Human Subjects Institutional Review Board (HSIRB) Meeting Minutes Spring I 2024 February 9, 2024

In attendance:

Scientific Concerns: Jessica Williamson (Vice Chair),
Brittany Sanchez, Isabel Sumaya (Alternate: RERC), Marianne Wilson, (RER),
Chandra Commuri, Zach Zenko, (Alternate)
Non-Scientific Concerns: Christopher Livingston, John Stark
Nate Olson, (Chair), Aaron Wisman
Community Concerns: Raj Cheshire (left at 11 am), Grant Herndon
Doug Cornell (ITS Representative)
Gwen Parnell (Research Compliance Analyst-GRaSP)
Absent: Stanley Peterson (Prisoner Representative)
Location: Zoom: https://csub.zoom.us/j/87987351169

I. CALL TO ORDER: Chair Olson called the meeting to order at 8:36 am

II. APPROVAL OF MINUTES: Stark motioned to approve the Fall II 2023 minutes and Sanchez seconded (votes: 7-0-0).

III. ANNOUNCEMENTS - None

IV. OLD BUSINESS

A. International Human Subjects Research Discussion- update- Sumaya let the board know that the Mexico research study was approved. Sumaya noted that due diligence was done by the PI and Parnell in terms of local or State regulations.

B. Oral History Policy – The board determined that it would be a good idea to post this on the GRaSP IRB website and send out a campus wide email to let them know that we have a new Oral History policy.

C. Classroom Projects – Checklist in progress (Attachment B) – the board was asked to provide feedback at the next meeting. There was a discussion regarding the collection of data. Sumaya reported that Wilson, Parnell, and she had worked hard to prepare a document to address Dr. Rhonda Dugan's concerns. We now have a 3-page guidance on classroom projects for the board to review and approve. The flowchart has been cleaned up.

D. Follow up on draft version of Data Storage Policy – Update (Attachment C)- Tabled

V. NEW BUSINESS

A. Introduction of Broad Consent Pamphlet – (Attachment D) Specific to Blood Draw and Response from OHRP Regarding altering the Broad Consent ICF – Parnell Updated the board to let them know OHRP said the form can be altered to add more protections. Sumaya asked

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Sanchez and Zenko to edit the University of Michigan as a first draft for the Department of Kinesiology and the collection of specimens.

B. Full Board Review Protocols [3]:

1. Time 8:45 – 9:30 am: IRB Protocol 24-160 - Development of Community Level Adverse Childhood Experiences Scale

PI: Andrea Lopez

Primary Reviewer: Williamson Secondary Reviewer: Stark

After introductions, the PI provided an overview of the project. After a discussion and questions of clarification asked of the PI, the protocol was approved with the conditions. listed below.

- 1. The student research assistant may post recruitment fliers but may not actively engage with students in the recruitment process per the Board. Please revise that in your protocol.
- 2. Add redirects at multiple places in the Qualtrics survey to link to the gift card request in case participants do not want to continue the survey.
- 3. Include the resource pamphlet at the beginning of the survey as well as again at the end of the survey.
- 4. Specify in the protocol that the data will be stored in your CSUB password protected laptop and in the CSUB Box drive.
- 5. Include in questions 24 and 25 of your survey a "do not know" option.
- 6. Note in the consent form that the resources offered for possible adverse events are all free to the public.

Votes: Stark motioned to approve with conditions, Williamson seconded, (9-0-0).

2. Time 9:30 – 10:15 am: IRB Protocol 24-123 Facilitating Meaningful Participation through UDL: A Participatory Action Study in Building School Climate

PI: Scott Raymoure

Faculty Mentor: Michael Szolowicz

Primary Reviewer: Olson Secondary Reviewer: Stark

After introductions, the PI provided an overview of the project. After a discussion and questions of clarification asked of the PI, the protocol was approved with the conditions. listed below.

- 1. Provide permission from the district supervisor or designated authority allowing you to collect data at your school sites. The letter must be on district letterhead and uploaded to the protocol.
- 2. Add Spanish forms of all materials (consent forms, surveys, etc.) for parents.
- 3. You may not use cell phones for recording. You may use your secured laptop. Also, you may use CSUB's Google Forms only. Please revise this in your protocol.

- 4. In Section 3, make the responses about your recruitment consistent in questions 4 and 5 (in 4 it says that you will use Google Forms for registration/recruitment; in question 5, it says only that you will be tabling for recruitment).
- 5. Revise your compensation to snacks and drinks.
- 6. Use documented (signed) consent for students. Add a signature line at the bottom of your consent form.
- 7. Remove the statement that you will ask students who they would like to be in the room for the focus group and revise the protocol to state that you and a staff member will be in all of the focus groups.
- 8. Clarify the number of focus groups as there are different numbers in different places in the protocol.

Votes: Olson motioned to approve with conditions, Stark seconded, (7-0-0).

3. Time 10:25 – 11:25 am: IRB Protocol 24-134 The Inclusion and Experiences of Secondary School Students with Disabilities in Freetown, Sierra Leone

PI: Marie Rogers

Faculty Mentor: Alemseghed Kebede

Primary Reviewer: Commuri Secondary Reviewer: Olson

After introductions, the PI provided an overview of the project. After a discussion and questions of clarification asked of the PI, the protocol was disapproved, based on the cost benefit analysis. A follow-up email will be sent to the PI listing some of the major issues of the protocol and recommending submission of a new protocol.

Votes: Commuri motioned to disapprove, Stark seconded, and Zenko abstained (7-1-2).

VI. Formal Board Affirmations

Exempt [8]

- 1. 24-192 Imposter Phenomenon and Misogyny: Anne Duran, Principal Investigator
- 2. 24-226 Politics, Personality, and Attitudes: John Womick, Principal Investigator
- 3. 24-178 Analyzing students' preparedness on analytics skills: Ji Li, Principal Investigator
- 4. 24-145 Personality Survey: John Womick, Principal Investigator
- 5. 24-228 National College Health Assessment 2024: Lauren Hedlund, Principal Investigator
- 6. 24-183 Re-Centering Literacy in Content Specific Classrooms: Shaylyn Marks, Principal Investigator
- 7. 24-222 Relationship Between Past High School PE Teacher Behaviors and Young Adult Physical Activity Predictors: Miranda Miller, Principal Investigator
- 8. 24-163 Healthcare Beyond Borders: A Comprehensive Analysis of Medical Tourism and Patient Perception: Baleria Silva Ruiz, Principal Investigator

Votes: Livingston motioned, Commuri seconded, Zenko abstained, (8-1-0)

Modifications [8]

- 1. 24-209 Leader workaholism and employees' work and non-work outcomes: Sunjin Pak, Principal Investigator
- 2. 24-242 Chronic Cannabis Usage and Vascular Health in Health Young Population: Jahyun Kim, Principal Investigator
- 3. 24-116 Urge to Stop or Continue Scale Initial Validation: Zachary Zenko, Principal Investigator
- 4. 24-228 National College Health Assessment 202: Lauren Hedlund, Principal Investigator
- 5. 24-110 Predicting long-term exercise adherence based on fatigue, perceived exertion: pleasure, enjoyment, and arousal: An exploratory sequential mixed methods study Stephanie Durra, Principal Investigator
- 6. 24-70 Job Satisfaction Among Special Educators: Matthew Kabel, Principal Investigator
- 7. 24-242 Chronic Cannabis Usage and Vascular Health in Health Young Population: Jahyun Kim, Principal Investigator
- 8. 24-98 The Effects of Music on Fatigue, Affect, and Recovery from Exercise: Ainsley Nommensen, Principal Investigator

Votes: Stark motioned, Cheshire seconded, Zenko abstained, (6-1-0)

Renewals [2]

- 1. 23-173 The Effect of Exercise on Cognitive Function in Pre and Postnatal People: Daniela Mazal, Principal Investigator
- 2. 07-91 Evaluation for Kern County Children and Families (KCCFC)07-91: Jianjun Wang, Principal Investigator
- 3. 22-187 Repeated remote ischemic preconditioning and arterial stiffness in young healthy: prehypertensive population. Jahyun Kim, Principal Investigator
- 4. 23-2 Affect-Exercise Moderators: Zachary Zenko, Principal Investigator

Votes: Olson motioned, Livingston seconded, Zenko abstained, (6-1-0)

Closures [1]

1. 24-6 Program Evaluation of Pediatric Palliative Care Services for Medical Beneficiaries. Cassandra Estrella, Principal Investigator

Votes: Sanchez motioned, and Livingston seconded, (8-0-0)

VII. Adjournment: 12:05 pm

VIII. Training:

A. International Human Subjects Research - Dr. Sumaya would like all members to read IRB Protocol 24-134, Rogers/Kebede, our first protocol involving international HS research.

B. As recommended by Stark at the last meeting, Parnell added a text box for space to add a justification for Waiver of Informed Consent in the Cayuse IRB protocol in Section 3 at Question 4.2.— (4.2 is displayed if the box above is checked).

C. At the last meeting, Stark asked about the incentives the PI planned to provide to participants and if participant initials would satisfy the IRB and auditors. Please know that Gwen has worked very hard in the past with the CSUB Business Unit to ensure confidentiality of research subjects who are offered compensation for participating in research. We worked together to create a special form (see below) that instructs the PI to only use Research Study Participants codes on the forms that are submitted to BAS/Accounting necessary for IRS purposes. This form is required for projects funded by Federal or State granting agencies. The form is located on the CSUB Campus Forms Webpage. For private funds, it is expected that the research team will take full responsibility to track any participants that earn \$600 in a calendar year which would trigger the need for a 1099 IRS form. Private funds used for research projects are not tracked by the IRB or GRaSP.