1019 39th Ave SE / Suite 120
Puyallup, WA 98374
855-818-2289
www.wcgirb.com

May 20, 2022

Timothy Ken Mackey, MAS, PhD
S-3 Research LLC
6170 Cornerstone Ct. E, Suite 310
San Diego, California 92121

Dear Dr. Mackey:

SUBJECT: IRB EXEMPTION—REGULATORY OPINION
Investigator: Timothy Ken Mackey, MAS, PhD
Sponsor Protocol No.: 1U01FD007558-01
Protocol Title: Co-creation of digital tools to enhance young adult minority participation in COVID- 19 trials

This is in response to your request for an exempt status determination for the above-referenced protocol. WCG IRB's IRB Affairs Department reviewed the study under the Common Rule and applicable guidance.

We believe the study is exempt under 45 CFR § 46.104(d)(2), because the research only includes interactions involving educational tests, survey procedures, interview procedures, or observations of public behavior; and any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

This exemption determination can apply to multiple sites, but it does not apply to any institution that has an institutional policy of requiring an entity other than WCG IRB (such as an internal IRB) to make exemption determinations. WCG IRB cannot provide an exemption that overrides the jurisdiction of a local IRB or other institutional mechanism for determining exemptions. You are responsible for ensuring that each site to which this exemption applies can and will accept WCG IRB's exemption decision.

WCG IRB's determination of an Exemption only applies to US regulations; it does not apply to regulations or determinations for research conducted outside of the US. Please discuss with the local IRB authorities in the country where this activity is taking place to determine if local IRB review is required.

Please note that any future changes to the project may affect its exempt status, and you may want to contact WCG IRB about the effect these changes may have on the exemption status before implementing them. WCG IRB does not impose an expiration date on its IRB exemption determinations.

If you have questions, please contact WCG IRB Regulatory Affairs at 855-818-2289, or e-mail RegulatoryAffairs@wirb.com.

TMM:mr
D2-Exemption-Mackey (05-20-2022)
cc: WCG IRB Accounting
WCG IRB Work Order 1-1549015-1

CALIFORNIA STATE UNIVERSITY, FULLERTON

Office of Research and Sponsored Projects
P.O. Box 6850 or 1121 N. State College Blvd., 2nd Fl., Fullerton, CA 92831 / T 657-278-7719 / F 657-278-7238

APPROVAL NOTICE

From the Institutional Review Board
California State University, Fullerton

April 12, 2022

From: **Dr. Matt Englar-Carlson, Chair**
CSUF Institutional Review Board

To: **PI: Joshua Yang**

Application No. HSR-21-22-309
Study Title: Co-creation of digital tools to enhance young adult minority populations in COVID-19 trials

Re: Initial Exempt Review

The forms you submitted to this office regarding the use of human participants in the above-referenced proposal have been reviewed by the Regulatory Compliance Coordinator and the Chair of the California State University, Fullerton, Institutional Review Board. Your proposal is determined to be Category 2.(ii). Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording).
Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.
.

The CSUF IRB has not evaluated your proposal for scientific merit, except to weigh the risk to the human participants and the aspects of the proposal related to potential risk and benefit. This approval notice does not replace any departmental or additional approvals which may be required.

In addition, all research personnel must follow the institutional safety guidelines outlined for CSUF's Presidential Directive 22. Additional information can be found in the TITANS RETURN: COVID-19 Recovery website.

It is of utmost importance that you strictly adhere to the guidelines for human participants and that you follow the plan/methodology/procedures described in your research proposal. Since your proposed was determined to be exempt, there is no further review or annual renewal required by the CSUF IRB. **However, any change in protocol or consent form procedure requires re-submission to the CSUF IRB for approval prior to implementation**. Additionally, the principal investigator must promptly report, in writing, any unanticipated or adverse events causing risks to research participants or others.

Please be advised that if you are seeking external funding for this proposal, the above-reference title should match exactly with the title submitted to the funding sponsor. Any changes in project title should be submitted to the CSUF IRB prior to implementation.

By copy of this notice, the chair of your department (and/or co-investigator) is reminded that their responsibility for being informed concerning research projects involving human participants in the department, and should review all protocols of such investigations as often as needed to ensure that the project is being conducted in compliance with our institutional policies and with DHHS regulations.

The institution has an Assurance on file with the Office of Human Research Protections. The Assurance Number is FWA00015384.

Cc: IRB Office

ADDITIONAL RESOURCES:

Withdrawal - A withdrawal submission notifies the Research Compliance Office that you no longer wish to submit your initial submission and want to withdraw the study. Withdrawn studies are marked as finalized and can no longer be modified. You may create a withdrawal submission at any point once an initial submission has been created, until it has been approved. If the initial submission had been approved, you must create a closure submission in order to close the study if you no longer wish to conduct the research. For additional guidance, access the step-by-step instructions for Cayuse IRB: Submitting a Withdrawal Notification.

Modification - If you wish to change any of the details of the study after it has been approved, you must submit a modification which must be approved before you can proceed with the changes. Modifications will only be available after initial approval is issued. Modifications will be linked with the initial application and you will make revisions to the initial application based on the modifications you are requesting. For additional guidance, access the step-by-step instructions for Cayuse IRB: Submitting a Modification.

Renewal - When a study is nearing its expiration date, you must submit a renewal request in order to continue with the research. Expiration notices will be emailed from Cayuse. Renewals, like modifications, will only be available after initial approval is issued. For additional guidance, access the step-by-step instructions for Cayuse IRB: Submitting a Renewal.

Incident - You must submit an incident report to inform the IRB Office of any adverse incidents, as required by your

institution. Incident reports may be submitted at any time after a study has been approved, including after it has been closed. More than one incident report may be created for a given study, as needed. For additional guidance, access the step-by-step instructions for Cayuse IRB: Submitting an Incident Report.

Closure - A closure submission indicates that the research is complete and will not be continuing. Closed studies are marked as finalized and can no longer be modified. For additional guidance, access the step-by-step instructions for Cayuse IRB: Submitting a Closure Request.