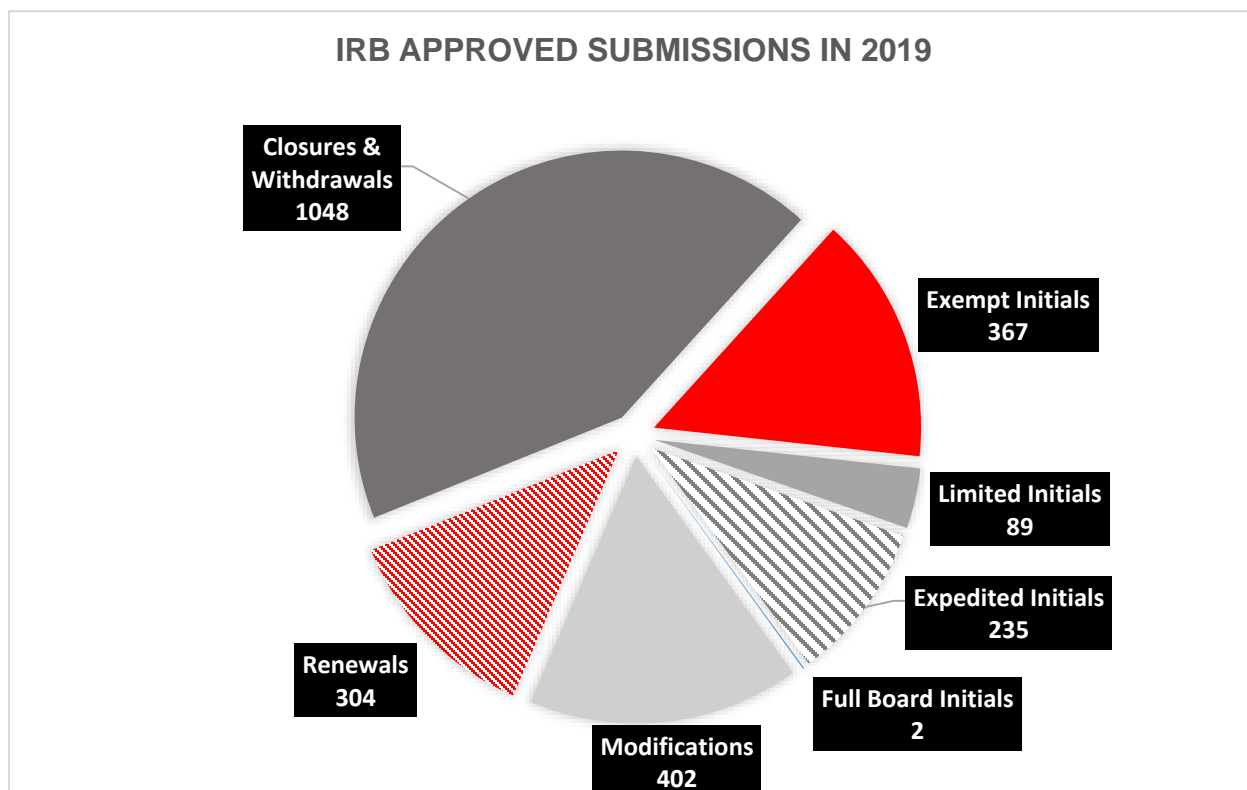


TEXAS TECH UNIVERSITY
INSTITUTIONAL REVIEW BOARD/
HUMAN RESEARCH PROTECTION PROGRAM
2019 ANNUAL REPORT



EXECUTIVE SUMMARY

COMMITTEE PURPOSE

The Institutional Review Board (IRB) regulates all activity involving research with human subjects that (a) is conducted by TTU personnel during their employment by the university or (b) uses TTU facilities or resources. This committee operates in accordance with TTU OP 74.09 and federal regulations stated in 45 CFR 46.

PROPOSAL VOLUME

There were a total of 2,080 research protocols active in 2019.

- This is a 38% increase from 2015, and an 6% decrease from 2017.
 - In 2019, the HRPP implemented an administrative check-in. This process encouraged PIs to close IRB protocols that were no longer active.
- 82 protocols involved sponsored projects.
 - 25 were federally funded.
 - 23 were federal pass throughs.
- 531 protocols included a form of participant compensation.
- IRB reviewed a total of 2,532 submissions (initial, renewal, modification, closure).
- IRB approved a total of 2,447 submissions.

BUILDING REVIEWER AND STAFF CAPACITY

- Five scientific potential IRB reviewers began their training under the IRB Chair and Associate Chair. They will complete their training in Spring 2020 and begin reviewing proposals in Fall 2020.
- Two medical representatives were added to the board. One representative can also serve as a prisoner representative.
- We avoided fall semester backlog by providing summer salary to five members to review submissions over the summer semesters.

GOALS

This upcoming year, the IRB will continue to examine methods for increasing the flexibility of our IRB reviews and policies. As OHRP releases guidance on the revised common rule, the IRB will implement these changes to remain in compliance with our Federalwide Assurance. The IRB will continue to monitor the COVID-19 pandemic and incorporate procedures and guidance that will protect participants and the research community. The IRB will continue to strive for a 10-workday period of review for initial and subsequent review of exempt and expedited proposals.

ABOUT THE IRB/HUMAN RESEARCH PROTECTION PROGRAM

The mission of the IRB is to protect the rights and welfare of human research subjects by minimizing risks, ensuring that people are fully informed before they participate in research, and promoting equity in research participation.

The Texas Tech University Institutional Review Board for the Protection of Human Subjects (IRB) complies with the Federalwide Assurance registration guidelines through the Office for Human Research Protections of the U.S. Department of Health and Human Services regulated by 45 CFR 46 under number FWA00001568. It is also identified by IORG 0000166 and IRB

00000276 codes. Registration is current and the FWA expires on May 5, 2023.

The Human Research Protection Program (HRPP) carries out administrative duties involving the Institutional Review Board. The HRPP is supervised by Dr. Alice Young, Associate Vice President for Research Integrity, and Dr. Marianne Evola, Director of Responsible Research, under the oversight of the Vice President for Research.

FACULTY LEADERSHIP

CHAIR AND ASSOCIATE CHAIR

Dr. Scott Burris continued in his role as Interim IRB Chair while Dr. Kelly Cukrowicz was on development leave for spring 2019. Dr. Burris reviewed throughout the summer and officially went off the board in December 2019. Dr. Burris reviewed 40 proposals and mentored 1 IRB member in 2019. Dr. Burris served on the IRB from 2012-2019 and reviewed 732 proposals total.

Dr. Kelly Cukrowicz returned from development leave in the summer and assumed her role as Chair of the IRB. Dr. Malinda Colwell continued in her role as Associate Chair. Dr. Cukrowicz reviewed a total of 114 proposals during 2019. In addition, she trained 5 potential IRB reviewers and mentored 1 of them. Dr. Colwell conducted 126 proposal reviews during 2019. She contributed to the training of new IRB members and mentored 1 IRB member. Drs. Cukrowicz, Burris, and Colwell have worked to increase the efficiency and effectiveness of the IRB review process.

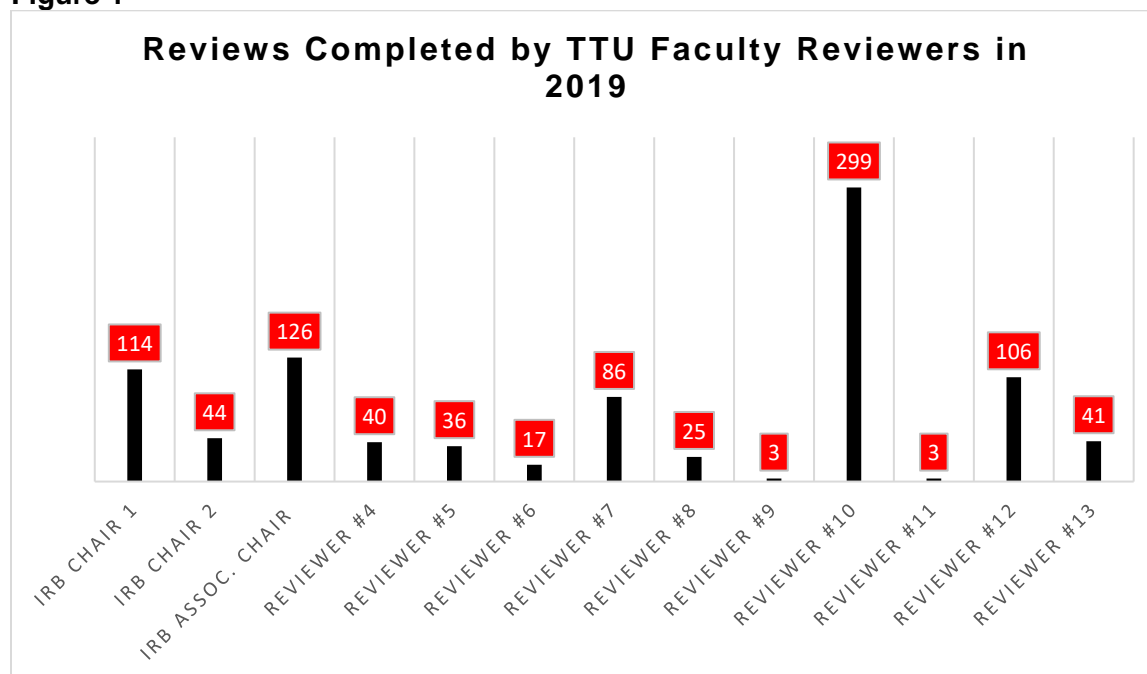
IRB MEMBERS

In 2019, the IRB Committee had 15 members, five alternates, and eight ex-officio members. Most IRB members were assigned 1-3 proposals to review each week. In the spring, 12 members reviewed proposals weekly. In the fall, 10 members reviewed proposals weekly. **Figure 1** shows the number of reviews completed by TTU IRB reviewers in 2019. Note, reviewer 10 reviews only renewals, and reviewer 12 primarily reviews modifications.

Also, in 2019, two members resigned from the IRB and two moved to alternate status due to administrative demands and sponsored project research.

The Committee is an exceptional group of people: they are committed, sensitive to the complexities involving the protection of human research subjects, and helpful to the university community. A current roster of the IRB Committee can be found on page 7.

Figure 1



STAFF LEADERSHIP

HRPP MANAGER

Dr. CassiDe Street serves as the Manager for HRPP. Dr. Street oversees all staff activities for the HRPP office. This includes review of incoming Cayuse IRB submissions for appropriateness of selected review type, advising staff on assignment of submissions to IRB reviewers, and communication between reviewers and researchers as needed. Dr. Street provides a great deal of assistance and consultation to Principal Investigators on research design and issues of concern for IRB review (pertinent to 45 CFR 46 and the Belmont Report). Dr. Street developed and launched the TTU Human Subject Training Series (a 5-session training series). She assists faculty members in completing the Cayuse IRB proposal, as well as responding to reviewers. Dr. Street oversees all activities related to Institutional Authorization Agreements and Clinical Trials. She also makes presentations on the IRB to TTU researchers. Dr. Street also works with IRB reviewers to ensure consistency of reviews, and serves as an expert for the board on the federal regulations.

STAFF

Ms. Esther Lucey continues as an Analyst handling Cayuse IRB submissions, trainings, and monthly statistics. She handles administrative closures for faculty departures. Ms. Lucey administratively withdraws unsubmitted IRBs created in the previous calendar year. Ms. Lucey continues to earn education credits for the CIP (Certified IRB Professional) by attending conference and webinars.

Ms. April Ortegon is an Analyst in the HRPP office. Ms. Ortegon helps with the maintaining of records and statistics for reports. She helped in the creation and launch of the TTU Human Subject Training Series. Ms. Ortegon conducts IRB presentations for the research community. Ms. Ortegon addresses questions or concerns regarding IRB protocols and navigating Cayuse IRB. Ms. Ortegon conducts HRPP/IRB presentations for faculty, staff, and students.

Mrs. Maricela Ramirez is an Analyst in the HRPP office. In this role she is responsible for pre-

reviewing IRB submissions, renewals and closures. She works directly with renewals for expedited and full board studies. Mrs. Ramirez handles administrative closures for expired IRBs. She also provides support to TTU researchers and the IRB members in promoting the conduct of ethical human research.

Ms. Lucey, Ms. Ortegon, and Mrs. Ramirez conduct all pre-reviews and post-reviews for exempt and expedited proposals using a checklist prepared by Dr. Street. They also process and assign incoming studies for IRB review. The analysts assist with the review process for exempt IRBs and modifications.

ACTIVITIES IN 2019

MEETINGS

The IRB met three times in 2019 for full board meetings. IRB members discussed research articles and educational materials at each meeting. The minutes of the IRB Full Board Meetings are available to the public by contacting the IRB Section Manager at 806-742-2064 or hrpp@ttu.edu.

PROFESSIONAL DEVELOPMENT

Staff development is a critical component of the work of the HRPP. Dr. Street and staff members attended several webinars and short-courses offered by TTU and Public Responsibility in Medicine & Research (PRIM&R). PRIM&R conference in Boston, MA was attended by Dr. Cukrowicz, IRB Chair, Dr. Colwell, IRB Associate Chair, Dr. Street, Ms. Esther Lucey, and Ms. April Ortegon. Information from PRIM&R was shared with the IRB.

PROTOCOLS

The number of IRB protocols has more than doubled since 2007. In 2019, we actively continued to limit unnecessary IRB proposals and complied with regulatory requirements. Thus, the number of protocols decreased in 2019, owing to administrative efforts to close inactive proposals rather than reflecting decreased review activity. We continued to monitor IRB protocols of PIs that separated from TTU.

Year	Research Protocols
2007	824
2008	1,001
2009	1,152
2010	1,206
2011	1,243
2012	1,213
2013	1,214
2014	1,458
2015	1,508

2016	1,894
2017	2,211
2018	2,616
2019	2,080

Of the active IRB protocols, 82 involve sponsored projects.

BUDGET

The HRPP budget includes salaries for the HRPP Manager, three analysts, 25% salary for the IRB Chair, 2 months of summer salary for IRB Reviewers, and one course release for the Associate Chair. We also have one-quarter time undergraduate student assistant. The budget allows some funds for professional memberships, travel to educational conferences, and a modest amount for relevant journals, books, and supplies.

ACCOMPLISHMENTS AND GOALS

We continue to improve the functionality of the HRPP and IRB by helping investigators with the least restrictive necessary level of IRB review, continuing to pre-screen proposals for completeness before they are sent to reviewers, and continue to help every IRB member with training and educational opportunities.

ACHIEVED IN 2019

1. We implemented the Final Rule (federal update to human subjects regulations).
2. We revised the Cayuse IRB templates to follow the Final Rule.
3. We implemented the Administrative Check-In procedures.
The administrative check-in is sent to the research team one year after approval. This email is to remind the research team to make any modification necessary, report any incidents, and close IRB protocols that are no longer active. If the research is ongoing without any changes no action is required from the research team.
4. We updated all recruitment and informed consent documents.
5. We created and executed the TTU Human Subject Training Series.
These training are conducted each semester. There are five trainings with three sections for researchers to pick from. A researcher will receive a completion certificate after attending all five trainings.
6. With the help of university administration, we paid summer IRB Reviewers to address high volume of IRB proposals.
7. There were six incident reports submitted to the IRB. These were corrected through modifications or submissions made in Cayuse IRB.
8. An HRPP staff member served as the liaison to the Faculty Senate.
9. We created an IRB reviewer manual.
10. Five potential IRB reviewers began their training under the IRB Chair and Associate Chair.
They will complete their training in Spring 2020 and begin reviewing proposals in Fall 2020.
11. Two medical representatives were added to the board. One representative can also serve as a prisoner representative.

GOALS FOR 2020

1. We will expand upon Post-Approval Policies in our HRPP/IRB Manual.
2. We will update the renewal submission used in Cayuse IRB to meet federal guidelines.
The submission will also be used for post-approval monitoring.
3. We will continue to examine methods for increasing the flexibility of our IRB reviews and policies.
4. We will explore requiring human subject training for TTU researchers.
5. We will update the CITI training courses to be more impactful for our researchers.
6. We will update the HRPP manual and make it more user friendly.
7. We continue to incorporate changes in the Final Rule into our training and review process.
8. We will continue to monitor the COVID-19 pandemic and incorporate procedures and guidance that will protect participants and the research community.
9. We will continue to strive for a 10-workday period of review for initial and subsequent review of exempt and expedited proposals.

Kelly Cukrowicz, Ph.D.
Chair, Institutional Review Board
Professor, Psychological Sciences

Malinda Colwell, Ph.D.
Associate Chair, Institutional Review Board
Professor, Human Development and Family Studies

CassiDe Street, Ph.D.
Manager, Human Research Protection Program

TEXAS TECH UNIVERSITY
 INSTITUTIONAL REVIEW BOARD
 PROTECTION OF HUMAN SUBJECTS COMMITTEE
 August 2020 – August 2021

CHAIRS				
Name	Term	Department	Phone	Email
Kelly Cukrowicz,* Ph.D. (Chair, Scientific)	2021	Psychological Sciences MS 2051	806-834- 8485	kelly.cukrowicz@ttu.edu
Malinda Colwell, Ph.D. (Associate Chair, Scientific)	2023	Human Development & Family Studies MS 1230	806-834- 4179	malinda.colwell@ttu.edu

MEMBERS		
Name	Term	Department
Martin Binks, Ph.D. (Scientific)	2023	Nutritional Sciences
Eric Cardella, Ph.D. (Scientific)	2019	Rawls College of Business
Sherice Gearhart, Ph.D. (Scientific)	2023	Public Relations
Stephanie J. Jones, Ed.D. (Scientific)	2023	Education
Cynthia Jumper, MD, MPH (Prisoner/Scientific/Medical)	2023	TTU Health Science Center - Lubbock
Patricia Maloney, Ph.D. (Scientific)	2021	Sociology, Anthropology & Social Work

Jacalyn McComb, Ph.D. (Scientific)	2021	Kinesiology & Sport Management
Susan Mengel, Ph.D. (Scientific)	2021	Computer Science
Patrick Metze, J.D. (Non-Scientific/Prisoner)	2021	Director of Criminal Clinics – TTU Law School
Lainey Morrison (Non-Scientific/Non-Affiliated)	2020	City of Lubbock
Cory Powell (Non-Scientific)	2022	Division of Diversity, Equity & Inclusion
Brian Quinn, M.S. (Non-Scientific)	2021	University Libraries
René Saldaña, Ph.D. (Scientific)	2023	Curriculum & Instruction
Andreas Schneider, Ph.D. (Scientific)	2021	Sociology, Anthropology & Social Work
Goutam Pada Shome, MD, Ph.D., FACP, FAAAAI (Scientific)	2022	Covenant Medical Group
Roman Taraban, Ph.D. (Scientific)	2023	Psychological Sciences
Ryan Williams, Ph.D. (Scientific)	2021	Agricultural and Applied Economics

ALTERNATES		
Name	Term	Department
Jessica Alquist, Ph.D.	2022	Psychological Sciences

(Scientific)		
Joaquin Gonzales, Ph.D. (Scientific)	2022	Kinesiology & Sport Management
Alan Reifman Ph. D. (Scientific)	2021	Human Development & Family Studies
Ryan Scheckel (Non-Scientific)	2019	Undergraduate Education

Kelly Cukrowicz: Licensed Psychologist, State of Texas

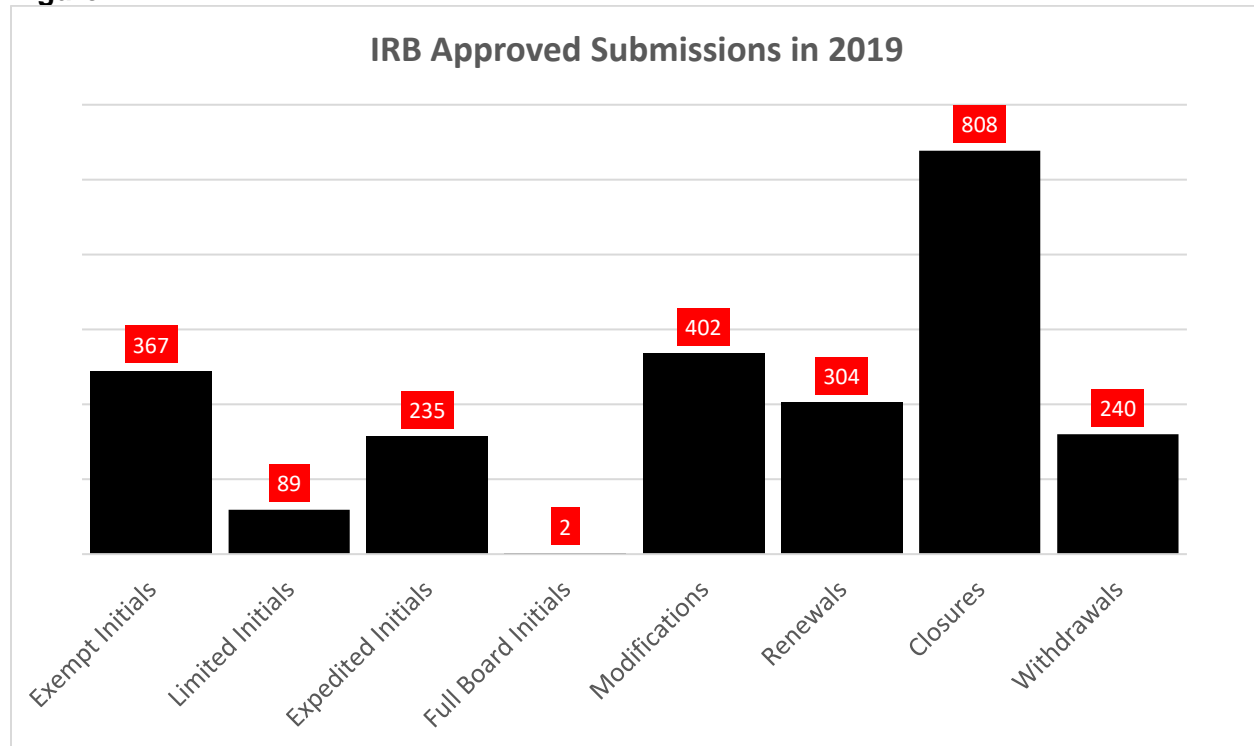
EX-OFFICIO	
Name	Title
Alice Young, Ph.D. (Institutional Official)	Associate Vice President for Research-Responsible Research, Office of Research & Innovation
Katherine Austin Beltz, Ph.D.	Assistant Vice President for IT, Information Technology and CIO
Bobbie Brown	Registrar, Office of the Registrar
Amy Cook, J.D.	Managing Director, Office of Research Services
Marianne Evola, Ph.D.	Director, Responsible Conduct of Research
Sherri Johnston	Lubbock Privacy Officer, TTUHSC Institutional Compliance
Matt Roe M.S.	Assistant Vice President for Environmental Health and Safety, Environment Health and Safety
Cui Romo, J.D.	Attorney, Office of Research Services

ANNUAL STATISTICS

APPROVED SUBMISSIONS

Figure 2 shows the number of submissions approved by the IRB in 2019. The IRB members approved a total of 2,447 submissions. Most of the approvals were closures ($n = 808$), followed by the combination of initial submissions ($n = 693$). Please note not all submissions were approved.

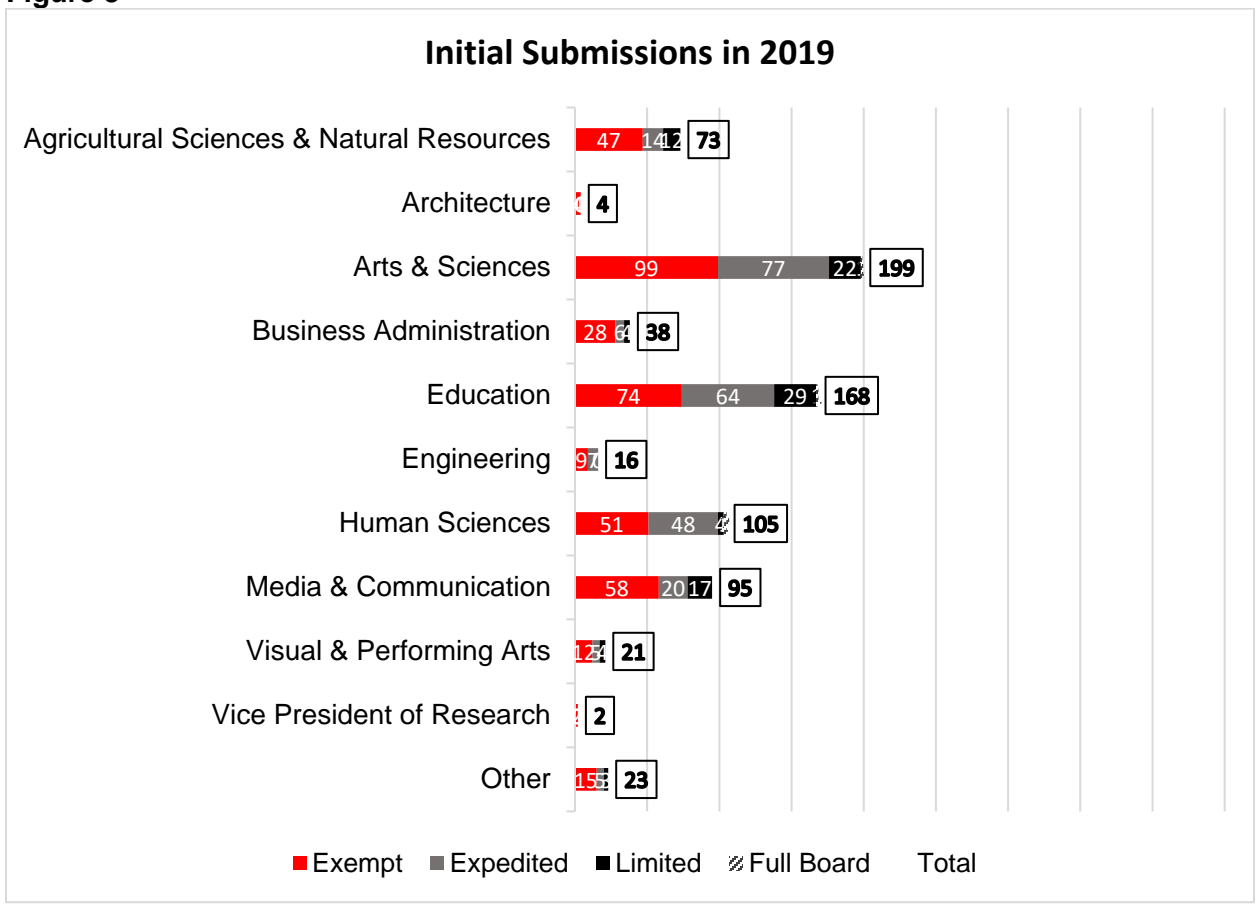
Figure 2



INITIAL SUBMISSIONS RECEIVED

Figure 3 shows the number of new initial submissions that were created and submitted in Cayuse IRB during 2019. These submissions are new research proposals submitted to the IRB, however, this does not mean all submissions were approved. Every submission ($n = 744$) was reviewed by an IRB member and approved or returned for revision. The IRB received 399 exempt, 246 expedited, and four full board submissions. Most of submissions are from the College of Arts and Sciences ($n = 199$), specifically, the Department of Psychological Sciences ($n = 79$). Please note not all submissions were approved.

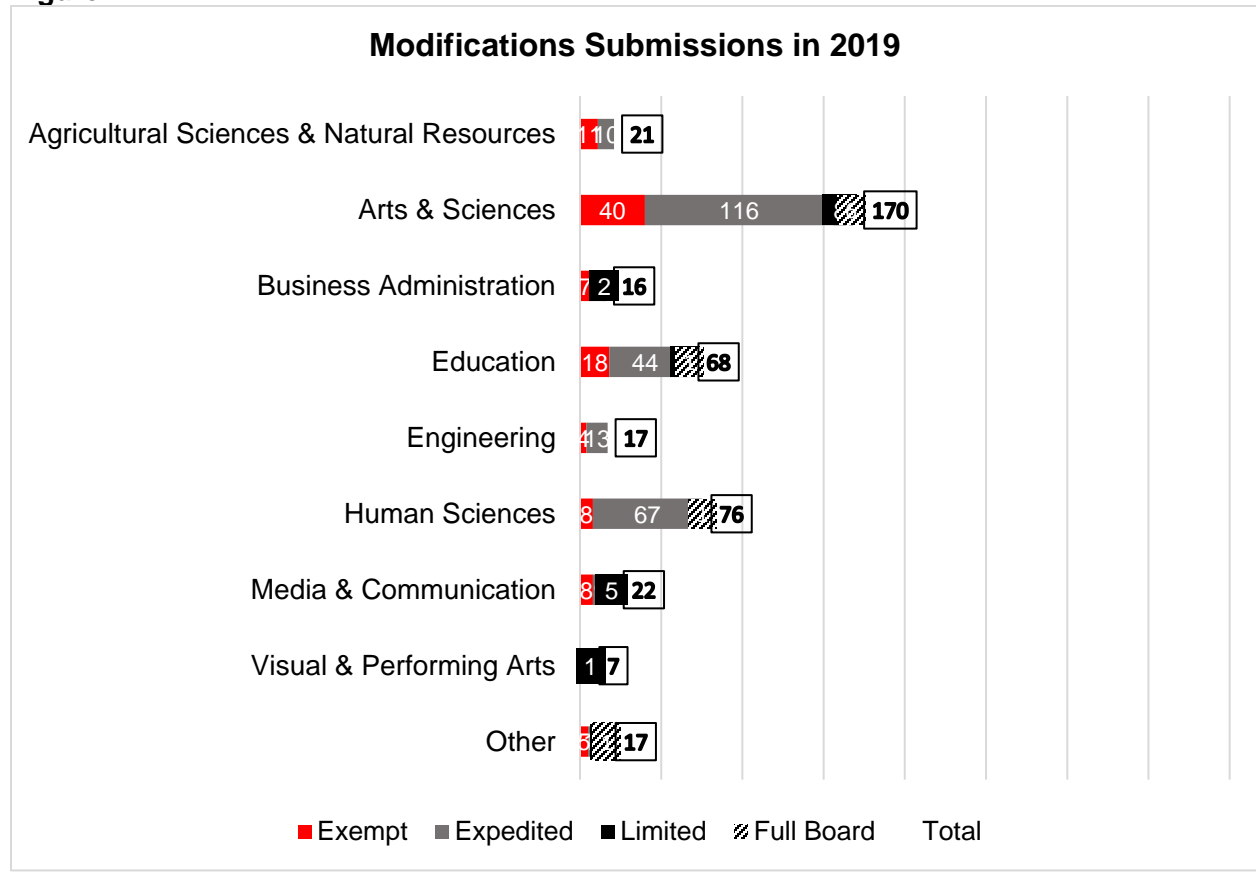
Figure 3



MODIFICATIONS RECEIVED

Figure 4 shows the number of modifications that were submitted in 2019 on an approved study. These modifications ($n = 414$) were reviewed by an IRB member and approved or returned for revision. The College of Arts and Sciences ($n = 170$) submitted the most modifications followed by the College of Human Sciences ($n = 76$). A total of 110 exempt, 281 expedited, 22 limited, and nine full board modifications were submitted by TTU researchers. Please note not all submissions were approved.

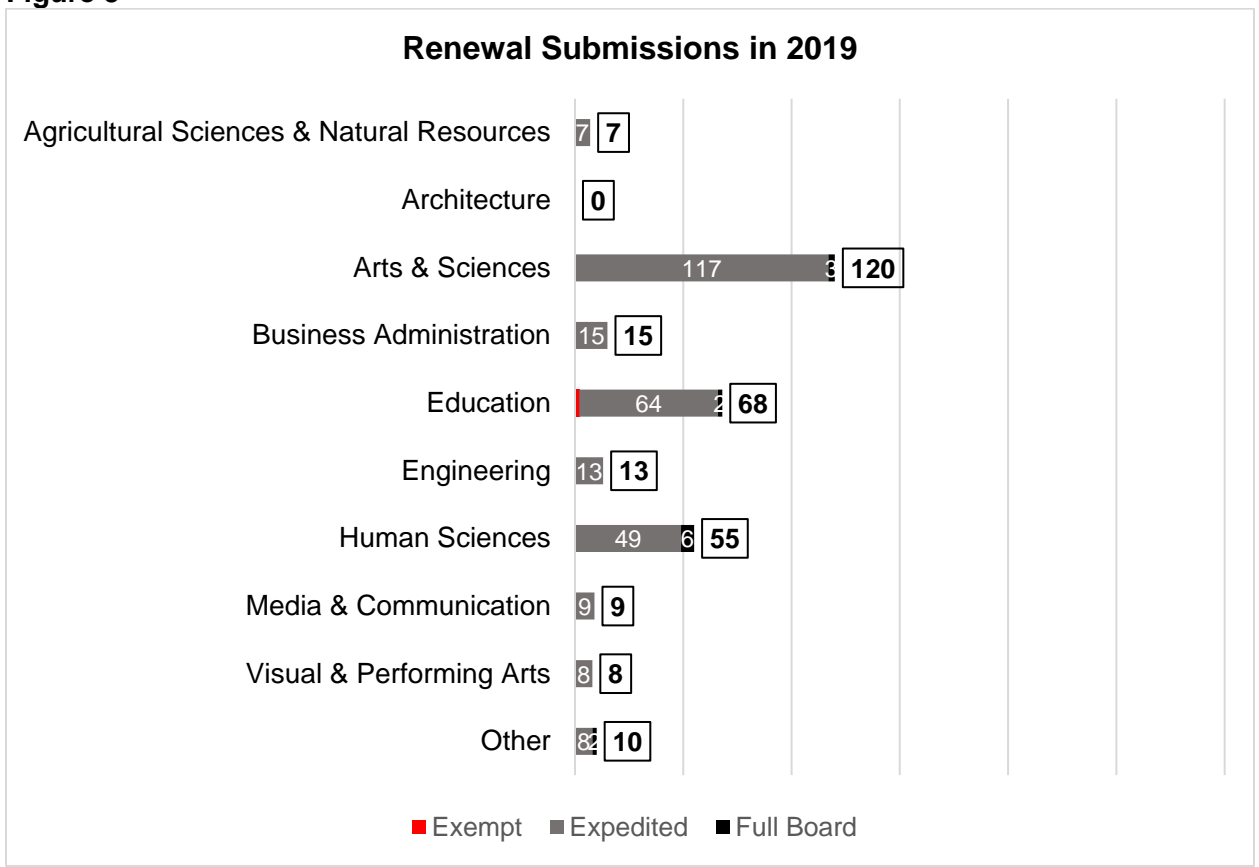
Figure 4



RENEWALS RECEIVED

Figure 5 shows the renewal submissions for approved expedited and/or full board studies. One IRB member is dedicated to reviewing renewals ($n = 302$). Most expedited studies must be renewed every year; however, some studies have a different renewal time frame. The renewal date is noted in the IRB approval letter. HRPP staff administratively closed studies that were not renewed. Researchers submitted 302 renewals for expedited studies and 13 renewals for full board studies. There were two exempt studies renewed in order to remove the expiration date.

Figure 5



SUBMISSIONS BY COLLEGE

The following figures, **Figures 6** through **10**, show the number of submissions by selected departments within their respective colleges. The departments were chosen because of the variety of research conducted within the college. Please note not all submissions were approved.

Figure 6 shows the number of submissions by the selected departments within the College of Arts and Sciences in 2019. Most submissions were from Psychological Sciences ($n=351$), Kinesiology and Sport Management ($n = 137$), and English ($n = 98$).

Figure 6

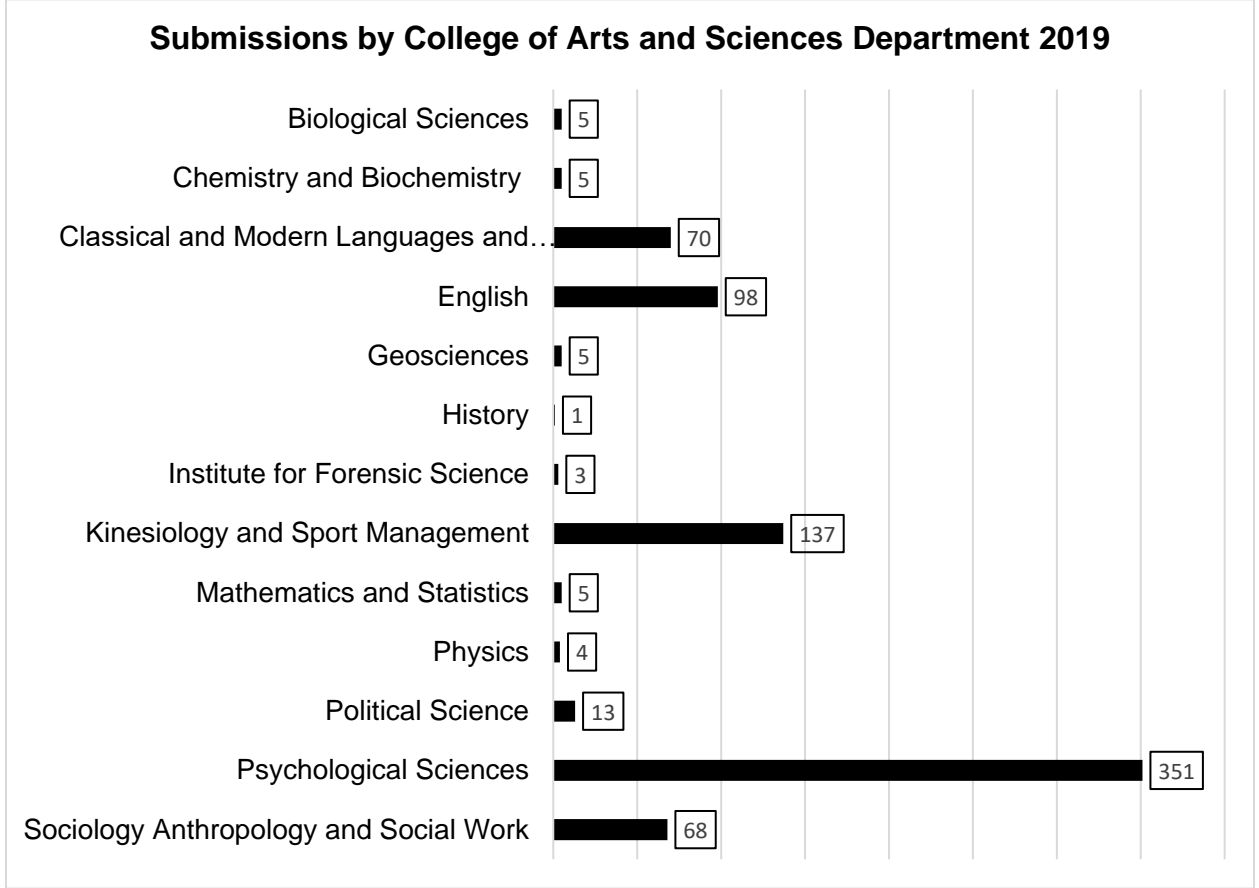


Figure 8 shows the number of submissions by the selected departments within the College of Agricultural Sciences and Natural Resources. Most submissions were submitted by Agricultural Education and Communications ($n = 130$) and Animal and Food Science ($n = 64$).

Figure 8

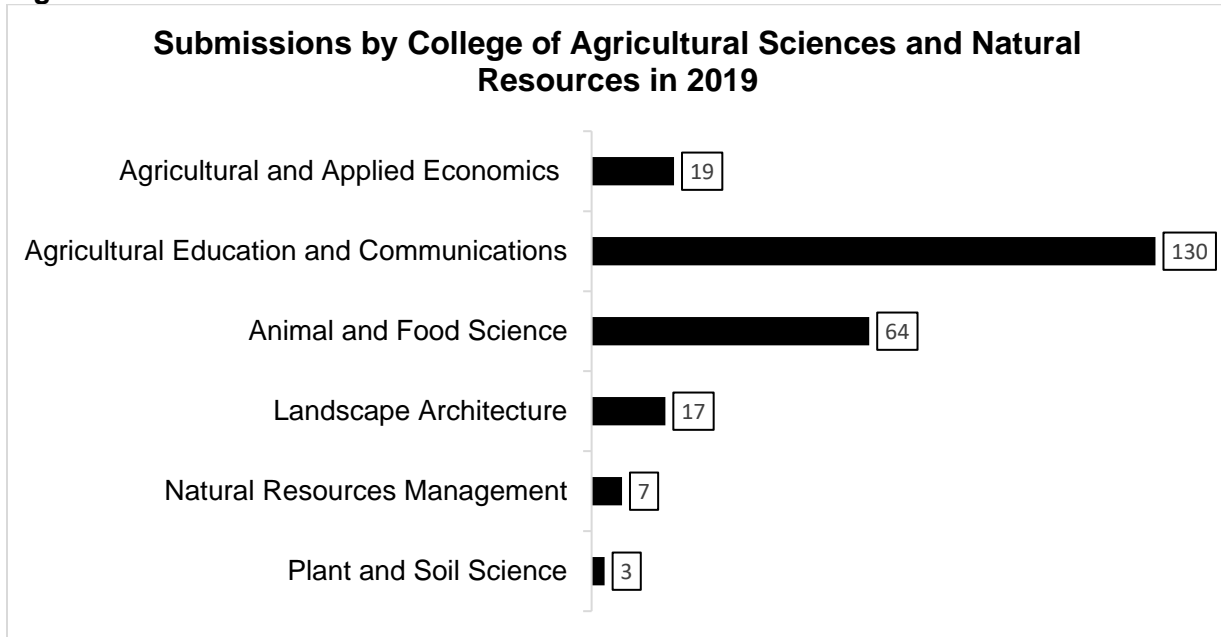


Figure 9 shows the number of submissions by the selected departments within the College of Human Sciences. Most submissions were submitted by Community Family and Addiction Studies ($n = 127$) and Human Development and Family Studies ($n = 114$).

Figure 9

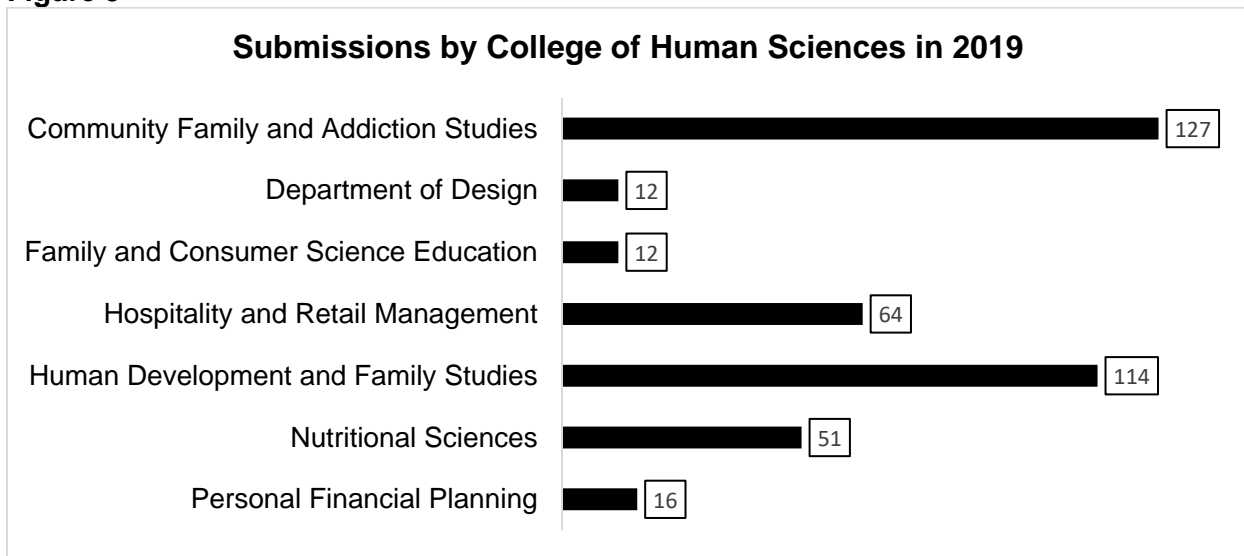


Figure 10 shows the number of submissions by the selected departments within the College of Education. Most submissions were from the Department of Educational Psychology Leadership ($n = 321$) and Curriculum & Instruction ($n = 214$).

Figure 10

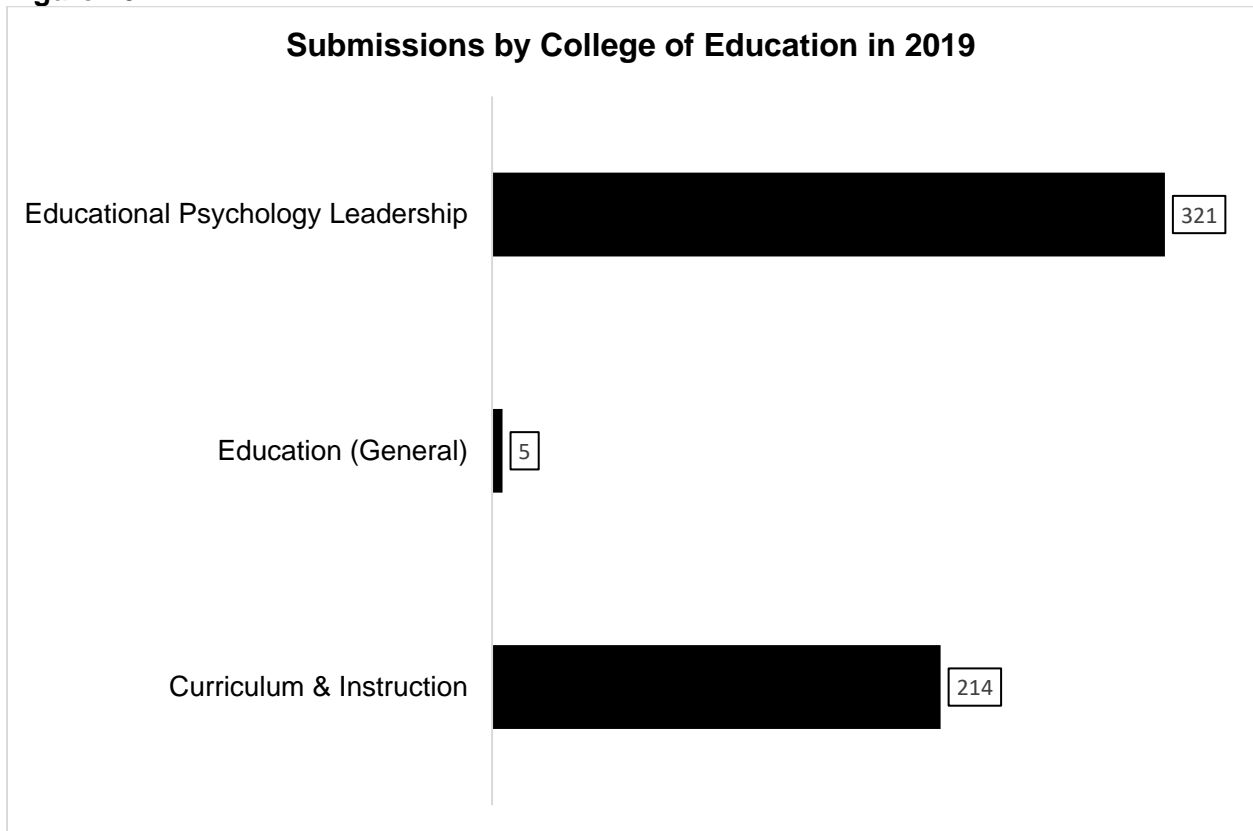
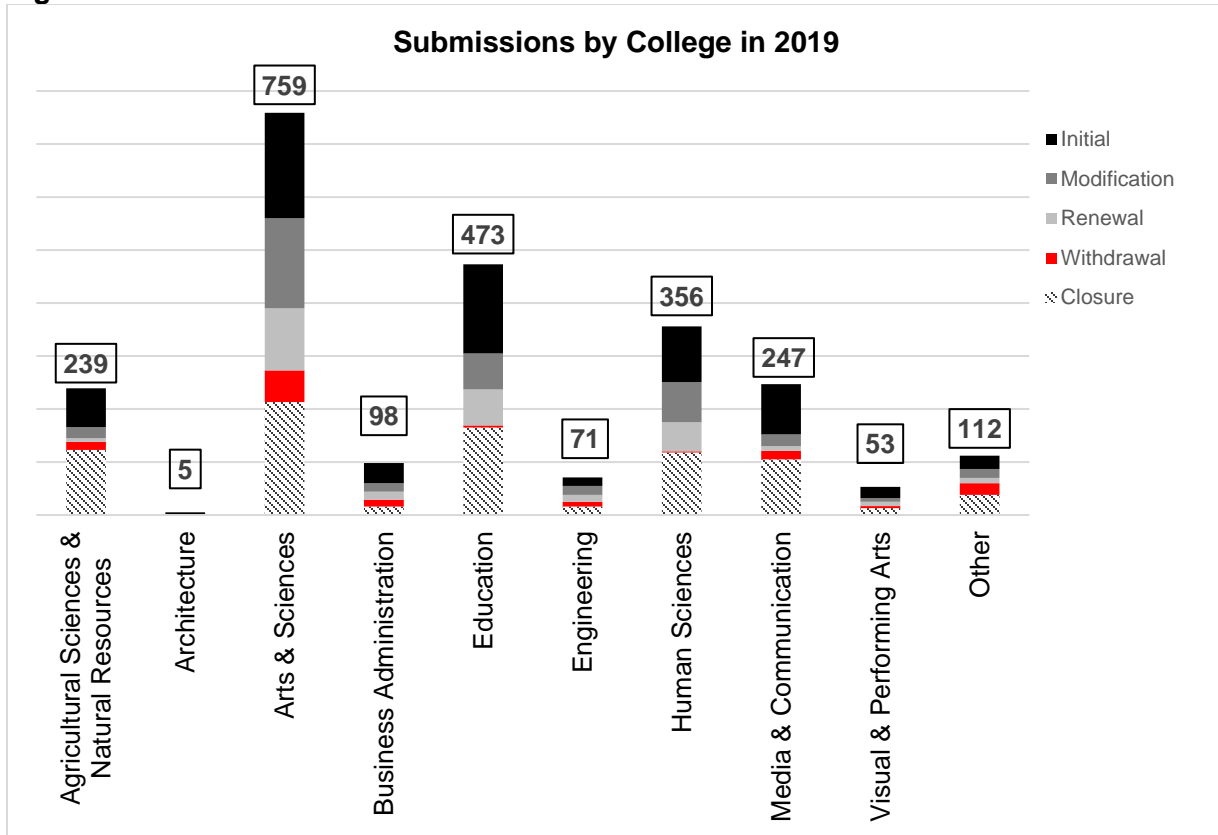


Figure 11 is the total number of submissions by college. The College of Arts and Sciences submitted the most submissions with a total of 759. The College of Education submitted 473 and the College of Human Sciences submitted 356. Please note not all submissions were approved.

Figure 11



If you would like specific statistics for your college or department contact the HRPP office.