

Human Subjects Institutional Review Board (HSIRB)  
Meeting Minutes Spring II 2023

**In attendance:**

Jessica Williamson (Vice Chair, Scientific Concerns),  
Brittany Sanchez (Scientific Concerns)  
Isabel Sumaya (RERC, Alternate-Scientific Concerns)  
Marianne Wilson (RER, Alternate-Scientific Concerns)  
John Stark (Non-Scientific Concerns)  
Grant Herndon (Community Concerns)  
Chandra Commuri (Scientific Concerns)  
Nate Olson (Chair, Non-Scientific Concerns)  
Zack Zenko (Alternate-Scientific Concerns)  
Gwen Parnell (RCA-GRaSP)

**Absent:**

Raj Cheshire (Community Concerns) & Chris Livingston (Non-Scientific Concerns)

I. CALL TO ORDER

Chair Olson called the meeting to order at 8:02 am.

II. APPROVAL OF MINUTES

The meeting minutes were approved. Williamson motioned, Commuri seconded (6-0-0).

III. ANNOUNCEMENTS

A. The new meeting dates for 2023-2024 were presented to the board.

Semester	Submission Deadline	Meeting Date
2023 Fall I	Friday, September 1, 2023	Friday, September 15, 2023
2023 Fall II	Friday, November 3, 202	Friday, November 17, 2023
2024 Spring I	Friday, January 26, 2024	Friday, February 9, 2024
2024 Spring II	Friday, April 26, 2024	Friday, May 10, 2024

Discussion ensued about adding an additional meeting and moving the Fall II meeting from November to October. There was consensus that an additional meeting would be useful. If it there are not any new protocols to review, then the additional meeting will be utilized for policy development and training. Commuri suggested blocking off at least ½ of the meeting for training purposes to keep our skills sharp. The following changes were made to the meeting dates and deadline for 2023-2024:

Semester	Submission Deadline	Meeting Date
2023 Fall I	Friday, September 1, 2023	Friday, September 15, 2023
2023 Fall II	Friday, October 13, 2023	Friday, October 27, 2023
2023 Fall III	Friday, November 27, 2023	Friday, December 8, 2023
2024 Spring I	Friday, January 26, 2024	Friday, February 9, 2024
2024 Spring II	Friday, April 26, 2024	Friday, May 10, 2024

B. Thank you for your service-T-Shirt. Sumaya encouraged the board members to provide their preferred sizes to Parnell.

#### V. OLD BUSINESS

A. Community Concerns-Prisoner-Olson. Olson reported that Stanley Peterson, who's the director of Project Rebound is interested in serving as the Prisoner Representative on the CSUB HSIRB. Parnell noted the Prisoner Representative must be an official member of the HSIRB and must have the CITI IRB Member training. Sumaya reported the Kraybill prison study project/IRB protocol is on hold as things are still being ironed out. PI Kraybill is working hard to meet the conditions the board prescribed. Stark motioned to approve of the new Prisoner Representative, Commuri seconded, (7-0-0). Sumaya will reach out to Stanley Peterson to discuss service on the board in this capacity.

B. Oral History Policy Update: tabled for the Fall I meeting because Livingston, the lead, was absent.

C. Export Control – Tabled for the Fall I meeting because a campus wide policy is currently being developed and must go through the Academic Senate for approval.

D. Data Storage Policy –Discussion about the use of external drives for data storage was continued from the last meeting. Other CSU IRBs have been moving to only allow data to be stored in school firewall protected cloud storage. Although CSUB Cayuse protocols still allow the option of using flash drives, it has been questioned except when absolutely necessary. Discussion ensued about the level of security and how PIs would be instructed in proper use and security of flash drives. There was quite a bit of discussion about whether password protection would be enough, and whether it might be better to use encryption or ask for the use of flash drives only when necessary, with cloud storage being the default. It was clear in discussion that PIs should clearly state in the protocol if they are using flash drives for data storage and how they are securing the flash drives. The discussion ended with Sumaya stating there appeared to be a consensus on a policy: data encryption plus password protection for external/flash drives and recommend use of CSUB Cloud services where possible. For example, Stark stated that when researchers are collecting data in a remote location where there is no internet, there may be a need for the use of external or flash drives. Olson motioned to approve the policy that flash

drives must have data encryption plus password protection, but that Cloud storage should be recommended where possible. Williamson seconded, (8-0-0).

E. Broad Consent: Parnell sent a template to the board in February 2023. The board voted to review and approve this document at the next meeting. (Attachment B)

#### IV. NEW BUSINESS

A. Case Study Policy (Attachment C) not discussed.

B. Full Board Review Protocols [3]:

➤ **9:00 am**

**IRB Protocol 24-98: The Effects of Music on Fatigue, Affect, and Recovery from Exercise**

Principal Investigator: Ainsley Nommensen & Faculty Sponsor: Zachary 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. Add to the protocol that all research personnel are First Aid trained.
2. Add to protocol the amount that participants will receive as compensation (Amazon Gift Card).
3. Because you are collecting data at two time points, describe how you will link the two together without using names.
4. Add to the protocol that the participants will be prescreened during recruitment for previous knee injuries.
5. Please include a copy of the recruitment flyer.
6. In the protocol briefly define muscular fatigue and how it relates to your study.

Votes: Wilson motioned, Commuri seconded, and Zenko abstained, (6-1-0)

➤ **9:45 am**

**IRB Protocol 24-99: The Effect of Mental Fatigue on Endurance Performance**

Principal Investigator: Ashley Sevier & Faculty Sponsor: Zachary 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. In protocol explain how you will get the emails and who will send the email out for you.
2. Add to the protocol the contraindications for HR (ACSM).

Votes: Olson motioned, Sanchez seconded, and Zenko abstained, (7-1-0)

➤ 10:30 am

**IRB Protocol 24-III: The effects of chronic creatine supplementation on cardiovascular function, lower body strength, and fall risk in older adults.**

Principal Investigator: Jahyun Kim

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 to the rational and background the research on the safety of the supplement and how it is widely used and a representation of the data showing the supplement is used in the treatment of diseases (ex. Parkinson's Disease, Huntington's Disease, Alzheimer's etc. – so positive effects). Also, add possible problems and side effects.
2. Need to add to the protocol your protocol (in detail) of how you will handle your blood samples and how you will store them.
3. Add to the protocol, in the study procedures, the role each personnel will play being very specific (who is going to draw blood, who is going to do the stop and go test, who is in charge of what). Make sure to include the roles that your co-PIs will play.
4. Add to the consent form the shift to 20mg to 10 mg so that participants will be clear what they should be doing.
5. Add to the protocol and to the consent form (if not already there) how long the sessions will be and how many sessions.
6. Clean up the protocol removing any info about a crossover design since this is not what you are doing.
7. Make clear in the protocol that photos that will be taken will not include their faces - only legs, arms etc.
8. In the data handling section, clarify that you will store the consent forms separately from the data.

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

C. Board Member Re-appointments: Williamson [9/30/2023] & Zenko [8/23/2023].

## V. FORMAL BOARD AFFIRMATIONS

Below are the details of the formal board affirmations of protocols previously approved since the last meeting.

Closures [275]

Cooperative Agreements [0]

Exempt from Full Board Review [63]

Expedited [8]

External Investigator Agreements [0]

External Investigator Reliance Agreement [0]  
Full Board [1]  
Expedited Full [0]  
Modifications [20]  
Renewals [11]  
Section 118 Designation [0]  
Third Party Access to Existing Data [0]

**Expedited Full [1]**

Votes: Olson motioned, Wilson seconded, (7-0-0)

**Expedited [1]**

Votes: Stark motioned, Sanchez seconded, (7-0-0)

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

Votes: Olson motioned, Stark seconded, Wilson and Sanchez abstained, (7-2-0)

**Initial [0]**

Votes: None

**Modifications [12]**

Votes: Stark motioned, Olson seconded, and Zenko abstained, (7-1-0)

**Renewals [8]**

Votes: Livingston motioned to approve, Stark seconded, and Zenko abstained, (6-1-0)

**Closures [3]**

Votes: Williamson motioned, Sumaya seconded, and Zenko abstained, (7-1-0)

**Meeting adjourned at 12:05 am**

Training: None