

Saddleback College Recruitment Contact: _____

Department: _____ Email Address: _____

For IRB internal purposes.		**IRB #:**	
IRB Contact:		Date Received:	
Date Approved:		Date Expired:	

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Part II: Purpose and Methodology

1. Please describe the purpose of the study.

2. Describe the methodology of the study (or attached a document describing the methodology). Please be specific and include: 1) the anticipated sample size
   2) the age of the targeted group
   3) if a specific ethnic group, institutionalized or protected group will be targeted
   4) if deception will be used
   5) if audio or videotapes will be used in the study
   6) how you will get consent
   7) if you are waiving informed consent
   8) extra costs to subjects for participating (if applicable)
   9) attach copies of grant applications (if applicable)

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3. Please check all the populations you wish to study at Saddleback College:

☐ Administrators ☐ Faculty ☐ Staff ☐ Students ☐ Other:

4. Please check that the **consent form** includes all of the following, as required by federal law (CFR 46.116):

☐ 1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

☐ 2. A description of any reasonably foreseeable risks or discomforts to the subject;

☐ 3. A description of any benefits to the subject or to others which may reasonably be expected from the research;

☐ 4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

☐ 5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

☐ 6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

☐ 7. An explanation to contact Jennifer Klein, Director, Office of Planning Research and Accreditation, at (949)582-4565 for answers to pertinent questions about the research and research subjects' rights, and in the event of a research-related injury to the subject; and

☐ 8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

☐ CHECK HERE IF YOU WISH TO WAIVE INFORMED CONSENT

Describe why you are waiving consent (if applicable): _____

_____

_____

_____

_____

When appropriate, one or more of the following elements of information shall be included in the consent form:

☐ 9. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

☐ 10. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

☐ 11. Any additional costs to the subject that may result from participation in the research;

☐ 12. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

☐ 13. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

☐ 14. The approximate number of subjects involved in the study.

Part III. Confidentiality and Minimizing Risk

5. Please describe how you will address confidentiality issues. Specifically, indicate how you will protect the privacy of participants, store and safeguard data, and the actions you will take if confidentiality is broken by law .

6. If there are any potential risks, describe precautions you will take to minimize any risk to participants.

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Part IV. Benefits of the Study

7. Please describe the potential benefits of this study.

Part V. Acknowledgement of Interim Reporting and/or Continuing Review Requirements

After initial review and approval, the IRB chair has the authority to determine which studies need verification from sources, other than the investigators, that no material changes have occurred since previous IRB review. Sponsor agency generated modifications (or addenda) require review and approval by the IRB or Screening Committee, as appropriate. The investigator is expected to provide all sponsor documentation and summarize how the changes affect the approved protocol, recruitment, enrollment, treatment and follow-up of participants. Progress reports that include reports of protocol violations and/or deviations and any other instances of investigator non-compliance may be requested by the IRB as needed.

Part VI. PI Assurance and Signature

As the PI, I attest that all of the information on this form is accurate, and that every effort has been made to provide the reviewers with complete information related to the nature and procedures to be followed in the research project. Additional forms will be immediately filed with the IRB to report any change in subject(s), selection process, change of PI, adverse incidents, and final completion date of project. I also attest to abide by all government regulations that apply to this study. Upon completing the research study, I agree to submit a copy to the Saddleback College IRB along with the required study Closure Form.

PI Signature Date

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