

2016-2017 Year-End Committee Report Form

Committee: Institutional Review Board – Human Subjects Committee

Chair:
Wendy Quach

Chair-Elect for 2017-2018:
Bernd Becker
[408.808.2348](tel:408.808.2348)

Number of Meetings Held:
6

bernd.becker@sjsu.edu

(Please include phone/zip/email if available)

Items of Business Completed 2016/2017

1. The IRB Committee received and processed 281 applications from faculty and students from June 1, 2016 through May 31, 2017. One full IRB review was conducted.

Below is a breakdown of the applications:

2016 (from June - Dec)

Faculty: 72

Students: 90

2017 (from Jan - May)

Faculty: 46

Students: 73

2. After the IRB Coordinator's evaluation of electronic IRB (eIRB) vendors, a decision was made to go with Evisions Cayuse IRB. The implementation of an eIRB system is dependent on funding. The committee reviewed the protocol narrative and other forms to determine the revisions and improvements to be implemented in preparation for online smart forms.
3. We had extensive discussions of the Revised Common Rule. The committee reviewed and discussed the definition of Broad Consent and exemption categories. The revised Common Rule is expected to take effect January 2018; however, due to delays in government administrative reviews, it is likely to be delayed.

Unfinished Business Items from 2016/2017

1. Implementation of eIRB system.

New Business Items for 2017/2018

1. Implementation of eIRB system.
2. Implementation of Common Rule revisions.

Please return to the Office of the Academic Senate (ADM 176/0024) by May 31, 2017.

2SJSU IRB Meeting Agenda Items
September 23, 2016

1. Introductions
2. Training Binders
3. CITI training requirement for new members - Deadline September 30, 2015.
4. Discussion of expectations:
 - turn around time for review,
 - attendance, and
 - participation.
5. Alena's summer project

SJSU IRB Meeting Agenda Items
October 21, 2016

1. Introductions
2. Approval of minutes from 9/23/16 05/13/16
3. IRB Protocol Review
4. Review of training binders - questions
5. Discussion re: current forms to convert to online format

**SJSU IRB Meeting Agenda Items
December 9, 2016**

1. Approval of minutes from 10/21/16
2. Announcements
3. Discussion re: current forms to convert to online format
4. Winter availability
5. Spring meeting dates: (Fridays, 9:30-10:30, SH 332)
 - Jan 27
 - Feb 17
 - Mar 17
 - Apr 21
 - May 12
6. Other items

SJSU IRB Meeting Agenda Items
February 17, 2017

1. Approval of minutes from 12/9/16
2. The final common rule.
 - The link to the new regulations can be found here:
<https://www.federalregister.gov/documents/2017/01/19/2017-01058/federal-policy-for-the-protection-of-human-subjects>
 - Please read this before our meeting
3. eIRB protocol application.
 - Update from Alena
4. Other items
 - Responsible Conduct of Research seminar in Fall 2017 to UGs

SJSU IRB Meeting Agenda Items
March 17, 2017

1. Approval of minutes from 2/17/17
2. Full board review
3. IRB Chair for 2017-18
4. The final common rule.
 - The link to the new regulations can be found here:
<https://www.federalregister.gov/documents/2017/01/19/2017-01058/federal-policy-for-the-protection-of-human-subjects>

SJSU Institutional Review Board – Meeting Minutes

Friday September 23, 2016

9:30-10:30am

Present: Sergio Bejar, Emily Chan Craig Cisar, Elizabeth Mullen, Maureen Smith, Sabrina Pinnell , Leslie Speer, Brandon White, Alena Filip

Absent: Marjorie Freedman, Wendy Quach (IRB chair), Gilles Muller, Edith Kinney

Agenda Items Covered:

1. Introductions + recap of number of reviews and departments that submit protocols. Most common problem protocols = novice student researchers w/ poor methodology, inadequate advising.
Availability of IRB chair and other reviewers as resources for advice on problematic protocols. Question about the extent that discussion of protocols can be shared outside the committee. If seeking expertise feedback – ok, maintain anonymity of PI.
2. Training Binders – were distributed. Goal for next meeting for all reviewers – go over training binders; come in with any questions.
3. CITI training requirement for new members - Deadline September 30, 2015.
Complete IRB member specific training.
4. Discussion of expectations:
 - turn around time for review – 2 weeks or less
 - attendance, and
 - participation – 3 missed meetings can result in dismissal at the chair’s discretion.
Email chair and Alena if you know you will miss a meeting. Attendance at full reviews is especially crucial as a quorum is needed.

Questions: difference between suggested vs required comments on protocol (the difference should clearly be designated on the reviewer sheet). Suggestions may include acknowledging limitations of the study, or improvement in design.

5. Alena’s summer project – evaluating different types of eIRB vendors. Alena’s recommendation – Evisions Cayuse IRB. Waiting for funding (hopefully begin 2017). Suggested agenda item for next meeting – take a look at the protocol narrative and other forms to see what improvements can be implemented in preparation for online smart forms.

Meeting adjourned 10:05am

Minutes prepared by Alena Filip

SJSU Institutional Review Board – Meeting Minutes

Friday October 21, 2016

9:30-10:30am

Present: Emily Chan, Craig Cisar, Marjorie Freedman, Elizabeth Mullen, Maureen Smith, Sabrina Pinnell, Leslie Speer, Brandon White, Wendy Quach (IRB chair), Alena Filip

Absent: Sergio Bejar, Priya Raman, Gilles Muller, Edith Kinney

Agenda Items Covered:

1. Approval of 5/13/16 and 9/23/16 Meeting Minutes
5/13/16 – motion was made to approve -> 4 abstained; 5 approved.
9 voting members present – quorum achieved.

9/23/16 – motion was made to approve -> 3 abstained; 6 approved.
9 voting members present – quorum achieved.

2. Discussion of Protocol “Improving Instructional Decision Making to Make Learning Visible: A Focus on Formative Assessment Moves for Mathematics Teaching”

Educational Leadership doctoral dissertation protocol proposes to study the functioning of teaching tools related to in-class formative assessments practices of posing, pausing, and probing. Subjects are teachers who would be asked to participate in 3 group meetings with PI (an intake session, a lesson planning session, and a reflection session) and observe and video record the teachers’ enactment of the lesson plan developed in the second session.

The discussion of the protocol was not a full review. Rather the primary reviewer wanted to get feedback/guidance from IRB members regarding the design of the study. The primary reviewer’s comments were outlined in an email prior to the meeting:

1. There is no testable hypothesis that I can see nor control groups. Everything appears to be self-directed with self-assessment. I do not see how the data obtained will be analyzed or how it supports the questions/hypothesis being posed.
2. The PI indicates that the test subjects will go from “novice to more expert knowledge and skills”. However, as best I can tell since nothing is being repeated and the “experiment” is only being done once. I question the validity of this question that is being explored (under abstract in protocol).
3. The other two questions listed under the abstract are not really testable that I can tell either. I realize this is more qualitative but because it is self-assessment, I am not sure what the PI hopes to accomplish?

4. The justification for math teachers seems to be something that the principle of the school district wants, which leads me to believe there is a lot of bias to this protocol and therefore the results obtained could be skewed. This suggests to me that there may be a conflict of interest involved. This is difficult to determine though.

5. The PI wants to videotape the teacher and students in the class but indicates consent/assent is not needed for the students because the experiment is on the teacher. I disagree completely with this because it is a classroom environment and how the teacher reacts to the students probably is important.

Discussion of the protocol focused on:

- The need to acknowledge that minors are participants in the research if their interaction with the teacher must be recorded. In addition to parental consent, which was submitted, assent is needed for minors. There also needs to be clarification on what will happen to those students who have not provided consent and assent.
- Extensive dissemination is planned. It was proposed that parents and students have a choice (e.g., check boxes on consent and assent documents) about the degree of dissemination.
- Risks need to be described on the consent form and need to be consistent with what is stated in the protocol narrative; PI cannot claim that there is no risk.
- To what degree should comments about design be required edits for a minimal risk protocol. The discussion brought new reviewers up to date on the ongoing issues with the department over whether much of the activity meets the definition of research and whether the action research approach can yield valid results. It was agreed that:
 - * Consistency is needed from all reviewers if design will be a factor in review.
 - * PIs should be alerted to design issues; if a resubmission results in some improvement, IRB should exercise flexibility in allowing the protocol to move forward towards approval.

Meeting adjourned 10:30am

Minutes prepared by Alena Filip

SJSU Institutional Review Board – Meeting Minutes

Friday December 9, 2016

9:30-10:30am

Present: Sergio Bejar, Emily Chan, Craig Cisar, Marjorie Freedman, Daoping He, Edith Kinney, Elizabeth Mullen, Priya Raman, Leslie Speer, Brandon White, Wendy Quach (IRB chair), Alena Filip

Absent: Maureen Smith, Sabrina Pinnell, Gilles Muller

Agenda Items Covered:

1. Approval of previous meeting minutes from 10/21/2016.
A motion was made to approved the meeting minutes from 10/21/2016
8 voting members were present during the vote, achieving a quorum, with 4 voting to approve and 4 abstaining.
2. Discussion of application template for online submission system
 - Reason for one application instead of multiple applications: limits confusion about which form to submit; exempt work still requires consent and oversight, so the same requirements must be fulfilled as for an expedited review. Exemption screening is embedded into the form.
 - Reordering of current narrative to avoid redundancy.
 - Separating description of research design and methods from study methods so that PIs are prompted to address each of these items separately.
 - Elimination of an “abstract section” – replaced with “study introduction” section that itemizes purpose/research questions, background, design, data collection methods, and analysis. PIs prompted to explain how design, data collection, and analysis will be done in a way that answers the research questions.
 - Replace “confidentiality” section with “data management” section, which includes confidentiality when applicable.
 - New items: qualifications section includes segment on international research; retention plan included in data management section.
 - Required vs. optional fields.
 - Continued discussion of quality improvement of protocols – getting faculty members to take responsibility for student protocols. Addition of check boxes to faculty approval signature; explicit text about taking responsibility for reviewing design, analysis, and integrity of the research. Check box assuring protocol is clearly written in laymen’s language.

- A pdf version of the online application would be available on the research website so that PIs can prepare before creating an account.

3. Winter availability

Meeting adjourned 10:10am

Minutes prepared by Alena Filip

SJSU Institutional Review Board – Meeting Minutes

Friday February 17, 2017

9:30-10:30am

Present: Bernd Becker, Craig Cisar, Elizabeth Mullen, Sabrina Pinnell, Priya Raman, Maureen Smith, Brandon White, Wendy Quach (IRB chair), Alena Filip

Absent: Sergio Bejar , Marjorie Freedman, Edith Kinney, Gilles Muller, Leslie Speer

Agenda Items Covered:

1. Approval of previous meeting minutes from 12/9/2016.

A motion was made to approve the meeting minutes from 12/9/2016.

9 voting members were present during the vote, achieving a quorum, with 5 voting to approve and 4 abstaining.

2. Discussion of eIRB protocol application:

- Whether to add study timeline to application.
- Modifications to Introduction section language – whether to call it an “overview” or “research summary,” add 1 paragraph limit, provide list of examples for research design.
- Conflict of interest section – is an imbalance of power the same as a conflict of interest? Decided to move this to recruitment section where it asks whether research team has supervisory role – if so, they must address potential for undue influence. Conflict of interest section to address financial conflicts only.
- Consent form checkboxes – does this make sense? Is it too lengthy? Decided to keep.
- Alternative procedures section – divide into 2 sections – one for classroom activities and an “other” section.
- Omit section asking about how research approach will answer research questions – redundant – belongs in the introduction section.
- Clarify what is meant by “experimental procedures” in the What Subjects Will be Asked to Do section.
- Use of “subjects” vs “participants” – use one for consistency (participants preferred).

3. The final common rule:

There was not enough time to discuss all the changes. Clarification was provided on what “Broad Consent” means – can be used only if PI wants to apply the two new exemptions (1) storage and maintenance of identifiable secondary data or biospecimens, or (2) use of identifiable secondary data or biospecimens. PI’s can either

apply for these exemptions and use broad consent or they can go through IRB review and obtain study specific consent or request a waiver of documentation as well as a waiver of some or all of the elements of consent. Broad consent contains more info than study-specific consent because it is designed to allow use of identifiable secondary data or biospecimens for future research without re-consenting the subjects.

4. Briefly announced library's research training program for undergraduates and asked for volunteers to teach the workshops.

Meeting adjourned 10:30am

Minutes prepared by Alena Filip

SJSU Institutional Review Board – Meeting Minutes

Friday March 17, 2017

9:30-10:30am

Present: Bernd Becker, Sergio Bejar, Craig Cisar, Marjorie Freedman, Elizabeth Mullen, Gilles Muller, Sabrina Pinnell, Priya Raman, Maureen Smith, Brandon White, Wendy Quach (IRB chair), Alena Filip

Absent: Edith Kinney, Leslie Speer

Agenda Items Covered:

1. Approval of previous meeting minutes from 2/17/2017.
A motion was made to approve the meeting minutes from 2/17/2017.
9 voting members were present during the vote, achieving a quorum, with 8 voting to approve and 1 abstaining.
2. Full review of appeal request for IRB protocol S17005 “Barriers in Accessing Valley Transportation Authority (VTA)'s Transit Service for Homeless People in San Jose”
The protocol proposes to recruit homeless individuals to interview them about their use of public transit and what barriers they may encounter in using public transit. The student PI proposes to work with Homeless Outreach Team (HOT), a program managed by the Department of Housing in the City of San Jose, and have HOT volunteers identify potential participants and help with subject recruitment. The faculty supervisor on the study asked to waive the request made during the expedited review to obtain a letter of support from the program documenting this collaboration. The faculty supervisor indicated that members of the program did not want to sign a letter of support because they viewed it as a contract. The full review only concerned itself with the appeal request.

After some discussion a motion was made to deny the appeal to waive the request for a letter of support from agency. All 11 voting members present voted in favor of denying the appeal. The discussion points included:

- Agency may back out of assisting the student, in which case the student would not be able to use the data.
- Concerns about liability were the agency to violate city policies regarding client privacy and data sharing practices.
- Speculation as to why the agency viewed the request as a contract, why the student had to work with this particular agency or any agency at all.

- Accepting that a verbal agreement was obtained by the faculty supervisor would set a precedent; the practice has been to obtain written documentation of such collaborations.
 - The city's various agencies have worked with this department previously without having issues with providing letters of support.
 - Question about including this requirement in the upcoming policy revisions – outlining circumstances when such a letter would be needed (e.g., when a participating institution is engaged in the research but does not have an IRB vs. situations such as posting flyers and sending an advertisement through a gatekeeper at the institution).
3. Discussion of exemption categories under the revised common rule.
 - Read through 4 of the 8 categories and clarified some of the new language added to the exemption categories under the revised common rule. To be continued in next meeting.
 4. Nominations for IRB chair for the next academic year to be sent to Alena by Friday 3/24.

Meeting adjourned 10:30am

Minutes prepared by Alena Filip

SJSU Institutional Review Board – Meeting Minutes

Friday April 21, 2017

9:30-10:30am

Present: Bernd Becker, Sergio Bejar, Craig Cisar, Edith Kinney , Elizabeth Mullen , Sabrina Pinnell, Priya Raman, Maureen Smith, Alena Filip

Absent: Marjorie Freedman, Gilles Muller, Leslie Speer, Brandon White, Wendy Quach (IRB chair),

Agenda Items Covered:

1. Approval of previous meeting minutes from 3/17/2017.
A motion was made to approve the meeting minutes from 3/17/2017.
9 voting members were present during the vote, achieving a quorum, with 8 voting to approve and 1 abstaining.
2. Discussion of Revised Common Rule
 - Exempt Categories
 - Additional changes – continuing review, single IRB, and consent
 - Question about new faculty members with outside IRB approval – can register the protocol at SJSU.
3. Discussion of protocol studying prenatal risk factors for autism – lengthy 2 hour survey of mothers of children with autism, asking highly sensitive questions about sexual activity, drug use, and health during pregnancy to be done online and in person.
 - \$50 compensation to be distributed after completion of survey – too coercive for in-person survey. Subjects should be able to decline to answer questions and still get compensation.
 - Risks and benefits of online vs. in-person survey.
 - Request emphasis of certain info on consent (duration, sensitive nature of the questions, compensation offered regardless if subject doesn't answer questions).
4. Reviewers make sure to renew membership asap if you want to continue to serve on the IRB – several faculty have expressed interest in joining and current reviewers may be replaced.
5. Request for volunteers for responsible conduct of research seminar for undergraduates in the fall.

Meeting adjourned 10:20am

Minutes prepared by Alena Filip