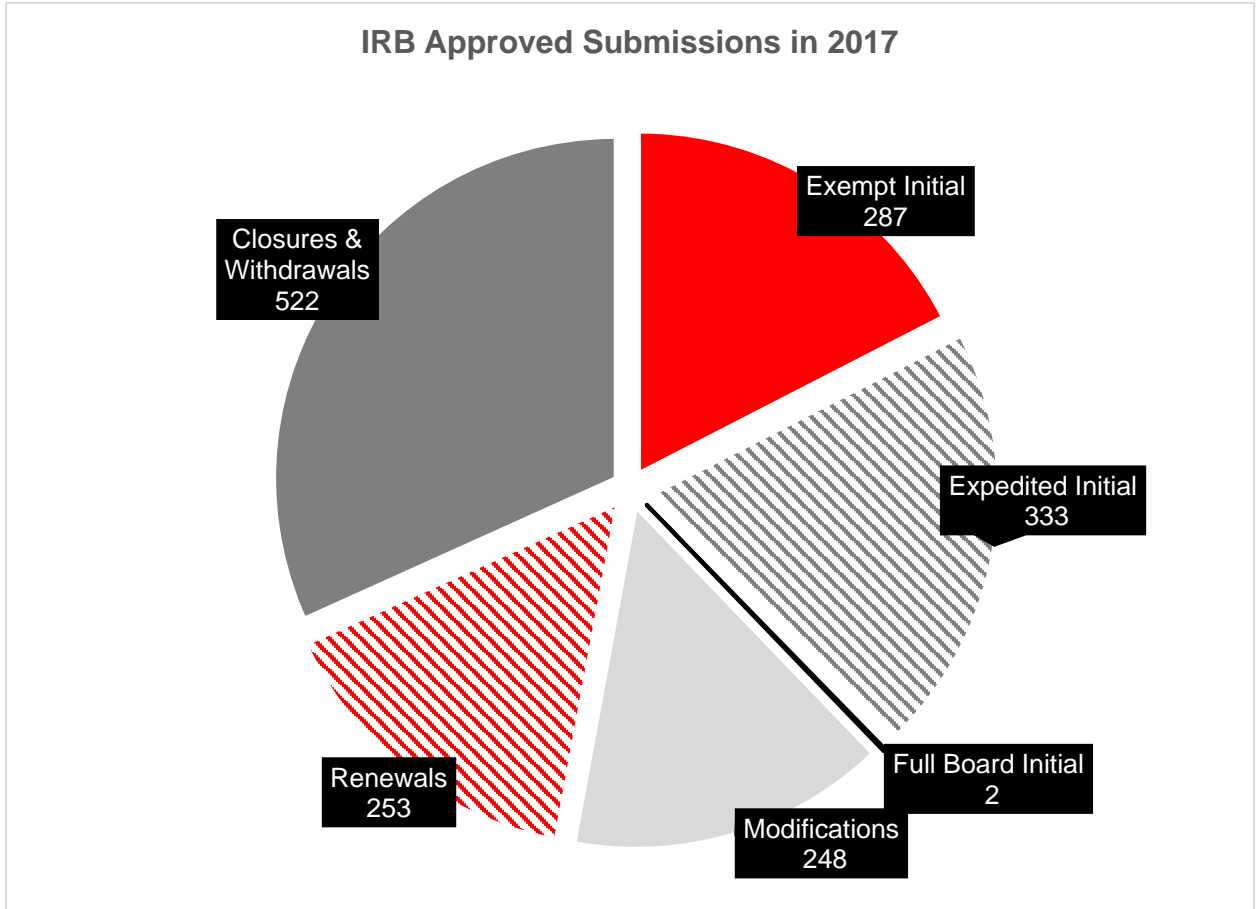


TEXAS TECH UNIVERSITY
INSTITUTIONAL REVIEW BOARD/
HUMAN RESEARCH PROTECTION PROGRAM
2017 ANNUAL REPORT



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 regulation stated in 45 CFR 46.

PROPOSAL VOLUME

There was a total of 2,211 research protocols conducted in 2017.

- This is a 32% increase from 2015.
- 197 involved sponsored projects.
- 456 IRBs included a form of participant compensation (at the close of 2017).
- IRB reviewed a total of 1,732 submissions.
- IRB approved a total of 1,123 submissions.

BUILDING REVIEWER AND STAFF CAPACITY

- Five new scientific IRB members and one non-scientific member trained under the IRB Chair and Associate Chair.
- We avoided fall semester backlog by providing summer salary to seven 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. This will include an examination of the application of Office of Human Research Protections (OHRP) options for differential review of funded vs. unfunded research. The new guidelines for the Common Rule are out and we will continue incorporating these changes into our training and review process. 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 November 30, 2022.

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

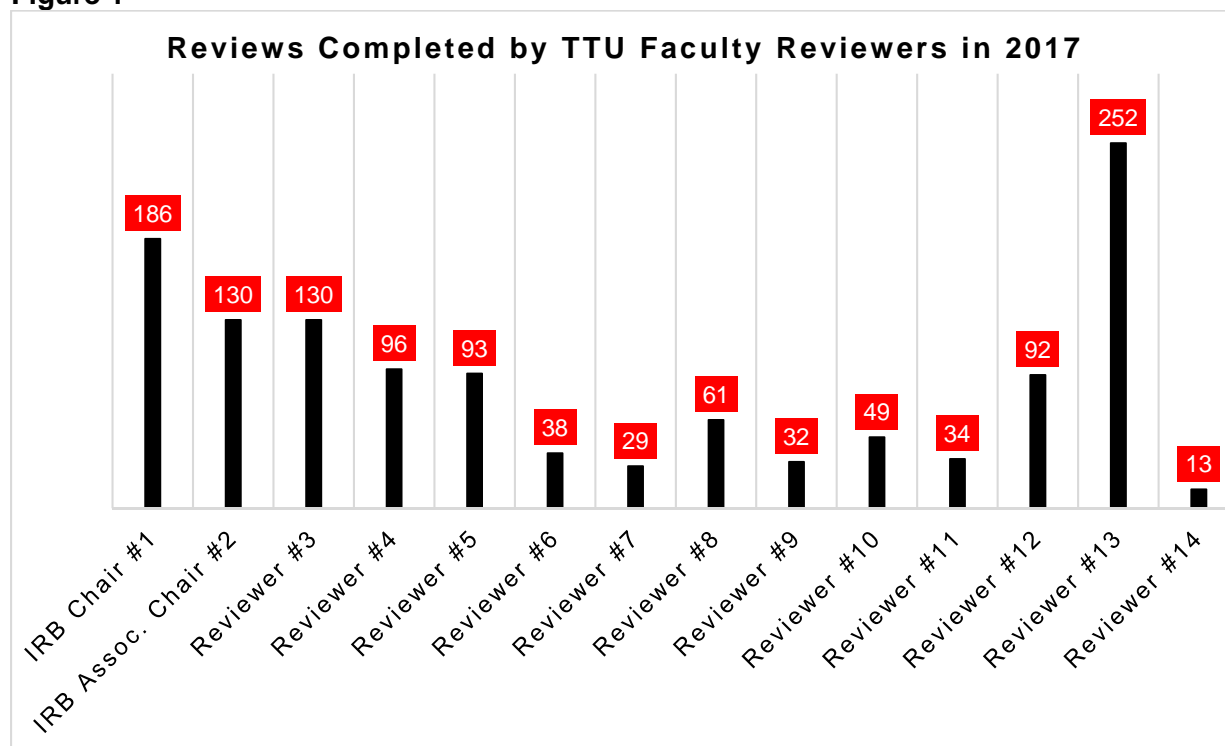
Dr. Kelly Cukrowicz continued as Chair of the IRB, with Dr. Scott Burris serving as Associate Chair. Dr. Cukrowicz reviewed a total of 186 proposals during 2017. In addition, she created a new Reviewer Manual for IRB member, trained 6 new IRB members and mentored 1 of them, and has continued to work with the university community and IRB members to increase the efficiency and effectiveness of the IRB review process. Dr. Burris conducted 130 proposal reviews during 2017. He contributed to training of new IRB members, mentored 1 IRB member, and has worked with Dr. Cukrowicz to increase the efficiency and effectiveness of the IRB review process.

IRB MEMBERS

In 2017, the IRB Committee had 17 members, four alternates, and eight ex-officio members. Most IRB members are assigned 1-3 proposals to review each week. In the spring, 14 members reviewed weekly. In the fall, 12 members reviewed weekly. **Figure 1** shows the number of reviews completed by TTU Faculty Reviewers in 2017. Note, reviewer 13 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 2017, two members resigned from the IRB due to administrative demands. The HRPP/IRB mentor-mentee program is currently training 6 new faculty members as reviewers.

Figure 1



STAFF LEADERSHIP

HRPP MANAGER

Dr. CassiDe Street completed her first year 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. Dr. Street continues to make changes and think of new ways to improve the submission templates in Cayuse IRB. 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, 2018. The changes have been delayed by the U.S. Department of Health & Human Services until July 19, 2018.

STAFF

Ms. Esther Lucey continued as Lead Analyst in 2017 handling administrative closures for faculty departures and expired IRBs. Ms. Lucey also handles the record retention of IRBs closed prior to the implementation of Cayuse IRB. She writes the Hot Topic/Tip of the Month. In her professional development efforts, Ms. Lucey earned continuing education credits for the CIP (Certified IRB Professional), attended webinars and a conference.

Mr. Tyler Sims was promoted to Lead Analyst in September. He investigates complaints and concerns made by human subjects participating in research studies, performs post-approval monitoring, and conducts HRPP/IRB presentations for faculty, staff, and students. He handles all pre-reviews and post-reviews of renewal submissions. Mr. Sims launched the Access database to report on the IRB statistics. The database generates instant reports needed to continually improve the service provided to the university. Mr. Sims will sit for the CIP in September 2018.

Ms. Lucey and Mr. Sims pre-review and post-review exempt and expedited proposals using a checklist prepared by Dr. Street. They also process and assign incoming studies for IRB review.

ACTIVITIES IN 2017

MEETINGS

The full IRB met three times in 2017. 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 PRIM&R. The Public Responsibility in Medicine & Research (PRIM&R) conference in San Antonio this year was attended by the IRB Chair, Dr. Kelly Cukrowicz, the IRB Associate Chair, Dr. Scott Burris, Dr. Street, Ms. Esther Lucey, and Mr. Tyler Sims. 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 2017, we actively continued to limit unnecessary IRB proposals and comply 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

Of the active IRB protocols, 197 involve sponsored projects.

BUDGET

The HRPP budget includes salaries for the HRPP Manager, three analysts, 25% salary for the Chair, and 2 months of summer salary 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 continuing to help every IRB member with training and educational opportunities. In 2017, we continued to implement the 2011 5-10 year strategic plan for the HRPP.

ACHIEVED IN 2017

1. We trained five new scientific IRB members through training sessions and our mentor-mentee program, as well as one new non-scientific IRB member.
3. With the help of university administration, we paid summer IRB reviewers to address high volume of IRB proposals.

4. We conducted six post-approval reviews that were all for cause. The post-approval reviews found one minor deviation, one unanticipated problem, and one noncompliance. These were corrected through modifications or submissions made in Cayuse IRB. Three had no violations.
7. In 2017, we had 616 new proposals; in 2016 we had 529 new proposals.
8. 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.
9. TTU IRB currently has 34 institutional authorization agreements and nine individual authorization agreements. These agreements facilitate collaboration between TTU investigators and external investigators. TTU researchers collaborated with 86 external investigators that did not require authorization agreements.
10. A member of the IRB continued to be a liaison to the Faculty Senate.

ACCOMPLISHED FROM 2017 GOALS

1. We created an IRB Reviewer Manual to use as a guide during reviews and help with reviewer consistency.
2. We created and incorporated an Access database that allows us to run statistics on Cayuse IRB submissions and the details provided in the submission.
3. We trained 6 new IRB members.
4. We began preparations for the changes made to the Common Rule (45 CFR 46).

GOALS FOR 2018

1. We will expand upon Post-Approval Policies in our HRPP/IRB Manual and add a new section for Reviewers.
2. We will continue to examine methods for increasing the flexibility of our IRB reviews and policies. This will include an examination of the application of OHRP options for differential review of funded vs. unfunded research.
3. We continue work to incorporate changes in the Final Rule into our training and review process.
4. 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
 Associate Professor of Psychology
 Department of Psychological Sciences
 Texas Tech University

Scott Burris, Ph.D.
 Associate Chair, Institutional Review Board
 Interim Chair, Department of Agricultural
 Education and Communications
 Texas Tech University

CassiDe Street, Ph.D.
 Manager, Human Research Protection
 Program
 Office of the Vice President of Research
 Texas Tech University

TEXAS TECH UNIVERSITY
 INSTITUTIONAL REVIEW BOARD
 PROTECTION OF HUMAN SUBJECTS COMMITTEE

September 2017-August 2018

MEMBERS				
Name	Term	Department	Phone	Email
Kelly Cukrowicz, Ph.D. (Chair, Scientific)	2018	Psychological Sciences MS 2051	(806) 834- 8485	kelly.cukrowicz@ttu.edu
Scott Burris, Ph.D. (Associate Chair, Scientific)	2018	Ag Education & Communications MS 2131	(806) 834- 8689	scott.burris@ttu.edu
Jessica Alquist, Ph.D. (Scientific)	2019	Psychological Sciences MS 2051	(806) 834- 7553	malinda.alquist@ttu.edu
Eric Cardella, Ph.D. (Scientific)	2019	Rawls College of Business MS 2101	(806) 834- 7482	eric.cardella@ttu.edu
Amanda Chattin (Non-Scientific)	2019	Sociology, Anthropology & Social Work MS 1012	(806) 834- 5584	amanda.chattin@ttu.edu
Malinda Colwell, Ph.D. (Scientific)	2019	Human Devel. & Family Studies MS 1162	(806) 834- 4179	malinda.colwell@ttu.edu
Angela Eaton, Ph.D. (Scientific)	2019	English MS 3091	(806) 742- 2501	angela.eaton@ttu.edu
Joaquin Gonzales, Ph.D. (Scientific)	2019	Kinesiology & Sport Management MS 3011	(806) 834- 5944	Joaquin.gonzales@ttu.edu
Stephanie J. Jones, Ed.D. (Scientific)	2020	Education MS 1071	(806) 834- 1380	stephanie.j.jones@ttu.edu
Andy King, Ph.D. (Scientific)	2020	Media & Communication MS 3082	(806) 834- 3535	andy.king@ttu.edu
Susan Mengel, Ph.D. (Scientific)	2018	Computer Science MS 3104	(806) 834- 6866	susan.mengel@ttu.edu
Lainey Morrison (Non-Scientific/Non- Affiliated)	2020	Lubbock City Hall 1625 13th St	(806) 775- 2316	LMorrison@mail.ci.lubbock.tx.us
Melanie Sarge, Ph.D. (Scientific)	2020	Media & Communication MS 3082	(806) 834- 2831	m.sarge@ttu.edu
Andreas Schneider, Ph.D. (Scientific)	2018	Sociology, Anthropology & Social Work MS 1012	(806) 834- 7502	andreas.schneider@ttu.edu
Sarah Wakefield, M.D. (Scientific/Non- Affiliated/Prisoner)	2019	Psychiatry – TTUHSC MS 8103	(806) 743- 2800	sarah.wakefield@ttuhsc.edu

MEMBERS				
Name	Term	Department	Phone	Email
Andy Young, Ed.D. (Scientific/Non-Affiliated/Prisoner)	2018	Behavioral Sciences Lubbock Christian University 5601 19th Street	(806) 720-7830	andy.young@lcu.edu
Ryan Scheckel (Non-Scientific)	2019	Undergraduate Education MS1062	(806) 834-7402	ryan.scheckel@ttu.edu

Kelly Cukrowicz: Licensed Psychologist, State of Texas

ALTERNATES				
Name	Term	Department	Phone	Email
Zhen Cong, Ph.D. (Scientific)	2020	Human Development & Family Studies/Gerontology MS1230	(806) 834-8082	zhen.cong@ttu.edu
Jim Johnson, PharmD, MPA, FACHE (Non-Affiliated, Scientific Prisoner Rep)	2020	Senior Vice President of Hospital Services 602 Indiana Ave.	(806) 775-8516	jim.johnson@umchealthsystem.com
Alan Reifman, Ph.D. (Scientific)	2018	Human Development & Family Studies MS1162	(806) 834-5174	alan.reifman@ttu.edu
Kamau Siwatu, Ph.D. (Scientific)	2019	Education Psychology and Leadership MS1071	(806) 834-5850	kamau.siwatu@ttu.edu

EX-OFFICIO			
Name	Department	Phone	Email
Alice Young, Ph.D.	Associate Vice President for Research Research Integrity MS1075	(806) 742- 3905	alice.young@ttu.edu
Katherine Austin Beltz, Ph.D.	Assistant Vice President Information Technology MS2008	(806) 742- 5156	kathy.austin@ttu.edu
Bobbie Brown	Office of the Registrar MS5015	(806) 834- 5765	bobbie.brown@ttu.edu
Amy Cook, J.D.	Managing Director Office of Research Services MS1035	(806) 742- 3884	amy.cook@ttu.edu
Marianne Evola, Ph. D.	Responsible Conduct of Research MS1075	(806) 834- 4166	marianne.evola@ttu.edu
Matt Roe, M.S.	Assistant Vice President Environmental Health and Safety MS1090	(806) 834- 6010	matt.roe@ttu.edu
Cui Romo, J.D.	Attorney, Office of Research Services MS1035	(806) 834- 5765	cui.romo@ttu.edu
Sherri Johnston	Director, Institutional Compliance	(806) 743- 4007	sherri.johnston@ttuhsc.edu

Figure 2 shows the number of submissions approved by the IRB in 2017. The IRB members approved a total of 1,123 submissions. Most of the approvals were expedited submissions ($n = 333$), followed by exempt submissions ($n = 287$).

Figure 2



Figure 3 shows the number of new initial submissions that were created and submitted in Cayuse IRB during 2017. These submissions are new research proposals submitted to the IRB, however, this does not mean all submissions were approved. Every submission ($n = 680$) was reviewed by an IRB member and approved or returned for revision. The IRB received 313 exempt, 365 expedited, and two full board submissions. Most of submissions are from the College of Arts and Sciences ($n = 219$), specifically, the Department of Psychological Sciences.

Figure 3

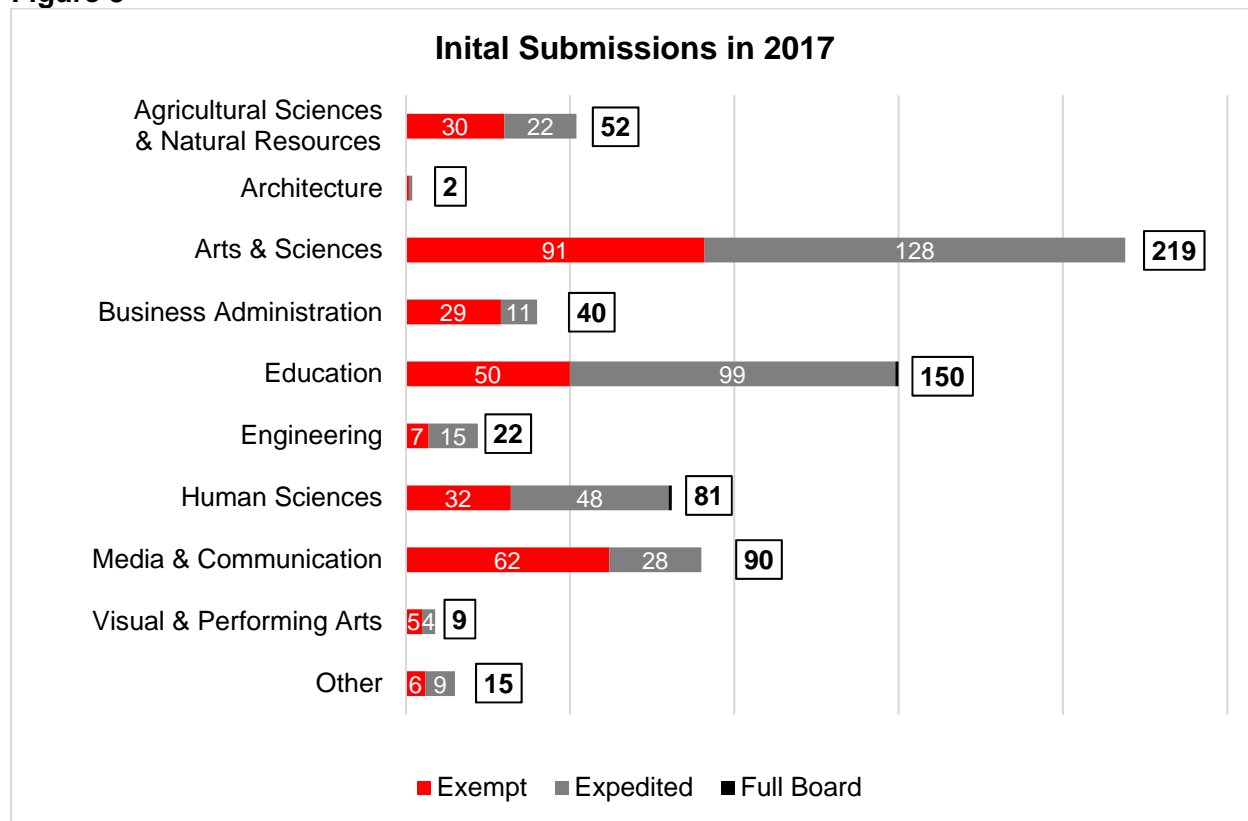


Figure 4 shows the number of modifications that were submitted in 2017 on an approved study. These modifications ($n = 263$) were reviewed by an IRB member and approved or returned for revision. The College of Arts and Sciences ($n = 116$) submitted the most modifications followed by the College of Human Sciences ($n = 46$). A total of 70 exempt, 189 expedited and four full board modifications were submitted by TTU researchers.

Figure 4

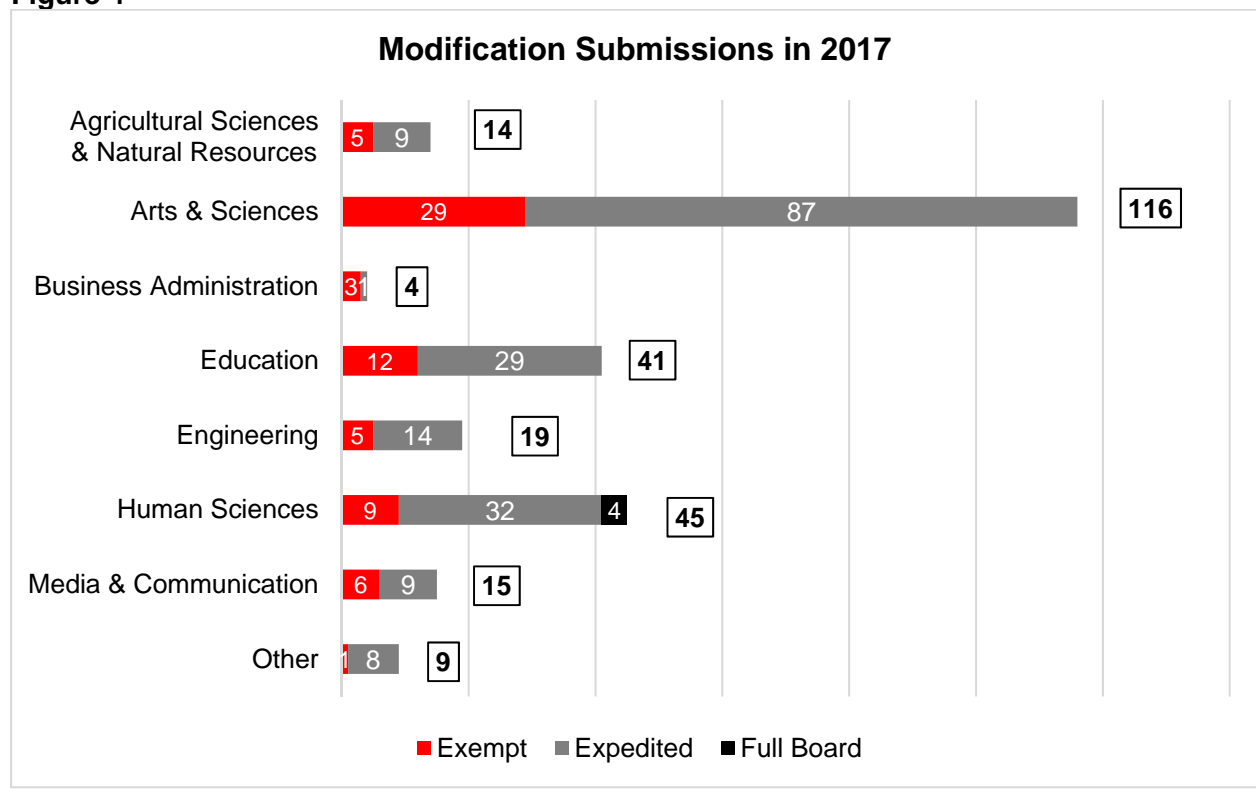


Figure 5 shows the renewal submissions for approved expedited and/or full board studies. One IRB member is dedicated to reviewing renewals ($n = 269$). Most expedited studies must be renewed every year, however, some studies have a different renewal time frame. The renewal date is noted in the IRB approval letter. HRPP staff administratively closes studies that are not renewed. Researchers submitted 246 renewals for expedited studies and six renewals for full board studies. There were 17 exempt studies renewed to remove the expiration date.

Figure 5

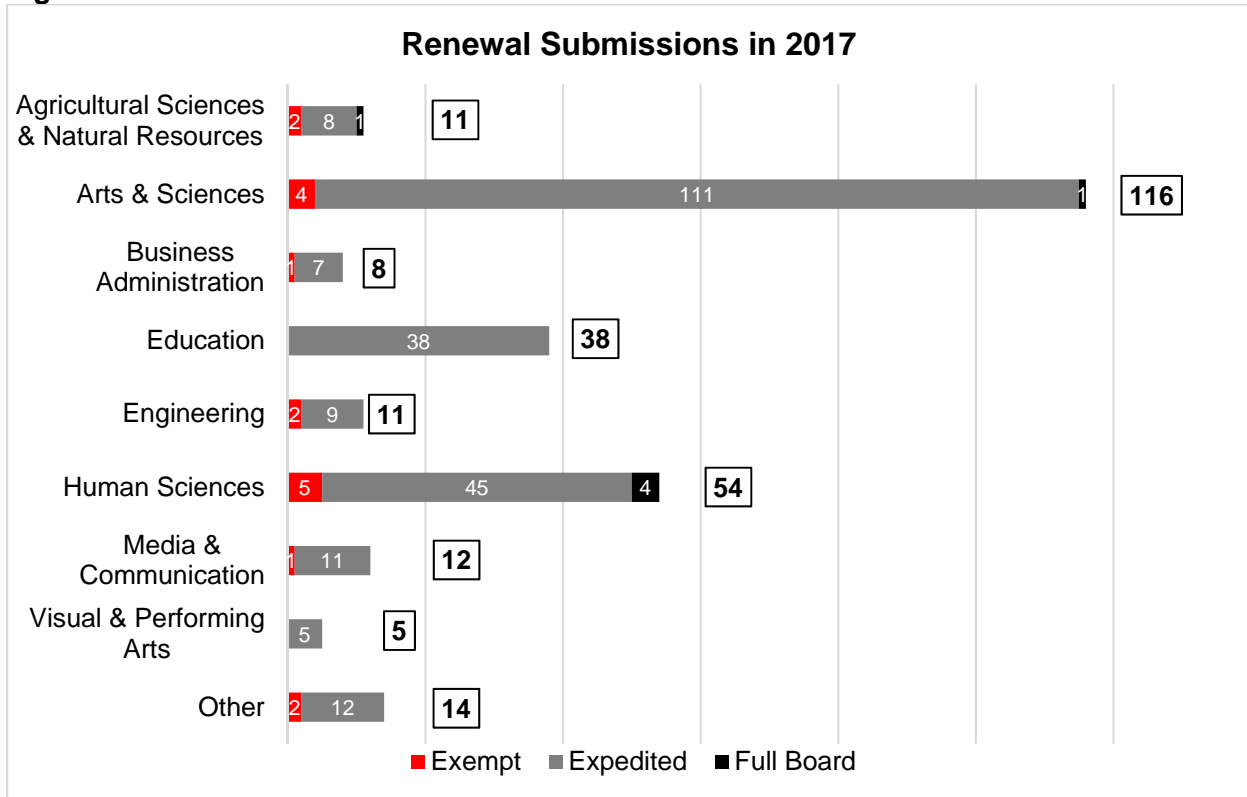
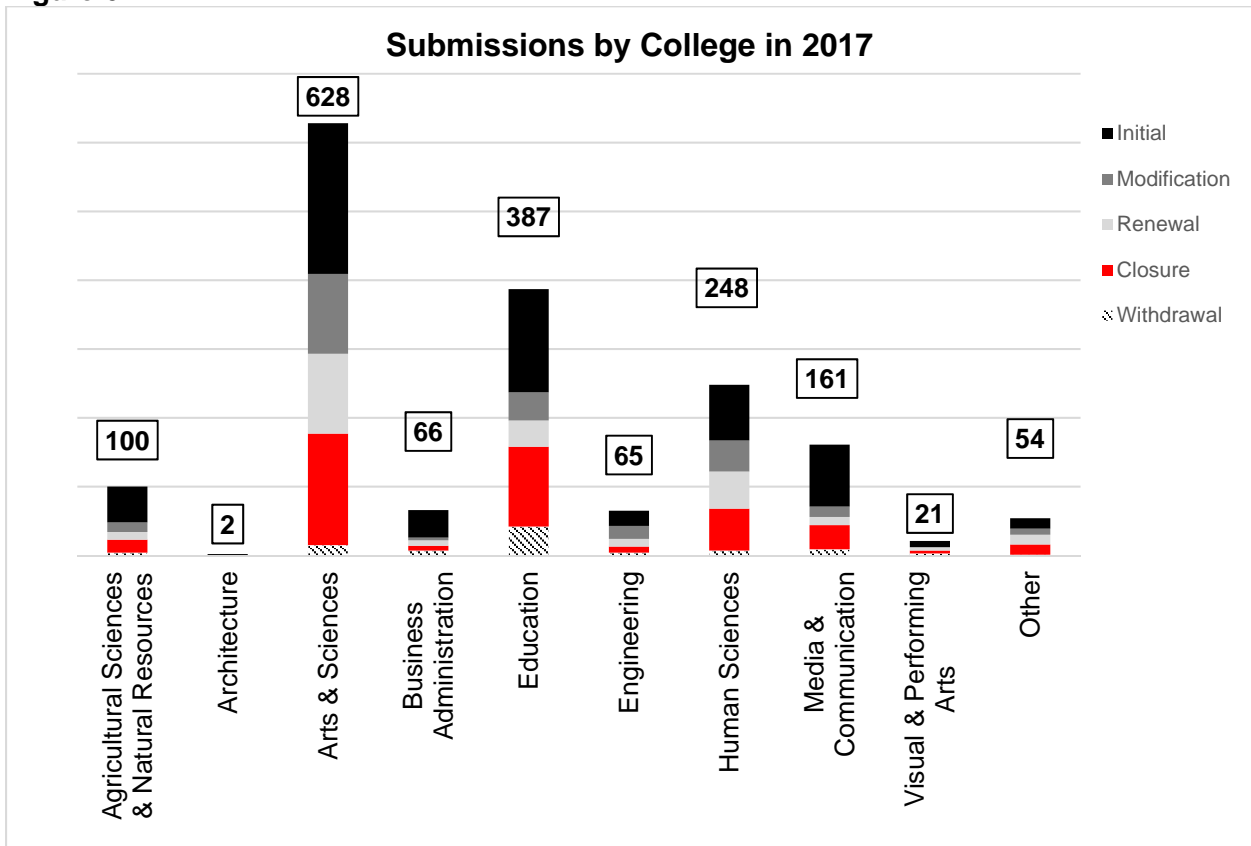


Figure 6 is the total number of submissions by college. The College of Arts and Sciences submitted the most submissions with a total of 628 submissions. The College of Human Sciences submitted 248 and the College of Education submitted 387.

Figure 6



The following figures, **Figures 7 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 7 shows the number of submissions by the selected departments within the College of Arts and Sciences in 2017. Most submissions were from Psychological Sciences ($n=229$), Sociology, Anthropology, and Social Work ($n = 61$), and Kinesiology and Sport Management ($n = 52$).

Figure 7

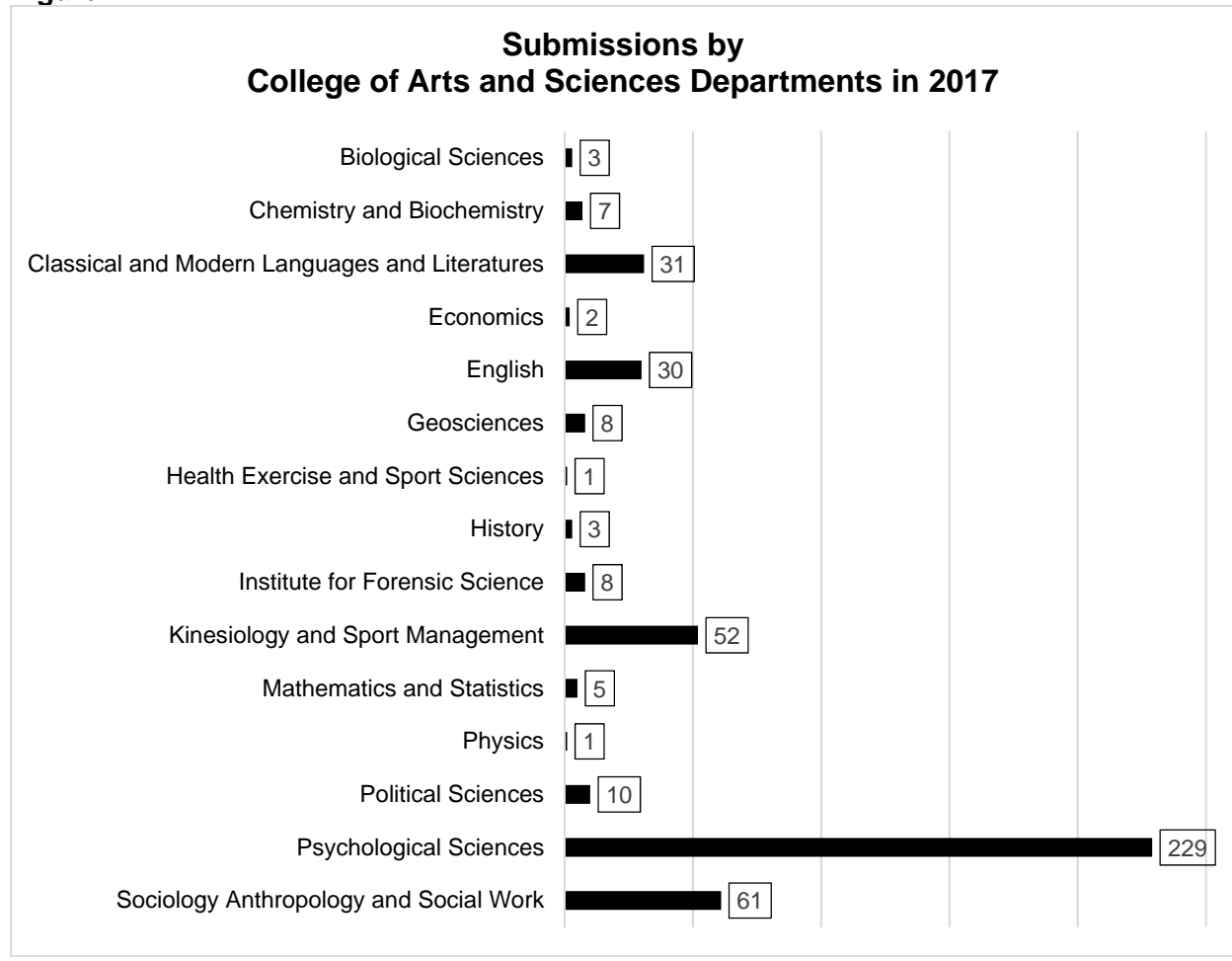


Figure 8 shows the number of submissions by the selected departments within the College of Agricultural Sciences and Natural Resources. The majority of submissions were submitted by Animal and Food Science ($n = 32$) and Agricultural Education and Communications ($n = 31$).

Figure 8

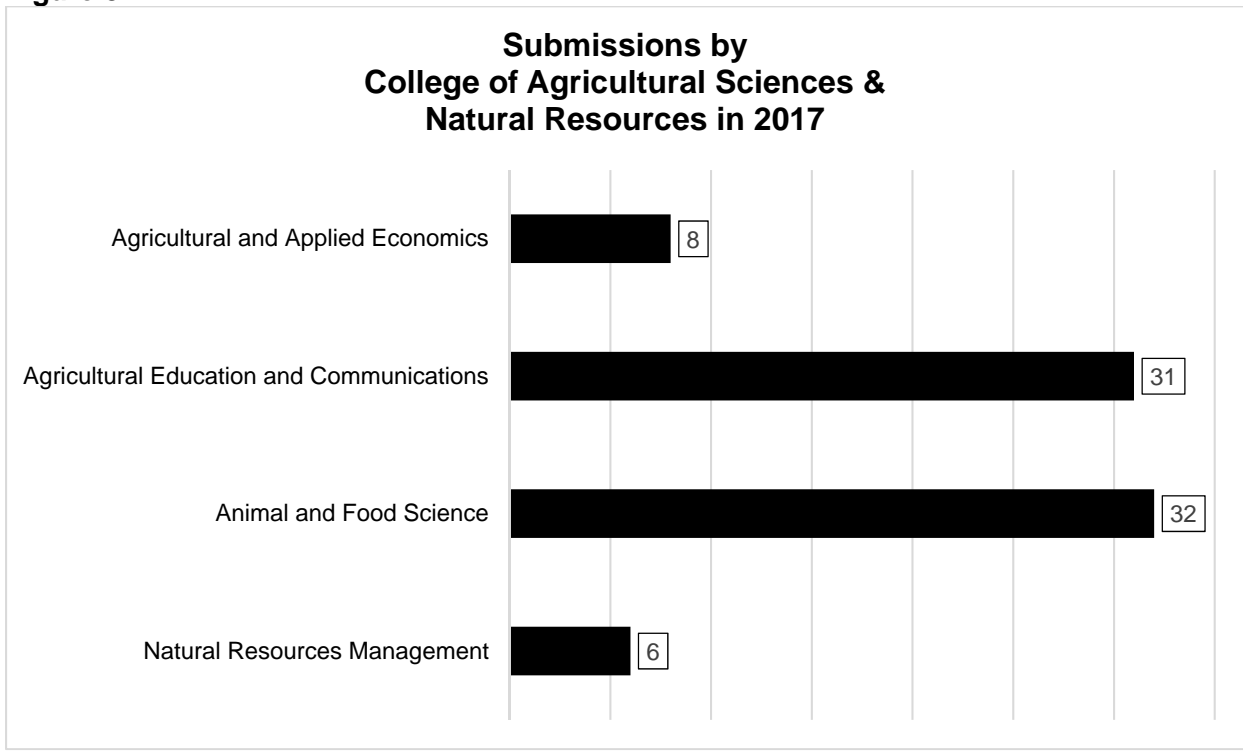


Figure 9 shows the number of submissions by the selected departments within the College of Human Sciences. The majority of submissions were submitted by Human Development and Family Studies ($n = 68$).

Figure 9

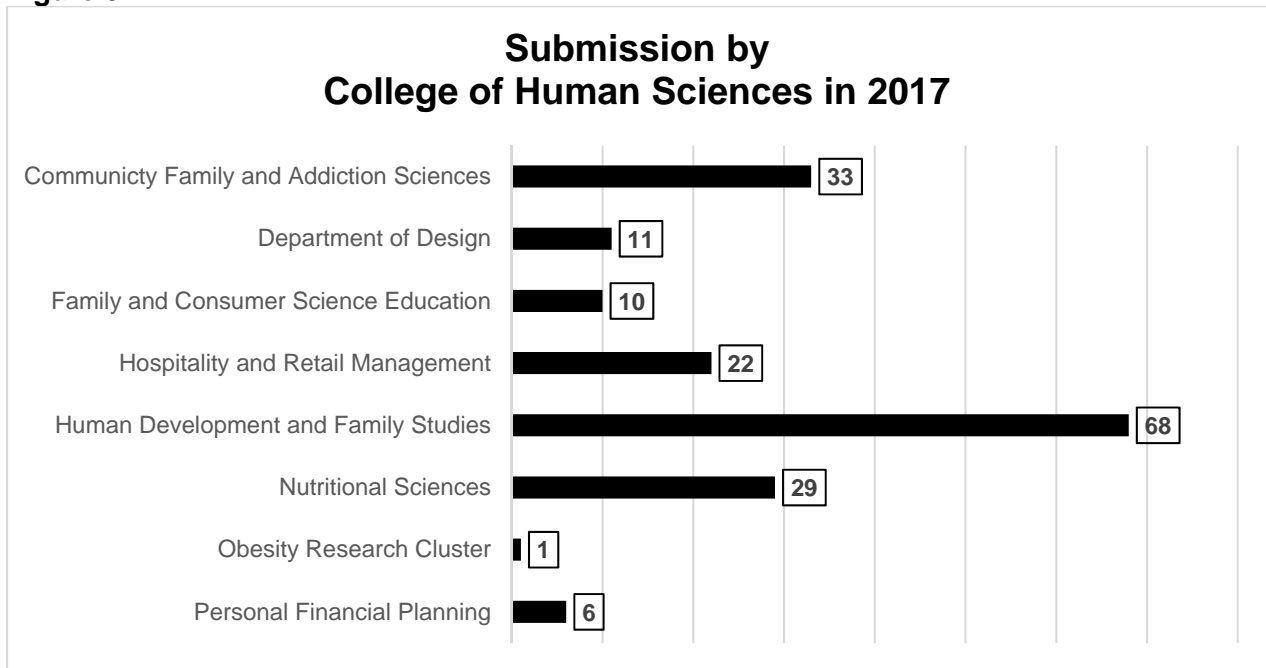
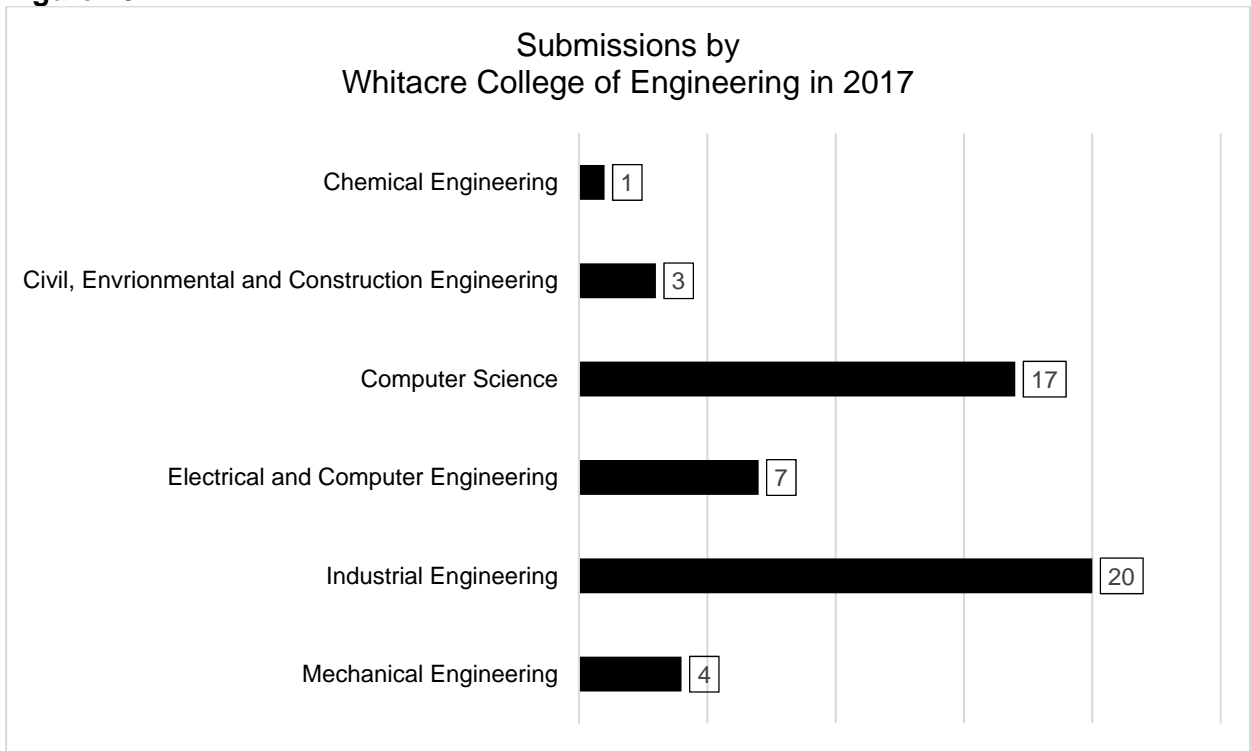


Figure 10 shows the number of submissions by the selected departments within the Whitacre College of Engineering. The majority of submissions were from the Department of Industrial Engineering ($n = 20$) and the Department of Computer Science ($n = 17$).

Figure 10



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