2015-2016 Year-End Committee Report Form

Committee:

Chair:	**Chair-Elect for 2016-2017**:
Number of Meeting held:	(Please include phone/zip/email if available)

Items of Business Completed 2015/2016
1.   2.   3.
Unfinished Business Items from 2015/2016
1.   2.   3.
New Business Items for 2016/2017
1.   2.   3.

Please return to the Office of the Academic Senate (ADM 176/0024) by May 31, 2016.

SJSU IRB Meeting Agenda Items
September 18, 2015

1. Introductions
2. New members need to formally join via academic senate. Vacant seats in Humanities, Engineering, General Unit, Student
3. CITI training requirement for new members - Deadline September 30, 2015.
4. Discussion of expectations: turn around time for review, attendance, and participation.
5. IRB Reviewer Sheet
6. Discussion of main differences between SJSU policy and federal regulations.

SJSU IRB Meeting Agenda Items
October 16, 2015

1. Introductions.
2. Approval of meeting minutes from the 9/18 and 5/1 meetings.
3. CITI training for new reviewers: Due date - Sept 30.
4. Pam Stacks:
   - Discussion of research vs. non-research protocols (the direction that the Office of Research is taking in handling of non-research activities, particularly for student work).
   - Quality control experiment - areas of improvement.
5. Alena Filip:
   - Overview of IRB reviewer desk reference.
   - Overview of sample protocols.
   - Invitation of Anthropology faculty to Dec meeting.
   - Changes to federal regulations on the horizon.

SJSU IRB Meeting Agenda Items

November 20, 2015

1. Approval of meeting minutes from the 10/16 meetings.
2. Social work protocols
3. Sample anthropology protocols
4. Highlights from the SBER and AER conferences - Alena

SJSU IRB Meeting Agenda Items

December 4, 2015

1. Approval of meeting minutes from the 11/20 meetings.
2. Discussion with Anthropology faculty

SJSU IRB Meeting Agenda Items

March 11, 2016

1. Approval of meeting minutes from the 12/4/15 meeting
2. Discussion of screening tool - any revisions or questions that reviewers have
3. IRB-relevant things learned from the survey workshop from those who attended
4. Recruitment of students

SJSU IRB Meeting Agenda Items

May 12, 2016

1. Approval of meeting minutes from the 3/11//16 meeting
2. Full review of IRB protocol

SJSU IRB Meeting Minutes
Friday, September 18, 2015
9:30 - 10:30 AM

Present: Bernd Becker, Craig Cesar, Amy D'Andrade, Jim Duzak, Liz Mullen, Sabrina Pinnell
Wendy Quach (chair), Priya Raman, Maureen Smith, Brandon White,

Absent: Alena Filip

Agenda Items Covered
1. Introductions
2. New members need to formally join via academic senate. Vacant seats in Humanities,
   Engineering, General Unit, Student, Community Representative
   a. Question from reviewer: do the student and community representative need to
      attend all the meetings?
3. CITI training requirement for new members - Deadline **September 30, 2015.**
4. Discussion of expectations: turn around time for review, attendance, and participation.
5. IRB Reviewer Sheet
   a. expedited review categories: http://www.hhs.gov/ohrp/policy/expedited98.html
6. Discussion of main differences between SJSU policy and federal regulations. - Tabled
   for next meeting.

Meeting adjourned at 10:25AM
Minutes prepared by Wendy Quach

SJSU Institutional Review Board – Meeting Minutes
Friday October 16, 2015
9:30-10:30am

Present: Craig Cisar, Elizabeth Mullen, Maureen Smith, Wendy Quach (chair), Bernd Becker, Mark Van Selst, Priya Raman, Sabrina Pinnell, Alena Filip, Pamela Stacks

Absent: Amy D'Andrade, Jim Duzack, Ryan Ludman, Brandon White

Agenda Items Covered:

1. **Introductions**
2. **Approval of meeting minutes from 5/1/2015 and 9/18/2015**
   * Motion was made to approved 9/18/2015 minutes – all 8 voting members present approved.
   * Motion was made to approve 5/1/2015 minutes – 7 voting members approved and 1 abstained.
   A quorum was present for both votes.
3. **CITI training for new reviewers**
4. **Pam Stacks, Institutional Official (IO) for IRB:**
   * IO has authority to disapprove research that the IRB approved, but not the other way around.
   * IO's role in evaluating protocols – overview of all protocols; ability to audit and tackle gray areas.
   Quality control experiment – areas of improvement.
   * Same protocol sent to all reviewers last fall semester; protocol was pieced together from 2 different protocols – narrative did not correspond to data instruments and consent form. An array of responses was received from reviewers – some approved, some had comments without recognizing main problem, some disapproved.
   - Inconsistency – biggest complaint from PIs
   - Spot checking vs. need for more methodical approach
   - Gray areas – requires engagement with evolving concepts
   - Important to keep current
   - Interplay between faculty investigator and IRB reviewers – some PIs want a template/structure for everything, but this does not allow for nuance or for the PI to stay intellectually engaged
   - IRB reviewers do an important job
   - Upcoming revision of regulations – fewer protocols for IRB members,
   Expanding role of IRB reviewers to create community within academic departments that is responsive to human subject protections.

Comment: reviewers depend on IRB coordinator to interpret their comments; suggestion was made to have a mechanism for internal dialogue (e.g., on the reviewer sheet have comments to editor vs. comments to author).

Discussion of research vs. non-research protocols and the direction that the Office of Research is taking in handling of non-research activities, particularly for student work.
* Fields grappling with whether their methodology is research. Iterations of student protocols are received because they and their department are not sure. Some depts say none of their students are doing research and some require all to go through IRB regardless. Some students want to do research even though their methods may not be perfect.
* Decision making process will be transferred to faculty once we revise our exclusion screening tool to include instructions and to accommodate upcoming changes in regulations – more exclusion categories (not just not research, not human subjects).

5. **Alena Filip:**
SJSU IRB stats:
* ~ 500-600 protocols per year; however, more than half qualify for exemption (some are determined to be excluded altogether) and are not reviewed by the IRB.
* Jan-Aug 2015 – each reviewer, on average, evaluated 11 protocols (expected to be 20-30 for the entire year).
* Protocols are sent via campus mail; expected turnaround time is two weeks or less.

Overview of IRB reviewer desk reference.
* Basic tool containing training resources that every IRB reviewer is expected to utilize and learn. Includes:
    i. IRB structure and role of team members.

ii. & iii. SJSU policy and federal regulations – what are some of the major differences?
        a. SJSU policy only allows exemption categories for children (except category 2) *unless* the work will be published, while the federal regulations allow exemption (except for category 2) irrespective of publication (a flaw in SJSU policy, as we don't screen for publication and a researcher may not know ahead of time whether the work will be published; if the work is not intended to contribute to generalizable knowledge, it is not research and is excluded from oversight rather than exempt for review.

b. SJSU has a registration process for exempt work that includes the requirement that some type of consent process occur.

c. SJSU policy specifies the structure of the consent form (specifically that the pronoun "you" be used and legible font size).

d. SJSU policy defines different kinds of risks (psychological, individual social, and group social); this is only mentioned in the federal guidance but not in the regulations.

e. SJSU policy states that the IRB will consider the need for additional safeguards for research involving individuals who have been institutionalized because of a mental disability and "other potentially vulnerable groups."

iv & v. IRB reviewer form and worksheet. The worksheet is an expanded version of the reviewer form to help reviewers conduct a more methodical review rather than spot checking (a separate sheet is provided for protocols that involve devices). Note, an individual IRB reviewer cannot reject a protocol – that can only be done by full committee; when marking resubmit/need extensive revisions, it's with the understanding the PI will be able to address the reviewer's concerns.

vi. IRB full committee template – created in an effort to make full committee meetings more organized and productive. The primary reviewer responsible for the original review of the protocol presents all of the info outlined under #4 on this worksheet to the full committee and provides a summary of recommended revisions and a suggestion for the vote. After this presentation there is an open discussion of questions and unresolved issues by all committee members, followed by a vote.

Comment: It was suggested that the primary reviewer, after selecting the protocol for full review, select a second reviewer to also do the same presentation to the full committee to ensure differing points of view and address the issue of inconsistency.

vii. Relevant articles on the most common types of research that occur at SJSU. Other articles may be periodically provided for discussion during meetings (e.g., article on ethnography for Dec meeting with Anthropology).

Overview of sample protocols.
Second training component (in digital format only) as a compliment to the reviewer desk reference – provides examples of different types of reviews and protocols from different colleges.

Action item for reviewers: review first two protocols in the packet of sample protocols from Anthropology students by the December 4th meeting.

Invitation of Anthropology faculty to December meeting
Invitation as a result of faculty expressing concern that IRB members are making comments about methods and theory employed by students although the protocols have already been approved by their faculty members. After reviewing the first two protocols in the packet of sample protocols and the literature provided by the IRB coordinator, be prepared for the following discussion points:

* Questions about participant observation and ethnography – do these methods qualify as research under the federal definition? (e.g., Are the methods systematic? Is the info gathered generalizable or anecdotal?)

* IRB responsibilities for ensuring sound research design – how can we help students get IRB approval when needed? What are some of the underlying problems that we've encountered with these protocols? (e.g., theories that are drawn from personal biases with no references or citations that provide a rationale for the study; data instruments that are not designed to answer the research questions posed).

* How might the upcoming changes in federal regulations affect the status of this kind of work?

Changes to federal regulations on the horizon
* Expansion of exclusion criteria to 11 categories (some current exemption categories will be excluded).
* Expansion of exemption criteria to 8 categories (most protocols that are currently reviewed under an expedited review will qualify for exemption).
* Work with biospecimens will constitute human subjects involvement.
* Future use of secondary data (non biospecimens) will fit into either exclusion or exemption categories – the data need not exist beforehand to qualify.
* Much fewer protocols for the IRB to review; increased workload for Office of Research.

Meeting adjourned 10:35am

Minutes prepared by Alena Filip

SJSU Institutional Review Board – Meeting Minutes
Friday November 20, 2015
9:30-10:30am

Present: Amy D'Andrade , Craig Cisar, Jim Duzack, Elizabeth Mullen, Maureen Smith, Wendy Quach (chair), Bernd Becker, Mark Van Selst, Sabrina Pinnell, Brandon White, Gilles Muller, Alena Filip

Absent: Ryan Ludman, Priya Raman

Agenda Items Covered:

1. **Approval of meeting minutes from 10/16/2015**
   Motion was made to approve 10/16/2015 minutes – 8 voting members were present at the time of the vote. 5 voted to approve and 2 abstained.
   A quorum was present for the vote, and the minutes were approved.

2. **Social Work Protocols**
   Informal deadline for MSW protocols – November 30th. Streamlined process – will send to each reviewer in batches. Please try to have initial responses back before winter break!

3. **Sample Anthropology Protocols**
   Invitation of Anthropology faculty members to December meeting - result of faculty members expressing concern that IRB members are making comments about methods and theory employed by students although the protocols have already been approved by their faculty members. Two protocols in the packet of sample protocols from the Anthropology Department were reviewed in preparation for this meeting.

   IRB Questions for Anthropology:
   - To what extent does the department view the work conducted by students as meeting the federal definition of research? Are there circumstances in which research that employs ethnography and participant observation meets the federal definition of research and other circumstances when it does not?
   - For those protocols that do meet the federal definition of research, what concerns do Anthropology faculty members have with recent reviews? Are there instances where IRB members have made requests that go beyond ensuring best practices and compliance with existing policies and regulations?
   - What are your students' goals when preparing an IRB protocol? What are the faculty members' goals when reviewing a student's IRB protocol?

- What is the department's approach to supervising students who propose to conduct research involving human subjects?
- Are students required to take a research methods class and, if so, what is the timing in relation to submission of their IRB protocols?
- What expectations do the faculty members have of the IRB?

IRB Expectations for Student Work That Meets the Federal Definition of Research:

"Risks to subjects are minimized by using procedures which are consistent with sound research design" - Criteria for IRB Approval - 45CFR46.111(a)

- Protocols provide a clear research question(s).
- A rationale for the study is provided, which includes a brief summary of the literature (with references).
- The methods are operationalized to answer the question(s) posed (e.g., for anthro protocols the purpose of recorded observations is often unclear).
- The data instruments are compatible with the research questions posed.
- The protocol is reasonably well-written and can be understood by a general audience.
- The supervising faculty member serves as the primary investigator and takes responsibility for ensuring the above expectations are met.

Expectations for Student Work That Does Not Meet the Federal Definition of Research:

- SJSU policy requires student research practicum to be no greater than minimal risk and should not target special populations or include sensitive subject matter. (S08-7 IV C)
- The course instructor or faculty supervisor is responsible for teaching students ethical conduct and providing direct supervision for each project. (S08-7 IV C)
- The consent forms provided by the Office of Research should not be used. Though project specific consent forms can be designed, they should not reference the Office of Research or the IRB.
- Care should be taken to not mislead participants into thinking that the work has been approved by the university and constitutes research that will contribute to generalizable knowledge. Terms such as "student project or "research practicum" should be used instead.

4. **Other Points Discussed**
   - Issues with current forms: Exclusion screening tool does not come with instructions and needs to be separated from application; suggestion to provide checkboxes on application that outline expectations for faculty signee.
   - Expansion of CITI to include SJSU-specific instructions.
   - Range of faculty responses to IRB comments on student work: some faculty members might take it personally, while others might defer to the IRB too much.
   - Stigma with calling something a project vs. research. Activities outside of the federal definition of research may be perceived as less credible.

5. **Highlights from the Social Behavioral and Education Research (SBER) Conference and the Advancing Ethical Research Conference (AER) Sponsored by Public Responsibility in Medicine and Research (PRIM&R)**

   - IRB Revolt (UC Berkeley) – IRB was inundated with undergraduate student projects – said this is not research. Students revolted and insisted that their work be acknowledged as research. Compromise reached – creation of guidelines for students and expectations for faculty members.

Meeting adjourned 10:40am

Minutes prepared by Alena Filip

Present: Amy D'Andrade , Craig Cisar, Jim Duzack, Elizabeth Mullen, Maureen Smith, Wendy Quach (chair), Bernd Becker, Mark Van Selst, Sabrina Pinnell , Priya Raman, Brandon White, Alena Filip

Guest: Dr. Jan English-Lueck, Department of Anthropology

Agenda Items Covered:

1. **Approval of meeting minutes from 11/20/2015**
   Motion was made to approve 11/20/2015 minutes – All twelve voting members were present. 10 votes for approval and 2 abstentions.
   A quorum was present for the vote, and the minutes were approved.

2. **Discussion with guest Dr. English-Lueck from the Department of Anthropology**
   Faculty concerns with IRB reviews of student protocols:
   - Research design an IRB review criteria
     -- shift in culture; a decade ago IRB did not take design into consideration. Risk benefit analysis triggers evaluation of soundness of design. [How is "soundness" defined/measured?]
   - Confusion about requirement for literature review. Protocol instructions do not state that a literature review is needed, so students are confused when feedback from IRB requests it.
     -- IRB needs a rationale for the study and assurance that a theory or approach that is unfamiliar to IRB members is building on previous research. A full lit review is not the goal, but enough background info to provide a basis for the research and an understanding if its importance. Protocol should also define potentially unfamiliar terms in a way that makes sense for a general audience.
     -- Students, as inexperienced researchers, have the challenge of building credibility (both with subjects and with research community). IRB review can be a considered a start to that process.
   - Unstable/inconsistent reviews when protocols are resubmitted several times. Some reasons:
     -- Change in reviewers [new reviewers come on board at the beginning of fall semester]. Previous reviewers may cycle off committee.
     -- Initial review may be an attempt to understand the purpose of the research. With further clarification, new issues may arise.

-- Inherent inconsistency when different people evaluate something (different styles and biases). IRB is working on standardizing reviews and resolving inconsistencies as much as possible.

Some questions from the IRB:

- Does ethnography fit the federal definition of research?
  -- Is systematic, but not generalizable in the classic sense.
  --Validity (what is being observed taken at face value w/ emic or etic perspectives - Jan's research) vs. Reliability (consistent measurements – Mark's research).
- How does the department approach student research that involves human subjects?
  --Currently research proposals are separate from IRB proposals; methods courses in second semester may be moved to first semester – rethinking graduate curriculum; currently some ambitious students as well as some inherited students.
  --Applied anthropology – students may be working with clients – issues of ownership of data and subject confidentiality when reporting recommendations.
  --Evolution of methods in the discipline – e.g., cyberethnography, heritage management.
- Perspective on covert observations?
  --Department does not allow students to conduct observations covertly – usually the risks outweigh any benefits.
  --Some of the protocols may seem covert because the reason for observing and the nature of the observations is not explained – general approach could be too broad to have a sense of what will be needed – challenge of ethnography. In terms of protocol preparation, IRB needs info from PIs about how they will explain to subjects what they will be observing.
      --Comes down to purpose of the research and what PI will do with the data. How will it be analyzed?
          -- Methods vs. ethics

Other discussion topics:

- Group harm – any conversation that leads to an epiphany on the part of the subject may be distressing and emotional – that by itself should not be cause to dismiss the research. Need to balance the magnitude of harm with the benefits of the research – could still be beneficial to subjects and to importance of the knowledge to be gained.

--Research involving heritage management and issue of community harm – not an area that the IRB is very familiar with.

Mutual goals:

- To create a rubric for faculty supervisors to use when evaluating student protocols that ensures IRB expectations are met. Anthropology department may create a department specific rubric. There will also be a general checklist added to the IRB application in front of faculty signature.
- Benefits of templates for students? Students tend to copy rather than think about the concerns.

Meeting adjourned 10:35am

Minutes prepared by Alena Filip

SJSU Institutional Review Board – Meeting Minutes
Friday March 11, 2015
9:30-10:30am

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

Absent: Amy D'Andrade, Mark Van Selst, Gilles Muller

Agenda Items Covered:

1. **Approval of meeting minutes from 12/4/2015**
   Motion was made to approve 12/4/2015 minutes – 10 voting members were present.
   9 votes for approval and 1 abstention.
   A quorum was present for the vote, and the minutes were approved.

   Comment: since the previous meeting, the Anthropology department has created a template for the protocol narrative for their students to follow based on review criteria of IRB members.

2. **Discussion of screening tool – any revisions or questions that reviewers have**
   Both reviewers and PIs have wondered whether certain activities meet the definition of research:
   - Student poster sessions? (Is public access a determining factor?)
   - Published abstracts? (In cases where abstracts make procedures, methods, and instruments available – some papers cite only abstracts)
   - Action research? (Old, recurring discussion – except now PIs have an "out" – if they don't take it, IRB will review protocol according to criteria established for IRBs)

   Screening tool now allows PIs to independently make that determination, but some PIs will submit regardless as a precaution. Culture of over-compliance and also concerns about ethical conduct for student work that does not met the threshold for definition of research – faculty believe IRB review protects them. Suggestion to have PIs submit the screening tool with protocols – then Office of Research is back to the procedural burden of having to respond to inconsistencies between protocol and screening tool and ultimately determining what is research.

   SJSU's more restrictive HSR policy part of the problem. Work with minors not exempt if published and even exempt work requires consent. Some don't know whether their

intent is to publish or disseminate. [Note: "Not sure" option on screening tool directs to protocol submission]. To change or not to change policy prior to upcoming changes in federal regs?

A suggestion was made to revise the first heading on the screening worksheet to say "Does It Meet the Federal Definition of Research?" This will be implemented so that PIs are aware what we mean when we refer to the word research.

3. **IRB-relevant things learned from the survey workshop for those who attended**
   - Importance of wording a question carefully.
   - Choice of scales – tendency to use 5 pt. scale
   - Benefit of open-ended questioning.
   - Phenomenon of acquiescence.

Survey workshop info and slides can be found on the Office of Research website:

http://www.sjsu.edu/research/events/2016_01-surveys/

4. **Consistency of review topic: who can recruit on behalf of teachers who want to use their own students?**

Some protocols have indicated ok to have another teacher recruit (historically, this has been ok for IRB), while some have requested it to be someone not affiliated with the school to mitigate potential coercion.

Discussion points:

- Investigating your own teaching methods does not meet the federal definition of research! Ok, but some faculty will still submit protocols regardless.
- Who do the students and parents trust? Having a complete stranger visit the school to solicit participation for a teacher that works at the school is awkward and time-consuming.
- Recruiting from another classroom or school – also time consuming and the investigation/instruction isn't tailored to the teacher's own class situation (e.g., special ed, special needs, all may have different needs).
- Who is able to answer questions about the research? Why can't the teacher/PI recruit if the study entails normal educational practices? How about submitting a protocol after the data are collected if the intervention will be conducted anyway? (What if IRB finds the intervention to be problematic?!)

- What benefit is there to having a colleague speak for the teacher/PI? How does this mitigate coercion?

Ultimately a motion was made and seconded that a colleague or other person who does not have direct supervision in the classroom can recruit student subjects. All 10 voting members present approved.

Meeting adjourned 10:35am

Minutes prepared by Alena Filip

Present: Amy D'Andrade, Craig Cisar, Elizabeth Mullen, Maureen Smith, Wendy Quach (chair), Bernd Becker, Sabrina Pinnell , Priya Raman, Mark Van Selst, Alena Filip

Absent: Jim Duzak, Gilles Muller, Brandon White

Agenda Items Covered:

1. **Approval of meeting minutes from 3/11/2016**
   Motion was made to approve 3/11/2016 minutes – 8 voting members were present at the time of the vote. 7 votes for approval and 1 abstention. A quorum was present for the vote, and the minutes were approved.

2. **Full Review of IRB Protocol S15174 "Digital Camouflage: Uncovering Hidden Effects in the Pixelization of Print Perception" by Che Vicente Menses, Master's student in the School of Journalism and Mass Communication (Faculty supervisor Scott Fosdick)**

Analysis by primary reviewer
Student is interested in how the experience of reading differs between print and digital platforms for Spanish-speaking bilingual students. He proposed a multi-method study involving an experimental design, survey, interviews, and observations, with the experiment requiring participants to read four news articles. The study design, variables and their measures, and analysis plan were not clear from the proposal. The lack of clarity was such that as a reviewer I did not have confidence that the student could conduct the study and learn what he wanted to know. In other words, I did not have confidence that any credible knowledge for the field would be gained from doing the study, or even that the student would have a meaningful learning experience from doing the study. Requested revisions did not result in improvement in the areas of concern. Given the time and activities asked of the participants, I did not feel I could approve the approval.

Full review template prepared by secondary reviewer:

Investigator qualifications
The student PI has an MA and experience working and teaching in an academic environment, but it does not appear that he has conducted an experimental study before. It's also not clear that the supervising faculty members have the expertise to advise this student. This is not a department that typically employs an experimental design in research.

According to the faculty supervisors, the student wants to get into a Ph.D. program and wants to do a master's thesis instead of a project.

Subject recruitment plan

The method for recruitment – having professors share email addresses of eligible students – would be acceptable. A preferred method to protect privacy would be to have the professors forward the script of the email or a recruitment flyer to subjects and have interested subjects contact the PI, but the proposed strategy would be accepted. Problems with the email script:

- Overstates the benefits of the research (e.g., development of scientific instruments needed to measure news reading behaviors – this is not the stated purpose of the study in the protocol).
- Underestimates the amount of time needed to complete the experiment. It will take longer than 20 minutes altogether. The reading portion alone will take 20 minutes if done quickly.

Risks

The proposed research poses minimal risk to participants. The primary risk is that participants will volunteer their time to be in a study that is unclear in its goals, flawed in its design, and inconsistent in its approach. The questions for the IRB to consider have less to do with risk and more to do with ethics. Is it ethical to approve a study that continues to have these problems after multiple iterations? Is it ethical to provide the institutional stamp of approval that the other institutions involved will rely on?

Potential benefits

There are no obvious direct benefits to subjects. The indirect benefits regarding the importance of the knowledge to be gained are overstated.

Risk/benefit ratio

Although there is only minimal risk, the potential benefits (both direct and indirect) are zero. Given that there is an ethical concern in approving a study that purports to contribute significantly to scholarly knowledge but does not deliver specifics, the risk/benefit ratio does not favor approval of the study.

Primary Reviewer Notes: Given my interpretation of risk to include burden, to me the risk to value ratio was too high – there was no value to be derived from the study, and considerable burden to be asked of the participants; it does not seem ethical to allow this.

Confidentiality

The protocol does not explain how the recordings will be handled (e.g., what device will be used, how the recordings will be stored and kept secure, whether they will be transcribed and by whom, and the retention plan for the recordings).

Data oversight/management

Since this is not a clinical study, ongoing oversight by the IRB would not be needed. However, the PI does not provide info on the type of statistical analysis that will occur in order to answer the research questions.

Informed consent process

The protocol contains no detailed info about how and when the consent will implemented. No debriefing script or procedures have been submitted, though the protocol does state subjects will be debriefed. The consent form is not designed to facilitate the implied mild deception; it should explain what subjects will be asked to do, risks, benefits, confidentiality, without revealing the true purpose of the study, which would be covered during the debriefing.

The consent form also has some technical problems:

- The faculty supervisor's name should appear at the top, along with the student's name.
- The consent form mentions course participation credit or extra credit, which is not mentioned in the protocol. Extra credit should not be offered if the PI cannot guarantee that an alternate form of extra credit will be offered to students who want extra credit but don't want to participate in research. Course credit should not be offered at all. Subjects' course grades should not be dependent on participation in the research.
- Contact info: Complaints about the research should be directed to the department chair. If the department chair serves as a faculty advisor for the research, then complaints should be directed to the college dean instead. Dr. Stacks' office should be corrected to the Office of Research.
- The consent document should contain the signature lines as outlined on our templates and an opt-in check box to audio recordings.

Vulnerable populations

The subjects are adults and are not part of a vulnerable population. Assent is not applicable.

Compensation and costs

The compensation section does not contain any relevant info pertaining to compensation.

Summary of unresolved issues by primary reviewer

Study describes a multi-method strategy using 1) an experiment with intervention, 2) a survey, 3) observation, and 4) interviews.

How each of these methods will be employed needs to be much more clearly described.

Why each method is needed needs to be justified.

The protocol needs to outline what questions will be answered by each method.

Each of the multiple research constructs named – user effects, archive effects, affinity, task orientation, language preference, language proficiency, news consumption, recall - needs to be defined and operationalized (the student PI needs to explain how it will be measured and/or developed from data collected).

Plans for analysis from each of the methodologies to be employed need to be detailed. What kind of statistical analysis, using which variables, will be conducted? What kind of a qualitative analysis will be done? Etc.

Summary of unresolved issues by secondary reviewer

- Proposal to measure changes in user experience between digital and print reading. PI does not define what is meant by "user experience." It's also not clear whether PI really wants to measure changes in experience vs. difference in experience.
- The post experiment interview does not specifically measure change; instead it focuses on past experience, as does the pre-test survey. The protocol does not clarify whether the survey will be administered again after the intervention. If another survey is to be used, it was not submitted. If the same survey were to be used, the protocol would need to identify how such a methodology could address the research question, given that the pre-test does not focus on experiences in the study.
- Proposal to investigate user preferences does not require an experiment/intervention.
- PI does not define what he means by bilingual. Clearly there is a difference between the terms English or Spanish dominate and bilingual (see Pew Center results). The PI states he wants to target bilingual speakers, yet he wants to measure how the level of *English* proficiency affects user preferences (see RQ1-RQ4). Later, the PI states that he intends to control for English proficiency, prohibiting any meaningful distinction in the scale to be used. The PI's pre-test survey, on the other hand, applies the scale to Spanish proficiency and *not* English. Moreover, the Low, Moderate, and High scale is not defined clearly for subjects and is bound to result in confusion and inaccuracy.

- PI does not have a measure to determine perceived intellectual growth and accomplishment based on the experiment, though this is one of the research questions.
- The PI relies on Potter's description of constructed interventions which "refers to special treatments designed by researchers to increase some aspect of media literacy (usually acquisition of some new knowledge or improvement of some media exposure skill) among targets." (Potter, "The State of Media Literacy", 2010). Increasing media literacy is not the stated goal of the research and the research is not designed to do that.
- The PI confuses the meaning of independent vs. dependent variables (age and sex are listed as dependent variables!), and has an extensive list for each, making it unclear how results will isolated.
- A plan to analyze the data was not provided.
- Hacko & Redish appear to be talking about user and task analysis in relation to a product and its interface design, whereas this study proposes to apply their analysis to a mode of delivery. Is it appropriate to apply this type of analysis to reading preferences? Are "readers" synonymous with "users"?

Other problems:

- The protocol does not explain where/when the study will take place. It makes reference to classrooms, but does not specify whether the research will be conducted during class time or outside of class time.
- The start date continues to be retroactive.

Recommended vote by primary reviewer
My recommendation is to disapprove protocol. Protocol does not describe a competent research proposal that justifies the time/effort asked of research participants.

Vote by full committee
A motion was made to not approve protocol S15174. All 10 members present unanimously agreed to not approve the protocol. A quorum was present for the vote.

Further discussion
There was some discussion about how to convey the problems with the protocol in a way that either encourages meaningful and substantial change so that it could be approved or steers the student PI to an alternative option that does not require IRB review. It was agreed that the IRB should not determine the course of action the student must take or prohibit the student from submitting a protocol again. A consensus was reached that both student and faculty member will receive a brief statement about the outcome of the review and general problems with a

protocol along with a supplemental attachment of excerpts from the meeting minutes that summarizes the unresolved issues in greater detail.

3. **Summer Schedules**

IRB members continue to be needed over the summer for review. Please email Alena if you will be away for a longer period or of you prefer to receive protocols via email rather than campus mail.

Meeting adjourned 10:30 am

Minutes prepared by Alena Filip