Southern Utah University Institutional Review Board 2019-2020 Annual Report May 2020

Prepared by Dr. Bryan Koenig, IRB Chair, and Samantha Harper

1. Abstract

The SUU IRB increased from 9 to 11 members this year, adding two new positions to help with the workload of reviewing applications done by the chair. Neither new position has any compensation or course reassignments. This was the first year in which the IRB chair had a 2 course reassignment (rather than 1) and a 5-hour-per-week student worker. These changes were invaluable in enabling the IRB to begin updating its procedures and policies to align with federal regulation changes that were mandated to be implemented on 21 January 2019. They also facilitated (a) IRB-training for the IRB chair (i.e., attending two IRB conferences), (b) the IRB chair providing training sessions for first-year faculty and the EDUC faculty, (c) procedural improvements, such as the new IRB email (irb@suu.edu), and (d) enhanced record keeping (such as this report).

During the 2019-2020 academic year, the SUU IRB received 219 applications. This was 9 fewer than the prior academic year but 30 more than any other year on record. The overall trend across years of increasing numbers of submitted applications is expected to continue. This year, the College of Education and Human Development and the College of Humanities and Social Sciences accounted for 54% and 33% of all applications, respectively. Of the applications that were approved, 19 were approved as class projects, 148 as exempt, 22 as expedited, and 7 were full board reviews. A quarter of applications were approved in about 1 week, half in 2 weeks, and three-quarters in a month; the average review time was 21 days.

Looking forward, the SUU IRB seems to be in good shape regarding membership. Also, many improvements are ongoing and planned. Ongoing (incomplete) projects include revising SUU's IRB policy (Policy 6.20) and revising the IRB guidance for researchers regarding the preparation of their consent documents (to align with the revised federal regulations). Planned projects include improving the application forms themselves, switching to an online application submission platform, and revising the SUU IRB webpage. Summer semester workload starting 2021 is an unaddressed issue that will need to be considered.

2. SUU IRB Committee Membership

The SUU IRB committee was comprised of 11 members at the conclusion of the 2019-20 academic year (see Table 1). Two positions were created during the year (Vice Chair and Teacher Education reviewer, "EDUC"). Both positions were intended to help the chair with review of non-full board reviews (usually the chair reviews all non-full board reviews). The Teacher Education reviewer started doing reviews in the last month of the academic year, and the Vice Chair was still in training and so did not get to start reviews yet. Howard Hu replaced Roy Johnson, who retired, in representing the College of Business. This was also the first year in

which the IRB had a student worker (5 hours per week). The student worker did a preliminary review of applications for completeness and provided a courtesy notification of receipt of applications. She also compiled much of the data included in this report.

Table 1. IRB committee membership at the end of the 2019-2020 academic year

Role	Name	Email	Expiry
IRB Chair	Bryan Koenig (began May 2019)	bryankoenig@suu.edu	Ongoing
Vice Chair	*Mark Siemon (began March 2020)	marksiemon@suu.edu	Ongoing
SPARC	Sylvia Bradshaw (began May 2019)	sylviabradshaw@suu.edu	Ongoing
HSS	Michael Ostrowsky	ostrowsky@suu.edu	Spring 2022
BUS	⁺ Howard Hu	shu@suu.edu	Spring 2021
CPVA	Brian Beacom	brianbeacom@suu.edu	Spring 2022
COEHD	Jim Mock	jimmock@suu.edu	Spring 2020
SIEL	Scott Lanning	lanning@suu.edu	Spring 2021
COSE	Matt Schmidt	schmidt@suu.edu	Spring 2020
Community Member	Kelli Price	kelliannprice@gmail.com	Spring 2021
EDUC	*Betty Ann Rember	bettyrember@suu.edu	Spring 2022

^{*} New position this year

3. IRB Application Submission Counts

The SUU IRB received 219 applications this academic year (see Table 2).

Table 2. Number of submissions during the last six academic years

Acad. Year	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	Total
2019-20	3	2	7	5	27	11	69	8	19	24	36	8	219
2018-19*	6	3	2	5	21	41	41	5	24	18	33	29	228
2017-18	8	4	8	6	17	32	17	11	17	35	20	14	189
2016-17	5	1	5	4	12	21	11	6	20	20	15	11	131
2015-16	3	2	3	9	9	22	13	5	14	17	12	11	120
2014-15	2	5	8	9	17	22	24	4	13	24	13	6	147
average	5	3	6	6	17	25	29	7	18	23	22	13	172

^{*}Reported numbers are approvals rather than submissions, as submission date was unavailable.

This was 9 fewer than last year, but the second highest in record (going back to 2014-15). Across years, the average number of submissions during fall semester (Sept-Dec) is 78, spring semester (Jan-Apr) was 76, and summer (May-Aug) was 20. Overall, the trend has been for an increase in the number of submissions, with a low of 120 in 2015-16 and a high last year of 228, which corresponds to a 90% increase comparing those years (see Figure 1).

⁺ New member, replaced Roy Johnson, who retired from SUU

IRB Application submissions by year

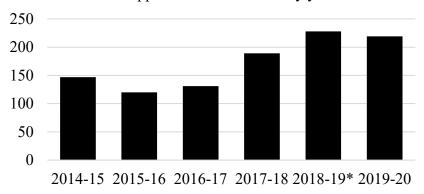


Figure 1. Number of IRB application submission by academic year, for the last six academic years (*note: 2018-19 is IRB approvals rather than submissions)

Researchers in 4 colleges submitted at least on application to the SUU IRB (see Table 3).

Table 3. Number of applications submitted by college (or programs/departments within college, which are not added to totals)

College	2019-20	2018-19	2017-18	2016-17
Aerospace Sciences and Technology	0 (0%)	-		
Education and Human Development	119 (54%)	-	58 (32%)	50 (35%)
Education	87 (40%)	-		
Kinesiology/Outdoor Recreation	30 (14%)	-		
Humanities and Social Sciences	73 (33%)	-	78 (43%)	54 (38%)
Psychology	40 (18%)	-		
Performing & Visual Arts	0 (0%)	-	2 (1%)	1 (1%)
Science and Engineering	16 (7%)	-	22 (12%)	18 (13%)
Business	2 (1%)	-	5 (3%)	2 (1%)
Other	9 (4%)	-	15 (8%)	19 (13%)
Total	219 (99%)		180 (99%)	144 (101%)

*Notes: Data unavailable for 2018-19. Years 2017-18 and 2018-19 included the following summer, whereas the prior summer is included in 2019-20 and for all years in Table 2.

Of the 219 submitted applications, the College of Education and Human Development (COEHD) submitted the most, 54%, and their Master in Education graduate program accounted for 40% of all applications, more than any other department or college. The College of Humanities and Social Sciences (HSS) accounted for 33% of all applications. Combined, COEHD and HSS comprised 87% of all applications. Note that these numbers are imprecise because some applications included researchers from multiple departments. The "Other" category for 2019-2020 included 3 applications from Student Affairs, 1 from Counseling and Psychological Services (CAPS), 5 applications for Interdisciplinary Studies, and 1 from the Library.

Given expectations of increased student enrollment, the IRB chair anticipates continued overall increases in the number of applications. Notably, the Masters in Education Graduate program

anticipates adding a summer research class next year (summer 2021) that may have 20-40 IRB applications, although the impact of COVID-19 on this plan is unclear.

4. IRB Turnaround Time and Approval Types

Whereas the number of applications submitted is the primary indicator of IRB workload, turnaround time reflects IRB workload, availability, and efficiency—and (probably) influences "customer satisfaction." Numerous factors influence how long applications take to review. Perhaps the most important is whether the application is a full board review or not. If not full board, then the IRB chair or a designee can review the application when convenient for them. Full board reviews, in contrast, must wait until the next monthly IRB convened meeting. Another factor that increases approval time is when submitted applications omit critical information. In such cases, the IRB must request clarification, and often researchers take a while to reply. Such reviews are included here.

The overall average number of days that approved applications were under review was 20.72 days (SD = 19.81; see Table 4).

Table 4. Review times for approved IRB applications.

Approval Type	Mean days under review	SD	N
Class project	8.42	6.87	19
Exempt	20.83	17.71	148
Expedited	16.36	14.47	22
Full	65.57	35.94	7
Total	20.72	19.81	196

The SUU IRB approves applications under four categories: class projects, exempt, expedited, and full board reviews. The review times differed substantially across these types of approvals (see Table 4 and Figure 2).

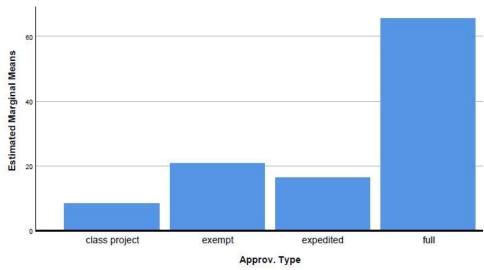


Figure 2. Mean days from submission to approval for approved IRB applications, by type of approval.

Class projects were approved most quickly, then expedited reviews, exempt reviews, and full board reviews took the longest, on average. The longer review times for exempt approvals compared to expedited approvals may seem counter intuitive (because expedited reviews are generally determined to have greater "risk" for participants than are exempt reviews). Two factors likely produced this pattern. First, exempt reviews have a simplified application form, and therefore exempt applications often omit information critical for the IRB review, resulting in a lag following IRB requests for clarifications. Second, the IRB received applications for Masters of Education graduate students primarily in two batches with about 40 and 20 applications per batch. It takes a while to work through the batches, so the later arriving applications in the batch have longer review times.

There was substantial variation in approval times across applications. The distribution of approval times was positively skewed, with only a few applications taking longer than 45 days (see Figure 3).

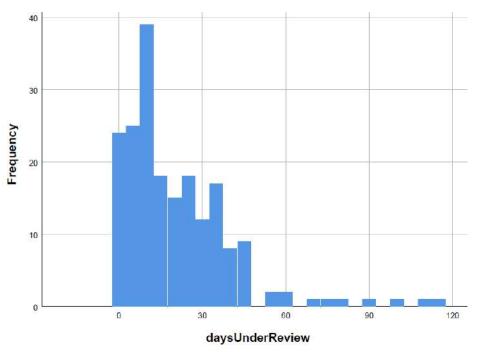


Figure 3. Histogram of how long applications were under review.

Overall, 25% of applications were approved within 7 days, 50% within 15 days, and 75% within 30 days. The appendix includes the number of days under review for each approved application.

5. IRB Completed achievements

The second course reassignment for the IRB chair was invaluable in allowing the IRB to update its policies to comply with federal regulations that had a mandated implementation date of 21 January 2019. The additional course reassignment and student worker also afforded the opportunity to make other improvements, such as this detailed report. The following list summarizes some key accomplishments during the 2019-2020 academic year.

- 1. Established a permanent IRB email account (i.e., irb@suu.edu), which will allow continuity across IRB chairs, access to the IRB email by others (e.g., the student worker), and an archive of IRB-related communications
- 2. Developed IRB-shared documentation via google docs
 - The master list of applications
 - The files for all applications
 - Viewable by IRB committee members
 - Modifiable by chair, vice chair, EDUC reviewer, and the student worker
- 3. Collaborated with Dr. Joel Judd, Assistant Professor of Education, on developing templates for consent documents used on research on standard educational practices
- 4. Developed SUU SOP for review of applications for research on standard educational practices
- 5. IRB Chair, Dr. Bryan Koenig, attended two IRB conferences for professional development (Northwest Association for Biomedical Research Conference, and PRIM&R conference on Social, Behavioral, and Educational Research)
- 6. Added two new position to the IRB, both able to help with review of exempt and expedited applications—unlike regular board members.
 - The Vice Chair of the IRB will help the IRB Chair to review applications, can run convened IRB meetings if the Chair is unavailable, and is an extra-strong candidate to become the next IRB chair—so that the vice chair could help maintain cultural knowledge and continuity across sequential IRB chairs. We are happy that this position was taken by Dr. Mark Siemon, PhD, RN, PHNA-BC, CPH, and Assistant Professor of Nursing.
 - The Teacher Education Reviewer is an expert in K-12 educational contexts and helps to review the applications for research on standard educational practices. We are happy that this position was taken by Betty Ann Rember, Assistant Professor and Director of Field Services in the College of Education & Human Development.
- 7. Had a 5-hour per week student worker assist with IRB responsibilities (e.g., communicating with researchers, recording application details in the master list, compiling IRB-related statistics)
- 8. Revised research ethics training requirements: specifically, the required training modules were revised, and the re-training period was set to 3 years, which is common across institutions of higher education
- 9. Provided an IRB orientation to 1st year faculty as part of the CETL's first year faculty training classes (12 Nov 2019, 2:30-3:30; 14 Nov 2019, 4-5pm; 15 Nov 2019, 9-10)
- 10. Provided IRB training on 8 October 2019, by invitation of Dr. Tony Pellegrini, Director of Graduate Studies in Education, for the Faculty of the Master in Education MA Education program
- 11. Implemented many revisions required by the updated federal regulations, although this is not completely done.

6. IRB Ongoing projects

- 1. Revising SUU Policy 6.20 (i.e., SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS)
- 2. Revising informed consent guide to fit updated federal regulations.

3. Revising application forms and guides.

7. IRB Anticipated projects

- Exploring online IRB application management software
 Revise SUU IRB webpage