

2018-2019 Year-End Committee Report Form

Committee: Institutional Review Board (IRB)

Chair:
Bernd Becker, Associate Librarian

Chair-Elect for 2019-2020:

Priya Raman, Associate Professor
priya.raman@sjsu.edu
Campus Zip: -0112

Number of Meeting held: 3

Items of Business Completed 2018/2019

1. Integrated Federal revisions to Common Rule ensuring that SJSU is now fully compliant with new regulations regarding human subject research
2. Continued review of new data management policies/procedures. Items will be added to new Data Management Handbook for PIs.
3. Developing best practices for reviewers regarding areas of concern for SJSU protocols (Video Recording, PIs as service providers to pools of research subjects, athletic teams as pools of research subjects)

Unfinished Business Items from 2018/2019

1. Completion of new Data Management Handbook. Particular points of interest that protect research subject data will continue to be identified and compiled into the handbook (ETA: 19/20)
- 2.
- 3.

New Business Items for 2019/2020

1. None.
- 2.
- 3.

Please return to the Office of the Academic Senate (ADM 176/0024) by June 4, 2019.

IRB Meeting Minutes

Date/Time: 10/19/2018 9:30am

Location: MLK Library, Room 525

IRB Members Present: Bernd Becker (Chair), Craig Cisar, Justin Rietz, Elizabeth Mullen, Maureen Smith, Emily Slusser, Josh Nelson, Wes Maciejewski, Priya Raman, Sabrina Pinnell, Grace Shefcik, Alice Butzlaff, Edith Kinney, Alena Filip

1. **Greetings & Introductions**
2. **Status of federal regulations:**

- A revised common rule for HSR, years in the making, was to take effect at the beginning of 2018.
- SJSU was prepared, having passed a new HSR policy in November 2017, but feds delayed the implementation date days before it was to go into effect.
- To deal with this delay without having to redo our policy, we decided to apply the new rules to non-funded research only (the majority of the protocols we review) which is not subject to federal oversight. For the few that are funded, we would apply the pre-2018 rules until the new rules go into effect.
- Update in July 2018 from OHRP: The revised common rule is delayed until January 2019, but the IRB may implement some of the burden reducing measures to all protocols, including funded protocols, beginning July 2018. Below is a summary of all the changes that the revised common rule embodies. The first 3 (in bold) may be implemented now.
- Update September 2018: CSU IRB forum in Bakersfield – presentation by OHRP representative who stated that OHRP does not anticipate further delay and there will be no further revisions to the revised common rule.

Summary of common rule revisions:

- **Definition of research explicitly excludes certain activities: oral history, journalism, literary criticism, legal research, historical scholarship; public health surveillance activities, criminal investigations, national security.**
- **No continuing review is required for research initially evaluated under expedited review.**
- **No longer need to register studies pending grant review with the IRB.**
- New exemption categories (e.g., benign behavioral interventions), clarification to existing categories (e.g., limited review for some categories required), clarification on how new exemptions apply to vulnerable groups (see [Table of Exemption Categories \(pdf\)](#)).
- Consent documents must make sense to the target population and the consent process must be comprehensible to prospective subjects; this includes minimization of situations that may cause undue influence or present a conflict of interest. (Expansion of the concept of vulnerability to include coercion and undue influence).
- Expansion of info needed on consent documents when biospecimens are used (e.g., use for future research, use for commercial profit).

- Broad consent options for unspecified future research on secondary data or bio-specimens.
- Single IRB mandate – only one IRB conducts a review when multiple institutions are engaged in collaborative research.
- Expanded definition of clinical trials to behavioral health-related outcome and some new requirements for clinical trials.

Summary of 2017 SJSU-specific policy revisions that go beyond the common rule:

- Exemption categories apply to vulnerable groups in the same way as the federal regulations – previous SJSU policy was more restrictive.
- Continue to apply more stringent consent requirements than the federal regulations for exempt research – most exempt research will only require a consent notice as opposed to a signed consent form, except when the subjects are minors or when the research is subject to other laws (e.g., FERPA) that require written consent.
- No parental permission is required for college students under the age of 18 participating in school-based research.
- Assent (verbal or written) is required, when appropriate, or researchers must provide an explanation for why assent is not appropriate.
- SJSU has chosen not to adopt the broad consent provisions and accompanying exemption categories outlined in the federal regulations (which enables the creation of databases that are primarily of interest to biomedical research).

3. Quick announcement about new regulations that might affect some research (EU GDPR and California Consumer Privacy Act).

- GDPR (May 2018) – applies to EU citizens as well as individuals who are in the EU. Consent-based model compatible with IRB requirements. Resource available in Office of Research: European Data Protection Law and Practices (published by the International Association of Privacy Professionals).
Resource provided by OHRP: <https://www.hhs.gov/ohrp/international/gdpr/compilation-of-gdpr-guidances-tables/index.html>
- [CA Consumer Privacy Act \(June 2018\)](#)
Resource available in the Office of Research: California Privacy Law (published by the International Association of Privacy Professionals)

4. New data management handbook (ETA: 2019)

- Handout – outline of data management steps. Questions, comments? Will ask reviewers for feedback in the near future.

- Final product will be a detailed handbook – one place for info on all HSR-related data management issues; a short version checklist like this handout; a fillable spreadsheet for PIs; and a video.
- Resulting revisions to application TBD.
- Needs – check with IT about: classification (sound recordings and eye-tracking are classified as Level 1 biometric data, but are routinely collected by researchers); resource material on encryption for different types of documents; someone with expertise on export/import laws as they pertain to data security.

5. Quick overview of the protocol process for new reviewers (and advice from returning reviewers)

- Maximum number of protocols per reviewer per semester ~ 5. Need reviewers over winter and summer break also.
- AF request that reviewers send quick confirmation when receiving a protocol for review from irb@sjsu.edu
- Review protocol within 10 business days or less.
- Refer to IRB reviewer desk reference for tips and detailed review criteria; ask another experienced reviewer; ask Alena or Bernd.
- Common issues: inconsistencies, poorly written consent forms or consent forms that are too technical, issues with undue influence (investigators in a dual role), lack of background info and references in protocols.
- Ongoing discussions: the extent to which IRBs are allowed to make comments about research design (regs allow when design increases risk to participants). Considered on a case by case basis.

6. Questions from reviewers about anything IRB-related.

- Crucial concern raised around data management: cloud-base data storage – no SJSU product available; researchers must vet vendors carefully and understand terms and conditions of service; location of data stored in the cloud may be uncertain and the legal jurisdiction may be unclear; some data may be too sensitive to be store in the cloud; IRB can make recommendations on trusted products but cannot mandate the use of a specific product.

Meeting adjourned at 10:30

Prepared by Alena Filip

IRB Meeting Minutes

Date/Time: March 15, 2019 9:30am

Location: MLK Library, Room 525

IRB Members Present: Bernd Becker (Chair), Craig Cisar, Justin Rietz, Elizabeth Mullen, Maureen Smith, Emily Slusser, Josh Nelson, Wes Maciejewski, Priya Raman, Sabrina Pinnell, Alice Butzlaff, Edith Kinney, Alena Filip

1. Discussion of protocols involving video recording.

- * Educational settings – recordings are routine? Is parent consent and child assent needed? If so, what happens when some students do not participate in the research?
- * Blurring/editing still means they are recorded.
- * Seating students based on consent/assent may be stigmatizing and may still result in capture of non-participants since they may still participate in class activities.
- * Clear justification needs to be provided in the protocol; previous agreements that a school has with parents about video-recordings (e.g., CALPTA and teaching credential activities) don't mention research and are often recordings of the teacher only; explicit consent for research needed because parents may want to know and have a right to know the purpose of recording their child and what will be done with the recording; acknowledgement that lack of comprehensibility of the consent form may be a barrier for some parents; also some parents may feel compelled to provide consent because their child's teacher is asking – see next discussion item.

2. Discussion on protocols involving PIs who are service providers to the pool of research subjects.

- * Revised common rule: two places where there is new language about undue influence.

§46.111 Criteria for IRB approval of research. (a)(3) "Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons."

§46.116 General requirements for informed consent. (a)(2) "An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence."

- * Criteria that were previously implicit have been made explicit.
- * SJSU IRB has applied considerations about undue influence to protocols in some departments, but we need to do this more consistently for all departments. Example: kinesiology where student researchers might have a dual role as athletic trainers, coaches, etc.

* Options to minimize the potential for undue influence = 1) make data collection anonymous so research team does not know who participated (does not work for small subject samples of people who the researcher is familiar with), 2) have a neutral third party conduct the recruitment, obtain consent, collect the data, and provide the researcher with de-identified data (poses a burden on the third party to conduct almost all research activities), 3) have a third do the same as 2 but provide the researcher with the consent forms and data once the researcher no longer has a dual role -- e.g., once a student is no longer in a teacher's class -- (assumes the PI's dual role is time-limited), or 4) collect the data from another group where the conflict of interest and potential for undue influence does not exist.

3. Discussion on the reliance of athletic teams as pools of research subjects.

* Sample stats: we currently have 6 active protocols using the baseball team from one PI. Might not be as much of an issue if the research is strewn out over multiple semesters and years, but these were all submitted around the same time in the past year. How to best handle the issue without derailing the PI's research? Suggestions include: 1) consolidating submission into one or two protocols and doing the measurements together using one consent form or, 2) having researchers who use athletic teams get a letter of support from the athletic director who can monitor whether a specific team is being over-utilized (athletic director would be better than coach, and would potentially provide objective monitoring so that the IRB does not have to do that). IRB member for college of HHS will run it by his department.

4. Common Rule Changes

Common rule was made into law Jan 2019; no changes since last discussion regarding its contents. Updated desk reference will be provided in Fall 2019 (currently it has been provided in digital form only).

Meeting adjourned at 10:30

Prepared by Alena Filip

IRB Meeting Minutes

Date/Time: May 17, 2019 9:30am

Location: MLK Library, Room 525

IRB Members Present: Bernd Becker (Chair), Elizabeth Mullen, Maureen Smith, Emily Slusser, Wes Maciejewski, Priya Raman, Sabrina Pinnell, Alice Butzlaff, Anand Ramasubramanian, Alena Filip

1. Confirmation of IRB chair

The majority of IRB members confirmed their support via email prior to the meeting for nominee Priya Raman as IRB chair for AY 2019/2020.

Congratulations Priya!

2. Approval of minutes from last meeting

8 members, a quorum, were present when a motion was made to approve the meeting minutes from 3/15/2019. 7 members approved and 1 member abstained. The minutes from 3/15/2019 were approved.

3. Updates to IRB application

- Correction to definition of non-significant risk device: An NSR device, as defined by the FDA, does not present a potential for serious risk to the health, safety, and welfare of the subject **and** is 1) not intended as an implant, 2) not needed for sustaining human life, diagnosing, curing, mitigating, or treating disease. (AF originally though it was an or statement).

Recall, IRB has to make a NSR determination if a device is an experimental device that is not approved for commercial use or if the research involves a device approved for commercial use but the study is intended to look at new uses for the device – this might apply to protocol submissions from Industrial Systems Engineering or Kinesiology.

- Removed first yes/no question under data management plan about whether the research team will collect identifying or potentially identifying info. Too many applicants mark “no,” presumably with the assumption that they do not intend to disseminate identifying or potentially identifying info. Now, PI’s have to fill out items i-xi or indicate N/A for each one.
- May make additional changes over the summer as the data management handbook becomes available; will cover any revisions at first IRB meeting during fall semester.
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- Alena will monitor if an applicant needs to use the updated form – reviewers don't have to do this.

4. New SJSU process for research that includes contracts with external entities.

- Any agreement between researchers and an external entity that requires approval or signature of the University, may not be signed by the PI but needs to go through contracts and purchasing (if not related to a grant going through the foundation). This includes non-disclosure agreements, data use agreements, memorandums of understanding, etc.
- Process starts in PI's department. A department administrator creates a requisition through FTS → Office of Research and Contracts and Purchasing → funneled to appropriate offices for vetting (e.g., IT) → Department receives signed copy.
- Temporary solution. No info about this on Research website.
- May take time to get university signatures – PIs should plan ahead.
- Q: IRB approval contingent upon completion of the contract first?

5. Summer availability and reminder to renew term memberships

Make sure to renew your appointment with the academic senate if your term is expiring and you wish to continue to be on the IRB. Committee on committees sends an announcement about committee vacancies in the spring. Contact the CoC Chair if you have any problems with renewing your appointment.

Make sure to let Alena know your schedule over the summer.

6. Changes to application? Changes to IRB Reviewer Desk Reference?

Request to label sections of application more distinctly so that reviewers can point to the specific sections that require revisions (AF will work on this over the summer).

Meeting adjourned at 10:15

Prepared by Alena Filip