2013-2014 Year-End Committee Report Form

Committee: Institutional Review Board (IRB)

Chair: Kristen Radsliff Rebmann	**Chair-Elect for 2013-2014**: Maureen Smith, *Associate Professor, Child & Adolescent Development* San José State University; One Washington Square San José, CA 95192-0075; (408) 924-3774 maureen.smith@sjsu.edu
Number of Meetings held: 6	

Items of Business Completed 2013/2014

1. Statistics collected for work completed by the IRB (July-December 2013 & January-June 2014).

Summary of 2013/2014 IRB Protocols.

Total Reviewed:	**557**
July-December 2013	291
January-June 2014	266

Protocols Receiving Full Board Review:	
2013	1
2014 (through May)	0

Reviewer-Approved Protocol Submissions:	
July-December 2013	133
January-June 2014	53
Approval - Expedited Total	**186**

2. Updated, revised, and developed new consent forms to assist researchers in preparing new protocols.

3. Filled challenging medical advisory board member vacancies. The full membership status of the IRB placed the committee in full federal compliance.

4. Continued holding committee meetings via campus-wide adopted conferencing software (Webex).

Unfinished Business Items from 2013/2014

1. Collecting resources for IRB reviewers to refer to as they review challenging submissions.
2. Online submission systems.

New Business Items for 2013/2014
1. Ongoing review of new protocol submissions.

Please return to the Office of the Academic Senate (ADM 176/0024) by June 2014.

SJSU Institutional Review Board – Meeting Minutes

Friday September 20, 2013
10am - 11am

Present via WebEx: Michael Adduci, Shahab Ardalan, Bernd Becker, Ryan Ludman , Kristen Rebmann (Chair),

Present on campus: Craig Cisar, Alena Filip (IRB Coordinator), Maureen Smith, Meg Virick, Brandon White

Guests: Janis Ost (student researcher), Alicia Henderson (sponsoring professor)

Absent: Mark Van Selst, Wendy Quach

Agenda Items Covered:

1. **Full review of protocol S1304006 "The Effects of Service Learning on Middle School Students in SDC Program"**
   Student PI: Janis Ost
   Faculty PI: Alicia Henderson

Background

The proposed research is to conduct a service-learning program with a select group of students in special day classes who have mild to moderate learning disabilities. The students would be asked to sell tea in different venues, including the school, a local store in Santa Cruz, and an animal shelter. The profits from sales at the school would go to the school, while the profits from outside sales would go to charity (foodbanks). The business – Schoolhouse Chai – is owned by the investigator, Janis Ost. Ms. Ost is also a general education teacher at the school from which the students are being recruited. The instrument used to measure the effectiveness of the program includes a pre/post survey for both the participants and their teachers that seeks to determine whether there was any change in their behavior, self-esteem, and social skills.

The issues of concern brought to the full committee are 1) conflict of interest inherent - multiple roles of the PI, 2) Promotion of a for profit business in research design, 3) Potential risk to subjects (stress, stigmatization) compared to no discernible benefits 4) Project seems to benefit PI more than subjects, 5) Not clear how assent can be achieved.

Comments and clarifications provided by Janis Ost

- The potential subjects would not be the PI's own students. The PI is a general education teacher at the school. She has a prior relationship with some of the special day class students whom she met (as well as their parents) through previous workability programs.

- Teachers receive funds from a workability office to create programs such as the one proposed for the research that students might be interested in. The students provide input about what they want to do. The Schoolhouse Chai project developed out of previous projects that involved selling items such as biscuits and store bought tea. The teacher reports back to the workability office about the effectiveness of the program. The difference now is that the tea that's being sold is from the PI's business.

- PI stated that the previous programs increased student self-esteem and that the teachers noticed improvements in the students.

- PI has a letter of support from the superintendent of the district for the project, indicating broader support by the community.

- The service learning component, according to PI, can be vocational training in food and hospitality services. She also mentioned that a primary goal is for students to learn the nature of giving. The students would be provided with transportation to their field work.

- PI contends that there should be trust in researcher to report results accurately.

Comments and questions by IRB members

- Is it service-learning? The field experiences seem to be more about fundraising. The instrument does not measure what the students have learned.

- Can the PI conduct the research objectively? Not if marketing/promoting a product that benefits the PI. Even self-reflective practice requires degree of objectivity that the proposed research is not designed to promote. PI assumes research will be beneficial to students and as a result has not effectively analyzed risk. Standards for research include designing the activities in a way that mitigates any bias towards a specific outcome. Can the research be done in any way that is disassociated with the product?

- PI clearly feels that the activity will benefit participants based on similar programs in the past and has not made an attempt to anticipate any potential risks and how to mitigate them. IRB members gave some examples of potential harm: stress of competing with fellow students for sales, the anxiety of having an additional job besides school work, a student may want to drop out of the project but will not do so out of fear of stigmatization, stigmatization of students with learning disabilities (will they feel the project is insulting?), inequitable subject selection (6 out of 10 students). Though the PI stressed that the activity is not designed to be completive, she has not taken into account the potential for students to interpret this way. If there is no plan in place to deal with/mitigate the harms, the research could result in damage to students' self-confidence.

- Though the community clearly wants the activity, there may be an institutional conflict of interest because the PI is donating money to the school. The administrators may be thinking about the gains for the institution as opposed to the direct benefits to students. The business and school may benefit from each other's mutual goodwill, but this reciprocal relationship does not automatically benefit the students.

- The research not only involves a protected group (minors) but also a vulnerable group (students with mild to moderate learning disabilities. There is incomplete about the status of the subjects and therefore no ability to determine if assent is possible. Students with mild to moderate learning disabilities are not usually placed into special ed day classes. They are usually place into general education classrooms unless there are other factors in play or they have other special needs. More detailed background information about this subject group is not provided.

- There are flaws in the survey design. Not only does it not measure service learning outcomes, but the questions for the youth are yes or no questions, which can be confusing and problematic (i.e., if the youth mark "yes" to high self-esteem on the post survey, when they marked "no" on the pre-survey this may be erroneously attributed to the program instead of other factors). The survey does not offer a range of possible answers like the teacher survey, and is limiting. It is also not a valid instrument for measuring self-esteem.

Decision

All nine voting members present voted unanimously to reject the protocol. A summary of justifications are

- The PI is tightly connected to the project and the outcomes, which lends itself to inherent bias and is a conflict of interest. Achieving objectivity is not a matter of the IRB placing trust in the researcher to be objective; it should be a built-in component of the research design.

- There may be an institutional conflict of interest. If the school anticipates it may receive funds, the administrators may have approved the project because the school may benefit, not because there are direct potential benefits to the students.

- There are flaws in the survey design. The yes/no questions for students are limiting and they may not provide an accurate measure of whether it was the program itself that resulted in any changes. The instrument also does not measure service learning outcomes.

- The subject population is not described in detail. Since most students with learning disabilities are placed in general education classrooms, it's not clear if there are other factors aside from their learning disabilities that the IRB must consider. Whether assent can be achieved cannot be determined.

- There are risks to students (stress, stigmatization) that have not been anticipated. There is an assumption that the subjects can only benefit.

Recommendations
Though this specific proposal cannot be approved, the IRB suggested some alternatives that the PI can work on with the help of the sponsoring professor:

- Consider partnering with workability to design a project such as a needs assessment for the school.

- Change the setting so that that the work that students are involved in does not involve selling a product. Instead focus on a topic that allows students to learn about volunteering instead of fundraising for the research (e.g., volunteering time at the animal shelter).

- If self-esteem is going to be measured, use an established instrument, such as the Rosenberg self-esteem scale.

- If students with learning disabilities will be selected provide more background information about why they are in a special ed day class and if they have any other needs. This includes getting a letter from the special ed teacher that provides context about the type of students who are being recruited, what their needs are, and whether they are all able to provide assent.

- If the research includes the above population, have a counselor available to check in with students and see how they're doing while participating in the research.

2. **Discussion of protocol F1304032 "Alcohol Class." Questions raised by Mark Van Selst.**

Protocol submitted by the Office of Student Conduct to measure effectiveness of mandatory Alcohol Class for students who violated student conduct code because of drinking behaviors. Pre/Post test data are already collected during the class, but the office would like to be able to share the information about the effectiveness of the program with outside institutions.

a) Is alcohol intervention a "normal educational process?"

b) The research appears to exclude minors but the alcohol interventions will most certainly not.

c) Pre-training approval may induce coercion and thus post-intervention (at post-test) would seem to be better (but potentially retroactive)

The IRB member's recommendations were to:

- Asking participants of the class if their data can be used for research purposes after they have completed the class. The data can be reported in aggregate.

- Ok to use archival data if it's anonymous.

- Drop people younger than 18 from research data.

The meeting adjourned at 11:16am

Minutes prepared by Alena Filip

SJSU Institutional Review Board – Meeting Minutes

Friday October 18, 2013
10am - 11am

Present via WebEx: Michael Adduci, Mark Van Selst

Present on campus: Bern Becker, Craig Cisar, Alena Filip (IRB Coordinator), Barbara Fu, Wendy Quach, Kristen Rebmann (IRB chair), Maureen Smith, Meg Virick, Brandon White

Absent: Shahab Ardalan, Julia Curry, Ryan Ludman

Agenda Items Covered:

1. **Introduction of IRB Members / Breakfast**

2. **Approval of Meeting Minutes for 5/3/13 and 9/20/13**
   Three members abstained (Barbara, Maureen, Wendy). The minutes were approved by the remained of members present.

3. **Announcements by IRB Coordinator**
   - CITI refresher training needed from members who have done the training more than 5 years ago. Please complete the training by the beginning of spring semester.
     https://www.citiprogram.org/

   - IRB members should read the handbooks for School of Social Work and the College of Education in preparation for reviewing these protocols this semester.
     http://www.sjsu.edu/gradstudies/irb/irb_workshop/index.html

4. **Upcoming Projects**
   - Simplification of consent forms for readability. Simplify language. Suggest omitting letterhead requirement and initial line requirement. Bring in samples to look at for next meeting.

   - IRB Member handbook as potential informational resources for reviewers.
     http://www.amazon.com/dp/1449647448/ref=cm_sw_su_dp

The meeting adjourned at 11:10am

Minutes prepared by Alena Filip

SJSU Institutional Review Board – Meeting Minutes

Friday December 6, 2013
10am - 11am

Present via WebEx: Michael Adduci, Shahab Ardalan, Bernd Becker, Craig Cisar, Julia Curry, Kristen Rebmann (Chair), Meg Virick, Brandon White

Absent: Alena Filip, Mark Van Selst, Maureen Smith, Wendy Quach

Agenda Items Covered:

1. **Approval of meeting September 2013 minutes.**
2. **Consent redesigns for spring.**
3. **IRB chair for 2014/2015.**

SJSU Institutional Review Board – Meeting Minutes

Friday February 28, 2014
10am - 11am

Present via WebEx: Michael Adduci, Shahab Ardalan, Bernd Becker, Craig Cisar, Julia Curry, Alena Filip, Gali Levi-McClure, Kristen Rebmann (Chair), Maureen Smith, Meg Virick, Brandon White, Barbara Fu

Absent: Mark Van Selst, Wendy Quach, Ryan Ludman

Agenda Items Covered:

1. **CITI Training for IRB Members**
   https://www.citiprogram.org/

2. **Discussion of Revised Consent Forms**
   - Major changes: discontinue use of initial line, use of letterhead optional (but strongly recommended for faculty), clear headings for elements of informed consent, instructions, and example consent forms.
   - Request example consent forms from reviewers.

3. **Exploring Canvas for Online Submission**
   Online submission process would need to include:
   - Accessibility for everyone, including outside investigators and individuals not familiar with canvas – needs to be easy to use.
   - Possibility to submit entire protocol, addendums, extensions, and IRB registration.
   - Accommodation for a sequence of reviews – Screening –> IRB Member-> AVP.
   - Needs to have a searchable database for record keeping of protocols.

   Canvas Pros:
   - Ability to layer submissions for individual "student."

   Canvas Cons:
   - May not be available in the future.
   - Difficult to search.
   - Teaching tool vs. record-keeping tool.

   Alternatives:
   - Outside vendor (expensive).
   - CSU-wide integrated system (for the future).
   - Attach to another software database tool already in use at SJSU.
   - Engineering department assistance to develop a submission system (Shahab).

Meeting adjourned at 11am
Minutes prepared by Alena Filip
Link to recording:
https://sjsu.webex.com/collabs/meetings/join?uuid=M70092ZFLKE77VDUUT5I88SC4E-3JZB

SJSU Institutional Review Board – Meeting Minutes

Friday April 11, 2014
10am - 11am

Present via WebEx: Michael Adduci, Shahab Ardalan, Craig Cisar, Alena Filip, Barabara Fu, Kristen Rebmann (Chair), Maureen Smith, Mark Van Selst, Meg Virick

Absent: Wendy Quach, Brandon White, Ryan Ludman, Julia Curry, Gali Levi-McClure, Bernd Becker

Agenda Items Covered:

1. **Electronic Submission Update**
   Discussion of IRBnet (http://www.irbnet.org) pros and cons:
   - Centralized support for online IRB submission from third party vendor.
   - Expensive ~ 10k a year. Cost per usage.
   - Need to include in budget every year for continuous access.

   Alternatives:
   - Create in-house submission system.
   - Use existing platform from another CSU.
   - Open source software.

2. **Senate Report Planning**
   - Report to senate includes # of protocols reviewed, # exempt or registered.
   - Other items to be included? How many are resubmitted? Length of time for reviewer return?
   - Reports to IRB chair – GS&R tracking spreadsheet.

3. **Planning For Fall 2014**
   - Selection of IRB chair in May.
   - GS&R guidelines for IRB chair.

   Meeting adjourned at 10:30am
   Minutes prepared by Alena Filip
   Link to recording:
   https://sjsu.webex.com/collabs/meetings/join?uuid=M3EW3O2LXOC1XT8XVTCSMNN6QG-3JZB