Human Subjects Institutional Review Board (HSIRB)

Meeting Minutes Fall II 2022

In attendance:

Scientific Concerns: Jessica Williamson (Vice Chair),

Brittany Sanchez, Isabel Sumaya (Alternate: RERC), Marianne Wilson

Non-Scientific Concerns: Christopher Livingston, John Stark

Community Concerns: Raj Cheshire, Grant Herndon

Chandra Commuri, Nate Olson, (Chair)

Alternate Member: Zack Zenko (Scientific Concerns)

Visitors: Gwen Parnell (RCA-GRaSP), Daniel Mezal, Simran Grewal, Kyle Susa

Special Guest Presenter: Vaso Rahimzadeh, Assistant Professor, Center for Medical Ethics and Health Policy, Baylor College of Medicine

Absent: None

CALL TO ORDER. Chair Commuri called the meeting to order at 8:01 am.

APPROVAL OF MINUTES . The meeting minutes were approved. Stark motioned to approve the minutes; Livingston seconded (8-0-0).

ANNOUNCEMENTS

Senate Meeting/Update. Chair Commuri, Chair Olson, and RERC Sumaya provided and update on the recent meeting with the senate regarding issues of timeliness of reviews as a complaint was brough to the floor of the senate. Data were shared with the senate about the protocol in question showing that the time lag was mostly due to time it sat with the PIs. From the discussion suggestions were made for the HSIB to consider. Suggestions were to post stats on website, post typical review time frames for each type of review on website, send out anonymous IRB satisfaction survey , and post a link on the website for submission of feedback on IRB process.

Alternate Board Member. Sumaya let the committee know that Joseph Florez was willing to serve as an alternate member of the board and recommended the appointment. A vote was taken to support her recommendation. Livingston motioned, and Stark seconded, (8-0-0).

RER Wilson voiced her concern over her negative experiences with PIS during the review process based on a variety of issues. A discussion took place and suggestions were made that might mitigate the lack of knowledge on the part of PIs of what is expected in a protocol. Suggestions were: make instructional videos for navigating the IRB process to post on the website, post examples of strong protocols on website (perhaps we can ask those who have received awards for their protocols for permission to use a good examples).

OLD BUSINESS .

Oral History Policy. Tabled for next meeting.

An inclusionary statement for diversity in research was selected to add to the Cayuse IRB protocol form. Stark motioned, Livingston seconded (7-0-0).

NEW BUSINESS

Provost Annual Report. Sumaya asked the board for any revisions to the 2021-2022 Provost report. No one had comments. It was agreed to allow members one more week to review the document and provide feedback.

Export Control Policy. Tabled for Spring I Meeting.

Updates on Cayuse IRB protocol. Parnell, Wilson, and Sumaya reported working on revising and updating in earnest, meeting weekly to get it done. The plan is to roll out the updated version in the Spring 2023.

FULL BOARD REVIEW PROTOCOLS [2]

23-160- Understanding the Role of Alcohol Use in Indian College Students (Grewal/Susa).

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. Add that you will use pseudonyms when reporting the data.

2. Please add in the protocol under your credentials that you have training in risk assessment and distress, you are a second year counseling student in the graduate program and that have worked in the clinic as a clinician.

3. In the protocol, clarify that only you will conduct the study and that you will not have research assistants.

4. Add in the protocol that you will only seek 4 to 7 participants

5. Add in the protocol that you will instruct the participants that they need to use pseudo names and to the best of their ability not reveal the names of family members if they are talked about in the interview.

6. Include in the protocol that if the participants begin to show discomfort that you will provide info in resources and refer them at the time.

7. Please add in consent form how many credits (hours) they will be receiving in participating in the study.

Votes: Olson motioned to approve, and Stark seconded (6-0-0).

23-173- The Effect of Exercise on Cognitive Function in Pre and Postnatal People, Mazal/Zenko

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. Please include in your protocol, who exactly is supervising the participants.

2. Please add how participants you are hoping to recruit (40: 20 experimental, 20 controls).

3. Please include in the protocol and in the consent form that the first session is required “live’ and that they agree to another 5 live sessions in at least 5 other weeks.

4. Please include in the protocol and in the consent form that if they are in the control group that they will have the option of getting the 12 week class after the study is complete and if they end up wanting to start exercising before the study is over they can drop out of the study to do so.

5. Add asking the participants where they plan to do their exercise. This is just incase of emergency and something happens you will know generally where they might be to contact emergency services.

6. Add in the protocol that there will be another instructor as a substitute for you. Please add the persons name and credentials. They will not have to do the CITI training as they will not be collecting data or recruiting participants.

Votes: Olson motioned to approve, and Stark seconded (6-0-0).

Formal board affirmations of 2 protocols previously tabled:

1. 22-167: Virtual vs In Person Office Hours: Faculty and Student Perspectives, Principal Investigator, Isabel Sumaya. Olson motioned to approve, Stark seconded, Sumaya and Wilson abstained (5-2-0).
2. 21-191: CSUB Art History Department Oral History Project, Principal Investigator, Christopher Livingston. Stark motioned to approve, Wilson seconded, and Livingston abstained (5-1-0).

**FORMAL BOARD AFFIRMATIONS-***tabled for the next meeting (ran out of time)*

Below are the details of the formal board affirmations of protocols previously approved since the last meeting.
Closures [3]
Cooperative Agreements [0]
Exempt from Full Board Review [12]
Expedited [1]
External Investigator Agreements [1]-Disapproved
External Investigator Reliance Agreement [0]
Full Board [1]
Expedited Full [1]
Modifications [12]
Renewals [8]
Section 118 Designation [0]
Third Party Access to Existing Data [0]

**Expedited Full [1]**

**Votes:** Commuri motioned, Livingston seconded (7-0-0)

**Expedited [1]**

**Votes:** Commuri motioned, Livingston seconded (7-0-0)

**Exempt from Full Board Review [13]**

**Initial**

**Votes:** Commuri motioned, Livingston seconded (7-0-0)

**Modifications [12]**

**Votes:** Livingston motioned, Stark seconded (7-0-0)

**Renewals [8]**

**Votes:** Livingston motioned to approve, Stark seconded (6-1-0)

**Closures [3]**

Votes: Olson motioned to approve; Livingston seconded (7-0-0)

**Meeting adjourned at 12:05 am**

**Training:  Broad Consent Presentation Special Guest Speaker- Vaso Rahimzadeh, Assistant Professor, Center for Medical Ethics and Health Policy, Baylor College of Medicine.**