Stockton University

Institutional Review Board
Documentation of Full Review

Title of Project: _____

Project Director: _____

IRB Reviewer: _____ **Date of Review:** _____

Requested Length of Approval: _____ **Granted Length of Approval:** _____

Does the study include biospecimens or identifiable private information? ☐ yes ☐ no
If yes, approval can be only for 1 year and then every 4 years thereafter. If no, approval can be granted for the length of time requested.

Does this project involve a clinical trial or behavioral health intervention? ☐ yes ☐ no

If yes, has external posting been included? ☐ yes ☐ no

Reviewer decision: ***Approved*** ☐ ***Request Modifications*** ☐ ***Not Approved*** ☐

General Comments:

Have the following issues been addressed adequately: *(you can add notes under each questions, if needed)*

1. Vulnerable populations? Yes ☐ No ☐ NA ☐
Notes:

2. Participant recruitment? Is a recruitment flyer attached if applicable? Yes ☐ No ☐
Notes:

3. Data collection format (survey ☐, questionnaire ☐, archives ☐, recording, etc. ☐ Yes ☐ No ☐
Notes:

4. Participant inducement or payment, if applicable: Yes ☐ No ☐
Notes:

5. Control group, if applicable? Yes ☐ No ☐
Notes:

6. Study design:
   a. Is literature/background adequate? Yes ☐ No ☐
   b. Is methodology adequate? Yes ☐ No ☐
   c. Have surveys, interviews, or other docs been provided? Problems? Yes ☐ No ☐

Reviewers notes:

7.1 Risk – Has risk to the subject been minimized? Yes ☐ No ☐

(i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risks; and (ii) whenever appropriate, by using procedures already being performed on the subjects.

Notes:

7.2 Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. Yes ☐ No ☐

7.3 Selection of subjects is equitable (particularly regarding vulnerable populations: children, prisoners, individuals with impaired decision-making, or economically or educationally disadvantaged persons). Yes ☐ No ☐

7.4 and 7.5 Informed Consent – **Does the ICF**:

• include Stockton/other letterhead?	Yes ☐	No ☐	N/A ☐
• give a brief description of the research topic?	Yes ☐	No ☐	N/A ☐
• discuss alternatives, if appropriate?	Yes ☐	No ☐	N/A ☐
• discuss benefits?	Yes ☐	No ☐	N/A ☐
• discuss compensation?	Yes ☐	No ☐	N/A ☐
• discuss risks?	Yes ☐	No ☐	N/A ☐
• If there are risks, was contact information for an appropriate agency given?	Yes ☐	No ☐	N/A ☐
• discuss any costs that the subject may incur?	Yes ☐	No ☐	N/A ☐
• say that participation is voluntary & remind about ability to withdraw at any time?.	Yes ☐	No ☐	N/A ☐
• say how long the research process will take?	Yes ☐	No ☐	N/A ☐
• give email/phone number of researcher or faculty sponsor?	Yes ☐	No ☐	N/A ☐
• state if the research is confidential or anonymous?	Yes ☐	No ☐	N/A ☐
• have appropriate signature lines or check box?	Yes ☐	No ☐	N/A ☐
• discuss the circumstances under which the subject's participation may be terminated, regardless of consent?	Yes ☐	No ☐	N/A ☐

If the research includes biospecimens:

• does ICF state the period of time for storage (can be infinite)?	Yes ☐	No ☐	N/A ☐
• does the ICF state how clinically relevant results will be shared with participant?	Yes ☐	No ☐	N/A ☐
• if biospecimen sharing will occur, is that noted in the ICF?	Yes ☐	No ☐	N/A ☐
• if sharing will occur, does ICF state who might use it (researchers/institutions, etc.)	Yes ☐	No ☐	N/A ☐
• if sharing will occur, does ICF state if will identifiers be removed?	Yes ☐	No ☐	N/A ☐
• if sharing will occur, does ICF state if additional ICF be gathered (it is not required?	Yes ☐	No ☐	N/A ☐
• if sharing will occur, does ICF state additional notification be given (not required)?.	Yes ☐	No ☐	N/A ☐

Reviewer's Notes:

7.6 When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects. Yes ☐ No ☐

7.7 When appropriate, there are adequate provisions to protect participants' privacy and to maintain the confidentiality of data. Yes ☐ No ☐

7.8 When some or all of the participants are likely to be vulnerable to coercion or undue influence, researchers are required to have additional safeguards in the study to protect the rights and welfare of these participants. If these vulnerable populations are targeted, have safeguards been used?

• Prisoners	Yes ☐	No ☐	N/A ☐
• Children (be sure applicant includes the appropriate assent form)	Yes ☐	No ☐	N/A ☐
• Individuals with impaired decision-making capacity	Yes ☐	No ☐	N/A ☐
• Economically or Educationally disadvantaged persons	Yes ☐	No ☐	N/A ☐