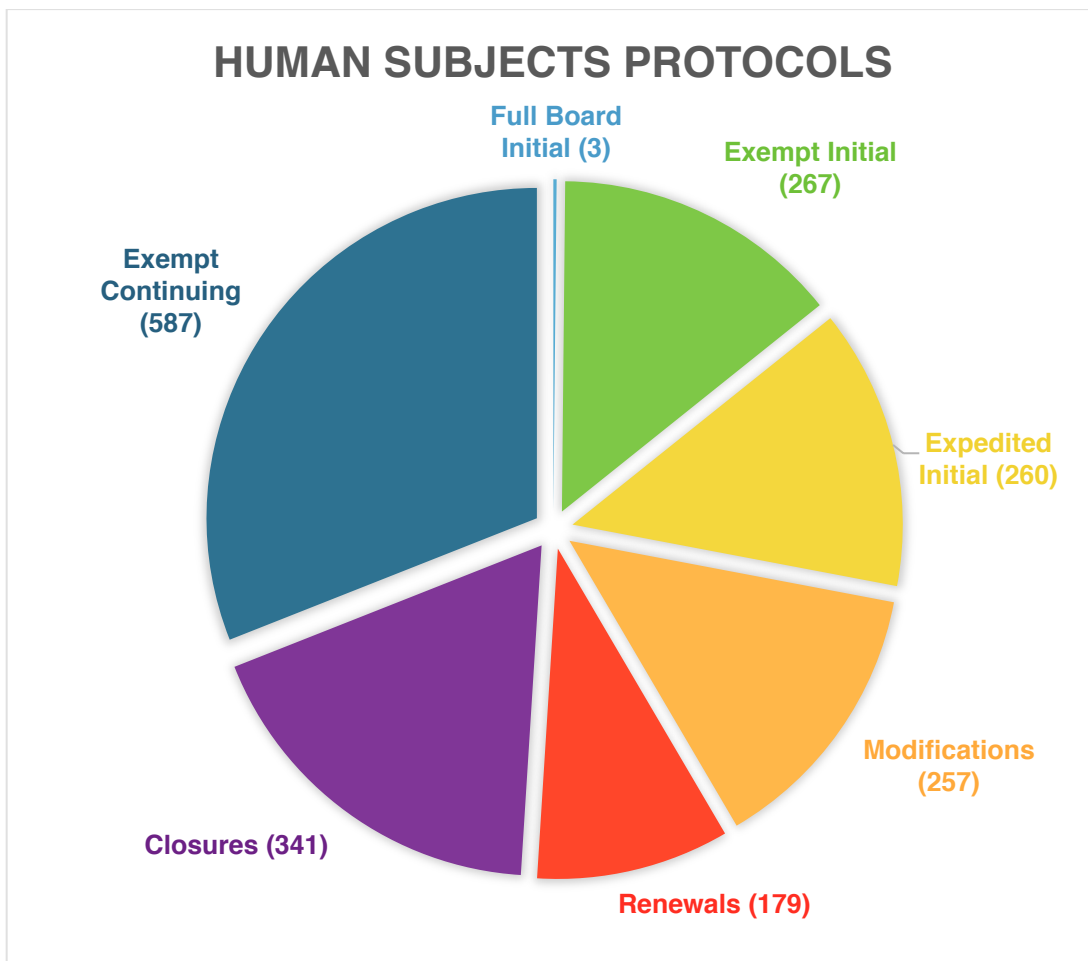


TEXAS TECH UNIVERSITY
INSTITUTIONAL REVIEW BOARD/
HUMAN RESEARCH PROTECTION PROGRAM
2016 ANNUAL REPORT



EXECUTIVE SUMMARY

COMMITTEE PURPOSE

The Institutional Review Board (IRB) regulates all activity that involves research with human subjects that (a) is conducted by TTU personnel in the course of 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 were a total of 1,894 current protocols at the end of 2016.

- This is a 25.6% increase from 2015.
- 126 involved sponsored projects.
- IRB reviewed a total of 966 submissions.
- HRPP/IRB moved to the Cayuse IRB electronic system.
- HRPP uploaded 1,366 legacy studies (approved paper submissions) into the new electronic system, Cayuse IRB.

BUILDING REVIEWER AND STAFF CAPACITY

- The IRB Chair and Associate Chair trained four new scientist IRB members and two non-scientist IRB members.
- The four reviewers were paid to review submissions over the summer, leading to a lack of backlog at the start of fall for the second year in a row.
- The HRPP office had a change leadership and hired Dr. CassiDe Street as the manager.
- Texas Tech IRB joined the State of Texas Master IRB Reciprocity Agreement to allow for easier research collaboration among higher education institutions in Texas.

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 OHRP options for differential review of funded vs. unfunded research. The new guidelines for the Common Rule are out and we will begin 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. A long-term goal is AAHRPP accreditation.

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 December 8, 2021.

The Human Research Protection Program (HRPP) carries out administrative duties involved with 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 213 proposals during 2016. In addition, she carried out many of the functions of the HRPP manager during the summer of 2016, completed a revision of the IRB manual, trained 4 new IRB members and mentored 3 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 185 proposal reviews during 2016. He contributed to training of new IRB members, mentored 2 IRB members, and has worked with Dr. Cukrowicz to increase the efficiency and effectiveness of the IRB review process.

IRB MEMBERS

In 2016, two IRB members from the HSC resigned from the IRB Committee due to medical issues. In addition, one TTU member resigned due to other administrative demands. Four new faculty members were trained under the HRPP/IRB mentor-mentee training program in 2016 and joined the IRB. One of these was an alternate who attended training and returned as a full reviewing member. In addition, two new non-scientists were added to the board. The Texas Tech University Responsible Conduct of Research Administrator (Dr. Marianne Evola), Attorney in the Office of Research Services (Cui Romo), and Director for Institutional Compliance on HIPAA (Sherri Johnston) accepted Ex-Officio roles. As of January 2016, there are currently 19 members of the IRB, 4 alternates, and 8 ex-officio members. A current roster of the IRB can be found on page 7. This is an exceptional group of people in terms of commitment, sensitivity to the issues involved in protecting human subjects, and willingness to be helpful to members of the university community. Most IRB members are assigned 2-3 proposals per week to review.

STAFF LEADERSHIP

HRPP MANAGER

Ms. Donna Peters retired from the position of Manager of the Human Research Protection Program on May 31, 2016. Dr. CassiDe Street took this position in August 2016. Prior to

retirement, Ms. Peters continued both pre-screening new IRB proposals before sending the proposals to reviewers and continued reviewing exempt proposals. She continued to make presentations about the IRB to TTU classes and groups. Ms. Peters had a current certification as Certified IRB Professionals (CIP). Dr. Street has completed much of the training required of an HRPP manager and will sit for the CIP exam in September 2018. She has begun restructuring elements of the review process to ensure greater reliance on IRB faculty reviewers. She is in charge of all activities related to Institutional Authorization Agreements. She also makes presentations on IRB to TTU classes and groups and works with investigators needing assistance.

STAFF

Ms. Esther Lucey and Mr. Rick Shupe continued as lead analysts in 2016. Both staff members are Certified IRB Professionals (CIPs). Both Ms. Lucey and Mr. Shupe do pre-reviews of exempt and expedited proposals using a checklist prepared by Dr. Street. Ms. Lucey worked with database entry for statistical analysis on a weekly, monthly, and annual basis. She performed data entry of active hard copy research studies into the new electronic system. Ms. Lucey continued her professional development through earning continuing education credits for the CIP, webinars and conference attendance.

Mr. Shupe has particular responsibility for post-approval review of protocols and for presentations about the IRB. Mr. Shupe is tasked with processing and assigning incoming studies for IRB review, investigating complaints and concerns made by human subjects participating in research studies, performing random post approval reviews, and conducting HRPP/IRB presentations for faculty, staff, and students.

Dr. Kelsie Jackson chose to move to a different position within OVPR in the spring of 2016. Tyler Sims was hired as the third staff member in the office. Mr. Sims has been constructing a new database system that will allow the HRPP office to better analyze the workflow process of the IRB and HRPP office. The HRPP office will be able to generate instant reports needed to continually improve the service provided to the university. Tyler has also been responsible for leading several presentations on campus and has begun meeting with principal investigators in their office to answer their IRB and HRPP questions.

ACTIVITIES IN 2016

MEETINGS

The full IRB met four times in 2016. IRB members discussed research articles, subject pool IRB protocols, and educational materials at each meeting. The minutes of the IRB Full Board Meetings are available to the public by contacting the IRB Coordinator 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 Anaheim this year was attended by the IRB Chair, Dr. Kelly Cukrowicz, the IRB Associate Chair, Dr. Scott Burris, Dr. Street, Dr. Marianne Evola, Ms. Esther Lucey, and Dr. Kelsie Jackson. Mr. Shupe attended the Evisions (software developer) annual conference.

CAYUSE IRB

In 2016, the IRB moved to the Cayuse IRB electronic system. The HRPP uploaded 1,366 legacy studies (approved paper submissions) into the new electronic system, Cayuse IRB. The HRPP office administratively closed 176 active protocols and TTU investigators closed 165 active protocols. The protocols were closed due to the study being completed or the investigator did not renew the expedited study. TTU investigators withdrew 19 submissions in 2016.

Staff participated in the training of the Cayuse IRB system. Training was available for all TTU researchers through the TLPDC, individual trainings at the researcher's office, on the phone and computer, and at class presentations.

PROTOCOLS

The number of IRB protocols has more than quadrupled since 2005. In 2016, we continued to take active steps to limit unnecessary IRB proposals and be within regulatory requirements. We continued to monitor IRB protocols of PIs leaving TTU to maintain research compliance. Working with these faculty and staff members, we closed 64 protocols and transferred 15 others to new Principal Investigators.

Year	Current protocols at the end of the year
2006	557
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

Of the active IRB protocols, 126 involve sponsored projects.

BUDGET

The HRPP budget includes salaries for the HRPP Manager, the three analysts, and 25% salary for the Chair, and 2 months of summer salary and one course release for Associate Chair. We also have one-quarter time undergraduate student assistant. The budget includes 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 2016, we continued to implement the 5-10 year strategic plan for the HRPP that we developed in 2011.

ACHIEVED IN 2016

1. We trained four new scientist IRB members through training sessions and our mentor-mentee program, as well as two new non-scientist IRB members.
2. We transitioned leadership of the HRPP office to a new Manager, Dr. CassiDe Street.
3. We were provided funds to pay summer IRB reviewers in order to address high volume of IRB proposals.
4. We joined State of Texas Master IRB Reciprocity Agreement.
5. We continued tracking payments to research participants. In 2016, 46 IRB protocols paid participants from sponsored projects, 119 from internal TTU awards, and 30 from researchers' personal funds.
6. We handled 26 For-Cause post-approval reviews and 3 random reviews. There were 3 findings of noncompliance that were corrected by amending the IRB protocol.
7. In 2015, we had 672 new proposals; in 2016 we had 529 new proposals.
8. We made 22 presentations to classes, groups, and administrative units reaching over 275 students and faculty involving 28 hours or scheduled trainings. 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 human subjects' research.
9. This year the TTU IRB had over 15 authorization agreements with several universities. These agreements facilitate collaboration between TTU investigators and others.
10. A member of the IRB continued to be a liaison to the Faculty Senate.

ACCOMPLISHED FROM 2016 GOALS

1. We completed the move to Cayuse IRB and have had more than 1150 IRB submissions through this system.
2. We revised the HRPP/IRB Manual to incorporate the new Cayuse IRB procedures and revised the Post-Approval Policies.
3. We worked with the TTU Information Technology Division to revise the Electronic Data Policy. This work stalled as new regulations from the state were issued that IT needed to incorporate prior to updating our policy.
4. We trained four new IRB members.

GOALS FOR 2017

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 will work to incorporate changes in the Common 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.

LONG TERM GOAL

1. Our continuing long-term goal is AAHRPP accreditation.

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 2016 - August 2017

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 and Communication MS 2131	(806) 834-8689	scott.burris@ttu.edu
Jessica Alquist, Ph.D. (Scientific)	2019	Psychological Sciences MS 2051	(806) 834-7553	jessica.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 Dev. & Family Studies MS 1162	(806) 834-4179	malinda.colwell.edu
Angela Eaton, Ph.D. (Scientific)	2019	English MS 3091	(806) 742-2501	angela.eaton@ttu.edu
Joaquin Gonzales, Ph.D. (Scientific)	2019	Kinesiology and Sport Management MS 3011	(806) 834-5944	Joaquin.gonzales@ttu.edu
Stephanie J. Jones, Ed.D. (Scientific)	2017	Education MS 1071	(806) 834-1380	stephanie.j.jones@ttu.edu
Andy King, Ph.D. (Scientific)	2017	Media & Communication MS 3082	(806) 834-3535	andy.king@ttu.edu
Sylvia Mendez-Morse, Ph.D. (Scientific)	2017	Education MS 1071	(806) 834-3137	sylvia.mendez-morse@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)	2017	Lubbock City Hall 1625 13th St	(806) 775-2316	LMorrison@mail.ci.lubbock.tx.us
Melanie Sarge, Ph.D. (Scientific)	2017	Media & Communication MS 3082	(806) 834-2831	m.sarge@ttu.edu
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James L. Smith, Ph.D. (Scientific)	2017	Industrial Engineering MS 3061	(806) 834-0129	james.smith@ttu.edu

Sarah Wakefield, M.D. (Scientific/Non-Affiliated)	2019	Psychiatry – TTUHSC MS 8103	(806) 743-2800	sarah.wakefield@ttuhsc.edu
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Ryan Scheckel (Non-Scientific)	2019	Undergraduate Education MS1062	(806) 834-7402	ryan.scheckel@ttu.edu

Kelly Cukrowicz: Licensed Psychologist, State of Texas

James Smith: Registered Professional Engineer-Texas; Certified Professional Ergonomist #577

ALTERNATES				
Name	Term	Department	Phone	Email
Zhen Cong, Ph.D. (Scientific)	2017	Human Development & Family Studies/Gerontology MS1230	(806) 834-8082	zhen.cong@ttu.edu
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Alan Reifman Ph. D. (Scientific)	2018	Human Development & Family Studies MS1162	(806) 834-5174	alan.reifman@ttu.edu
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EX-OFFICIO

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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 1 represents new initial submissions that were created and submitted in Cayuse IRB during 2016. These submissions are new research proposals submitted to the IRB, however, this does not mean all submissions were approved. Every submission (N = 530) was reviewed by an IRB member and approved or returned for revision. The IRB received 267 exempt, 260 expedited, and three full board submissions. The majority of submissions are from the College of Arts and Sciences (n = 165), specifically, the Department of Psychological Sciences.

Figure 1

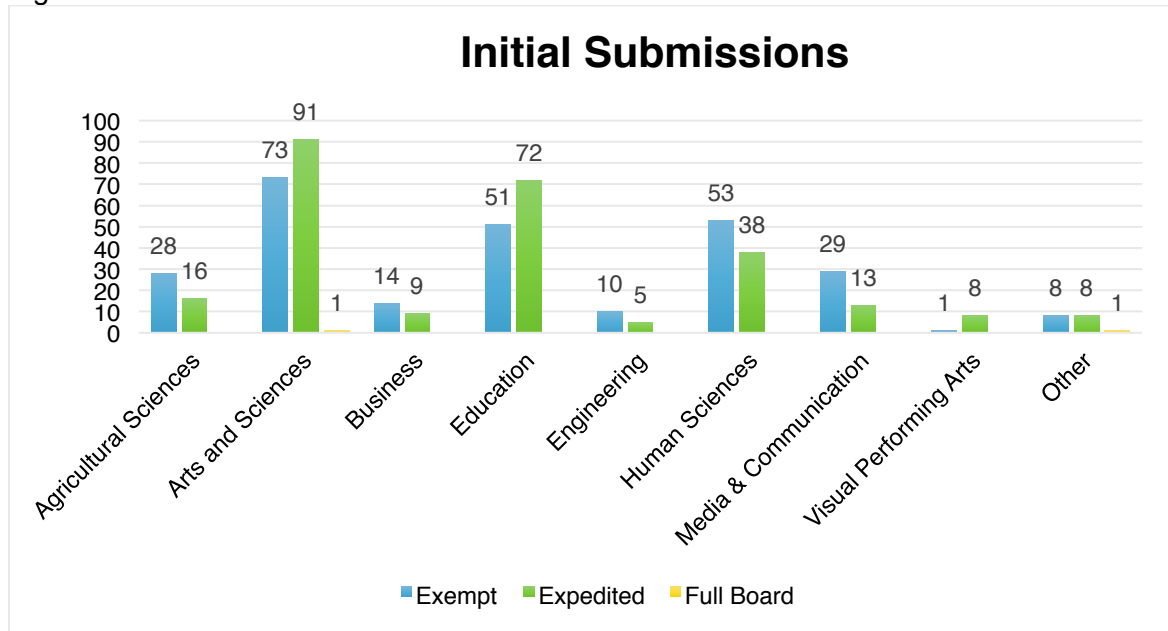


Figure 2 displays the modifications that were submitted in 2016 on an approved study. These modifications (N = 257) were reviewed by an IRB member and approved or returned for revision. The College of Arts and Sciences (n = 96) submitted the most modifications followed by the College of Human Sciences (n = 64). A total of 94 exempt, 158 expedited and five full board modifications were submitted by Texas Tech researchers.

Figure 2

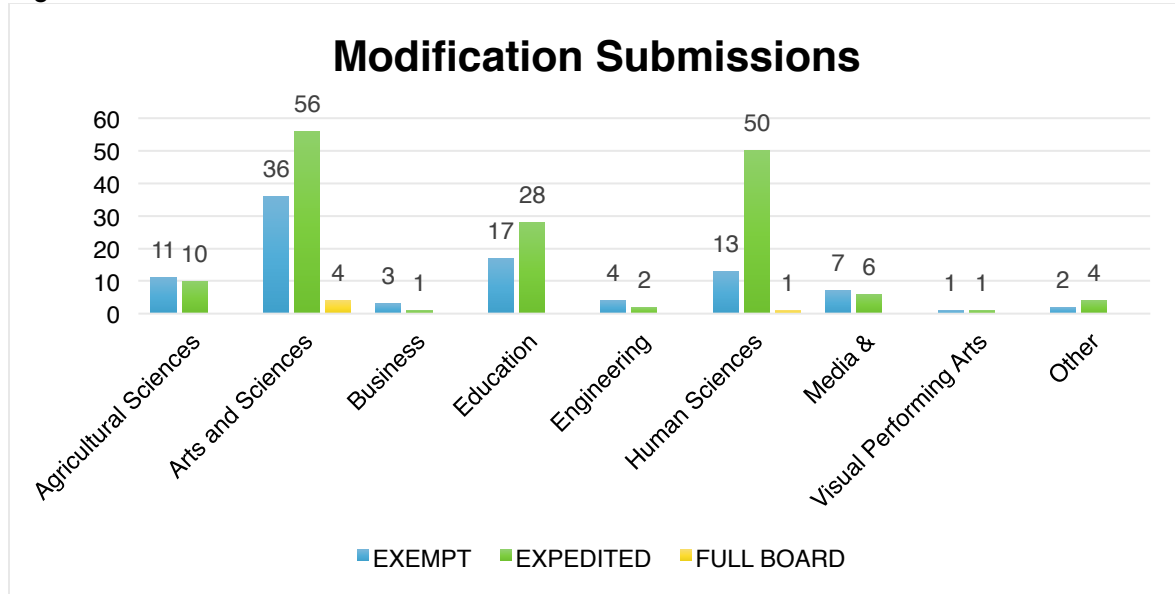


Figure 3 shows the renewal submissions for approved expedited and/or full board studies. The IRB has one member that is dedicated the reviewing all renewals (N = 179). Media and Communication did not submit a renewal in 2016. The majority of expedited studies have to be renewed every year, however, some studies have a different renewal time frame. The renewal date is noted in the IRB approval letter. If the study is not renewed the HRP staff administratively closes the study in Cayuse IRB. Researchers submitted 171 renewals for expedited studies and 8 renewals for full board studies.

Figure 3

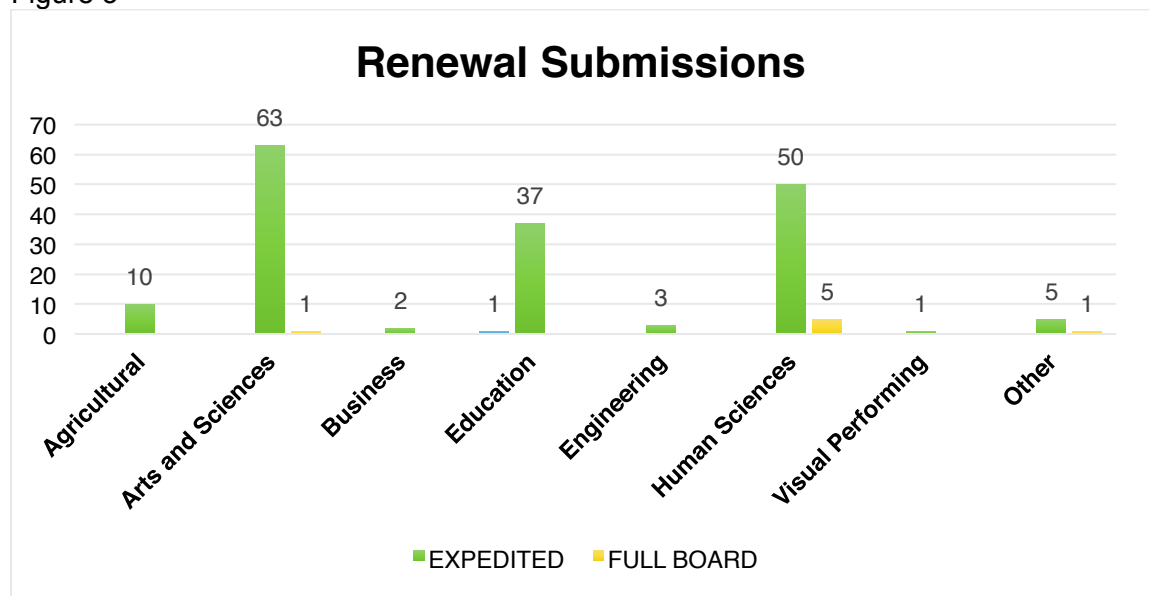


Figure 4 represents the approved legacy studies that were manually entered in Cayuse IRB. A legacy study is an approved IRB study prior to the deployment of Cayuse IRB. The HRPP staff entered a total of 1,366 legacy studies into Cayuse IRB.

Figure 4

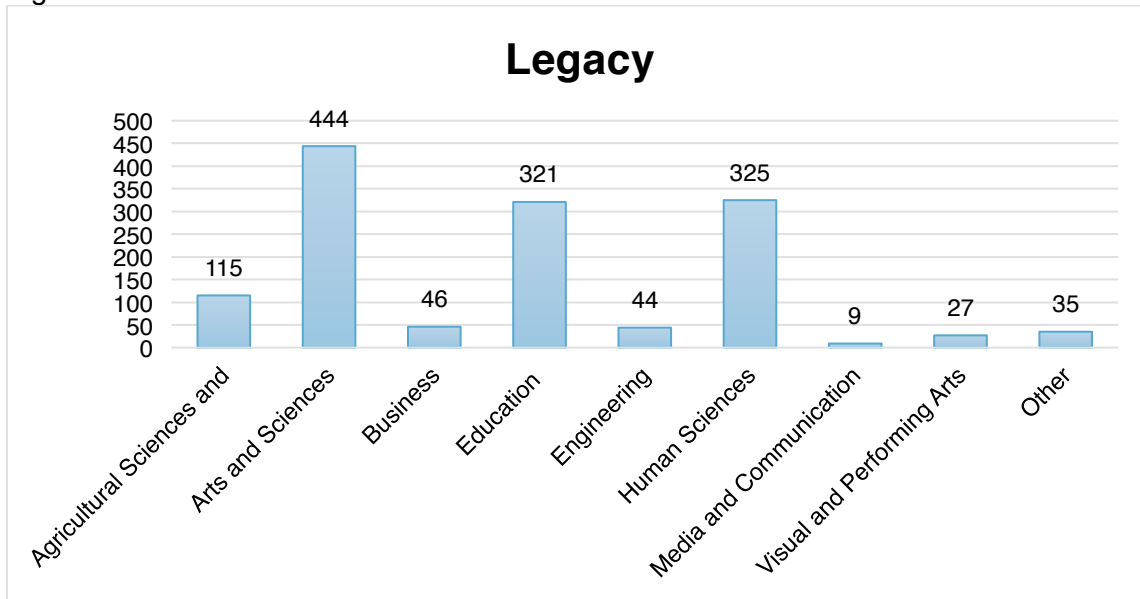


Figure 5 is the total number of submissions by college. The College of Arts and Sciences submitted the most submissions with a total of 453 submissions. The College of Human Sciences submitted 286 and the College of Education submitted 262.

Figure 5

