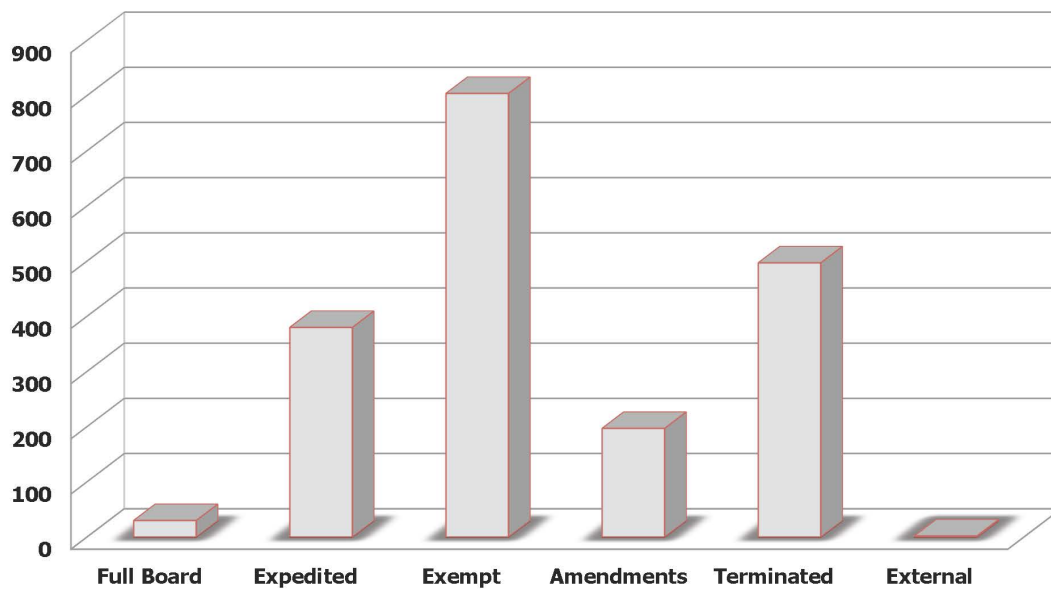


**Texas Tech University
Protection of Human Subjects
Institutional Review Board/
Human Research Protections Program**

2013 Annual Report

Total of 1,793 protocols in 2013
including 497 terminated protocols
but not including 197 amendments to protocols



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 29, 2017.

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, under the oversight of the Vice President for Research.

People

Chair, Manager, Program Coordinator, Program Coordinator for Post-Approval Review

Dr. Rosemary Cogan continued as the Chair of the IRB in 2013. Ms. Donna Peters continued as the Manager of the Human Research Protection Program. 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. She continues to work toward a Master of Public Administration. Both Dr. Cogan and Ms. Peters have a current certification as Certified IRB Professionals (CIP). Both attended the Public Responsibility in Medicine & Research (PRIM&R) conference in Boston, Massachusetts in November where they presented a poster (described below).

Ms. Esther Lucey and Mr. Rick Shupe continued as Program Coordinators. Ms. Lucey has particular responsibility for processing new proposals and maintaining records. Mr. Shupe has particular responsibility for post-approval review of protocols and for presentations about the IRB. Both Ms. Lucey and Mr. Shupe also do pre-reviews of Exempt and Expedited proposals. Both attended the Public Responsibility in Medicine & Research (PRIM&R) conference in Boston in November, including the pre-conference fundamental training session.

IRB Members

In 2013, one IRB member left TTU. Two alternate members became full members. Four new faculty members were trained under the HRPP/IRB mentor-mentee training program early in 2013 and joined the IRB. There are currently 17 member of the IRB. TTU faculty members receive workload credit for their IRB work. A current roster of the IRB can be found on page 6. 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.

Activities in 2013

Meetings

The full IRB met eight times in 2013. 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 HRPP Manager at 806-742-2064.

Staff Development

Staff development is a critical component of the work of the HRPP. Ms. Peters, and staff members attended the TTU Responsible Conduct of Research Conference, several webinars and several short-courses offered by TTU and PRIM&R.

Protocols

The number of IRB protocols has tripled since 2005. In 2013, we continued to take active steps to limit unnecessary IRB proposals and be within regulatory requirements. We arranged to have the names of faculty and professional staff members who would be leaving TTU sent to us each month. Working with these faculty and staff members, we have closed 70 protocols and transferred the others to new Principal Investigators. With these efforts, the number of IRB protocols remained stable this year.

Year	Current protocols at the end of the year
2005	326
2006	557
2007	824
2008	1,001
2009	1,152
2010	1,206
2011	1,243
2012	1,213
2013	1,214

Of the active IRB protocols, 108 involve sponsored projects (8.9%). Of the 108 sponsored projects, 69 are federally funded projects (63.8%).

Budget

The HRPP budget includes salaries for the HRPP Manager, the two Program Coordinators, and 25% salary for the Chair. We also have a half time undergraduate student assistant. A half time graduate student paid by the Graduate School, works with the IRB Chair and with HRPP projects. The budget includes some funds for professional memberships, travel to educational conferences, certification fees, and a modest amount for relevant journals, books, and supplies.

Accomplishments and Goals

We will continue to focus on the smoothest possible functioning of the HRPP by helping investigators with the least restrictive necessary level of IRB review, continuing to pre-screen proposals before they are sent to reviewers, and continuing to help every IRB member with training and educational opportunities. In 2013, we continued to implement the 5-10 year strategic plan for the HRPP that we developed in 2011.

Achieved in 2013

1. We trained four new IRB members.
2. We continued a line of work on payment to research participants by carrying out a survey of how payment issues are handled nationally. We presented the findings in a poster at the PRIM&R meetings. There is extreme variability in policies and we have recommended to PRIM&R that they arrange a session with someone representing the Internal Revenue Service at the next meeting.

Peters, D., Cogan, R., Austin, K., & Hollins, T. (2013, November). *Differences in policies for paying research participants*. Paper presented at meetings of Public Responsibility in Medicine & Research, Boston, MA.

3. We reviewed the titles of 186 dissertations completed at TTU in 2013 and listed in Dissertation Abstracts and found that 24.7% involved research with human subjects. TTU awarded more than 305 doctoral degrees and more than 1,365 master's degrees in 2013. Our best estimate is that 75 dissertations and 337 master's projects involved IRB protocols.
4. We considered a sample of IRB protocols active at the end of 2013 and found that 81% involved student co-investigators.
5. Of the 582 new proposals in 2013, 111 (19.1%) involved payment to research participants.
6. We identified 25 ethical concerns: 14 were concerns brought by subjects and/or possible adverse events and 11 were other issues of non-compliance. After investigation, we reported one problem to OHRP and resolved the others with the researchers.
7. We have continued to ask for and receive monthly reports of faculty terminations so that we can help faculty leaving TTU arrange to close or transfer active IRB protocols in an orderly way. In 2013, we closed 70 protocols of faculty leaving TTU.
8. In 2012, we had 522 new proposals; in 2013, we had 582 new proposals, an 11.5% increase.
9. Working with an IRB sub-committee, we formed a policy for handling human genetics research. Projects involving long-term storage of human genetic materials will come to the Full Board for the immediate future.
10. We made 20 presentations to classes, groups, and administrative units and developed three training videos and have added these to the HRPP website.
11. This year the TTU IRB had authorization agreements with several universities. These agreements facilitate collaboration between TTU investigators and others.
12. The HRPP website had over 15,284 hits for the year.

Goals for 2014

1. We will begin a formal program of post-approval review of active IRB protocols.
2. We are moving to an electronic system this year. TTU has contracted with Evisions/Cayuse as one of three test sites for the development of the IRB/HRPP system. This will take a considerable amount of time from Ms. Peters and the HRPP staff in 2014. TTU has been given a discount from Evisions/Cayuse for this partnership.
3. We need an Associate IRB Chair. This will provide for help with the workload and for continuity for the IRB Chair's job.
4. We need one new HRPP staff member. This person should be hired in Spring, 2014. This will provide for help with the workload, particularly as Ms. Peters and staff have time commitments for the development of the electronic system and with accreditation planning, working with the IRB Chair.
5. We will actively work on our self-study as a background for an application for AAHRPP accreditation.
6. We will train at least four new IRB members.

Long term goal

Our continuing long-term goal is AAHRPP accreditation. We would like to accomplish this by December, 2019.

Rosemary Cogan, Ph.D., ABPP, CIP

Donna Peters, CIP

TEXAS TECH UNIVERSITY
 INSTITUTIONAL REVIEW BOARD
 PROTECTION OF HUMAN SUBJECTS COMMITTEE
 September 2013

Name	Term	Department	Phone	Email
Rosemary Cogan, Ph.D., ABPP (Chair)	2014	Psychology	742-3711 #253	r.cogan@ttu.edu
Lillie Aguilar	2014	Community	763-4187	lillie.aguilar@mail.tmccentral.org
Jan Blackwell	2014	Community		jblackwell7@suddenlink.net
Scott Burris, Ph.D.	2015	Ag Ed & Comm.	742-2816 Ext 234	scott.burris@ttu.edu
Zhen Cong, Ph.D	2016	Human Development & Family Studies	742-3000 Ext 232	zhen.cong@ttu.edu
Angela Eaton, Ph.D.	2013	English	742-2500 Ext 229	angela.eaton@ttu.edu
John Fowler, Ph.D.	2015	HSC/Physiology	743-2083	john.fowler@ttuhsc.edu
Jamie Gorman, Ph.D.	2016	Psychology	834-2932	jamie.gorman@ttu.edu
Lorenz Lutherer, Ph.D., M.D.	2013	HSC/Physiology	743-2532	lorenz.lutherer@ttuhsc.edu
Shirley Matteson, Ph.D.	2015	Education	742-1997 Ext 270	shirley.matteson@ttu.edu
Susan Mengel, Ph.D.	2015	Computer Science	834-6868	susan.mengel@ttu.edu
Comfort Pratt, Ph.D.	2015	Education	742-1997 Ext 237	c.pratt@ttu.edu
Andreas Schneider, Ph.D.	2015	Sociology, Anthropology & Social Work	834-7502	andreas.schneider@ttu.edu
Autumn Shafer, Ph.D.	2016	Media & Communication	834-4816	autumn.shafer@ttu.edu
James L. Smith, Ph.D.	2015	Industrial Engineering	742-3543	james.smith@ttu.edu
Jeffrey N. Wherry, Ph.D., ABPP	2016	Human Development &	742-3000 Ext 242	jeffrey.wherry@ttu.edu

Name	Term	Department	Phone	Email
		Family Studies		
Andy Young, Ed.D.	2015	Behavioral Sciences Lubbock Christian University	720-7830	andy.young@lcu.edu

Rosemary Cogan: Licensed Clinical Psychologist, State of Texas #3676; Board Certified in Clinical Psychology, American Board of Professional Psychology; Board Certified in Psychoanalysis, American Psychoanalytic Association, Certified IRB Professional

Lorenz Lutherer: Licensed Physician, Texas Medical Board #E8682

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

Jeff Wherry: Licensed Clinical Psychologist, State of Texas # #32508, Licensed Specialist in School Psychology #32501; Board Certified in Clinical Psychology, American Board of Professional Psychology

Ex-OFFICIO

Name	Department	Email
Alice Young, Ph.D.	Associate Vice President for Research Research Integrity	alice.young@ttu.edu
Katherine Austin Beltz, Ph.D.	Assistant Vice President Information Technology	kathy.austin@ttu.edu
Jennifer Horn, J.D.	Associate Managing Director Office of Research Services	jennifer.horn@ttu.edu
Cliff Harris	Interim Director Environmental Health and Safety	cliff.harris@ttu.edu

ALTERNATES

Name	Term	Department	Email
Nancy Bell, Ph.D.	2015	HDFS	nancy.bell@ttu.edu
Elsa Bello-Reuss, M.D.	2015	HSC/Physiology	elsa.bello-reuss@ttuhsc.edu
Shannon Bichard, Ph.D.	2015	Media and Communication	shannon.bichard@ttu.edu
Lainey Castleberry	2016	Community member	l.castleberry@mail.ci.lubbock.us
Jim Johnson, Pharm.D., MPA, FACHE	2016	Community member	jim.johnson@umchealthsystem.com
Sylvia Mendez-Morse, Ph.D.	2015	Education	sylvia.mendez-morse@ttu.edu
Kelly Phelan, Ph.D.	2015	Nutrition, Hosp., Retailing	kelly.phelan@ttu.edu
Darcy Reich, Ph.D.	2015	Psychology	darcy.reich@ttu.edu
Alan Reifman, Ph.D.	2015	Hum Dev Family Studies	alan.reifman@ttu.edu

Figure 2.
Number of active proposals in each college

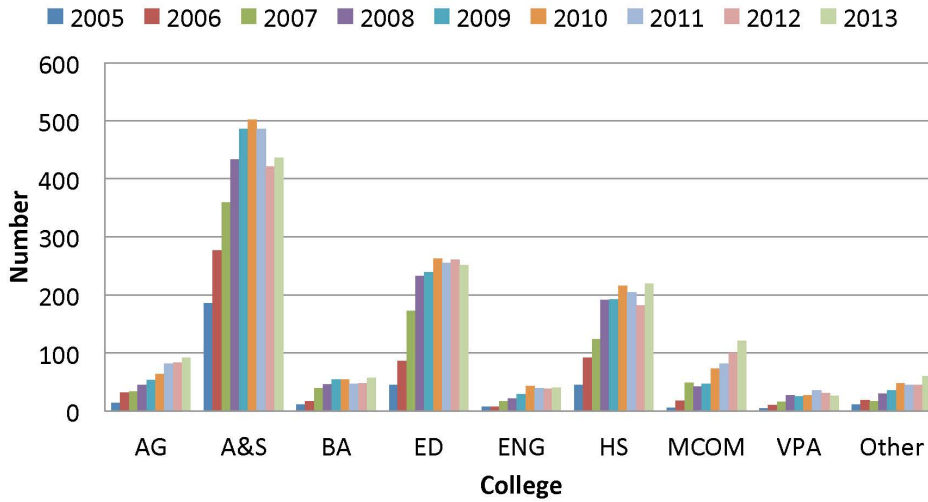


Figure 3.
Number of active proposals in departments in Arts & Sciences

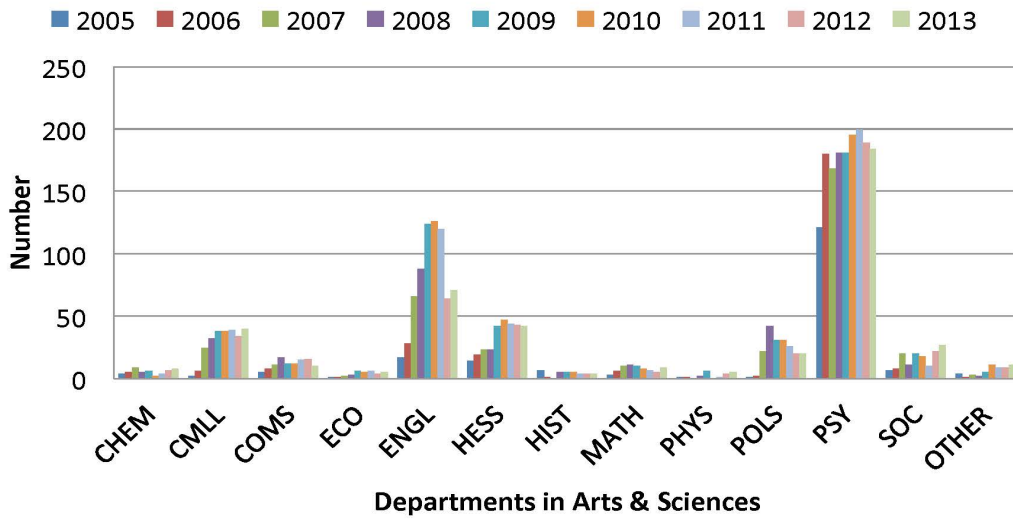


Figure 4.
 Number of active proposals in divisions in Education and Human Sciences

