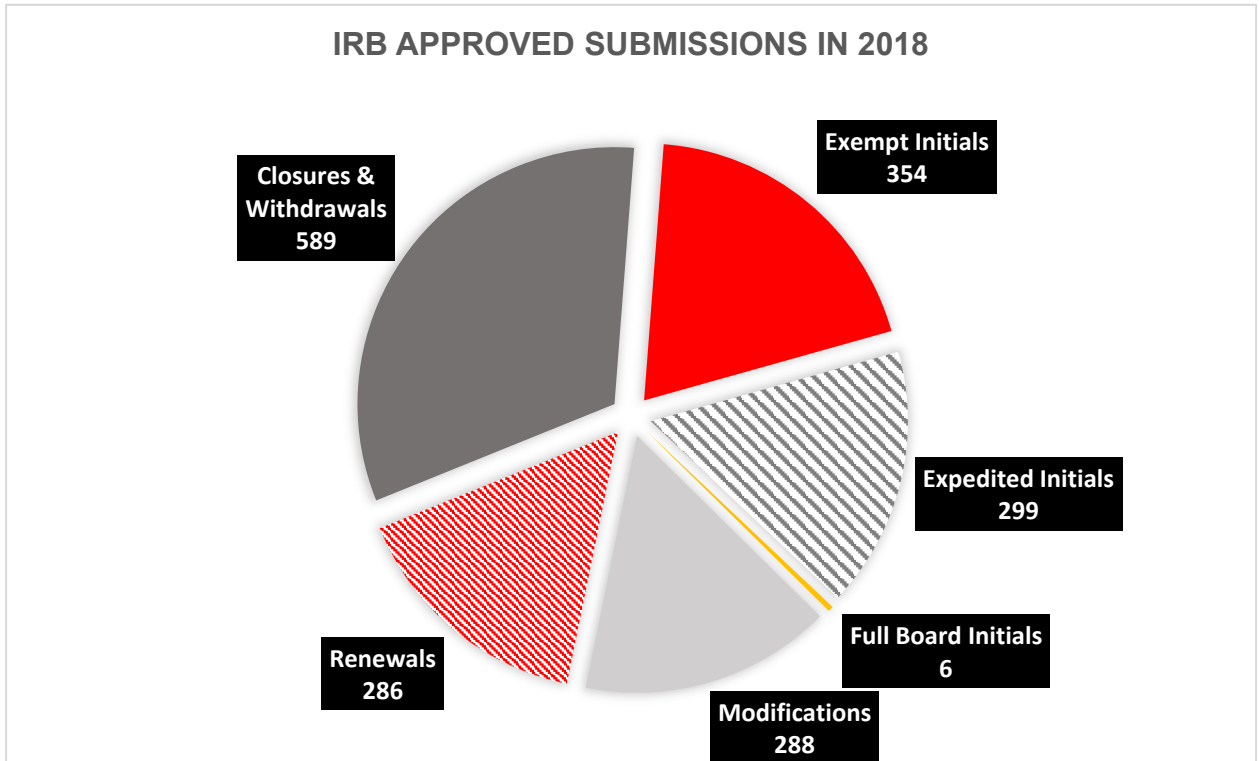


TEXAS TECH UNIVERSITY
INSTITUTIONAL REVIEW BOARD/
HUMAN RESEARCH PROTECTION PROGRAM
2018 ANNUAL REPORT



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 2,616 research protocols conducted in 2018.

- This is a 73% increase from 2015, and an 18% increase from 2017.
- 98 involved sponsored projects.
 - 23 were federally funded.
- 759 IRBs included a form of participant compensation.
- IRB reviewed a total of 1,833 submissions.
- IRB approved a total of 1,223 submissions.

BUILDING REVIEWER AND STAFF CAPACITY

- Three scientific IRB members and one non-scientific member completed their training under the IRB Chair and Associate Chair.
- A new prisoner representative was added to the board.
- 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. The IRB implemented the revised Common Rule. As OHRP releases guidance on these changes the IRB will implement these changes to remain in compliance with our FWA. 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. Kelly Cukrowicz continued as Chair of the IRB, with Dr. Scott Burris serving as Associate Chair. In the fall, Dr. Cukrowicz went on development leave. Dr. Burris assumed the role as Chair of the IRB. Dr. Malinda Colwell was appointed Associate Chair. Dr. Cukrowicz reviewed a total of 139 proposals during 2018. In addition, she trained 6 new IRB members and mentored 1 of them. Dr. Burris conducted 132 proposal reviews during 2018. He contributed to the training of new IRB members and mentored 1 IRB member. Dr. Colwell reviewed 74 proposals and mentored 1 IRB member. Drs. Cukrowicz, Burris, and Colwell have worked to increase the efficiency and effectiveness of the IRB review process.

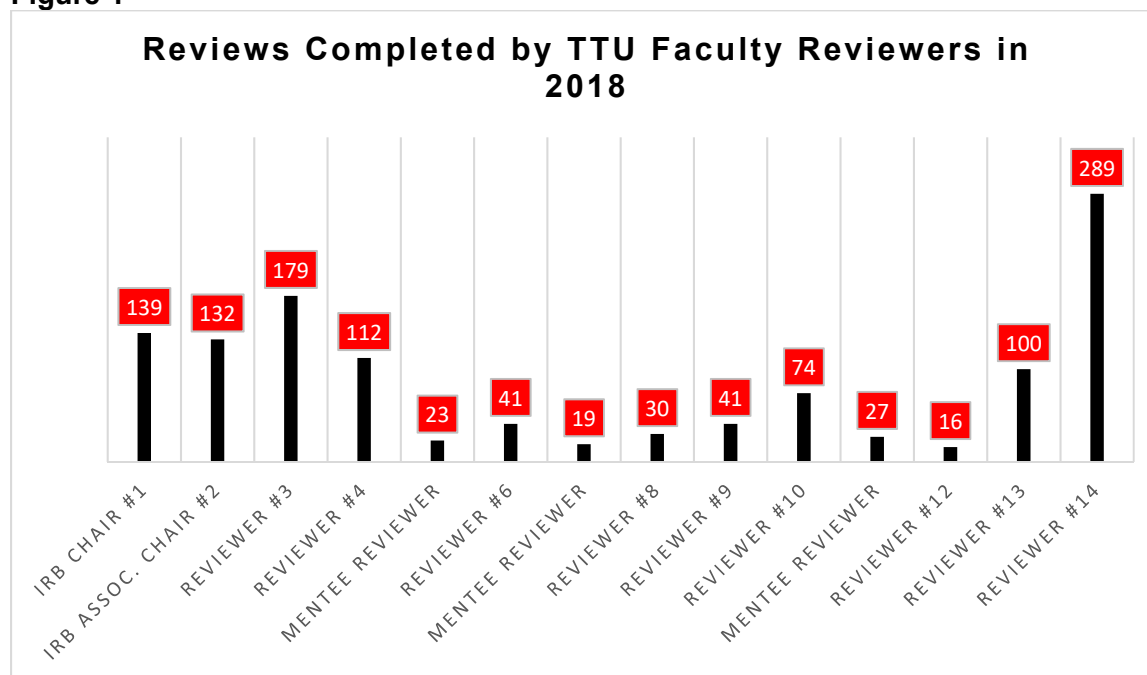
IRB MEMBERS

In 2018, the IRB Committee had 19 members, five alternates, and eight ex-officio members. Most IRB members were assigned 1-3 proposals to review each week. In the spring, 10 members reviewed proposals weekly. In the fall, 11 members reviewed proposals weekly.

Figure 1 shows the number of reviews completed by TTU Faculty Reviewers in 2018. Note, reviewer 14 reviews only extensions, and reviewer 3 primarily reviews modifications. 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.

Also, in 2018, one member resigned from the IRB due to administrative demands, three members left the university, and one did not complete the new member training.

Figure 1



STAFF LEADERSHIP

HRPP MANAGER

Dr. CassiDe Street serves as the Section Manager for HRPP. Dr. Street oversees all activities related to Institutional Authorization Agreements and Clinical Trials. She also makes presentations on the IRB to TTU researchers and works with investigators needing assistance. In May, Dr. Street implemented a new exempt template designed to reduce researcher and reviewer burden. In the fall semester, she spent most of her time preparing for the changes to the Common Rule (45 CFR 46) that were to go into effect on January 19, 2019.

STAFF

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

In 2018, Ms. April Ortegon is hired as a Senior Analyst in the HRPP office. She learns and implements the new federal regulations. Ms. Ortegon helps with the maintaining of records. Ms. Ortegon addresses questions or concerns regarding IRB protocols and navigating Cayuse IRB. Ms. Ortegon conducts HRPP/IRB presentations for faculty, staff, and students.

In 2018, Mrs. Maricela Ramirez is hired as Senior 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. 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.

ACTIVITIES IN 2018

MEETINGS

The full IRB met five times in 2018. 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 at 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 San Diego, CA was attended by Dr. Cukrowicz, IRB Chair, Dr. Colwell, IRB Associate Chair, Dr. Street, and Ms. Esther Lucey. Information from PRIM&R was shared with the full board at the November board meeting.

PROTOCOLS

The number of IRB protocols has more than doubled since 2007. In 2018, we actively continued to limit unnecessary IRB proposals and complied with regulatory requirements. 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

Of the active IRB protocols, 98 involve sponsored projects.

FINAL RULE

The Office for Human Research Protections (OHRP) released a revised Common Rule (45 CFR 46, Final Rule) for human subject research. OHRP and IRBs refer to these revisions as the Final Rule. These regulations went into effect on January 19, 2019. Researchers noticed changes to the HRPP website, policies and procedures, and the Cayuse IRB template.

Any research that received IRB approval prior to January 19, 2019 will remain under the pre-2018 Common Rule and will not be transitioned to the Final Rule. All research approved on or before Friday, January 18, 2019 is required to follow the pre-2018 Common Rule regulations. Researchers must continue to submit research team changes, modifications, renewals and incidents for any study that has received IRB approval prior to January 19, 2019. An IRB study must follow one set of regulations.

The biggest change for social behavioral research is in the exempt review type. OHRP has revised, removed, and added categories to the exempt review type. Also, there is an added review type within the exempt category called limited review. Limited review will now allow identifiers to be collected with the data if it is no more than minimal risk. The exempt categories that allow for limited review are: Category 2 - Educational Tests, Survey Procedures, Interview Procedures or Observation of Public Behavior; and Category 3 - Benign Behavioral Interventions. Research in the past that collected identifiers through surveys, interviews, or

focus groups were typically submitted under the expedited review type and used category 6 and 7. Researchers will now use exempt/limited review, category 2. Researchers will provide participants with an information sheet but will NOT collect the participant's signature. If the researcher feels it is important to collect a signature on the consent form, then the expedited review type should be used. An added exempt category is Benign Behavioral Interventions. There was never a clear category for this type of research in the pre-2018 Common Rule. Most researchers submitted this type of research under Expedited Category 4: Collection of Data Through Noninvasive Procedures Routinely Employed in Clinical Practice. Researchers will now use exempt, category 3. Limited cases of deception can be used in this category through a limited review if the participants authorize the use of deception during the consent process.

OHRP now requires a statement in the consent form and information sheet that discloses to participants the researcher's plan for data retention, future research, and distribution of data to secondary researchers.

Expedited IRBs approved after January 19, 2019 will no longer require renewal/continuing review. Full Board IRBs will still require renewal/continuing review. The HRPP office will email the PI and primary contact of all approved IRBs NOT requiring renewal on a yearly basis. The email will serve as a reminder to submit any modifications or incidents for the approved protocol. The PI must inform the HRPP office if the research has been completed and can be closed. This can be done by responding to the annual email or submitting a closure submission in Cayuse IRB. IRBs that remain active are subject to audit by the IRB.

Researchers should become familiar with the revised document to know the full impact it will have on their research. Additional information can be found on the Texas Tech University, Human Research Protection Program website.

The Final Rule removed some of the burdens on researchers, but this required a different protocol/template. A new IRB template was launched in Cayuse on 12/7 that met the Final Rule regulations. This allowed researchers to continue working on their IRB submissions over the winter break. The TTU IRB worked to review/approve all IRBs under the current Common Rule before they left for winter break on 12/14. This is the third year the TTU IRB did not review proposals while faculty off-duty. Starting 1/14, the TTU IRB worked over the next five days to review/approve protocols coming in under the Common Rule regulations. After January 1, 2019, any IRB submission using the Common Rule regulations will be reviewed on a case-by-case basis. The HRPP office contacted researchers that had reopened IRBs (IRBs that had been reviewed and required revisions) to let them know about the turn around.

The HRPP office contacted all researchers that had unsubmitted IRBs on the old template and requested that they create a new IRB. This communication began on Thursday, December 13. Researchers were able to copy and paste from one IRB to the new one. The HRPP office deleted all old unsubmitted templates on March 1, 2019. IRBs with the number 2018-1141+ are under the new template.

On January 29, 2019 IRB Reviewers were trained on the Final Rule regulations. On January 30, 2019 the reviewers began receiving and reviewing IRB proposals under the Final Rule regulations.

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 2018

1. We implemented the Final Rule and TTU IRB follows OHRP and TTU's FWA.
2. We launched a new exempt template to reduce researcher and reviewer burden.
3. With the help of university administration, we paid summer IRB Reviewers to address high volume of IRB proposals.
4. We conducted seven post-approval reviews that were all for cause. There were seven incident reports submitted to the IRB. These were corrected through modifications or submissions made in Cayuse IRB.
5. In 2018 we had 666 new proposals, in 2017 we had 616 new proposals and in 2016 we had 529 new proposals.
7. There was an increased push for researcher education and focus on providing more face-to-face and hands on training for faculty, staff, and students who were interested in conducting research with human subjects. 30 presentations were conducted.
8. An HRPP staff member served as the liaison to the Faculty Senate.
9. Three scientific IRB members and one non-scientific member completed their training and have been added to the IRB committee.
10. A new prisoner representative was added to the board.
11. Two analysts were hired and trained in the HRPP office.

GOALS FOR 2019

1. We will expand upon Post-Approval Policies in our HRPP/IRB Manual and add a new section for IRB Reviewers.
2. We will continue to examine methods for increasing the flexibility of our IRB reviews and policies.
3. We will add a medical reviewer to the IRB to assist with biomedical research.
4. We will explore requiring human subject training for TTU researchers.
5. We continue to incorporate changes in the Final Rule into our training and review process.
6. We will continue to strive for a 10-workday period of review for initial and subsequent review of exempt and expedited proposals.

Scott Burris, Ph.D.
 Chair, Institutional Review Board
 Professor, Agricultural Education and Communications

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
 September 2018 – August 2019

CHAIRS				
Name	Term	Department	Phone	Email
Scott Burris, Ph.D. (Chair, Scientific)	2019	Agricultural Education & Communications MS 2131	806-834- 8698	scott.burris@ttu.edu
Malinda Colwell, Ph.D. (Associate Chair, Scientific)	2019	Human Development & Family Studies MS 1230	806-834- 4179	malinda.colwell@ttu.edu

MEMBERS		
Name	Term	Department
Jessica Alquist, Ph.D. (Scientific)	2019	Psychological Sciences
Eric Cardella, Ph.D. (Scientific)	2019	Rawls College of Business
Amanda Chattin (Non-Scientific)	2019	Student Counseling Center
Joaquin Gonzales, Ph.D. (Scientific)	2019	Kinesiology & Sport Management
Stephanie J. Jones, Ed.D. (Scientific)	2020	Education

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
Lainey Morrison (Non-Scientific/Non-Affiliated)	2020	City of Lubbock
Patrick Metze, J.D. (Non-Scientific/Prisoner)	2021	Director of Criminal Clinics – TTU Law School
Brian Quinn, M.S. (Non-Scientific)	2021	University Libraries
Andreas Schneider, Ph.D. (Scientific)	2021	Sociology, Anthropology & Social Work
Ryan Williams, Ph.D. (Scientific)	2021	Agricultural and Applied Economics

ALTERNATES		
Name	Term	Department
Kelly Cukrowicz, Ph.D. (Scientific, Sabbatical Leave)	2020	Psychological Sciences
Jim Johnson, PharmD, MPA, FACHE (Non-Affiliated, Scientific Prisoner Rep)	2020	UMC

Alan Reifman Ph. D. (Scientific)	2021	Human Development & Family Studies
Ryan Scheckel (Non-Scientific)	2019	Undergraduate Education
Kamau Siwatu, Ph.D. (Scientific)	2019	Education Psychology and Leadership

Kelly Cukrowicz: Licensed Psychologist, State of Texas

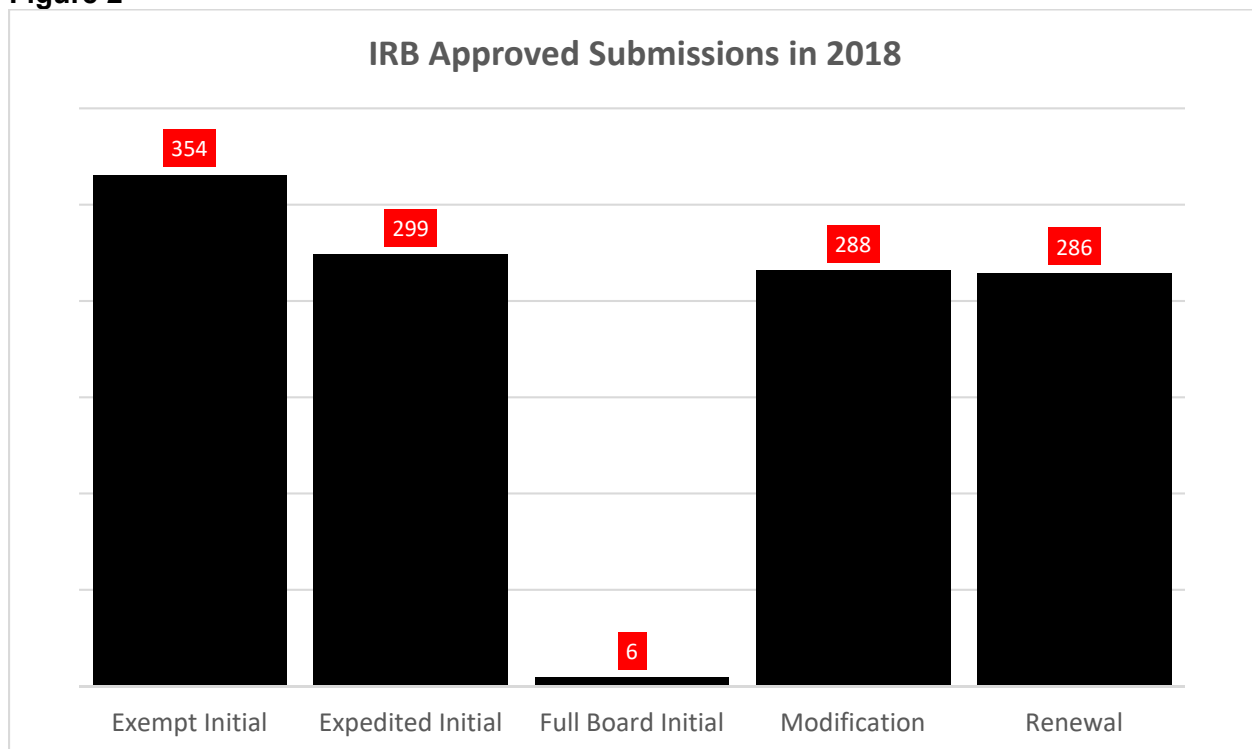
EX-OFFICIO	
Name	Title
Alice Young, Ph.D. (Institutional Official)	Associate Vice President for Research-Responsible Research, Office of Research & Innovation
Katherine Austin Beltz, Ph.D.	Assistant Vice President for IT, Information Technology and CIO
Bobbie Brown	Registrar, Office of the Registrar
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 2018. The IRB members approved a total of 1,233 submissions. Most of the approvals were exempt submissions ($n = 354$), followed by expedited submissions ($n = 299$).

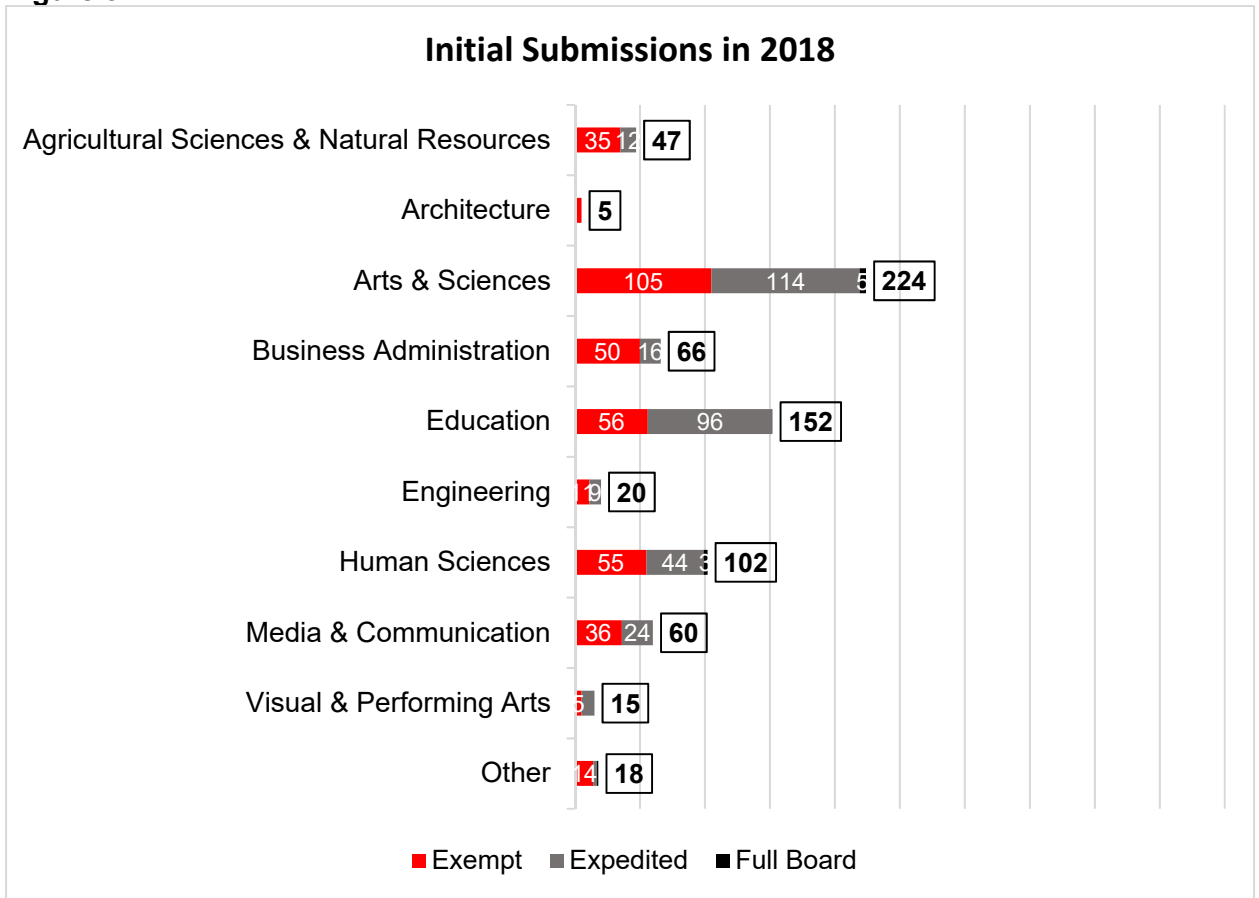
Figure 2



INITIAL SUBMISSIONS RECEIVED

Figure 3 shows the number of new initial submissions that were created and submitted in Cayuse IRB during 2018. These submissions are new research proposals submitted to the IRB, however, this does not mean all submissions were approved. Every submission ($n = 709$) was reviewed by an IRB member and approved or returned for revision. The IRB received 372 exempt, 328 expedited, and nine full board submissions. Most of submissions are from the College of Arts and Sciences ($n = 224$), specifically, the Department of Psychological Sciences.

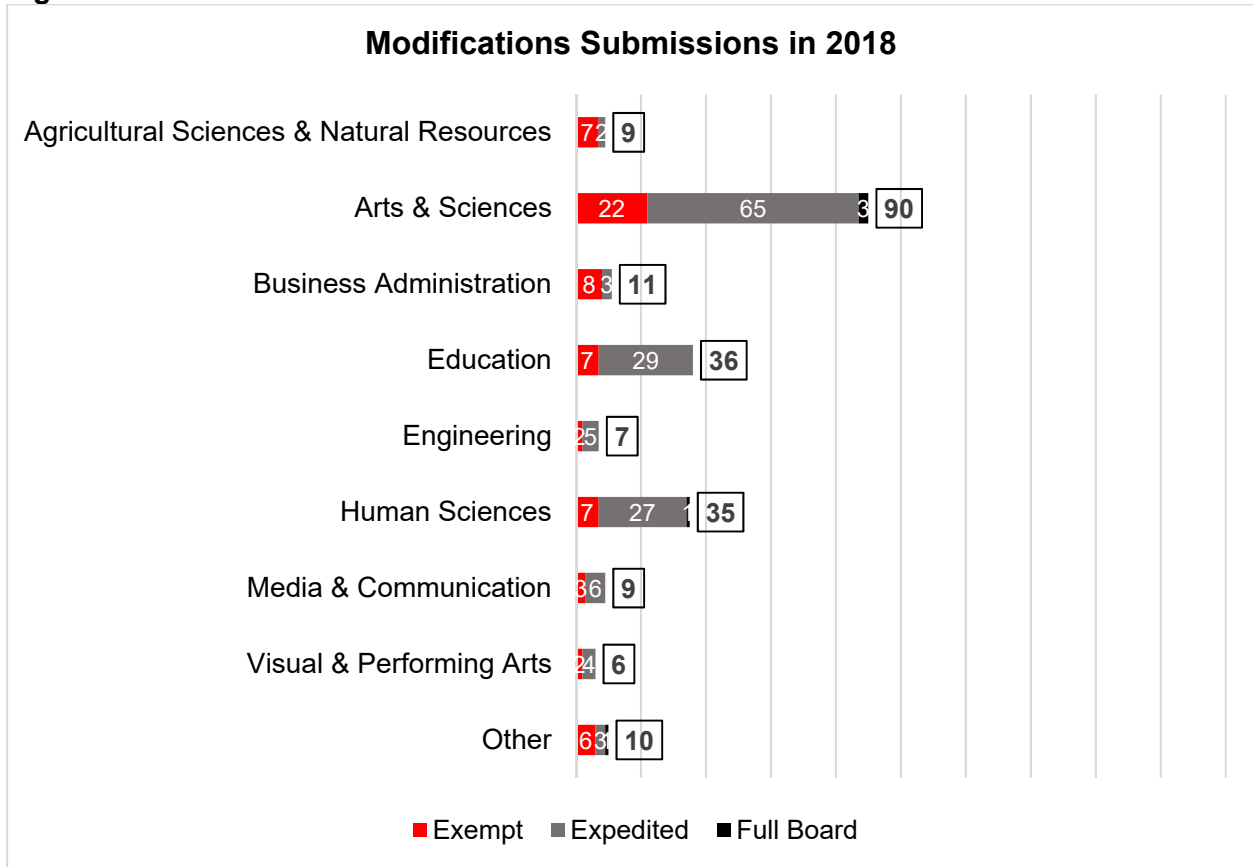
Figure 3



MODIFICATIONS RECEIVED

Figure 4 shows the number of modifications that were submitted in 2018 on an approved study. These modifications ($n = 213$) were reviewed by an IRB member and approved or returned for revision. The College of Arts and Sciences ($n = 90$) submitted the most modifications followed by the College of Human Sciences ($n = 35$). A total of 64 exempt, 144 expedited and five full board modifications were submitted by TTU researchers.

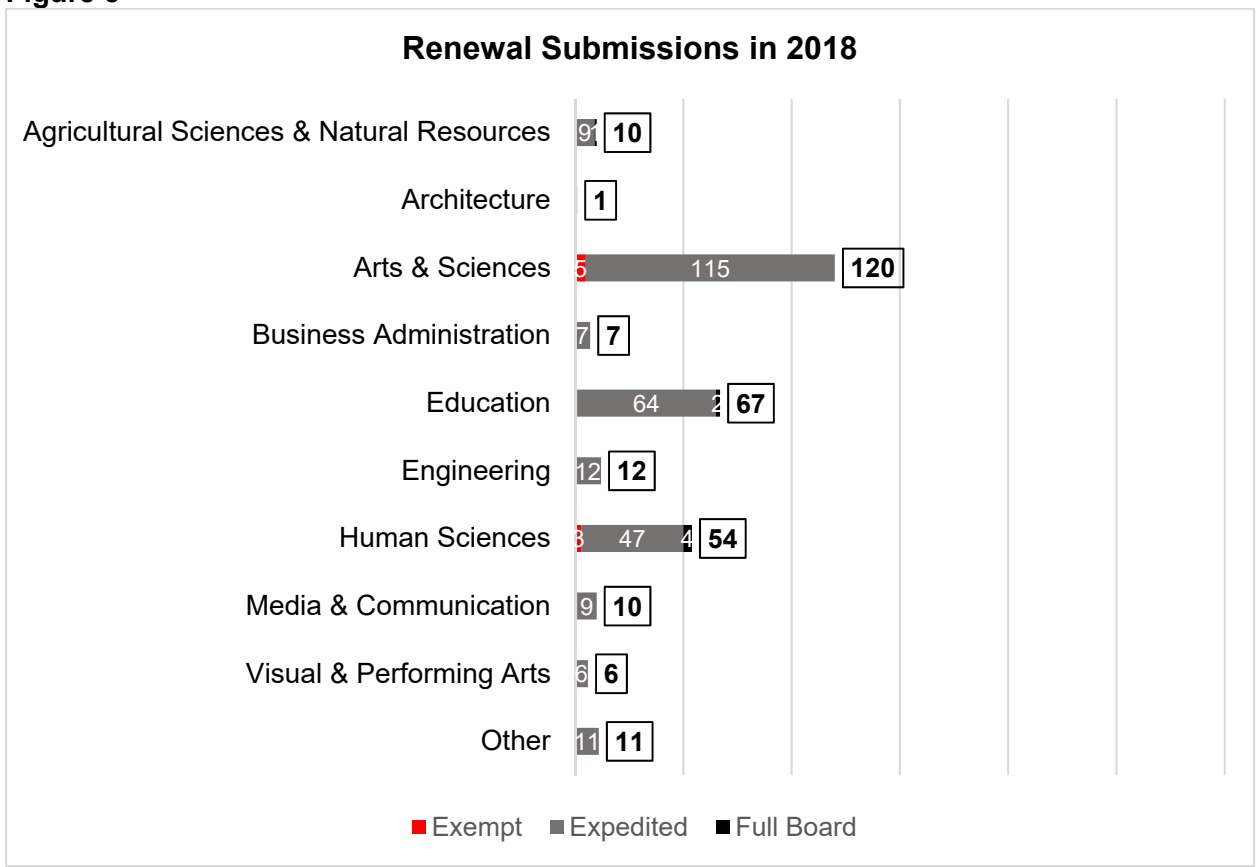
Figure 4



RENEWALS RECEIVED

Figure 5 shows the renewal submissions for approved expedited and/or full board studies. One IRB member is dedicated to reviewing renewals ($n = 298$). 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 283 renewals for expedited studies and seven renewals for full board studies. There were nine 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.

Figure 6 shows the number of submissions by the selected departments within the College of Arts and Sciences in 2018. Most submissions were from Psychological Sciences ($n=108$), Kinesiology and Sport Management ($n = 36$), and Classical and Modern Languages and Literatures ($n = 29$).

Figure 6

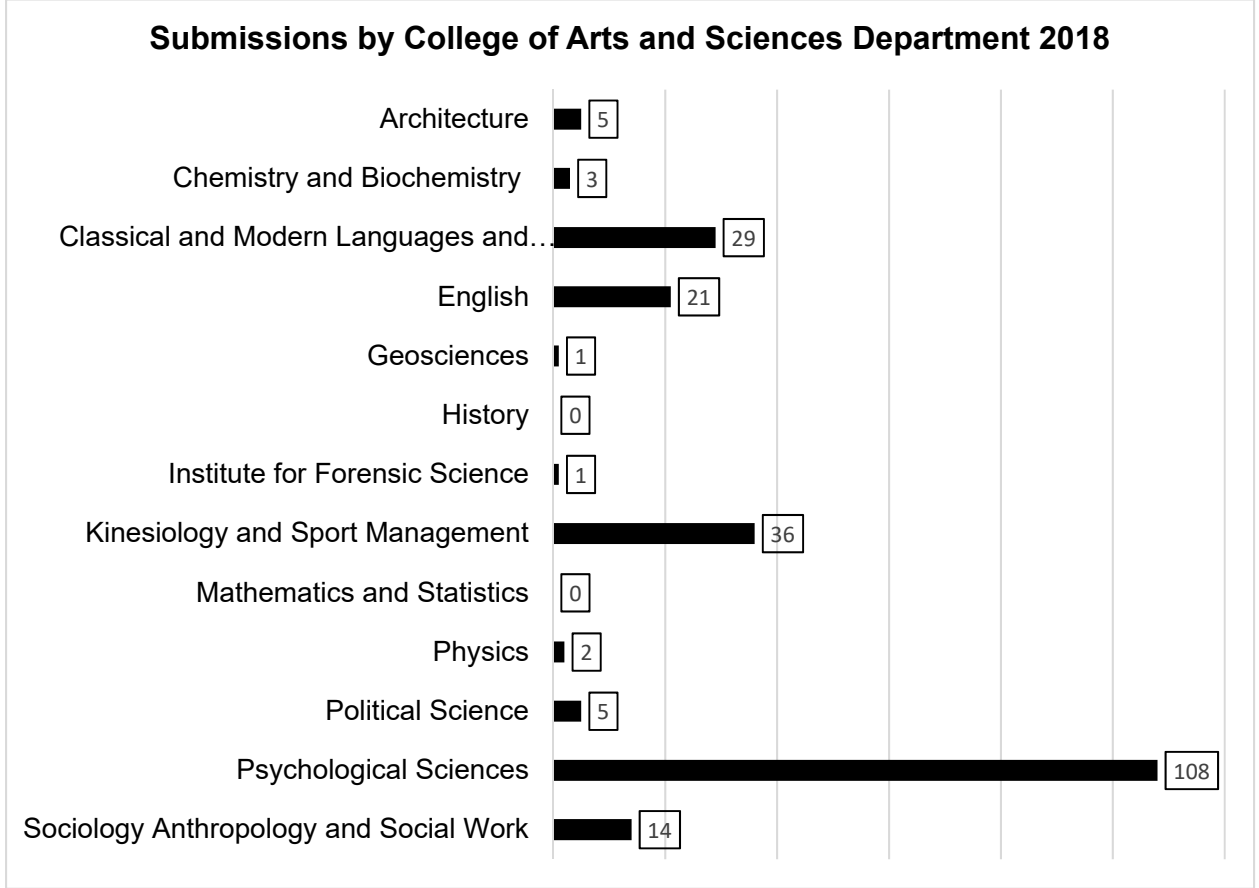


Figure 8 shows the number of submissions by the selected departments within the College of Agricultural Sciences and Natural Resources. Most submissions were submitted by Agricultural Education and Communications ($n = 37$) and Animal and Food Science ($n = 7$).

Figure 8

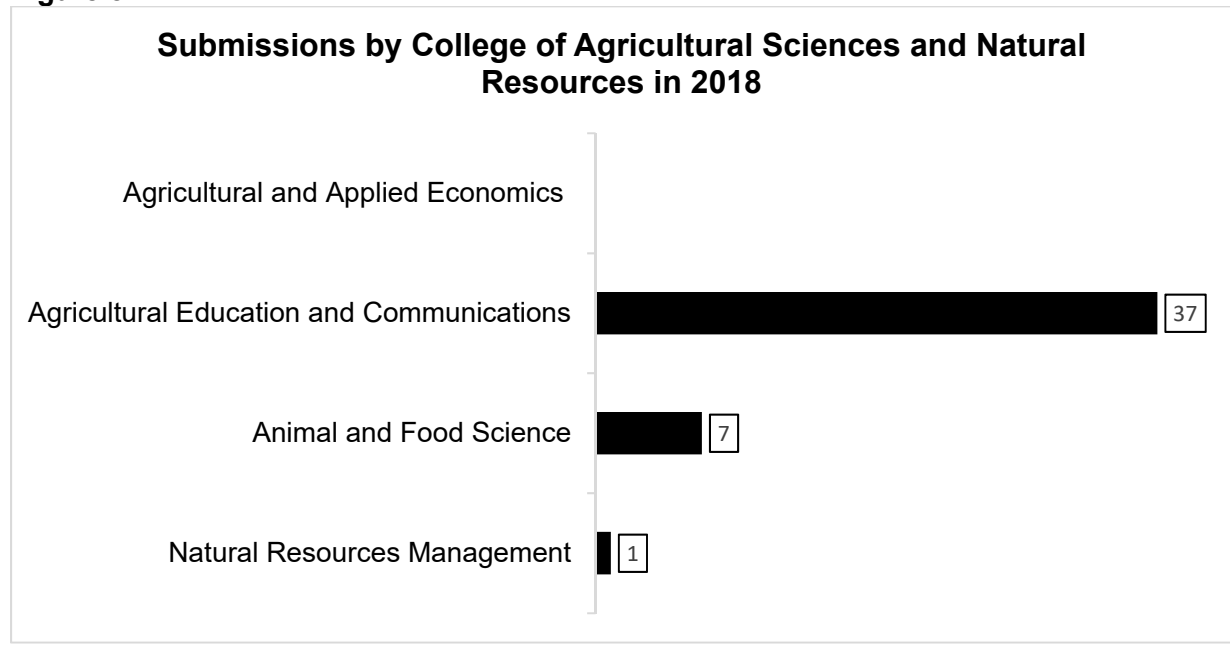


Figure 9 shows the number of submissions by the selected departments within the College of Human Sciences. Most submissions were submitted by Community Family and Addiction Studies ($n = 31$) and Human Development and Family Studies ($n = 18$).

Figure 9

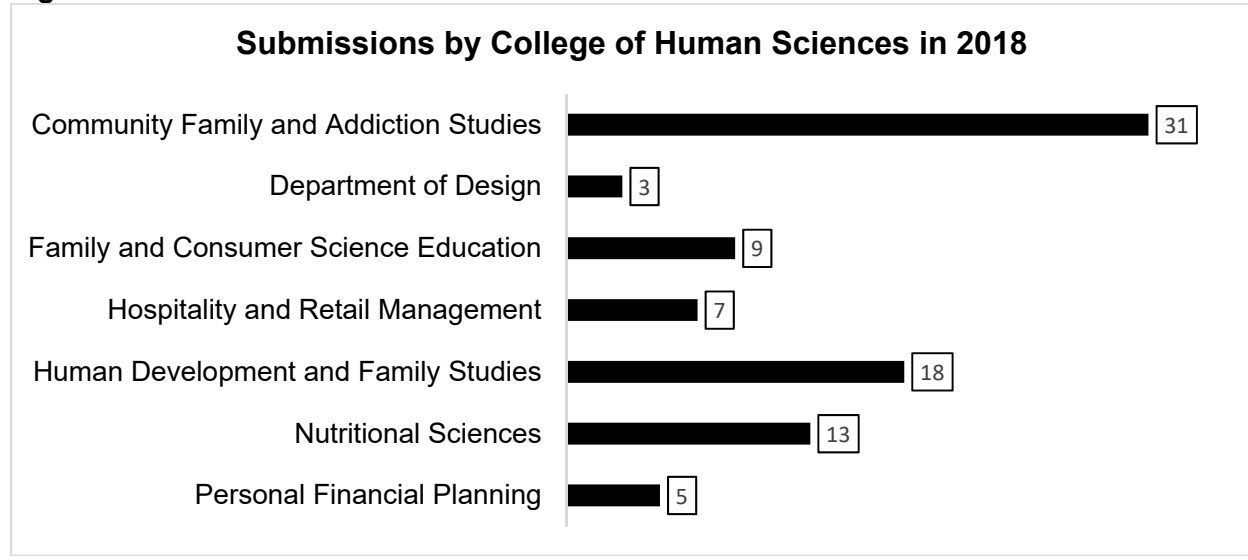


Figure 10 shows the number of submissions by the selected departments within the College of Education. Most submissions were from the Department of Educational Psychology Leadership ($n = 90$) and Curriculum & Instruction ($n = 57$).

Figure 10

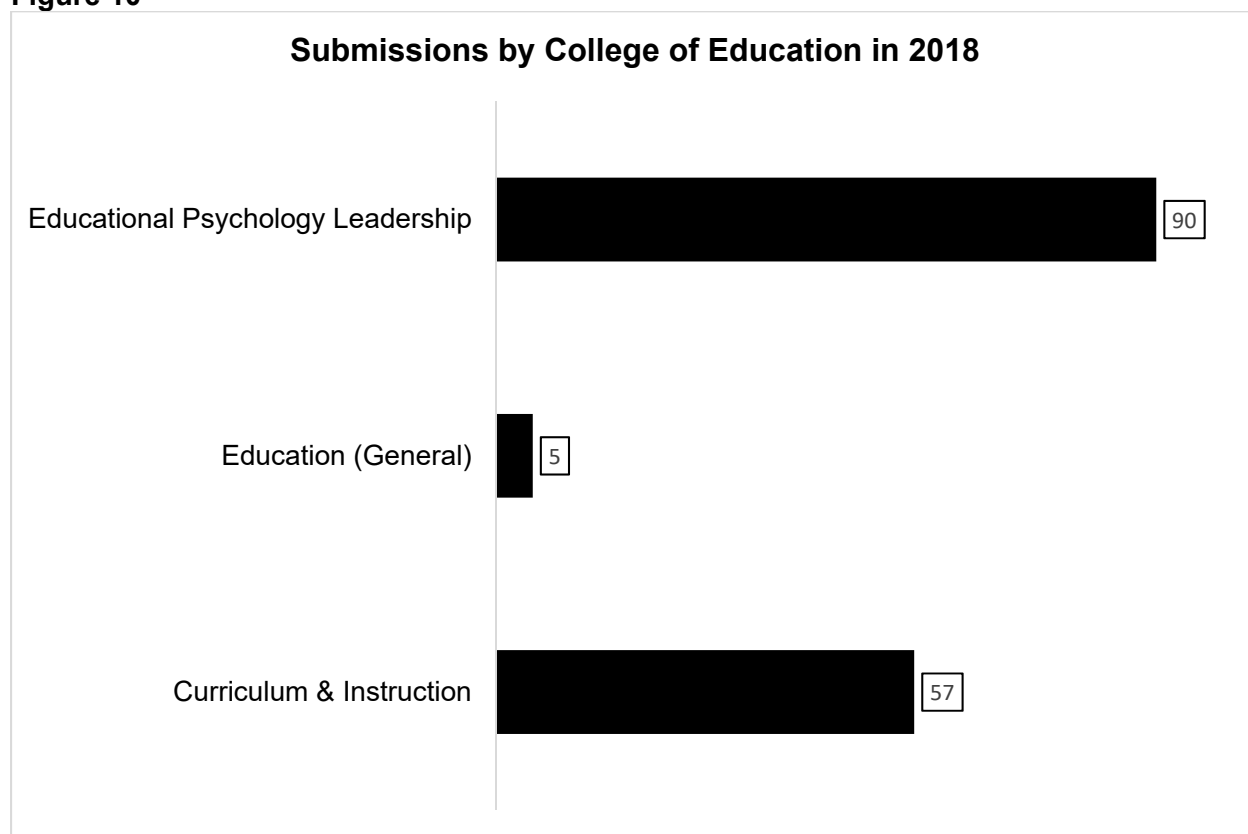
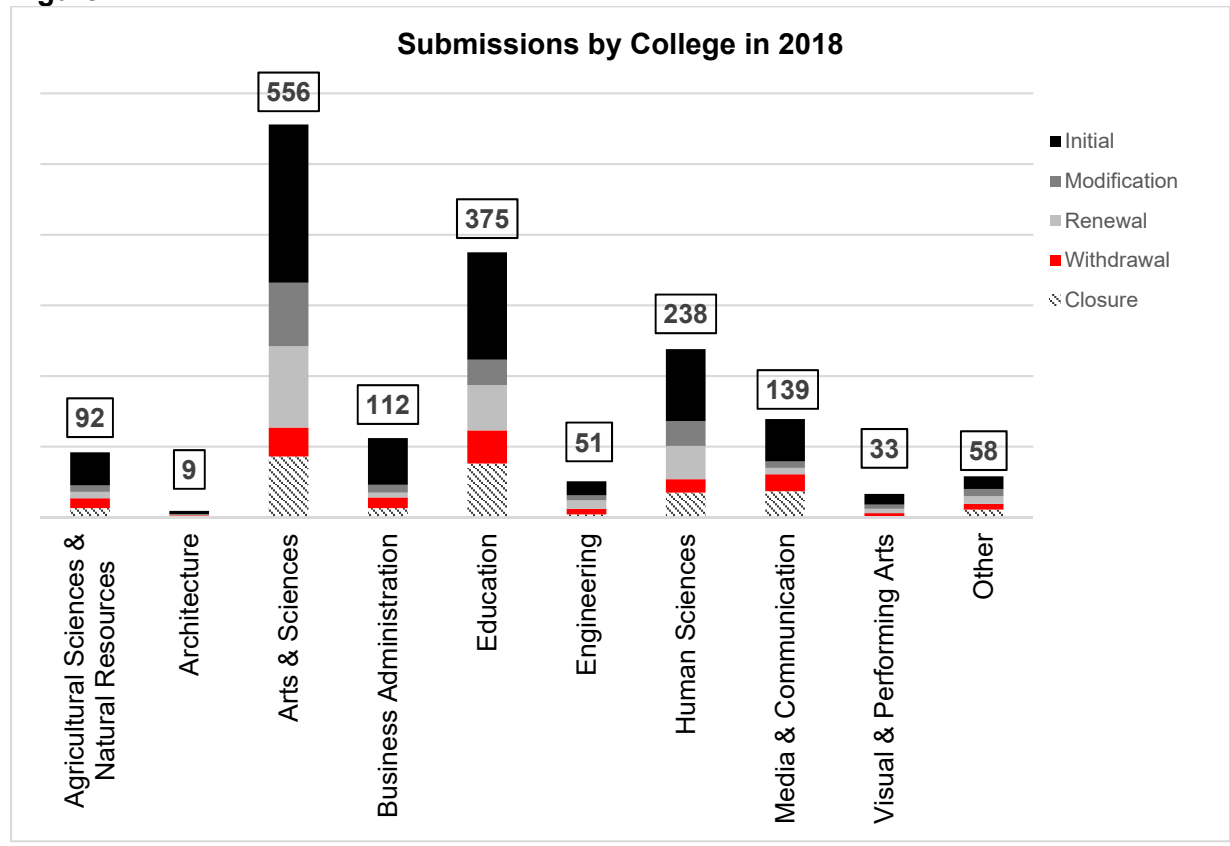


Figure 11 is the total number of submissions by college. The College of Arts and Sciences submitted the most submissions with a total of 556. The College of Education submitted 375 and the College of Human Sciences submitted 238.

Figure 11



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