

2014-2015 Year-End Committee Report Form

Committee: Institutional Review Board – Human Subjects Committee

Chair:
Maureen Smith

Chair-Elect for 2015-2016:
Wendy Quach
4-3682

Number of Meeting held:
7

0079

(Please include phone/zip/email if available)

Items of Business Completed 2014/2015

1. Reviewed and processed nearly 500 protocols from students and faculty between July 1, 2014 and June 1, 2015. Each faculty member reviewed 15-20 expedited protocols and additional five as full review.
2. Revised internal policies regarding review criteria and proposed, and submitted, policy changes regarding membership to the Academic Senate.
3. Engaged in on-going training to stay up-to-date with Federal policy and best practices for IRB committees.

Unfinished Business Items from 2014/2015

1. Continue the on-going training.
2. Revisit the proposed policy changes for membership.
- 3.

New Business Items for 2015/2016

1. This is determined by needs that arise over the course of the academic year. Internal IRB review policies are updated by the committee on an on-going basis as issues arise (e.g., changes in technology, news reports of problematic research like the FaceBook study two years ago, or within committee reviews of SJSU protocols).
- 2.
- 3.

Agenda 9/29

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Agenda 10/24

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Agenda 11/14

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Agenda: February 6, 2015

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Agenda: March 6, 2015

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Agenda: April 10, 2015

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SJSU Institutional Review Board – Meeting Minutes

Friday September 26, 2014

9:30am – 10:30am

Present: Bernd Becker, Jang Hyung Cho, Cesar, Marjorie Freedman, Alena Filip, Barabara Fu, Sabrina Pinnell, Maurice Smith (chair), Wendy Quach, Brandon White

Absent: Shahab Ardalan, Ryan Ludman

Agenda Items Covered:

1. Welcome and introductions

- x Update to reviewer sheet

Expedited review category must be indicated on IRB reviewer sheet (<http://www.hhs.gov/ohrp/policy/expedited98.html>)

- x Only minimal risk can undergo expedited review. What is minimal risk?

- Link provides guidance on greater than minimal risk of criminal or civil liability, financial standing, employability, insurability, reputation, stigmatization – unless protections are in place to prevent disclosures and risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

- x Full review for greater than minimal risk should only be selected after PI has been given opportunity to make revisions or design changes that can reduce risk of protocol to minimal risk.

Deviations from discussion

- x When is it appropriate to question research design?

- Requirement of regulations.

- x When is the work considered research?

2. Researcher and student training (CITI)

CITI training reminder

- x New reviewers need to complete IRB reviewer training no later than the next meeting 10/24.

3. Expectations for review

- x Turn around should be no greater than 2 weeks.

- x Fill out reviewer sheet completely.

- x Consult with other reviewers or chair for questions about a specific protocol.

- x Criteria for IRB review to be discussed at next meeting.

Meeting adjourned at 10:30am

Minutes prepared by Alena Filip

SJSU Institutional Review Board – Meeting Minutes

Friday October 24, 2014

9:30am – 10:30am

Present: Shahab Ardalan, Bernd Beckler, Jang Hyung Cho, Craig Cisar, Marjorie Freedman, Alena Filip, Barabara Fu, Sarah Pinnell, Priya Raman, Maureen Smith (chair), Wendy Quach, Brandon White

Absent: Ryan Ludman, Mark Van Selst

Agenda Items Covered:

1. Approval of meeting minutes from 9/24/14
Motion was made to approve the meeting's minutes and seconded.
Total voting members present - 11
Approved – 9 members
Abstained – 2 members
2. IRB membership changes
Brief discussion of membership changes to improve retention of experienced members and to keep in compliance with regulations:
 - x Request that appointments be made for 5 years rather than 3.
 - x Request that new members who wish to serve on the IRB submit a written statement describing their qualifications to be on the committee to be vetted by GS&R and IRB chair.
 - x Request that IRB coordinator be made a voting member to ensure compliance with review of minor addendums and extension requests.
3. Discussion of “Overview of Initial Protocol Review” from IRB Management and Function (2006)
Intent of article is to assist reviewers by providing worksheet questions that help focus the requirements for IRB review outlined by federal regulations. The worksheet covers: 1) introduction, specific aims, background, and significance, 2) drugs, devices, and biologics, 3) scientific design, 4) research procedures, 5)

- x What limits are there to IRB authority in this regard?
- x Requires expertise of IRB members.
- x Need for balance for minimal risk/minimal benefits research.
- x Next meeting will solely focus on this topic.

Statistical analysis

- x How data is interpreted is as im

SJSU Institutional Review Board – Meeting Minutes

Friday November 14, 2014

9:30am – 10:30am

Present: Shahab Ardalan, Jang Hyung Cho, Craig Cisar, Marjorie Freedman, Alena Filip, Barbara Fu, Sabrina Pinnell, Priya Raman, Maureen Smith (chair), Wendy Quach,

Absent: Bernd Becker, Ryan Ludman, Mark Van Selst, Brandon White

Agenda Items Covered:

5. Approval of meeting minutes from 10/24/14
Motion was made to approve the last meeting's minutes and seconded.
Total voting members present during vote 7
Approved – 7 members

6. Discussion of Reading Material from IRB Management and Function (2006).

Evaluating Study Design and Quality

Is IRB review of scientific design justified?

- x Yes, according to ethical and guidelines and federal regulations.
- x Need balance when it comes to

x Consultant– unfeasible if too many protocols need to be evaluated by

- x Suggestion include parsing out sections further in protocol narrative: subjects section, methods section (info on both qualitative and quantitative research), measures/tests section, materials and devices section, and preliminary data analysis section.

Meeting adjourned at 10:30am
Minutes prepared by Alena Filip

SJSU Institutional Review Board – Meeting Minutes

Friday February 6, 2015

9:30am – 10:30am

Present: Bernd Becker, Jang Hyung Cho, Marjorie Freedman, Alena Filip, Barbara Fu, Sabrina Pinnell, Priya Raman, Maureen Smith (chair), Mark Van Selst

Guest: Michelle Mussett, MSW student and PI for protocol S1404349

Absent: Shahab Ardalan, Craig Cisar, Ryan Ludman, Wendy Quach, Brandon White

Agenda Items Covered:

8. Approval of meeting minutes from 11/14/14
Motion was made to approve the last meeting's minutes and seconded.
Total voting members present during vote 8
Approved – 8 members

9. Full Review of Protocol S1404349 "The role of violent video games in reduction of hostility, depression, and negative self talk in undergraduate university students"
(PI is MSW student Michelle Mussett and Dr. Peter Lee, School of Social Work)

Nature of Study

The study proposes to examine the impact that violent video games have on hostility, depression, and negative self talk in undergraduate SJSU students. Student volunteers (N=60) will be randomly assigned to one of three groups: violent video game group, non-violent video game group, and reading a news article group. Each group will be given a frustration task, followed by pre-test measurements (hostility scale, profile of

Issues Discussed Pertaining to Risk and How to Address It

- x Collegestudents, especially younger undergraduates are a higher risk group than the general population– they face stresses that they may not have the experience and maturity to handle.
- x The study, as proposed, does not screen for PTSD and clinical depression. If the subset of students with these conditions were included in the study, it could trigger emotional distress that goes beyond minimal risk. This concern is contextual–there is a history of school shootings, and recent news of a first person shooter exercise that triggered a subject with PTSD (a veteran) and resulted in fatalities.
- x The need for a screening mechanism for PTSD and depression was reiterated, but the PI's ability to interpret the screening tools is crucial (needs to be simple and also proven effective). A plan is also needed for those who are screened but of the study. Does the PI have the ethical obligation to inform subjects who have indicated they have a problem? It might come as a surprise to subjects and the PI is not a counselor. Looking at alcohol studies, those that are identified as being high risk are assigned to the placebo group.
- x Discussion around convenience of an online format for the study vs. an in person study that would allow for monitoring of subjects for signs of distress. Online version may be less provocative than an in person version where subjects may experience additional stress from being observed. Would the in person version offer additional protections? Remediation would likely be the same– refer to counseling services. A tight screening tool may be more effective at addressing the risks of the study than in person monitoring.
- x Wider risk to public– if this study's findings conflict with current literature and are viewed as conclusive by non-experts this could potentially contribute to policy and practices that have a negative effect on the treatment of hostility and depression. This may be outside the scope of the IRB's responsibilities but it does raise the need for balance in the IRB's review of challenging research topics.
- x Level of risk may be diminished by the PI's selection of the frustration task (unsolvable anagrams) and choice of violent videogame (Quake– a fantasy based first person shooter game, where the targets are non-human). A milder version of more recent and more sophisticated first person shooter games shooter

Vote

SJSU Institutional Review Board – Meeting Minutes
Friday March 6, 2015
9:30am – 10:30am

Present: Bernd Becker , Craig Cismar, Marjorie Freedman, Alena Filip, Barabara Fu, Sabrina Pinnell, Wendy Quach , Priya Ramani, Maureen Smith (chair), Mark Van Selst, Brandon White

Absent: Shahab Ardalan, Jang Hyung Cho, Ryan Ludman

Guest: Cecilia Manibo

Agenda Items Covered:

10. Approval of meeting minutes from 2/6/15

The meeting minutes had a minor amendment since they were sent to IRB members on 2/6/15. Wording was changed to "violence catharsis" vs. "violent catharsis." Additional wording was added to instructions for full review protocol to use a type A hostility scale – "use a scale that literature has proven to be effective."

Motion was made to approve the meeting's minutes and seconded.

Total voting members present during vote - 7
Approved – 7

Some members came in late and did not vote on approval of the minutes, but a quorum was present nonetheless.

11. Full Review of Protocol F15022 "College Experience Survey"

(PI is Dr. Christopher Krebs – external investigator from the non-profit organization RTI International)

Nature of Study

The investigators want to use SJSU for the pilot study on campus climate with regard to sexual assault. The PIs want to survey students about their experience with sexual assault including perpetration.

In addition, the PIs are requesting a database of all undergraduate students that includes not only identifying directory info, but things like GPA, transfer status, and SAT scores. The PIs will use the data to create a stratified and equitable sampling frame, to measure non-response bias, to test different computer packages, as well as to correlate the survey to characteristics associated with sexual assault. Only students who complete the survey will be informed about the study. The consent process is tiered across multiple pages. The final consent page states the essential info related to access of student records: "RTI may combine your survey responses with basic administrative data about

you provided by your school (e.g., academic transfer status), but no information about your identity will ever be linked to your survey data." The consent information does not outline risks and benefits of participation. Students can skip any questions on the survey they don't want to answer.

Student records will be sent to the research team by SJSU staff who are provided with instructions on document encryption. The research team has a data management plan that entails merging non-identifying data from student records with the survey responses via a code that links the two data sets. The data management plan also includes a staff confidentiality pledge for those who will be handling the data.

Issues Discussed Pertaining to Benefits

- x Project is well-designed with a sound data management plan for both the security and confidentiality of the data.
- x It is important to conduct a statistically valid pilot study that will benefit future research on this topic.
- x SJSU will receive aggregate info about the survey results which will allow the university to have a picture of sexual assault statistics on campus.

Issues Discussed Pertaining to Risks and Problems

- x Because the team has a sound plan for protecting the security and confidentiality of the data, the principle risk has to do with an infringement on privacy. Should students have a choice in deciding when their academic records are released for the purposes of a study that does not directly benefit them? How would a student feel about having his/her records accessed? What would be the student response if records accessed?

There is no evidence that academic performance is in any way correlated with sexual assault and no background information on this topic was provided by the research team that underscores why having ac

Issues discussed Pertaining to FERPA

- x Distinction between directory info and student records. FERPA allows institutions to release directory info (e.g., student name, contact info, date and place of birth, dates of attendance) without prior consent of the student. The institution may still elect to restrict this information.
- x FERPA also allows institutions to disclose, at their discretion, student records beyond directory info without prior consent to organizations conducting studies for, or on behalf of, the institution to:
 - 1) Develop, validate, or administer predictive tests
 - 2) Administer student aid programs
 - 3) Improve instruction

Does a pilot study on sexual assault fit into one of the above categories? Ultimately, IRB members did not see any evidence that the protocol fit into one of the permitted categories. Though it was not clear what the FERPA legislation means by “predictive tests,” the protocol under review did not establish any hypotheses or make any predictions. The protocol is clearly not designed to improve instruction. Whether the study serves to administer student aid programs is questionable. Since this is a pilot study, SJSU would not be able to develop programs that are based solely on a data instrument that is being tested by the current study. SJSU might find the general statistics on sexual assault informative, but this is not likely to lead to direct benefits for the campus community.

Other Comments

Other surveys that include sexual assault topic have been and continue to be conducted nationally (e.g., American College Health Association, National Survey of Student Engagement). It's not clear what this study would add to the research that has been already done or what the SJSU response is to research that has already been conducted on this topic.

Vote

The 10 voting members presented, with 9 voting to provisionally approve the protocol with conditions/restrictions (outlined below) and 1 member abstaining. A quorum was present.

Conditions of Approval / Restrictions

- x Only student directory information may be released to investigators by the University without prior consent of the students. A complete list of directory information, as defined by FERPA, can be found here:

SJSU Institutional Review Board – Meeting Minutes
Friday April 10, 2015
9:30am – 10:30am

Present: Bernd Becker , Jang Hyung Cho, Cesar, Alena Filip, Barabara Fu, Sabrina Pinnell, Wendy Quach , Priya Raman, Maurice Smith (chair), Mark Van Selst, Brandon White

Absent: Shahab Ardalan , Marjorie Freedman, Ryan Ludman

Guest: Cecilia Manibo

Agenda Items Covered:

12. Approval of meeting minutes from 3/6/15

Motion was made to approve the meeting's minutes and seconded.

Total voting members present during vote - 7

Approved – 7

13. Discussion of Cheat Sheet for HSR Protocols Involving Devices

Recap of main points: when studies are exempt from FDA; when studies are not exempt, IRB must make significant risk determination; definition of non-significant risk (NSR) device; requirements when NSR status is determined.

Questions: what is considered a device?

14. Full Review of Protocol S15071 “Swimming Device for Overcoming Fear of Water and Motivating Long-Term Swimming Habits”

(PI is Jacob Arthur Abzzini, a student in Industrial Design, and Dr. Leslie Speer)

Nature of Study

The study proposes to test several swimming devices with children during swimming lessons and to qualitatively assess the child's level of comfort with the devices and how they interact with the devices in the water. The stated hypothesis is that these “instructional tools and devices” will prevent fear in children during initial water

devices different than what is currently being used? Why does this research need to be conducted?

- x Protocol lists more than one goal: 1) understand how children interact with water, 2) ways in which fear develops within the swimmer, 3) testing of a prototype to prevent fear, and 4) developing a way to keep children motivated to improve their relationship with water. There is no plan to meet each one of these goals. More focus and conceptualization is needed.
- x It's not clear whether the overall purpose is to test a product that is intended to go to market (and what the devices would add to the current market of products) or whether the purpose is to test attributes (e.g., fear, level of comfort, motivation) that the products affect. Is this marketing research or behavioral research?
- x The study does not have any measures for overcoming or preventing fear. It would be difficult to make any claims about the devices preventing fear without a control group. Even then, the study would have to be more in depth and would have to take place over multiple sessions to obtain meaningful data. In an email the PI indicated that he is seeking qualitative data from the testing to see how the devices aid in establishing level of comfort in the water. Establishing a sense of comfort does not automatically translate to preventing fear- the study is not designed to be able to make any claims about fear.

Discussion about Risks

- x Is the use of minors justified? Since it is likely that most swim students will be minors, targeting this group is appropriate if the devices are designed specifically for them. However, the study proposes a wide age range of minors (4-14 years old) without recognizing that the way that younger children interact with the devices may be different than the way adolescents interact with the devices. In addition, assent should be age appropriate.
- x Do the devices pose a risk that is greater

Vote

All 10 voting members present ~~to~~ unanimously to not approve ~~the~~ the protocol as written and to require further revisions and clarifications to the ~~ptocol~~ protocol before approving it. A quorum was present. The required revisions ~~are~~ noted below. The resubmitted protocol will be reviewed by subcommittee first and ~~th~~ presented by the subcommittee at the next full meeting.

Required Revisions

x

- x NGO collaborating with researcher; historically established relationship with researchers
- x Advisor to contact legal office – what legal responsibilities? Is student required to report illegal activity?
- x Previous NGO recommendations to educate police and locals on endangered species in hopes of preventing endangered wildlife from being caught
- x Protocol – problems with observations, why observe if you are interviewing?
- x