2017-2018 Year-End Committee Report Form

Committee: Institutional Review Board (IRB)

Chair: Bernd Becker	**Chair-Elect for 2018-2019**: Bernd Becker bernd.becker@sjsu.edu 408-808-2348 Zip -0028
Number of Meeting held: 5	

Items of Business Completed 2017/2018

1. IRB meetings with specific departments struggling with IRB protocols. Helping those departments succeed in writing, submitting, and gaining approval for their research.

2. Policy changes as they relate to IRB membership, recruitment, new HSR policy, and preparing for new federal regulations for human subject research.

3. Completed four (4) Full Committee Reviews of problematic research protocols.

4. Created new documents and templates for protocol submissions and reviewer forms.

Unfinished Business Items from 2017/2018

1. Develop policy or plan to fill seats for Physician, Community Member, and Student. These are federally mandated seats that need to be filled. We started working with O&G in the Spring of 2018 to iron out a plan.

2. The announced changes to the Federal HSR Policy are still being developed at the federal level. The SJSU IRB has begun policy preparation for these changes, but we will not be finished until the federal policies are in place and finalized.

New Business Items for 2018/2019

1. Monitor the changes at the federal level for HSR and create policy that accommodates those changes.

2. Fill seats for Physician, Community member, and Student.

Please return to the Office of the Academic Senate (ADM 176/0024) by May 31, 2018.

IRB Full-Committee Meeting Minutes

Date/Time: 10/20/2017 9:30am
Location: MLK Library, Room 525
Attendees: Bernd Becker (Chair), Gilles Muller, Brandon White, Wendy Quach, Elizabeth Mullen, Craig Cisar, Maureen Smith, Josh Nelson, Amy D'Andrade, Sergio Bejar, Alena Filip, Raul Lomeli (EdD student), Emily Slusser (College of Education Faculty)

0. **Introductions**
1. **Announcements: See #3 below**

2. **Approval of minutes from previous meeting**
   The approval of the 4/21/2017 minutes was tabled until the next meeting to save time.

3. **Continuing education:** A new HSR policy for SJSU has passed through the C&R committee and the first reading by the academic senate will be Monday. Some of the new language in the federal regulations will affect the College of Education:
   - Exemption category 1 (normal educational practices) includes the provision that the research cannot adversely impact students' opportunity to learn or the assessment of educators who provide instruction.
   - Language added to recruitment and consent procedures to minimize undue influence.

   It's not clear when the SJSU policy will be implemented, but the above info has already been provided in previous regulatory guidance.

4. **Protocol review: S17137**
   "From Deficit Ideologies to Critical Consciousness: A Principal/Teacher Led Effort to Shift Instructional and Relational Approaches through Critical Dialogue and Praxis"

Primary Reviewer Outline

Investigator qualifications – Is the investigator qualified? Are there any conflicts of interest?

- The SJSU student investigator is a principal at the school where the proposed research is to be conducted and has participated in Professional Learning Communities (PLCs) before, which makes him qualified to conduct the research.
- A conflict of interest exists because the PI has a supervisory role over prospective subjects, who are teachers at the school. The PI proposes, among other things, to "gather data as to how a principal and teachers can work collaboratively on an initiative aimed at addressing the achievement gap that particularly affects students of color" (section IVc). The protocol mentions potential risks such as "stress due to uncovering hidden racialized practices," (consent form). It's not clear how the PI's obligations as a principal can be ignored if this occurs. The reflective practices proposed to mitigate investigator bias do not change the hierarchical relationship that exists between supervisor and employee.

Subject recruitment plan – Who, where, when, how? Is the selection of subjects equitable?

- PI proposes to recruit teachers via email and meetings.
- The selection of subjects is equitable because all teachers will be invited to participate; however, it's not clear what happens to teachers who want to be in the PLC but not in the research, especially because the PI will be observing the PLC meetings and recording the exchanges (both written and audio recordings). It seems the only way for teachers to opt out of the study is to opt out of participation in the PLC.

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

- The risks stated in the protocol are vague -- "may lead to teachers learning to question and challenge themselves and they will be able to share these challenges in order to ask for support in addressing them."
- The risks stated in the protocol are inconsistent with those stated on the consent form – "low anxiety or stress due to uncovering hidden racialized practices that have maintained the status quo."
- The main risks appear to be **conflict of interest (COI)** and **PI bias**.
  -- **COI** is built into the study design because the PI has a dual role as student investigator and a supervisor of prospective subjects *and* the study proposes to investigate potentially contentious and subjective topics, such as how teachers' ideologies influence their teaching practices and teachers' body language ("I will be particularly looking for capturing teacher verbal, emotional, and facial/physical responses related to the research questions.").
  Q: Is the PI trained to assess physical, emotional, and facial responses?

  --**PI bias** is reflected by presumptuous language in the protocol regarding how participants will respond/feel (e.g., "critical praxis will ensure that all voices are heard and power dynamics are minimized"). The title of the study itself could be interpreted as expressing bias – Is the PI referring to deficit ideology of the teachers?
  Q: How will the PI know that trust and a true sense of shared power has been established when the PI is both the researcher and the principal?

Potential benefits – Direct vs. Indirect.

- Protocol states the direct benefits are "becoming more connected to and building relationships with teachers across multiple grades…may also help teachers develop knowledge and skills in teaching and a higher awareness of institutional structures, racial ideologies, deficit ideologies…"
- The stated benefits may be due to participation in the PLC and not the research.

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

- If the stated benefits are related to participation in the PLC, there are no direct benefits for participating in the research. The benefits do not outweigh the risks in the study as written. However, during the open discussion (see #5 below) IRB members offered some suggestions that could minimize the risk.

Confidentiality – Are provisions to protect privacy and confidentiality adequate?
Not as written.

- The protocol appears to contain a typo "these recordings will **not** be kept on my personal laptop that is password protected…"
- The protocol makes reference to "partial transcriptions" being shared with teachers. It's not clear what this means. It's also not clear who will transcribe the recordings.
- The protocol does not include a retention plan for any identifying info, including the audio recordings.

Data oversight/management – 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? Is the data retention plan reasonable?

- The study does not require ongoing monitoring for unexpected results.

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

- PI proposes to obtain written consent during an informational meeting with interested teachers.
- The consent form is inconsistent with statements made in the protocol, particularly wrt the purpose of the study.
- The consent form is only worded to seek consent for group meetings but not for individual interviews. The consent form also does not explain the PI's intent to capture teacher verbal, emotional, and facial/physical responses.

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?

- PI is not requesting either of the waivers.

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, the mentally disabled, 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?

- The study does not target a vulnerable population as defined by the federal regulations. However, the study does target employees who may be considered vulnerable because of their relationship with the PI.

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?

- No compensation is being offered to study participants.

Other

- The protocol is difficult to understand, containing jargon, undefined acronyms, confusing sentence structure, and extraneous info.
- The mixed methodology study lists numerous methods and theories (critical praxis/Freirean methodologies, phenomenology, testimonies, circulo, grounded theory), some with no clear connection to how they will help answer the research questions and minimize the main risks.
- The protocol makes references to things like student achievement that are mentioned once but never addressed again.
- Comparison protocol S16161 "Professional Learning Communities' Impact on the Digital Use Divide" was approved via an expedited review. The student PI was also a principal at the school and the protocol also involved observations of a PLC. Differences with S17137 include:

  -- Research focused on a technology specific PLC and the protocol was careful not to veer off topic or connect observations to potential student outcomes or teacher ideologies.
  -- Selection of subjects was based on their expertise.
  -- A third party provided a study overview to prospective participants and they could contact the PI if they were interested.
  -- Only research participants were participants of the PLC.
  -- No specific outcome was assumed or expected.

Summary of unresolved issues or needed revisions by primary reviewer

- Dialogic methods to reduce power dynamics in the research context do nothing to reduce teachers' fear of saying no to their principal in the 1st place (promising them it is voluntary is meaningless when the PI is also your immediate boss/supervisor). Additionally, what kind of protection will teachers' have when they hold and admit to 'ideology" or "racialized practices" that the PI views to be problematic? The entire protocol is written in such a way that the PI appears to hold very firm beliefs about culturally respectful practices (CRP), CPL, students of color and educational practices - - not sure the PI is objective and capable of separating his role as PI from his role as Principal.
- The PI repeatedly talks about teacher ideology, perceptions, and racialized practices, how are these measured objectively?

- Consistency between stated research questions and methods is needed.
- Consistency between statements made in the protocol narrative vs. the consent form is needed.
- More info needed in confidentiality section.
- More clarity in the writing is needed.

Recommended vote by primary reviewer: Not Approve

5. Open discussion of protocol by full committee mediated by chair. If investigator is present, include questions for investigator.

- Clarification of terminology from PI. PLC = Professional Learning Community = a kind of professional development activity that provides a forum for teachers and administrators to tackle a problem through a cycle of inquiry that is intended to improve teaching skills and student performance. In the PI's school district, participation in PLCs is required and is considered part of the normal educational practice. Teachers can participate in different PLCs on different topics. The PLC that the PI wishes to study is focused on culturally relevant teaching, is already ongoing, and has teacher buy-in. Facilitation of the discussion is conducted on a rotating basis and not just by the principal/PI.
- Observations vs. Individual Interviews. IRB members did not express concern about the proposed one-on-one interview as long as participants provide consent. The interview questions focus on participants' perceptions of process but not on the subject content of the PLC. IRB members mainly expressed concern with the observations and the role of the PI as a participant-observer at PLC meetings. Members expressed concern about the following:
  -- Lack of clarity and focus on what will be observed (verbal discussion only or body language and behavior?) and how this data would be interpreted.
  -- Data may not be accurate if the participants are inclined to adopt the view points of the PI/principal in order to incur favor.
  -- Lack of clarity on how info from the audio recordings of the meeting could be extracted in a way that only incorporates those who have chosen to participate (e.g., the speaker in the recording would have to be identified), especially if the research seeks to document process and how teachers appropriate new knowledge via interaction. Audio recording the PLCs is also not part of the normal education practice, so the PI would not be able to record the sessions if there were any teachers who do not want to participate in the research.
  -- Protocol alludes to affecting student outcomes, though this is not the topic of the research (it may be a topic of the PLC).
- Does the work meet the federal definition of research? This will depend on whether the PI wants to do a case study that is intended to affect teaching practices at the school only or if the PI wants to make more general conclusions that could be applied in other settings. Conducting the research in other settings would eliminate COI and would mitigate PI's own observer bias. However, this may not be feasible because of the large scope of such a project and because there is no guarantee that the PLC will be on a topic of interest to the PI. The exclusion decision tool -- which allows a student PI (with the support of the faculty supervisor) to document the intent of the activity -- can be used.
- PI vs. Principal obligations. In giving participants the consent form, PI agrees that participation will not affect employment – does this interfere with the principal's ethical and legal obligations? PI

pointed out that he would not be able to terminate an employee were he to uncover racial biases, but the IRB pointed out that such a discovery may influence his interactions and future assessment of the teacher.

- IRB member suggestions to PI:
  -- Have a neutral third party recruit participants.
  -- Only have teachers who have agreed to be research participants participate in the PLC and allow for a non-research PLC.
  -- Have a neutral third party conduct the observations and provide this individual (as well as the IRB) with information that allows the observer to focus on what the PI is interested in learning (e.g., prepare an observation intake sheet or questions that prompt reflection by the group). The info can be de-identified before it is presented to the PI.
  -- Instead of - or in addition to - observations ask teachers to journal about their experiences with the PLC. Ask participants to de-identify their journal or have a third party de-identify it before it is presented to the PI.
  -- Determine whether you want to conduct a study that contributes to generalizable knowledge (see exclusion decision tool at: http://www.sjsu.edu/research/docs/irb-exclusion-worksheet.pdf), and whether you can conduct the study at another institution or are willing to have a third party not affiliated with the PLC document observations. These decisions will determine if a protocol should be submitted and how it will be routed.

6. **Vote (only if quorum is present) – approve, conditionally approve, not approve, abstain, recuse**
   9 voting members were present during the vote, achieving a quorum.
   A motion was made to not approve the protocol as written. 8 members voted to not approve the protocol. 1 member abstained. The motion was passed; the protocol is not approved.

7. **Interval of IRB approval for protocol (if different than one year)**
   N/A

Meeting adjourned 10:30am

Minutes prepared by Alena Filip

IRB Full-Committee Meeting Minutes

Date/Time: 11/17/2017 9:30am
Location: MLK Library, Room 525
IRB Members Present: Bernd Becker (Chair), Gilles Muller, Brandon White, Wendy Quach, Elizabeth Mullen, Craig Cisar, Maureen Smith, Josh Nelson, Sabrina Pinnell, Sergio Bejar, Alena Filip

Guest: Arnold Danzig, Ed.D. Leadership Program Director

1. **Introductions**

2. **Approval of minutes from previous meetings**
   A motion was made and seconded to approve the minutes from 4/21/2017 and 10/20/2017.

3. **Ed.D Director discussion about possible ways to streamline the IRB process and rules of thumb that can be shared with faculty who supervise student investigators.**

4. **Protocol review: Resubmit of S17137 reviewed at 10/20 meeting**

"Critical Dialogue and Praxis at a Dual Immersion School: Understanding How a Professional Learning Community Contributes to Shifting Instructional Practices and School Leadership" (new title)

The student investigator made most of the main revisions recommended by the IRB at the last committee meeting except for the observation procedures. The resubmit proposes that the investigator act as participant observer during the PLC meetings with the following additions:

- Transcriptions of focus group meetings/PLCs: will be reviewed by an EdD student not in the study in order to indicate if there are any possible examples of coercion or inappropriate conversations or behaviors on the part of the principal or teachers.

- A trained researcher who is unaffiliated with the school will attend an initial PLC and observe the role of the Principal and his perceived impact on the discussion, providing feedback and suggestions to the Principal to ensure the integrity of both the PLC and the research.

The observations were the topic of discussion at this meeting.

Primary reviewer outline
Concerns with the plan for a trained observer:
(1) Without some kind of systematic investigation (e.g., asking teachers how they feel), how would the observer know that the PI's presence is impacting the teachers? It is not as if the teachers are going to

be actively saying or making their reactions obvious in a physical way (after all they want to keep their jobs).

(2) If the trained observer is the faculty supervisor or EdD director, then the potential bias that makes them believe this is a viable proposal will kick in and they may not notice (if that is even possible to notice) a problem.

(3) What guarantee do we have that (a) the feedback will be able to address the problem; and (b) that the PI will take it and adjust his behavior?

Summary of unresolved issues from previous review:

- Nature of the observations is still unclear, particularly when PI states that the PLCs will be recorded to allow the principal to focus on observations rather than notetaking – implying that something more than what is being discussed is the aim of the observations.
- The PI mentions (section IVc) that participants will have opportunities to provide anonymous feedback, but this is not clarified in the methods and procedures.
- Consent form still does not mention individual interviews in the procedures section.

Open discussion by full committee

Vote (if quorum is present) –approve, conditionally approve, not approve, abstain, recuse

5. New SJSU HSR Policy

The new SJSU HSR policy was passed by the academic senate and approved by the president on 11/2.
http://www.sjsu.edu/senate/docs/F17-1.pdf

6. New IRB Application

The application and protocol narrative have been consolidated into one document, and the changes required by the new HSR policy as well as the revised language and organization as discussed in our meetings last spring have been implemented.

Meeting adjourned 10:30am

Minutes prepared by Alena Filip

IRB Full-Committee Meeting Minutes

Date/Time: 12/15/2017 9:30am
Location: MLK Library, Room 525
IRB Members Present: Bernd Becker (Chair), Amy D'Andrade, Brandon White, Elizabeth Mullen, Craig Cisar, Maureen Smith, Josh Nelson, Anand Ramasubramanian, Edith Kinney, Alena Filip

1. **Approval of minutes from previous meetings**
   8 voting members were present, creating a quorum.
   A motion was made and seconded to approve the minutes from 11/17/2017.
   6 voting members approved, 2 abstained. The 4/17/2017 minutes were approved.

2. **New SJSU HSR Policy**
   The new SJSU HSR policy was passed by the academic senate and approved by the president on 11/2/2017: http://www.sjsu.edu/senate/docs/F17-1.pdf

   Summary of Revisions to HSR Policy

   - New exemption categories (e.g., benign behavioral interventions), clarification to existing categories, clarification on how new exemptions apply to vulnerable groups (see Table of Exemption Categories in policy link above).
   - Exemption categories apply to vulnerable groups in the same way as the federal regulations – previous SJSU policy was more restrictive.
   - Continue to apply more stringent consent requirements than the federal regulations for exempt research – most exempt research will only require a consent notice as opposed to a signed consent form, except when the subjects are minors or when the research is subject to other laws (e.g., FERPA) that require written consent.
   - No parental permission is required for college students under the age of 18 participating in school-based research.
   - SJSU has chosen not to adopt the broad consent provisions and accompanying exemption categories outlined in the federal regulations (which enables the creation of databases that are primarily of interest to biomedical research).
   - Consent documents must make sense to the target population and the consent process must be comprehensible to prospective subjects; this includes minimization of situations that may cause undue influence or present a conflict of interest.
   - Assent (verbal or written) is required, when appropriate, or researchers must provide an explanation for why assent is not appropriate.
   - No continuing review is required for research initially evaluated under expedited or exempt review. Will ask PIs to file a status report annually.
   - Adopted single IRB mandate – only one IRB conducts a review when multiple institutions are engaged in collaborative research.

How This Affects IRB Members

- More exempt reviews conducted by the Office of Research; less expedited reviews.
- Opens up more time for IRB members to provide college specific guidance.
- IRB member volunteers to cover IRB Analyst when on vacation?

3. **New IRB Forms and Procedures**
   - Update on eIRB vendor – still in contact negotiation. In the meantime will have email submissions to irb@sjsu.edu starting in Jan 2018 – reviewers will get protocol documents as separate attachments forwarded from this email.
   - Discussion of IRB Reviewer Form – digital signatures, consolidated review criteria, provided link to expanded review criteria, allows for iterative process.
   - Discussion of IRB Assurance Form – request to add "I have used the exclusion worksheet and have determined that the study meets the regulatory definition of human subjects research for which a protocol submission is required."
   - Discussion of IRB Application – review criteria remains the same, but the new form breaks down questions in more detail and asks PIs to be specific. Question about length of time needed to fill out the form – not sure. It may take more time for faculty because the form is unfamiliar; some might think the review criteria have changed and they might be alarmed. Will send out mass email at beginning of semester alerting faculty to the changes.
   - New materials will be posted on the web next week – we will have to toggle between new and old forms for some period. Will require use of new forms by the beginning of spring semester.

4. **Status of Protocols**
   Please check whether you have any protocols out to you before the holidays and let Alena know your availability. Office of Research is closed 12/23-1/1

Meeting adjourned 10:30 am

Minutes prepared by Alena Filip

IRB Full-Committee Meeting Minutes

Date/Time: 2/16/2018 9:30am
Location: MLK Library, Room 525
IRB Members Present: Bernd Becker (Chair), Elizabeth Mullen, Craig Cisar, Josh Nelson, Sabrina Pinnell, Anand Ramasubramanian, Amy D'Andrade, Edith Kinney, Alena Filip

1. **Protocol full review**

   "Exploring the Relationship between Firearm Ownership and Military Veterans' Attitude Toward Mental Health Service." Protocol # S17190

Primary reviewer outline
Continuing Education – Article about traumatic brain injury and PTSD in veterans: https://www.ptsd.va.gov/professional/co-occurring/traumatic-brain-injury-ptsd.asp

- **PI qualifications –** Student Investigator did not list any special qualifications to conduct the study, other than possessing an undergraduate degree. If the research requires any clinical training or background to assess the onset of distress and/or to debrief, the student does not have this experience – IRB needs to decide whether such training is needed in this case.

- **Recruitment plan –** Prospective subjects will be sent an email from the SJSU Veterans Center announcing the study to all students who are registered with the center and including the student investigator's contact info. There are no conflicts of interest. Protocol states that "PI will only select student veterans who are not under conservatorship and can make a legal decision to participate." How will investigator screen for cognitive impairment, conservatorship, and traumatic brain injury? What are the selection criteria if more than 10 students respond with interest in participating in the interview? Subject selection may not be equitable as the subjects are only selected from the student population and may not reflect a broader spectrum of veteran experiences.

- **Potential risks –** Investigator lists the risks as moderate, including anxiety and frustration, emotional distress, and reliving traumatic memories. The subjects will not be asked about their combat experiences directly; the focus is on mental health services and firearm ownership. However, what appears to be innocuous to us can be triggering to someone who is vulnerable (for example, asking about suicide assessment may trigger thoughts of death in combat; or asking about a gun may trigger memories of the last time the person was in a combat zone). AF additional comment: There may also be a therapeutic misconception on the part of subjects because the questions express an open-ended curiosity (tell me about your firearms) and solicit situational responses (how would you approach a situation with a potentially suicidal friend?) – the questions are framed the way a therapist would ask them, but the aim is to see if the participants change their responses once they learn about the legislation.

- **Potential benefits –** There are no direct benefits. Indirect benefits – satisfaction of contributing to a study with the aim of improving services and support for veterans.

- **Risk benefit ratio –** It seems that the study is essentially an inquiry into whether more education about gun legislation related to mental health issues might change veterans' attitudes toward seeking mental health services. Since there will be no way to measure whether new knowledge actually changed behavior, the data may not be useful enough to improve services offered to veterans. Risk/Benefit ratio favors risk – IRB will need to determine whether the risk is reasonable.

- **Confidentiality –** Will be maintained through the use of pseudonyms, a coding system, and limiting personal details shared in dissemination of the work, except in the case of a mandated reporting scenario. Suggest storing the interview recordings on a non-networked, password protected device and clarifying in the protocol who will transcribe the recordings.

- **Data oversight/management** – The study design does not necessitate ongoing monitoring of the data.

- **Informed consent process** – The study plan offers prospective subjects enough time to review the consent form and ask questions by emailing the participants the consent form ahead of the interview and reiterating consent info prior to the interview. The methods section mentions a debriefing, during which participants will be given a list of support resources. It's not clear whether they will be debriefed about the mini-intervention and the fact that the study seeks to measure a change in attitude after reviewing a summary of gun-related legislation.

- **Informed consent document –** A standard consent form is to be used. The consent document does a good job of providing enough information about the topic of the study in order for participants to make a decision about whether they want to be involved, without revealing the purpose of the mini-intervention.

- **Vulnerable populations –** The study does not involve a vulnerable population as defined by the federal regulations. However, participants may be vulnerable if they suffer from mental illness and/or perceive that the interview questions have a therapeutic intent – to share their story and have their opinion heard – which is not the intent of the research.

- **Compensation and costs –** No compensation is being provided and the study does not involve any costs to subjects.

Summary of unresolved issues:

- Should student investigator qualifications (or lack of) be a deciding factor in this case?
- Are the risks reasonable?
- Clarity is needed on how the investigator will screen for cognitive impairment, conservatorship, and traumatic brain injury and on subject selection in general.
- Is a more detailed debriefing needed?

Open discussion by full committee

- Study design issues: Although a hypothesis is not explicitly stated in the protocol, it is implied because the investigator states the objective is to measure whether there is a change in attitude towards seeking mental health services once the subjects are exposed to educational material that reveals restrictive legislation on gun ownership for individuals with serious mental health issues. The hypothesis implied by the protocol is that veterans are less likely to seek mental health services after exposure to the educational material. The protocol describes a quantitative study, but the interview questions are qualitative in nature and seem inappropriate for this reason. Participants may misconstrue the nature of the study in a way that can either led to defensiveness about gun ownership or therapeutic misconception.

  The investigator presumes there is a correlation between gun ownership and likelihood of accessing mental health services, but has not provided enough background info about veterans to justify the hypothesis. Are veterans more likely to own firearms in comparison to civilians? Are they more likely to have pro-gun/anti-legislation attitudes? Are they regularly subject to mental health screenings? Are they unlikely to be aware of legislation regarding gun ownership and mental health?

- Risks/Benefits:

Recruitment is not likely to be equitable and does not target the population that could most effectively answer the questions – veterans who own fire arms and have had a mental health assessment. The recruitment methods do not screen for these attributes and/or the protocol does not explain whether these attributes are typical to all veterans.

The consent form does not disclose the full nature of the questions and the interview questions may take subjects off guard. The protocol does not provide info about whether such assessments are typical for veterans. If they are not typical, then the reasoning behind the questioning may be confusing and triggering to some veterans.

Though the investigator does not have the capacity to diagnose participants, if the hypothesis were to be true, the subjects may be less inclined to seek mental health services if they own firearms upon participation in the study – a situation that does not benefit them and exposes them to greater risk. The questions are highly personal and there are no direct benefits; the stated indirect benefits do not seem

achievable with the methods used. It may be possible to study the research topic without having to ask such personal/sensitive questions.

- Investigator qualifications: some members felt strongly that the student investigator is not qualified to conduct the study that asks sensitive questions from veterans. In terms of ability to consent, however, the subjects are enrolled students – if they are able to attend college, they are not likely cognitively impaired or under conservatorship. Concern focused on student investigator's ability to handle a mandated reporting situation. It was clarified that MSW students are not limited reports (where the obligation is to report child abuse only) and they have an obligation to report potential harm to self or others to law enforcement.

Vote (if quorum is present) –approve, conditionally approve, not approve, abstain, recuse

9 voting members were present, achieving a quorum.
A motion was made to not approve the protocol and seconded.
8 members voted to not approve the protocol and 1 member abstained.
The motion was passed; the protocol is not approved.

Suggestions to investigator on ways to revise the study so that is can be approved:

- Align the methods to match the study purpose. If you want to do a quantitative study, use quantitative measures.
- The IRB suggests a qualitative approach that focuses on perceptions of and attitudes towards legislation as opposed to seeking specific info about mental health assessments and suicide ideation. Questions you can ask:
  - Did you know about x, y, and z legislation?
  - What are your thoughts on this legislation as a gun owner?
  - Do you think this legislation impacts whether and how you seek mental health services?
    - In what way?
  - How do you think other veterans view this legislation? etc
- Develop appropriate screening to target student veterans who are gun owners.
- Provide more background info in the protocol about the subject population (see some of the questions raised in the open discussion) and about previous research that informs your study and justifies the questions you want to ask subjects.

2. **Approval of 12/15/2017 minutes from previous meeting**
   9 voting members were present, achieving a quorum.
   A motion was made to approve the 12/15/2017 minutes with the correction to attendance roster (Amy D'Andrade was not present at this meeting).

The motion was seconded.
8 members voted to approve the minutes with the correction and 1 member abstained.
The motion was passed; the minutes were approved and the correction was made.

3. **Update from HHS regarding new HSR common rule**

   The Department of Health and Human Services sent a notice 2 days before the implementation date of the revised common rule that the implementation was delayed to July 2018, at which time, an additional Notice of Proposed Rule Making may be passed to delay the implementation date further. In announcing the delay, HHS made the unexpected announcement that institutions which implemented the revised common rule early would not be in compliance with HHS regulations.

   Given the time and effort that was devoted in 2017 to becoming ready for implementation by January 2018, the IRB analyst does not believe it feasible to backtrack. The majority of SJSU HS research is either unfunded or not federally funded. In addition, it would be inefficient to make any changes at this point until we know whether the revised common rule stands in terms of whether or not it will be repealed or when it will be implemented, and whether it will be implemented without further revisions.

   The IRB analyst proposed that we continue to implement the revised common rule for all but federally funded research, and this is the consensus of the SJSU IRB, the Office of Research, and other CSU IRBs.

Meeting adjourned 10:30am

Minutes prepared by Alena Filip

IRB Meeting Minutes

Date/Time: 4/20/2018 9:30am
Location: MLK Library, Room 525
IRB Members Present: Bernd Becker (Chair), Amy D'Andrade, Elizabeth Mullen, Maureen Smith, Craig Cisar, Josh Nelson, Sabrina Pinnell, Alena Filip

1. **Approval of 2/16/2018 meeting minutes**
   Approval of the previous meeting minutes was tabled to the next meeting since a copy was not distributed with the agenda.

2. **Alena's recap of meetings with EDD and Kinesiology dept.**

- EDD meeting covered: definitions (the 3 E's, HSR, etc); exclusion worksheet; research vs. quality improvement; Belmont Report ethical principles (how they inform review criteria); common issues with protocols (quality of writing, internal inconsistencies, privacy issues - including small sample sizes, incomplete info on data management, positional authority of researcher and expectation that this will be addressed and mitigated).

  Low turnout (5 students and 1 faculty supervisor) – may need to continue doing this each semester.

- Kinesiology meeting covered: recap of policy changes, common problems (complex technical jargon, unclear inclusion/exclusion criteria, dual role of investigator as athletic training, over-reliance on students as research subjects).

  Good turnout – most faculty members present.

Ongoing issues with all protocols: The majority of protocols we receive solicit participation from students as research subjects (e.g., SONA subject pools, human factors engineering projects, kinesiology exercise protocols). Most often there is no study specific or scientific justification and it conflicts with one of the ethical principles the IRB is required to apply → Justice = subject selection is equitable – the target population is a logical choice for answering the research questions.

AF suggested that researchers (particularly student investigators) should be made aware of this issue when it applies, so that they are mindful of the consequences of overburdening one population with research solicitations as well as the effects on the generalizability of data. This can be stated in a way that makes it clear that the outcome of the review is not affected, but that it's something to make note of as a limitation to the research.

Some reviewers expressed disagreement that the overreliance on student research subjects is an issue that needs to be addressed through IRB review and believe that commenting on the quality of the research, even if it is only a suggested rather than a required revision, weakens the validity of requests for other required revisions. There was also a request for guidance on

when suggestions about quality of research are appropriate. Concern was expressed that PIs may not understand the difference between a suggestion and a requirement, though communication with PI when this comes up has always been explicit (e.g., "this suggestion is optional and not a requirement"). AF noted that the potential for PIs to be offended by IRB suggestions is not a reason to not raise awareness of an important issue, one that has been brought up more broadly by other IRB professionals in venues such as PRIM&R conferences.

Another issue that was briefly discussed was complex technical jargon on consent forms. Multiples re-writes are sometimes needed before the consent form is clear. Student investigators may not know what is meant by the comment "this is too technical" – they are familiar with discipline-specific terms and may not realize their wording is unclear. Other than making comments to investigators more specific and asking investigators to explain what subjects will do in a language that is clear to a general audience, there may not be much else the IRB can do short of re-writing the consent form or asking a faculty supervisor to intervene.

3. **Check in with reviewers about new submission system and new forms - questions? problems? areas of improvement?**

- The check-boxes on the reviewer form are already pre-filled when a reviewer gets the protocol. This was a technical problem (couldn't figure out how to omit the checks once they were created!), but this has now been resolved. Reviewers can make changes to checkboxes as needed for their specific review.
- Data management section of application – most people mark "no" when it seems that they should state "yes." How to re-word this section? The current wording is:
  Will data collected from your data instruments, recording devices, or from secondary sources contain identifying information about participants or contain enough combined information to potentially result in identification of participants? *Note image recordings of people are generally considered identifiable unless an obscuring mechanism is built into the recording process.*

A suggestion was made to link to a separate document that lists what constitutes identifying or potentially identifying info – AF will implement this suggestion in the application.

4. **Recommendations to O&G for any policy changes as they relate to IRB membership (summary).**

- IRB chair was approached by O&G for input about any changes that we would recommend for the structure of IRB's membership.
- Ongoing need for a physician (or NP) and a community member (federally required) – recruitment gets punted back to IRB or the Office of Research.
- Ask O&G to pass policy that nudges Committee on Committees to take more action in this area?

Meeting adjourned 10:30am
Minutes prepared by Alena Filip

IRB Actions 5/18/2018

Location: Online

1. **Approval of 2/16/2018 and 4/20 IRB meeting minutes**
   Approval of the last two meeting minutes was voted on via email by the IRB membership per the IRB chair's email on 5/15/2018.

   Vote for 2/16/2018 minutes:

11 members sent in their vote = quorum.
8 members voted to approve the minutes, with one of the eight requesting a minor modification.
3 members abstained.

The 2/16/2018 minutes are approved with the following addition to the first bullet point on p 4 of the minutes: [AF note: after the meeting, it was clarified that while professional social workers are mandated reporters, an MSW student may or may not be, depending upon their current employment and internship placement. The School of Social Work has no enforcement or regulation of the reporting requirement, but it educates the students about the requirements of the profession. Update 5/18/2018]

   Vote for 4/20/2018 minutes:

11 members sent in their vote = quorum.
8 members voted to approve the minutes. 3 members abstained.
The 4/20/2018 minutes are approved.

2. **Appointment of IRB chair for AY 2018-2019**

Bernd Becker was the only nominee this year. His appointment was confirmed via email on 5/14/2018 by the IRB members and Bernd will serve as chair for AY 2018-2019.

Prepared by Alena Filip