2022-2023 End Committee Report Form

Committee: Institutional Review Board (IRB)

Chair: Areum Jensen	**Chair-Elect for 2023-2024**: Areum Jensen, areum.jensen@sjsu.edu, 408) 924-8153
Number of Meeting held: 7 (9am-10am on 8/19/22, 9/16/22, 10/21/22. 11/18/22, 02/17/23, 03/17/23, and 05/19/23) **LOCATION: Zoom (Check SJSU calendar invitation) or link** https://sjsu.zoom.us/j/81384879851?pwd=WDljREdWMjdRN2hjc2dZNWxaOHJ5Zz09 Password: 520633	

Items of Business Completed 2022/2023

1. Full reviews of 3 protocols: 2 protocols denied, 1 protocol for resubmission.
2. Extension of continuing review protocols: 4 protocols are passed to be extended.
3. IRB orientation: submission stats, updates, & tips for new reviewers
4. IRB Mentor training: A new online platform for IRB application submission and review.
5. Overview of New Student RSCA Consent form
6. Update on new SJSU policy about cash payments and guidelines for human research subjects.

Unfinished Business Items from 2022/2023

1. One protocol will be resubmitted and reviewed by a full committee during 2023/2024.
2. A new IRB Mentor system is launched in June 2023. Training for reviewers will be continued for new IRB members.

New Business Items for 2023/2024

1. Continuing IRB Mentor training for new IRB members.
2. Full reviews
3. Extension of continuing review protocols
4. Discussion on use of SJSU Students in classroom as human research participants

Please return to the Office of the Academic Senate (CLK 500/0024) by July 1, 2023.

IRB Convened Committee Meeting Minutes

Date/Time: May 20, 2022 via Zoom
Attendees: Danielle Mead, Bernd Becker, Josh Nelson, Sabrina Pinnell, Jeanne Rivard, Priya Raman (Chair), Alena Filip (IRB Analyst)

1. APPROVAL OF MINUTES FROM 2/18/2022 MEETING

A quorum was not present and a vote could not be held.

2. ACTION TO EXTEND EXPIRATION DATES OF PROTOCOLS F17113, F19054, 21143

These protocols are subject to continuing review because they involve DXA scans and cannot be reviewed under the expedited category. The continuing reviews for these protocols all happened on different meeting dates last year. Because the protocols all belong to the same PI and because the PI has another recently approved protocol (21168) that expires on 11/19, an action is requested to extend the expiration dates for all three studies so that they coincide. This will alleviate administrative burden on the IRB and allow the IRB to meet once to do a continuing review of all four of the PI's studies at the same meeting.

A quorum was not present and a vote could not be held.

THANK YOU TO PRIYA AND ALL IRB MEMBERS FOR THEIR SERVICE. HAVE A GREAT SUMMER.

Meeting adjourned at 10:20am

Minutes prepared by Alena Filip

IRB Convened Committee Meeting Minutes

Date/Time: September 16th, 2022 at 9am via Zoom

IRB Attendees: Areum Jensen (IRB Chair), Craig Cisar, Elisa Mattarelli, Danielle Mead, Emily Slusser, Bernd Becker, Josh Nelson, Bryce Westlake, Sabrina Pinnell, Ehsan Khatami, Edith Kinney, Lily Huang (Community Member/NS)

IRB Guests: Jessica Trask (Director of Research Compliance), Marie Haverfield

Number of voting members needed for quorum: 7 (There are currently 13 members on the roster, not counting the alternate community member; the Compliance Director is not counted as a voting member).

1. **INTRODUCTIONS**
2. **PROTOCOLS UNDER REVIEW**

Protocol 22104 "Communicating Resilience: Serial Arguments in the Romantic Relationships of Adult Children of Parents Who Harmfully Consume Alcohol"

Protocol 22200 "Dialogue and Nonviolent Communication: An Empathic Approach to Conflict within Romantic Relationships"

3. **Q&A WITH RESEARCH TEAM MEMBERS**

Dr. Marie Haverfield joined the meeting from 9:03 to 9:30

4. **PRIMARY REVIEWER OR IRB CHAIR SUMMARY OF PROTOCOLS UNDER REVIEW**

The primary reviewer who selected the full review or IRB chair presents a summary of the purpose of the research, type of subjects, and methods of the research protocols under review. The following key information should also be summarized by the primary reviewer:

- **Investigator qualifications** – is the investigator qualified? Are there any conflicts of interest?

Protocol 22104

While the faculty mentor has some experience with research involving this population, the students who will be conducting the study and, more importantly, coordinating the discussions and conducting the de-brief at the end, are not only not trained counselors, but have received no training in the management or de-escalation of interpersonal conflict.

Protocol 22200

The students have not had any experience with coordinating discussions of this type, nor do they have any experience or training in managing or de-escalating conflict.

- **Subject recruitment plan** – who, where, when, how? Is the selection of subjects equitable?

Protocol 22104

No specific issues regarding subject recruitment.

Protocol 22200

The recruitment plan is insufficiently detailed and there is no information on how recruitment materials will be distributed.

- **Conflicts of interest (financial and interpersonal)** – are any conflicts of interest (real or perceived) adequately mitigated?

Protocol 22104

None disclosed

Protocol 22200

None disclosed

- **Informed consent/assent process** – how, where, when? Written or verbal?

Protocol 22104

Written consent will be obtained.

Protocol 22200

Written consent will be obtained.

- **Informed consent/assent document or waiver of documentation or consent** – does the consent document accurately describe the important aspects of the study? Is the consent document likely to be understood by the subjects or guardians? Is the investigator requesting a waiver of documentation or a waiver of some or all of the elements of informed consent? If so, have the criteria allowing those waivers been met?

Protocol 22104

Informed consent does not adequately reflect the potential harms faced by the subjects.

Protocol 22200

Informed consent is not explicit about either the purpose of the research or the specific study aims.

- **Vulnerable populations** – does the study target a vulnerable group that needs additional protection (e.g., children, adults who are not competent to give informed consent, educationally or economically disadvantaged persons, prisoners, and pregnant women)? Is the recruitment of these subjects relevant to the research topic? Is the investigator sensitive to the ethical issues involved with research including vulnerable subjects and is the investigator committed to conducting the research according to the highest ethical standards? Are there any special safeguards?

Protocol 22104

This study includes only individuals over 18 and capable of providing informed consent.

Protocol 22200

This study includes only individuals over 18 and capable of providing informed consent.

- **Data management/oversight** – is the data management plan appropriate? Is the data collection, storage, dissemination, and retention plan reasonable? Does the study design require ongoing monitoring for the purpose of identifying unexpected results that would indicate a need for study revision? Who will perform data oversight?

Protocol 22104

The data management and oversight plan was adequately described.

Protocol 22200

The management of study data was not adequately described. The investigators need to provide additional details on how identifiable data will be physically separated from de-identified data.

- **Confidentiality** – are provisions to protect privacy and confidentiality adequate?

Protocol 22104

The protocol is not clear as to whether the investigators will be using anecdotal data or reporting aggregate data only.

Protocol 22200

The provisions for protecting confidentiality are adequate.

- **Compensation and costs** – if compensation is offered, is it reasonable? Is the investigator sensitive to the issue of coercion and undue influence? Does the study involve increased costs to subjects and, if so, is the increased cost ethical in this situation and adequately explained in the consent document?

Protocol 22104

The compensation is appropriate, given the time commitment and the study procedures.

Protocol 22200

The compensation is appropriate, given the time commitment and the study procedures.

- **Risks** – what are the main risks? Are they minimized by the study design? Are the main risks adequately summarized in the consent document?

Protocol 22104

The risks to subjects of emotional, mental, and physical harm are quite high, and are not minimized in the study document, or are they summarized in the consent document.

Protocol 22200

The risks to subjects of emotional, mental, and physical harm are quite high, and are not minimized in the study document, or are they summarized in the consent document.

- **Potential benefits** – direct vs. indirect.

Protocol 22104

Participation in this research offers the potential for neither direct nor indirect benefit.

Protocol 22200

Participation in this research offers the potential for neither direct nor indirect benefit.

- **Risk/benefit ratio** – are the risks reasonable in relation to the potential benefits?

Protocol 22104

The investigators are specifically selecting from a subject population at greater risk for unhappy non-family relationships, poor coping skills, and experience of dysfunctional home life. The study is designed to provoke conflict and risks emotional, mental, and physical harm to

subjects. In contrast, there are no possible benefits to participation in this study.

Protocol 22200

As written, this study has an unacceptable risk benefit ratio. The study should be redesigned to include additional protections for subjects, and study materials should be expanded to include more detailed instructions for subjects about the goals of the research and how the investigators expect them to approach the selected topic.

- **Summary of unresolved issues or needed revisions by primary reviewer**

Protocol 22104

The students conducting the study are not trained counselors, nor does the study design make any attempt to address potential triggers for uncontrolled conflict between subjects or the fallout of the conversation. A three-minute debrief conversation by the student and a resource sheet does not discharge the investigators of their responsibilities towards the subjects. In addition, the study protocol does not address in any way the fact that the subjects may instead become hostile towards the student investigator.

Protocol 22200

The protocol and study materials are not sufficient for approval in their current form. As this study had no primary reviewer, the unresolved issues and needed revisions are listed in Section 7 below.

- **Recommended vote by primary reviewer or IRB chair**

Protocol 22104

The primary reviewer recommended to move for Deny

Protocol 22200

The IRB chair recommended to move for Not Approve

5. OPEN DISCUSSION OF PROTOCOLS BY FULL COMMITTEE, MEDIATED BY CHAIR.

Protocol 22104

One committee member highlighted the fact that previous research (e.g. Hall and Webster) has identified potential features of the adult children of parents who harmfully consume alcohol as a subject population, including less "resiliency" to life stresses and fewer appropriate coping

mechanisms.

Protocol 22200

The committee's concerns about student preparation and support were similar (including a plan for responding if the conversation becomes heated or violent); however, the proposed subject population in this study does not have the same risk factors as the population being selected in 22104. Committee members felt that someone with training in counseling should be present during the discussions and have the ability to intervene should the risks to subjects become unacceptable. The committee also discussed the consent form and generally felt that it was insufficiently detailed; the subjects must have more information on the purpose of the study and potential risks.

6. VOTE ON PROTOCOLS UNDER REVIEW

Protocol 22104

13 voting members were present during the vote for Protocol # 22104
(7 Members are needed for a quorum).

A motion was made to Deny the protocol and the motion was seconded.

8 voted yes
2 voted no
3 abstained
0 recused

The committee asked that the IRB analyst communicate to the PI and Student that the protocol cannot be resubmitted and any similar future protocols must have both supervision and participation by a Marriage and Family Therapist.

Protocol 22200

13 voting members were present during the vote for Protocol # 22200.
(7 Members are needed for a quorum).

A motion was made to Not Approve the protocol and the motion was seconded.

13 voted yes
0 voted no

0 abstained
0 recused

7. IF CONDITIONALLY APPROVED OR RESUBMIT REQUIRED: IRB CHAIR LISTS/CONFIRMS SUMMARY OF REVISIONS TO BE COMMUNICATED TO RESEARCH TEAM

Protocol 22104

No further resubmit allowed.

Protocol 22200

- Recruiting subjects that are known to the researcher is not an adequate recruitment plan. Provide information on how you intend to identify and recruit additional subjects. For example, a flyer is included in the packet – where will these flyers be posted/distributed?
- The protocol states that recruitment will take place via email, but does not specify who will receive recruitment emails or how the investigators will identify potential subjects to send recruitment emails.
- The study procedures must specifically state where the subjects will be while on Zoom (i.e. both subjects in the same location, or in different locations.)
- The study protocol provides examples of "doing the dishes, time with friends" as topics. Even seemingly neutral topics can provoke strong emotional responses in some couples. The committee recommends that the investigators create a list of topics from which the subjects can choose three that they disagree over, and then the investigators can make the final selection.
- The study protocol should explain the investigator's rationale for how they will select the final topic, to reduce the chance that either subject will become hostile.
- The study protocol needs to provide additional details on how the investigators will instruct the subjects on what is expected of them (e.g. how subjects should address the chosen topic, on what specific aspect(s) of past arguments subjects should reflect, that they are not just having the same argument over again, etc.) in order the additionally reduce the risk of negative outcomes.
- Despite these actions, the subjects may still end up arguing or become hostile towards each other or the investigators. Because the students do not have adequate training in conflict management or de-escalation, the Faculty Mentor should also be present on the Zoom call to intervene if the discussion becomes heated.
- The study protocol needs additional detail on how identifiable data will be kept physically separate from de-identified data.

- While the study protocol says that the couple will be having a “virtual interaction” or “conflict conversation” while the consent form says that they will be “discuss[ing] the topic” or “discuss[ing] a mutual conflict.” Additional guidance is needed in the subject-facing instructions (both written and verbal) and the consent form that the subjects will be reflecting on and talking about the arguments that they have had on this topic, rather than rehashing past arguments.
- The consent form needs to explicitly state that the couples will provide a list of three potential topics and the researchers will select the final topic.
- The consent form needs more detailed information on the purpose of the study other than just “examine features of communication.” The study protocol states that prior to the interview, the investigator will “inform participants about the goals of the study.” That information also needs to be explicitly included in the consent form.
- The consent form needs to more clearly state the risk of conflict and the harms to subjects that may result from that conflict. The consent form also needs to state that the Faculty Mentor will be present during the discussion, and the conditions under which the mentor will intervene or end the discussion.

8. APPROVAL OF MINUTES FROM 8/19/2022 MEETING

12 voting members were present during the vote for the meeting minutes, achieving quorum. A motion was made to approve the 8/19/22 meeting minutes and the motion was seconded.

10 members voted to approve the minutes
2 members abstained.
1 recused

The motion passed and the 8/19/2022 minutes were approved.

Meeting adjourned at 10:06
Minutes prepared by Jessica Trask

IRB Convened Committee Meeting Minutes

Date/Time: May 20, 2022 via Zoom
Attendees: Danielle Mead, Bernd Becker, Josh Nelson, Sabrina Pinnell, Jeanne Rivard, Priya Raman (Chair), Alena Filip (IRB Analyst)

1. APPROVAL OF MINUTES FROM 2/18/2022 MEETING

A quorum was not present and a vote could not be held.

2. ACTION TO EXTEND EXPIRATION DATES OF PROTOCOLS F17113, F19054, 21143

These protocols are subject to continuing review because they involve DXA scans and cannot be reviewed under the expedited category. The continuing reviews for these protocols all happened on different meeting dates last year. Because the protocols all belong to the same PI and because the PI has another recently approved protocol (21168) that expires on 11/19, an action is requested to extend the expiration dates for all three studies so that they coincide. This will alleviate administrative burden on the IRB and allow the IRB to meet once to do a continuing review of all four of the PI's studies at the same meeting.

A quorum was not present and a vote could not be held.

THANK YOU TO PRIYA AND ALL IRB MEMBERS FOR THEIR SERVICE. HAVE A GREAT SUMMER.

Meeting adjourned at 10:20am

Minutes prepared by Alena Filip

IRB Convened Committee Meeting Minutes

Date/Time: March 17, 2023 at 9am via Zoom

IRB Members in Attendance: Areum Jensen (IRB Chair), Craig Cisar, Danielle Mead, Emily Slusser, Bernd Becker, Josh Nelson, Bryce Westlake, Sabrina Pinnell, Ehsan Khatami, Edith Kinney, Julian Vogel, Lily Huang (Community Member/NS), Ikaika Rapanot (Student Member/NS), Alena Filip (IRB Analyst/NS)

Number of voting members needed for quorum: 8

1. DEMO OF REVIEWER PROCESS IN IRB MENTOR

Please read through the user manuals previously provided to you so that you understand the review process on your end as well as the PI end.

Two methods of accessing mentor: 1) signing on via single-sign on (SSO) – the link is appended at the bottom of all notifications sent via Mentor, 2) Free-view link sent to reviewers in email notification upon assignment of protocol for review. Free-view link allows you to focus solely on conducting your review of the assigned protocol. Full access to the Mentor system is not available when accessing a protocol in free-view mode (i.e., you don't have access to other protocols you reviewed or protocol messaging).

1) Intro to reviewer dashboard via SSO:

- Upon login – We are using the Mentor system for both IRB reviews and Conflict of Interest (COI) reviews. COI process is already available via Mentor. Click on IRB to go to the IRB dashboard.

- Most info that you need access either as a PI or a reviewer is under the IRB tab. PIs who are not IRB members only have this tab on their account.
  - If you were creating a protocol as a PI you would go to My Protocols.
  - Under My Student Protocols you would have access to any student protocols that you supervise.
  - CITI Training Certs – we are integrating the CITI system into Mentor. In the meantime, the IRB analyst will check that investigators who are required to complete the training have done so.
  - If you want to see what protocols have been assigned to you as a reviewer, you would go to the Reviewer page. If you want to use a feature like protocol messaging to communicate about the protocol to the analyst or IRB chair, you would have to access

the protocol from this page. Messages have protocol info automatically appended to them.
- The info on the protocol info page is mirrored in both the single sign on version as well as the free-view version.

2) Conducting a review via the free-view link:

- All attached files are listed on the protocol information page; they can also be accessed within the application section where the file upload question appears. Various actions regarding files can be taken by clicking on the context menu next to the file. On the reviewer end, the most useful option will be the Compare to Prior Version option which will provide you with a side-by-side comparison of versions. On the PI end they have additional options such as Replace. (Replacing files does not delete them; the new version is displayed on the protocol info page, with prior versions hidden under a superscript).

- If you want to request revisions to an attached file, the best place to do that is under the file upload question within the application (Click on the Application Sections link)

- You may see various flags and alerts if the IRB analyst has already asked for revisions from the PI before delivering the submission to you. You can add a comment/request for revision on a specific question by clicking on the Reader comments link under each question. By default, your name is hidden from the study team. As well, your comments are not visible to the study team until the administrator makes them visible. I can edit, delete, or chose to not show certain comments. You have the option to display comments to other readers (other reviewers). The admin will enable this option anyway in order to facilitate a secondary or full review.

- Once you have inputted your revision requests, if any, complete your review by clicking on the Review button at the top of the page. This will open the reviewer checklist. Some items to note:
  - General comments are extracted from this page into the request revisions email to the PI. Don't input general comments if you are not making a request for revisions.
  - Internal comments are for the admin.
  - Make sure to indicate your decision on the protocol.
  - Last step, update the review status by selecting "completed." This notifies that admin that you are done with your review. If you forget to do this, the IRB analyst will not know that you have finished your review!

- If you request a resubmit and the revised protocol gets sent back to you, there will be a new button at the top of the protocol information page where a copy of the reviewer checklist that you filled out will be provided for you to edit. The same process to complete the form applies, including the need to update the review status to complete.

- Notice the post-approval tabs at the bottom of the protocol information page. You may be assigned to review a modification (the email notification will alert you to the type of review) and you will be directed to the tab to review the modification request and revised application section. The reviewer checklist in this case will appear as a link next to your name under the modifications tab. It's the same checklist as for initial review and the same process applies.

3) IRB Admin tab via SSO:

- Most items under this tab you are not likely to ever need to access. However, convened meeting agendas, full review protocols, and meeting minutes can be accessed under this tab.
- You will get an email with instructions on how to access the agenda when there is a full review. You also have access to all exempt and expedited reviews that occurred between two meetings. These are as an FYI to the IRB membership and access fulfills a regulatory requirement.
- You can input an IRB member note on full review protocols prior to the meeting. These notes are not shared with the PI unless the IRB analyst extracts them into a request for revisions that have been established as required by the full committee; the notes option is mainly to facilitate discussion where the primary reviewer (who has already provided their comments within the application) presents the protocol and issues to the full committee.
- After the meeting, the administrator will input the discussion notes to generate the meeting minutes. However, shadow minutes in a word document will also be provided to reviewers after the meeting.

2. WELCOME (NEW STUDENT MEMBER) AND INTRODUCTIONS

3. APPROVAL OF MEETING MINUTES FROM 10/21/2022 AND 2/17/2023

13 voting members were present during the vote for the 2/17/23 meeting minutes, achieving quorum.

A motion was made to approve the 2/17/23 meeting minutes and the motion was seconded. 12 members voted to approve the minutes 1 member abstained. The motion passed and the 2/17/23 minutes were approved.

12 voting members were present during the vote for the 10/21/22 meeting minutes, achieving quorum. The chair, whose continuing review protocols were part of the meeting minutes, recused and left the meeting prior to the vote.

A motion was made to approve the 10/21/22 meeting minutes and the motion was seconded. 9 members voted to approve the minutes 3 members abstained. The motion passed and the 10/21/22 minutes were approved.

Meeting adjourned at 9:55am

Minutes prepared by Alena Filip

IRB Convened Committee Meeting Minutes

Date/Time: May 19, 2023 at 9am via Zoom

IRB Members in Attendance: Areum Jensen (IRB Chair), Craig Cisar, Elisa Mattarelli, Danielle Mead, Emily Slusser, Bernd Becker, Josh Nelson, Bryce Westlake, Sabrina Pinnell, Ehsan Khatami, Edith Kinney, Julian Vogel, Lily Huang (Community Member/NS), Alena Filip (IRB Analyst/NS)

Number of voting members needed for a quorum: 8

1. APPROVAL OF MEETING MINUTES FROM 3/17/2023

13 voting members were present during the vote for the 3/17/23 meeting minutes, achieving quorum.

A motion was made to approve the 3/17/23 meeting minutes and the motion was seconded. 12 members voted to approve the minutes, and 1 member abstained. The motion passed and the 3/17/23 minutes were approved.

2. FULL REVIEW PROTOCOL 23104
MEASURING USER PERFORMANCE IN CONTROLLING A LOWER-LIMB EXOSKELETON THROUGH ASSISTIVE HUMAN-ROBOT INTERACTION

The purpose of the study is to assess the effectiveness of a lower limb exoskeleton on both able-bodied participants and then those with spinal cord injuries and post-stroke conditions who are at least 1-year post-injury. Subjects will be asked to take part in weekly 4-hour sessions for twelve weeks during which they will wear the exoskeleton for approximately 3 hours; they will walk using the exoskeleton for 5-6 segments, 30 minutes each.

Investigator qualifications – is the investigator qualified?

The PI is qualified to conduct the study.

Scientific design - Is the scientific design adequate to answer the question(s)?

The PI does not state the scientific design or the type of analyses that will occur in the sections where this is prompted. The lack of an explanation led to confusion among members regarding the purpose of using able-bodied participants and how their involvement relates to the inclusion of participants with neurological conditions.

Subject recruitment plan and inclusions/exclusion criteria– who, where, when, how? Is the selection of subjects equitable?

PI did not explain how the number of subjects was determined and did not provide a clear rational for inclusion of subjects in ether group (the rationale section provides info on inclusion/exclusion criteria but does not explain why the study is being done with those individuals).

Conflicts of interest – are any conflicts of interest (real or perceived) adequately mitigated?

The PI has stated that there are no conflicts of interest.

Risks – what are the main risks? Are they minimized by the study design? Are the main risks adequately summarized in the consent document?

Risk of instability and falling seem to be the principal risks; the protocol includes use of a wheeled walker and presence of two research team members to mitigate this risk. A question was raised regarding whether a medical professional will be on hand if there is a fall.

PI describes the device in the introduction as a "commercial lower limb exoskeleton." If the device is commercially available and will be used in accordance with the labeling, the IRB does not need to document an NSR/SR determination (but the need to conduct the study is also unclear in that case). Later in the protocol, PI marked "yes" to the response regarding whether the device is an investigational device and has confirmed its NSR status.

The IRB is unable to confirm whether a SR/NSR device determination needs to be made. The PI needs to clarify whether the device being used is commercially available and, if so, whether the device will be used according to the labeling or whether it is being used for a new indication or in a new population that deviates from the approved labeling. If the device is not commercially available but is like one in commercial distribution, this should be indicated (the application in Mentor directs the PI to responding to these additional questions).

Potential benefits – direct vs. indirect.

PI has outlined some benefits to participants with neurological conditions (proper gait motion and "improvements in their physical capabilities due to the provided repetitive walking motion"). It is not clear whether these benefits are only available while the exoskeleton is worn or if there are benefits after the exoskeleton is removed. Overall, there seems to be no direct benefits as a result of participation.

Risk/benefit ratio – are the risks reasonable in relation to the potential benefits?

Not evaluated during this meeting – to be determined at a later meeting after a resubmit.

Confidentiality – are provisions to protect privacy and confidentiality adequate?

PI needs to make clear on the consent form what participants' options are regarding the use of video and still pictures in dissemination (this was pointed out during the screening). PI did not explain how participating institutions are involved and whether identifying data will be shared with other institutions.

Data management/oversight – is the data management plan appropriate? Is the data collection, storage, dissemination, and retention plan reasonable?

This was not discussed during the meeting, but no major issues were identified during screening/preliminary review.

Informed consent/assent process – how, where, when? Written or verbal?

PI proposes obtaining written consent when participants arrive at their first session. The consent document should be provided to participants before they come into the lab so that they have time to read it and consider any questions they might want to ask.

Informed consent/assent document or waiver of documentation or consent – does the consent document accurately describe the important aspects of the study? Is the consent document likely to be understood by the subjects or guardians? Is the investigator requesting a waiver of documentation or a waiver of some or all of the elements of informed consent? If so, have the criteria allowing those waivers been met?

The consent form is too technical and lengthy, written for an audience familiar with engineering jargon and not a general audience. It needs to be re-written, simplified, and reduced in length. Edits identified during the screening of the protocol should be addressed. PI should focus on writing at a 6th grade reading level and focusing on the main items that participants would want to know in order to make decision about whether they want to be involved in the study.

PI is not requesting a waiver. The protocol meets the definition of a clinical trial and the final consent form will need to be posted on Clinicaltrials.gov after IRB approval.

Vulnerable populations – No vulnerable populations as defined by the federal regulations are included in the study.

Compensation and costs – No compensation/incentive is listed for participants. The main cost to participants is the time commitment, 48 hours total over the course of 12 weeks. Reviewers commented on the fact that no compensation is being provided to participants for a significant time commitment; it was pointed out that this is an equity issue – subject selection will not be equitable if only a certain demographic of eligible participants can commit the time without any compensation.

Recommended vote: Require resubmit and table to another full review meeting after the resubmitted protocol has been screened and any screening comments have been adequately addressed.

Vote (only if quorum is present)

14 voting members were present during the vote for protocol 23104, achieving quorum. A motion was made to table the protocol to another meeting after a resubmit. The motion was seconded.

13 members voted to table review of the protocol to another meeting after a resubmit

1 member abstained

The motion passed. PI will be asked to resubmit via the Mentor system and will be alerted to the fact that the submission must fulfill any screening requests made by the IRB chair and analyst prior to its inclusion on a future agenda.

Summary of unresolved issues or needed revisions

A full description of revisions is included in the screening comments provided by the IRB analyst and the preliminary review comments of the primary reviewer. A summary of the main items that need to be addressed are:

- Re-write the application so that it focuses on answering the questions and prompts and does not provide extraneous, irrelevant, or redundant information. Places where PI has not responded to the prompt (research summary that states design and analysis; rationale for subject selection; screening approach) need to be addressed
- In addition to clearly stating the research design, clarify the role of abled-bodied participants vs. participants with neurological conditions. Why are able-bodied participants needed? How will their data be compared with or inform procedures with participants with neurological conditions?
- Provide an explanation of screening procedures for eligibility and how the number of subjects was determined.
- Clarify whether the device being used is commercially available and, if so, whether the device will be used according to the labeling or whether it is being used in a new way or in a new population that deviates from the approved labeling. If the device is not commercially available but is similar to one in commercial distribution, this should be indicated (the application Mentor directs the PI to responding to these additional

questions).

- Re-write the consent form and recruitment email for a general audience, and clarify participant options regarding use of recordings in the application and consent form. The consent form needs to be re-written, simplified, and reduced in length. Edits identified during the screening of the protocol should be addressed. PI should focus on writing at a 6th grade reading level and focus on the main items that participants would want to know in order to make decision about whether they want to be involved in the study. Utilize the resources provided by the writing center to help with simplifying the writing.
- Ensure participants get a copy of the consent document prior to coming into the lab (revised consent process section of the application accordingly).
- Ensure that the time commitment, amount of time the exoskeleton will be worn vs. amount of time spent walking in the exoskeleton is consistent across documents.
- To ensure equitable subject selection and acknowledge the significant time commitment, please consider providing an incentive/compensation for participation.

3. A NEW SJSU POLICY ABOUT CASH PAYMENTS AND GUIDELINES FOR HUMAN RESEARCH SUBJECTS

- Link https://blogs.sjsu.edu/abso/2023/03/28/cash-payments-to-research-subjects/
- Guideline https://docs.google.com/document/d/e/2PACX-1vRd4jCVSOJ3K1mpGel-6-74HWE3_5efvpcJY_IiOuk6m3vT39hLWRM6IMWudw2Z_GqASSuoAmvyI2pU/pub

No cash incentives for state funding.

4. UPDATE ON IRB MENTOR PROJECT

Reviewers will start to receive protocols via Mentor over the summer. If you are not available, please let the IRB analyst know. We will check-in in the fall regarding any issues with Mentor.

5. DEPARTURE OF COMMITTEE MEMBERS

Thank you for your service! Drs. Craig Cisar and Sabrina Pinnell!

Meeting adjourned at 10am

Minutes prepared by Alena Filip