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.

September 16th, 2022 at 9am via Zoom

Areum Jensen (IRB Chair), Craig Cisar, Elisa Mattarelli, Danielle Mead, Emily Slusser, Bernd Becker, Josh Nelson, Bryce Westlake, Sabrina Pinnell,

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.

- – who, where, when, how? Is the selection of subjects equitable?

No specific issues regarding subject recruitment.

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

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

None disclosed

None disclosed

- – how, where, when? Written or verbal?

Written consent will be obtained.

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- – 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 provisions for protecting confidentiality are adequate.

- – 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?

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

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

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.

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- – direct vs. indirect.

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

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- – are the risks reasonable in relation to the potential benefits?

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.

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.

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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

mechanisms.

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.

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

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- 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 m

May 20, 2022 via Zoom

Danielle Mead, Bernd Becker, Josh Nelson, Sabrina Pinnell, Jeanne Rivard, Priya Raman (Chair), Alena Filip (IRB Analyst)

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

March 17, 2023 at 9am via Zoom

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)

Please read through the user manuals previously provided to you so that you understand the 18new tafree-viet notification upon assignment of protocol for review. Free-viev conducting your review of the assigned protocol. Full access t available when accessing a protocol in free-view mode (i.e., y protocols you reviewed or protocol messaging).

1) Intro to reviewer dashboard via SSO:

- Upon login – We are using the Mentor system for both Interest (COI) reviews. COI process is already available the IRB dashboard.

- Most info that you need access either as a PI or a revie are not IRB members only have this tab on their accou
  - If you were creating a protocol as a PI you would go t
  - Under My Student Protocols you would have access t supervise.
  - CITI Training Certs – we are integrating the CITI syste the IRB analyst will check that investigators who are re have done so.
  -

- 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.

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

May 19, 2023 at 9am via Zoom

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)

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

Require resubmit and table to another full review meeting after the

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.

- 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.

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.

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

Meeting adjourned at 10am

Minutes prepared by Alena Filip