SJSU SAN JOSÉ STATE UNIVERSITY

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SAN JOSE STATE UNIVERSITY
HUMAN SUBJECTS INSTITUTIONAL REVIEW BOARD

IRB Notice of Approval

Date of Approval: 7/1/2021

Study Title: Training Decay Selection for Medical Products Validation Testing

Principal Investigator (PI): Dr. Dan Nathan-Roberts

Other SJSU Team Members: Kelli Sum

SJSU Student(s): Yanshu Gu

Non-SJSU Team Members: Dr. Shannon Clark, Dr. Lana Sneath, Dr. Reggie Moore, Dr. Alyssa Kristedja, Dr. Cristina Tortora, Dr. Ali Decker, Dr. Ariana Perez, Dr. Miles Buroker, Dr. Kaivon Assani

Funding Source: FDA

IRB Protocol Tracking Number: F19089

Type of Review :

☒ Exempt Registration: Category of approval §46.104(d)(3iB)
☐ Expedited Review: Category of approval §46.110(a)(4)
☐ Full Review
☒ Modifications

* Increase sample size (~5%) with new group for one of the tasks (training and immediate testing condition).

* Overall change in configuration of tasks: 5 groups total

Condition 1: training and immediate testing (1 new group),

Condition 2: no immediate testing after training (3 groups),

Condition 3: testing with no training (1group)

* Reduction of time burden to groups.

* Revised compensation amount (reduction in compensation - up to $80 rather than $115).

*Risk mitigation procedure: added sterilization procedures to address safety concerns raised by COVID-19.

* Minor revisions to end of study questionnaire for clarification, wording, removal of questions, and simplification.

* Moved location of study to different room.

* Added new study personnel.

* Clarified First- Visit trial procedure for participants based on feedback from pilot study

* Minor revisions to screener to accommodate above revisions and clarification of wording.

* Minor revisions to consent form to accommodate above revisions and clarification of wording.

☐ Continuing Review

Special Conditions :
☐ Waiver of signed consent approved
☐ Waiver of some or all elements of informed consent approved
☐ Risk determination for device:
☒ Other: Review SJSU's RSCA's Adapt Plan page for info and requirements for conducting in-person research during the current phase of the COVID-19 pandemic. During phase 4 (starting July 1, 2021), submission of a RSCA project plan is not required. However, some record-keeping obligations may apply.

Continuing Review:
☒ Is not required. Principal Investigator must file a status report with the IRB one year from the approval date on this notice to communicate whether the research activity is ongoing. Failure to file a status report will result in closure of the protocol and destruction of the protocol file after three years.

☐ Is required. An annual continuing review renewal application must be submitted to IRB one

year from the approval date on this notice. No human subjects research can occur after this date without continuing review and approval.

IRB Contact Information:
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IRB Chair:
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Institutional Official:
Dr. Mohamed Abousalem
Vice President for Research & Innovation

Primary Investigator Responsibilities:

- Any significant changes to the research must be submitted for review and approval prior to the implementation of the changes. The modification request form is posted on our website.
- Reports of unanticipated problems, injuries, or adverse events involving risks to participants must be submitted to the IRB within seven calendar days of the primary investigator's knowledge of the event. The incident report form is posted on our website.
- If the continuing review section of this notice indicates that continuing review is required, a request for continuing review must be submitted prior to the date the provided.
- Comply with an SJSU IRB or Institutional Official (IO) decision to suspend or withdraw approval for the study

Approval Limitations:

- Although your study has been approved by the IRB, both the IRB and the Institutional Official (IO) for SJSU has the right to audit any approved study and withdraw approval.
- This approval is no longer valid once the SJSU PI is no longer affiliated with SJSU, unless the study is re-assigned to an SJSU-affiliated PI via a modification request.

- SJSU investigators may list external personnel in their applications. However, the SJSU IRB does not assume responsibility for the compliance of external personnel. Instead external personnel should contact their IRB, either to coordinate a reliance agreement with the SJSU IRB as the IRB of record or to have their IRB conduct a separate review for their activities. External personnel who do not have the support of an external IRB and have not established a contract with SJSU should not receive access to individually identifying information about subjects. SJSU investigators are encouraged to be judicious about who they add as part of the study personnel, as responsibility for compliance rests with the SJSU PI in the event that external personal do not have the support of an outside IRB.