

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 0079 <small>(Please include phone/zip/email if available)</small>
Number of Meeting held: 7	

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.

Please return to the Office of the Academic Senate (ADM 176/0024) by July 6, 2015.

Agenda 9/29

Our agenda is:

- 1) Welcome and introductions
- 2) Update to reviewer sheet; summary of expedited review categories
- 3) CITI training reminder for new members and deadline for completion
- 4) Expectations for review - amount of time, filling out reviewer sheet completely, soliciting help of experienced IRB members when needed.

Agenda 10/24

The agenda is as follows:

1. Approval of the minutes from 9/29/14 - please see the minutes attached below (originally sent by Alena)
2. Quick review of, and address questions about, the tracking spreadsheet - please see the excel file attached below (originally sent by Alena)
3. Detailed discussion of the IRB review process and article - please see the article attached below (originally sent by Alena)
4. Any additional issues that need to be discussed.

Agenda 11/14

1. Approval of the minutes from 10/24 - see Alena's email from 11/6
2. Discussion of the two readings - evaluating design and limits of IRB authority (see Alena's email 11/6)
3. Specific discussion of requesting information on data analyses; the following are questions to consider:
 - a. the form does not explicitly request that information and does not have any clear place to put it
 - b. if/when asking for the information, do you have a clear plan about how that information enhances your ability to determine risk (for example, given adequate sample size and reliable measures) does knowing that the PI intends to run an ANOVA vs. independent t-tests improve your evaluation of the risk to subjects.
 - c. what will you do when you disagree with a proposed analysis (both are valid, you think one is better than the other) - are you prepared to argue with a professor?
 - d. what will you do if you are not familiar with the proposed analysis technique?
 - e. is this even enforceable?
4. Use of cell phone to record data
5. Other.

No meeting in December

Agenda: February 6, 2015

Approval of the minutes from November 2014

Full Review of the attached protocol

Agenda: March 6, 2015

Approval of the minutes from 2/6/15

Discussion of the article on *informed consent*

Full review of a protocol from an outside agency for a pilot survey about sexual assault,

Additional agenda items from IRB members TBA and time pending

Agenda: April 10, 2015

Approval of Minutes from 3/6/14

Discussion of the cheat sheet on the use of devices in research

Full review of the protocol on "Swimming Device for Overcoming Fear of Water"

Additional agenda items from IRB members TBA and time pending

Agenda May 1, 2015:

1. approval of the April Minutes - see Alena's previous email.
2. election of a new chair for 2015/2016
3. review of the selected article - see Alena's previous email.
4. full review of the protocol - see Alena's previous email.

SJSU Institutional Review Board – Meeting Minutes

Friday September 26, 2014
9:30am – 10:30am

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

Absent: Shahab Ardalan, Ryan Ludman

Agenda Items Covered:

1. Welcome and introductions

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

- When is it appropriate to question research design?
- Requirement of regulations.
- When is the work considered research?

2. Researcher and student training (CITI)

CITI training reminder

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

3. Expectations for review

- Turn around should be no greater than 2 weeks.
- Fill out reviewer sheet completely.
- Consult with other reviewers or chair for questions about a specific protocol.
- 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 Becker, Jang Hyung Cho, Craig Cisar, Marjorie Freedman, Alena Filip, Barbara Fu, Sabrina 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 last 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:

- Request that appointments be made for 5 years rather than 3.
- 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.
- 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) inclusion/exclusion criteria for subjects, 6) statistical analysis and data monitoring, 7) subject privacy and confidentiality, 8) recruitment of subjects, 9) subject compensation and costs, 10) potential risks/discomforts and benefits, 11) informed consent/assent.

Discussion of article focused on importance of:

Design

- SJSU policy statements mirror federal regulations with regard to IRB's authority to ensure the soundness of research design.
- At SJSU there is no other institutional body that evaluates scientific design – it's up to the IRB.

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

Statistical analysis

- How data is interpreted is as important as how it is collected.
- Protocol narrative should address how the data will be analyzed and what methods will be used – something that seems to be lacking in many protocols.

Treatment vs. research

- Reviewers must differentiate between procedures that are part of routine care and evaluations and procedures used in the research.
- Research in an educational setting may employ interventions that are designed by the school. Protocols should describe whether treatment is part of the research or separate from it.

Waivers of documentation of consent vs. some or all elements of consent – applicability to parental consent.

- Example discussed: an MSW project in which a student wants to assess a drug treatment program for youth provided by Asian American Recovery Services by surveying and interviewing them. The youth, ages 13-18 years old, do not need parental consent to be treated. Requiring parental consent for research could violate the confidentiality of youth whose parents don't know they're receiving treatment.
- IRB waiver of consent would depend on whether the research meets the criteria outlined in federal regulations: minimal risk, does not adversely affect the rights of participants, could not otherwise be carried out, additional/alternative protection in place for youth.
- What constitutes additional alternative protection? An advocate, such as a drug counselor, who evaluates the research methods to determine if it is in the best interest of the youth?
- SJSU IRB approval will depend on the nature of the questions, and whether they are designed to measure program effectiveness. Why do an interview, and not an anonymous survey?

4. Other topics discussed

- Education of investigators and faculty training.

Meeting adjourned at 10:30am

Minutes prepared by Alena Filip

SJSU Institutional Review Board – Meeting Minutes

Friday November 14, 2014

9:30am – 10:30am

Present: Shahab Ardalani, Jang Hyung Cho, Craig Cisar, Marjorie Freedman, Alena Filip, Barabara 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?

- Yes, according to ethical and guidelines and federal regulations.
- Need balance when it comes to student research where there is virtually no risk (SJSU policy states that student research should be designed to be minimal risk)
“There are projects where the study design is flawed, but the risk is basically zero...In the absence of meaningful risk, there is really no ethical justification for the IRB to make such revisions a condition of IRB approval.”

What are IRB member requirements for review of scientific design?

- Expertise in the study area.
- Objectivity - attitudes/personal opinions about a certain research design should be separated from accepted facts and scientific consensus.
- Conflict of interest mitigation – will how a particular study is reviewed affect the IRB reviewer’s own area of research?

What are the criteria for review of scientific design?

- Balance between risks and benefits – risks must be reasonable in relation to benefits and subjects should not be exposed unnecessarily to risk.
- Lack of benefits to subject alone does not automatically make a study poorly designed. The study may still have social benefit.
- If revising the design will meaningfully decrease risk without compromising the persuasiveness of study results, the protocol should be revised.

What is the process for review of scientific design?

- Consultant – unfeasible if too many protocols need to be evaluated by a non-IRB member.
- PIs' department – maybe for student work where the sponsoring prof is uncooperative in assisting with redesign (however, department heads need to be on board with this). (Dartmouth has department chair verify that the PI is qualified and able to conduct the study).
- IRB – each protocol is evaluated independently rather than having a single standard for the study design overall.

The Limits of IRB Authority

- IRB is not an editing service – “A researcher who is not motivated to improve the consent document or who does not understand the basic goal of the consent document should not be doing research.”
- IRB is not a policy making committee -- should not make approval contingent on changes in policy, though the board can alert institutional officials to needed changes.
- IRB is not the risk-management department – “risk” meaning making decisions based on liability to institution (others at the institution can do that). The common question “what if we get sued?” is not a basis for IRB review.

7. Specific Discussion of Requesting Information on Data Analyses

- SJSU form does not explicitly request that information and does not have any clear place to put it.
 - * Review of local IRB forms (SFSU, CSU Monterey Bay, Stanford). All have a place for statistical analysis, though we don't know to what extent IRBs actually review this info.
- If/when asking for the information, do you have a clear plan about how that information enhances your ability to determine risk (for example, given adequate sample size and reliable measures)? Does knowing that the PI intends to run an ANOVA vs. independent t-tests improve your evaluation of the risk to subjects?
 - * The info reveals whether PI has a plan for what to do with the data – enhances confidence in the ability of the PI to contribute meaningfully to generalizable knowledge.
 - * IRB review can be limited to just requesting the info and evaluating the preliminary data analysis plan, knowing that it may change throughout the course of the research– no in depth scrutiny.
- What will you do when you disagree with a proposed analysis (both are valid, you think one is better than the other) - are you prepared to argue with a professor? What will you do if you are not familiar with the proposed analysis technique?
 - * Same issues as those with design – reviewer ability to be objective and to evaluate based on expertise.
 - * Issues of consistency across IRB membership.

- Suggestions 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, Barabara 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 mood states, and a self-talk questionnaire), followed by the group task. Finally the same scales are used as a post-test. The hypothesis is that students who participate in violent video game play will experience reductions in hostility, depression, and negative self-talk compared to the two other groups.

Issues Discussed Pertaining to Background and Design

- The violence catharsis hypothesis is challenged by existing literature, which says that the opposite will happen – that violent video games can lead to increased hostility and aggression. PI mentioned that the existing research is limited - a few studies have examined the positive impact of violent videos games on hostility and depression, but none have examined their impact on self-talk.
- Reasoning behind design: Is the study trying to prove a causal link vs. an association? A causal link is more challenging to prove and would require more knowledge of subjects' personal history as well as follow-up with subjects. An association opens up alternate forms of research design (e.g., can do qualitative interviews with people who play video games) and would widen the background and scope needed to move from theory building to theory testing for this sort of study.

Issues Discussed Pertaining to Risk and How to Address It

- College students, 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.
- 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.
- 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 out of the study. Does the PI have the ethical obligation to inform subjects who have indicated they have 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 higher risk are assigned to the placebo group.
- 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 – reference to counseling services. A tight screening tool may be more effective at addressing the risks of the study than in-person monitoring.
- 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.
- Level of risk may be diminished by the PI's selection of the frustration task (unsolvable anagrams) and choice of violent video game (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 and violent content in popular culture in general, this particular video game offers the same process and scenarios as would a more violent counterpart; the nature of this particular game is safer. The choice of frustration task and violent video game reduces the magnitude of harm, while the screening tool would aid in reducing the probability of harm. Ultimately, the IRB must weigh the magnitude and probability of harm against the importance of the knowledge to be gained.

Vote

All 8 voting members present voted, with 7 voting to provisionally approve the proposed experiment and 1 member abstaining. A quorum was present. The provisions/conditions of approval are noted below.

Conditions of Approval

1. Screening tools must be implemented prior to the experiment for:
 - Age – must be 20 years or older (whether undergraduate or graduate)
 - An acceptable type A hostility scale (use a scale that the literature has proven to be effective)
 - PTSD (use a scale that the literature has proven to be effective)
 - Clinical depression (use a scale that the literature has proven to be effective)
2. Subjects who are at-risk based on the screening tools, can be placed into the reading group. All subjects are given the same debriefing that explains the purpose of the study and the frustration task and provides references to counseling services.

Once the PI submits a revised narrative and screening instruments based on these conditions of approval, the materials will be sent to 2 IRB members, including the chair, and a consultant (to assess the screening tools). If found acceptable, the protocol will be forwarded to the Institutional Official, the Associate Vice President of the Office of Research, for final approval.

Meeting adjourned at 10:40am
Minutes prepared by Alena Filip

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

Present: Bernd Becker , Craig Cisar, Marjorie Freedman, Alena Filip, Barabara Fu, Sabrina Pinnell, Wendy Quach , Priya Raman, 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: 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 last 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 their pilot study on campus climate with regard to sexual assault. The PIs want to survey students about their experience with sexual assault including preperetration.

In addition, the PIs are requesting a data set on 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 compensation 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 most 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 data, 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

- Project is well-designed with a sound data management plan for both the security and confidentiality of the data.
- It is important to conduct a statistically valid pilot study that will benefit future research on this topic.
- 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

- 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 they found out? Can FERPA be interpreted in a way that allows the release of such data without prior consent? Does the data represent something that the investigators need to know to conduct the study?
 - With respect to how students might feel about their records being accessed without their permission, there was acknowledgement that this particular demographic may not be as concerned with privacy issues. However, the IRB does have an obligation to ensure the overall ethical conduct of research regardless if a risk identified by the IRB is a concern for a specific subject.
 - The FERPA question is discussed in a different section of these minutes.
- It’s not clear why the research team needs some of the data elements listed, such as cell phone number, addresses, major, SAT scores, and ETS code. The IRB members sensed that the team may either want to make a connection between sexual assault and GPA or they may be fishing for a correlation not yet identified.

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 access to all of this data is important.

- It's not clear why students could not be asked to self-report the data elements that the research team is interested in. The team expects/hopes that students will truthfully answer sensitive questions about sexual assault, so why would dishonesty be a factor in reporting less sensitive info about academic performance? Receiving the data elements directly from the school reduces inaccuracy in the study, but is this level of accuracy worth overlooking students' right to privacy?
- It's not clear how having identifying student record elements would help to eliminate or reduce non-response bias.
- Students who don't participate in the survey will not know that their records were released to the research team.
- The recruitment text reminders for the survey are increasingly coercive, with the compensation info rising to the top of the email with each successive attempt to contact the student.
- Students who participate in the survey may not understand that their responses will be correlated with their records. They will also not be given info about which data elements from their records will be correlated with survey responses and what risks a potential breach in security of the data might entail -- they can't make an informed decision about whether or not they want to take the survey.
 - Most of the essential info that relates to the above point is provided on the last page of the consent document before the students take the survey. Many students might not read through it carefully.
- The study objective isn't made clear to subjects. It is being represented as allowing students to share their experiences so that they can help inform positive change at SJSU – but that is not the main purpose of a pilot study.
- It's not clear what aggregate info will be reported to the campus. Since the survey collects demographic info that will be merged with student record elements, enough descriptive characteristics could potentially lead to re-identification of subjects, though the likelihood of this happening is low.
- The University cannot take action based on the results of the survey because the survey does not address why sexual assault happens.

Issues discussed Pertaining to FERPA

- 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.
- 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 about 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 as a 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 has been to research that has already been conducted on this topic.

Vote

The 10 voting members present voted, 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

- 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](#):

<http://familypolicy.ed.gov/content/ferpa-model-notice-directory-information>

- Student records and information that do not constitute directory information may not be released without prior consent of the student.

The research team may either incorporate the data elements they wish to obtain into the survey questions or must explicitly list on the informed consent text preceding the survey which data elements will be accessed by the researchers upon consent of the student to participate in the study.

The data transfer agreement and protocol would need to reflect any revised procedures.

Meeting adjourned at 10:45am
Minutes prepared by Alena Filip

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

Present: Bernd Becker , Jang Hyung Cho, Craig Cisar, Alena Filip, Barabara Fu, Sabrina Pinnell, Wendy Quach , Priya Raman, Maureen 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 last 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 wants 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 Abruzzini, 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 children'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 instruction and that they will feel more secure in the water. Aside from the testing of the devices, which is outlined and illustrated in the protocol, the PI wishes to interview the swim students in a group. An interview with experts (coaches, swim instructors, etc) is also proposed.

Discussion about Design

- Protocol is lacking in references; statements about fear and how it relates the age group under study need to be substantiated.
- Justification for the research: protocol does not explain how the proposed study compares to methods currently being used in swim instruction. How are these

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

- Protocol lists more than one goal: 1) to 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.
- 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?
- 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 into preventing fear – the study is not designed to be able to make any claims about fear.

Discussion about Risks

- Is the use of minors justified? Since it's 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.
- Do the devices pose a risk that is greater than the risk of a typical swim lesson? The IRB could not make a determination based on the info provided. In general, more info is needed about how the devices work, what materials they are made out of, and their construction (or deconstruction in the case of the starfish device), and a more explicit statement that the swim instructors will test each device with one subject at a time (i.e., they will not be overseeing the testing of multiple subjects simultaneously). Ideally a visual demonstration by the PI should be provided (could be a video). The IRB had concerns about each of the devices:
 - Starfish: concern that subjects may be pulled into the water underneath the device depending on how the pieces are removed. An explanation of how the pieces will be removed is needed. Will the pieces be tailored to the size of the student? Suggest different sizes be made available.
 - Pylon: concern that the pylon may bend and prevent the swimmer from reaching the surface. The sturdiness of the pylon should be demonstrated.
 - Mat: an explanation is needed of how the lights in the mat are powered.

Vote

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

Required Revisions

- Conceptualize the goals of the study better and limit the goals to a manageable number.
- Provide background info: how do the devices differ from what is currently being used in swim lessons? What do they add?
- Change the focus from fear to comfort. Prevention of fear cannot be measured as proposed.
- If the data cannot be collected for a longer period of time over multiple sessions, then any study report must disclose this as a limitation of the study (PI cannot say much about a subject's level of comfort with water based on one session).
- Design a protocol that adapts to different age groups (including assent procedures), or narrow the age group.
- Make explicit that there will be one instructor per student – that a device will not be tested simultaneously on multiple students with only one instructor.
- Provide more info about the devices by providing a video demonstration of their use by the PI. Address concerns about the device outlined in the discussion about risks section of these minutes. If pressed for time, suggest focusing on getting approval for one of the devices.

Meeting adjourned at 10:30am

Minutes prepared by Alena Filip

SJSU Institutional Review Board – Meeting Minutes
Friday May 1, 2015
9:30am – 10:30am

Present: Craig Cisar, Barabara Fu, Sabrina Pinnell, Wendy Quach , Priya Raman, Maureen Smith (chair), Brandon White, Marjorie Freedman

Absent: Shahab Ardalan, Bernd Becker, Jang Hyung Cho, Alena Filip, Mark Van Selst, Ryan Ludman

Guests: Billy Tu, Environmental Studies Student

Agenda Items Covered:

15. Full Review of Protocol S15092 “Evaluating Resettled Villagers Reliance on Forest Resources: A Case Study of Cuc Phuong National Park, Vietnam”
(PI is Billy Tu, a student in Environmental Studies, and Dr. Lynne Trulio)

Nature of Study

The human subjects portion of the study is to evaluate resettled villagers' reliance on the forest resources of the Cuc Phuong National Park (CPNP) in Vietnam; there is also a non-human subjects component to evaluate the threats and status of the keeled box turtle at CPNP. Villagers were relocated outside of the park boundaries in 1980s and 1990s. This study purposes to understand whether the villagers are still relying on forest resources and how they have adapted to the resettlement area through observations of their activities in the forest as well as through household interviews in three villages.

Risks of Harm

The two main risks of harm posed by this protocol are the risk of criminal/civil liability to villagers who may be observed engaged in illegal activities (harvesting resources, hunting) and the risk of group harm. Even if the PI does not identify individual subjects in his findings, the villagers can still suffer consequences as a group if it is reported that they are still relying heavily on CPNP resources. The magnitude is significant if both individuals or the group suffer consequences as a result of the research, while the probability of harm in this protocol is unclear because the PI has not provided background information on how illegal activities are typically dealt with in this environment and whether a report that does not recommend enforcement would be effective in mitigating this potential harm. There are no direct benefits of the research to outweigh the harm.

Committee Discussion – with Student PI:

- Approval needed from federal gov't and community office
- Community office has representation from villagers – they are involved in the decision making process
- Need to document this in the protocol

- NGO collaborating with researcher; historically established relationship with researchers
- Advisor to contact legal office – what are legal responsibilities? Is student required to report illegal activity?
- Previous NGO recommendations to educate local police and locals on endangered species in hopes of preventing endangered wildlife from being caught
- Protocol – problems with observations, why observe if you are interviewing?
- Sampling procedure – door to door or snowball sampling?
- Triangulating with NGOs or summarizing transcript with villagers
- Looking at forest resource use
 - behavioral observations – how many people are coming in and out? How long are they staying in the park? What are they coming out with? Who is coming in and out (e.g., villager vs. tourist)? How many other ways to get into the park?

○ **Committee Discussion/Concerns**

- concern for student researcher – would Vietnamese gov't retain passport to get names of villagers who are doing illegal activity?
- Concern about safety of the villagers who have self-reported illegal activity

Vote

8 voting members present voted.

- 8- voted to reject the protocol in its current form
- A quorum was present. The required revisions are noted below. PI should resubmit as a new protocol that will be reviewed by the primary reviewer and the IRB chair.
- 8 – voted to recommend that the PI alter focus to protect his own safety and the safety of villagers to collect information about beliefs and attitudes of villagers and park rangers regarding conservation (e.g., What are their attitudes about conservation? Why is conservation good or bad? What can be done to help with conservation?). Additionally, PI should consider have a parent or community member present during interviews with children.

16. Selection of new IRB chair for 2015/16

Three members want to run for chair. Interested members should self nominate (via an email to the IRB coordinator) by Thursday May 7. Faculty will vote via email by May 12th.

Meeting adjourned at 10:45

Minutes prepared by Wendy Quach