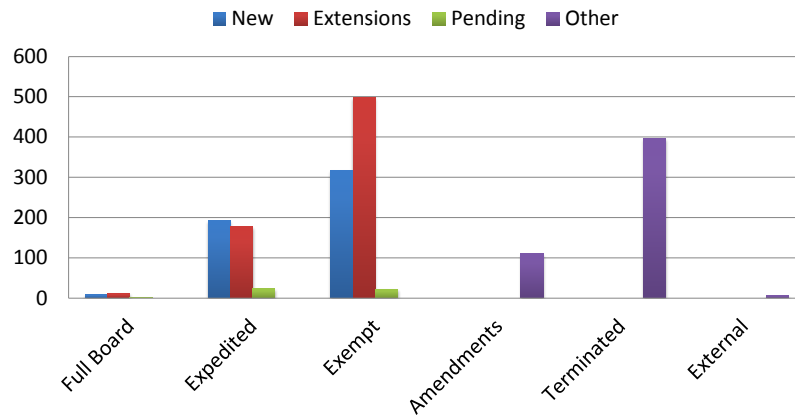


Texas Tech University Protection of Human Subjects Institutional Review Board

2011 Annual Report

Total of 1,760 proposals in 2011
including 519 terminated proposals
but not including 205 amendments to proposals



About the IRB

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 August 25, 2014. The IRB office was housed in Holden Hall for the first two months of 2011. The office moved to a temporary location in Drane Hall in March. The IRB is supervised by Dr. Alice Young, Associate Vice President for Research Integrity, under the oversight of the Dr. Taylor Eighmy, Vice President for Research.

People

Chair, Coordinator, and Assistant Coordinator

Dr. Rosemary Cogan continued as the Chair of the IRB in 2011. Donna Peters continued as the Coordinator of the IRB. Ms. Peters continued pre-screening new IRB proposals before sending the proposals to reviewers. She also began 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. Mr. Brian Piscacek continued to provide support to the operations of the IRB as Assistant IRB Coordinator.

Both Dr. Cogan and Ms. Peters have current certifications as Certified IRB Professionals (CIP). Dr. Cogan and Mr. Piscacek attended the Public Responsibility in Medicine & Research (PRIM&R) meetings in National Harbor, Maryland, in December (Ms. Peters was unable to attend this year.) Members of the TTU IRB presented three posters and an invited talk at the PRIM&R meetings (Abbott, Reich, Cogan, & Clopton, 2011; Cogan & Pujals, 2011; Cogan, Abbott, Reich, & Clopton, 2011; Peters, Piscacek, Austin, & Cogan, 2011).

Members

In 2011, one IRB member died and one member left TTU. One new member joined the IRB. One alternate board member moved to regular member status to complete the 15-member roster. Three new alternate members are in training now. Late in 2011, one Ex-Officio member retired. The Board consists of ten TTU faculty members, two HSC faculty members, and three community members. Board Members serve on the IRB as a service to the university community. A current roster of the IRB can be found in Appendix A. 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 2011

Meetings

The full IRB met six times in 2011. 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 Coordinator at 806-742-2064. The Chair and Coordinator attended additional meetings involving relevant issues such as fMRI studies and electronic data protection issues during the year.

Staff Development

Staff development is a critical component of the work of the IRB. Dr. Cogan, Ms. Peters, and Mr. Piscacek attended: TTU Responsible Conduct of Research Conference; webinars on the proposed changes to the Common Rule and Conflict of Interest rules; PRIM&R Conference in National Harbor, Maryland; multiple short-courses offered by the TTU Institutional Technology Division staff and the Library faculty; TTU Human Resources Management Program Course; the IRB Forum Listserv.

Proposals

The number of proposals coming to the IRB continues to increase. We are taking active steps to contain the work load within regulatory requirements. A related problem is the lack of a back-up for the IRB Chair. There is a very real ‘learning curve’ in the jobs of both the IRB Chair and Coordinator. As one part of their jobs, both are intensively involved in reviewing proposals. The IRB Chair completed 277 reviews of proposals in 2011 along with administrative work. Few reviewers are available in the summer months. The IRB Coordinator completed 270 reviews of Exempt proposals and amendments. **Our recommended solutions are described below.**

| Year | Current proposals at the end of the year |
|-------------|---|
| 2005 | 326 |
| 2006 | 557 |
| 2007 | 824 |
| 2008 | 1,001 |
| 2009 | 1,152 |
| 2010 | 1,206 |
| 2011 | 1,243 |

Of the active IRB protocols, 59 involve active sponsored projects and 6 have grants pending. Of dissertations in 2011, more than 40% involved IRB proposals.

Budget

The IRB Budget includes the salary for the Coordinator and Assistant Coordinator and 25% salary for the Chair. We have a half time undergraduate student assistant. The budget also allows

for professional memberships, travel to educational conferences, certification fees, and a modest amount for relevant journals, books, and supplies.

Goals

We will continue to focus on the smoothest possible functioning of the IRB 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.

Achieved in 2011

1. After having completed a thorough review of the policies and procedures for payment to research participants in 2010 we helped facilitate a revised OP 62.25 concerning payment to research participants in 2011.
2. Dr. Cogan, Ms. Peters, and Mr. Piscacek developed a 5-10 year strategic plan for the TTU IRB. To help with this, we consulted by phone and email with Julie Ozier, MHL, CHRC, CIP, from the Vanderbilt University Human Research Protection Program.
3. The TTU IRB and the TTU Health Sciences Center IRB agreed on a revised Memorandum of Understanding. The revision allows the TTU IRB to review and approve human subjects research involving TTUHSC faculty, students, and/or facilities when certain conditions are met.
4. With consultation from IRB Ex-Officio Kathy Austin Beltz, Dr. Cogan and Ms. Peters worked with Dr. Valerie Paton and others to clarify the limits on the data that Institutional Research can release for research purposes.
5. Federal regulators are considering revisions of the Common Rule (45 CFR 46). The possible revisions involve more than a dozen federal departments and agencies. Dr. Cogan, Ms. Peters, and Mr. Piscacek considered the proposed changes and sent advisory comments on 14 of the 74 changes being considered.
6. A self-assessment module helping researchers independently determine whether or not their proposed work requires IRB review is now on the web. We think this will be quite helpful to the university community and the IRB.
7. To help resolve questions about the handling of incidental findings with human research scans at the Texas Tech Neuroimaging Institute (TTNI), we formed a sub-committee to consider the issue, reviewed the literature, and consulted with others at TTU and around the country. We decided that incidental findings will not be reported to subjects and will not be included in consent forms. We also addressed the need for clear policy statements about multiple uses of the scanner, which ultimately involved a meeting with several institutional officials. We also attended a TTNI Board meeting to address the issues.
8. We made eight presentations to classes and groups including a faculty meeting of the Department of Classical & Modern Languages and Literatures and a graduate student organization in education.
9. We worked with department chairs to identify faculty members who left TTU during the year and arranged to close or bring into compliance all open IRB protocols of these investigators.
10. We completed a line of work reviewing published research on reactions to research participation involving sensitive topics and a line of research on the effects of debriefing to help student research participants connect their research experiences with class learning. The

teams were led by Drs. Cogan and Reich respectively.

11. This year, the TTU IRB had authorization agreements with Appalachian State University, Georgia Southern University, Kennesaw State University, Missouri University of Science and Technology, the University of Cincinnati, the University of Oklahoma, and The University of Texas – Pan American. These agreements facilitate collaboration between TTU investigators and others.

Goals for 2012

1. We will actively work on our self-study as a background for a possible application for national accreditation of the TTU IRB.
2. We will expand our communication to the TTU community about the IRB proposal process.
 - a. We will develop video of writing the consent form with Angela Eaton, IRB member from Technical Writing. This will be made available on the IRB web materials.
 - b. We will post on TechAnnounce quarterly to help communicate with the TTU community
3. We will work with Dr. Kathy Gillis, Director, University Writing Center on helping with recurring problems with writing of proposals.
4. We will develop a plan for post-approval monitoring (PAM). This will involve a new position.
5. We will continue to work with others to help select an electronic database system.
6. We will complete a formal assessment of the revised IRB web materials, working with the TTU English Usability Lab. This work was delayed because of the time required to complete the revision of the IRB web site.

Long term goal

We recommend that an Assistant IRB Chair be added. This person should be encouraged to work toward Certification and should be provided with summer support. This will also help ensure the availability of IRB reviewers for summer.

Rosemary Cogan, Ph.D., ABPP, CIP

Donna Peters, CIP

Brian Piscacek, MPA

2011 PRIM&R Presentations

Abbott, C., Reich, D., Cogan, R. & Clopton, J. (December, 2011). *Research Participation as an Educational Experience: Does Debriefing Matter?* Poster presented at meetings of Public Responsibility in Medicine & Research, National Harbor, MD.

Cogan, R. & Pujals, P. (December, 2011). *Research on sensitive topics: Don't be scared!* Poster presented at meetings of Public Responsibility in Medicine & Research, National Harbor, MD.

Peters, D., Piscacek, B., Austin, K. & Cogan, R. (December, 2011). *Changing the Path for Paying Research Participants.* Poster presented at meetings of Public Responsibility in medicine & Research, National Harbor, MD.

Cogan, R., Abbott, C., Reich, D., & Clopton, J. (December, 2011). *Research Participation as an Educational Experience: Does Debriefing Matter?* Invited presentation at meetings of Public Responsibility in Medicine & Research, National Harbor, MD.

Appendix A
MEMBER ROSTER
 September 2011

| Name | Term | College/Dept. | MS | Phone | Email |
|----------------------------------|------|-------------------------------|-------------|---------------------|--|
| Rosemary Cogan, Ph.D. (Chair) | 2014 | Arts & Sciences Psychology | 2051 | 742-3711 ext 253 | r.cogan@ttu.edu |
| Lillie Aguilar | 2014 | <i>Lubbock Community</i> | NA | 763-4187 | lillie.aguilar@mail.tmccentral.org |
| Jan Blackwell | 2014 | <i>Lubbock Community</i> | NA | NA | jblackwell7@suddenlink.net |
| Bill Downing | 2012 | <i>Lubbock Community</i> | NA | NA | brigadoon36@aol.com |
| Nancy Bell, Ph.D. | 2012 | HDFS | 1230 | 742-3000 ext 269 | nancy.bell@ttu.edu |
| Ken DeMarree, Ph.D. | 2013 | Arts & Sciences Psychology | 2051 | 742-3711 Ext 242 | ken.demarree@ttu.edu |
| Angela Eaton, Ph.D. | 2013 | English | 3091 | 742-2500 ext 229 | angela.eaton@ttu.edu |
| John Fowler, Ph.D. | 2012 | TTUHSC Physiology | HSC 6651 | 743-2083 | john.fowler@ttuhsc.edu |
| Lorenz Lutherer, Ph.D., M.D. | 2013 | TTUHSC Physiology | HSC 6651 | 743-2532 | lorenz.lutherer@ttuhsc.edu |
| Susan Mengel, Ph.D. | 2012 | Computer Science | 3104 | 742-3527 ext 224 | susan.mengel@ttu.edu |
| Kelly Phelan, Ph.D. | 2012 | Nutrition, Hosp. Retailing | 1240 | 742-3068 ext 296 | kelly.phelan@ttu.edu |
| Darcy Reich, Ph.D. | 2012 | Arts & Sciences Psychology | 2051 | 742-3711 ext 237 | darcy.reich@ttu.edu |
| Andreas Schneider, Ph.D. | 2012 | Soc., Anthro., Social Work | 1012 | 742-2401 ext 231 | andreas.schneider@ttu.edu |
| James L. Smith, Ph.D. | 2012 | Industrial Engineering | 3061 | 742-3543 | james.smith@ttu.edu |
| Eric Walden, Ph.D. | 2012 | Business | 2101 | 742-1925 | eric.walden@ttu.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.

Lorenz Lutherer: Licensed Physician, Texas Medical Board #E8682

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

ALTERNATES

| Name | Term | College/Dept. | MS | Phone | Email |
|-------------------------------|------|---|------|---------------------|--|
| Doug Hamman, Ph.D. | 2013 | Education | 1071 | 742-1997 ext 244 | doug.hamman@ttu.edu |
| Sylvia Mendez-Morse, Ph.D. | 2012 | Education | 1071 | 742-1997 ext 367 | sylvia.mendez-morse@ttu.edu |
| Comfort Pratt, Ph.D. | 2013 | Education | 1071 | 742-1997 ext 237 | c.pratt@ttu.edu |
| Alan Reifman, Ph.D. | 2012 | Human Sciences HDFS | 1162 | 742-3000 ext 274 | alan.reifman@ttu.edu |
| Jaeki Song, Ph.D. | 2012 | Business | 2101 | 742-8036 | jaeki.song@ttu.edu |
| Andy Young, Ed.D. | 2012 | Behavioral Sciences, Lubbock Christian University | NA | 720-7830 | andy.young@lcu.edu |

Ex-OFFICIO

| Name | Dept. | MS | Phone | Email |
|----------------------------------|--|------|----------|--|
| Alice Young, Ph.D. | Assoc Vice Pres for Research Integrity | 1075 | 742-3905 | alice.young@ttu.edu |
| Katherine Austin Beltz, Ph.D. | Asst Vice Pres Information Technology | 2008 | 742-5156 | kathy.austin@ttu.edu |
| Jennifer Horn, J. D. | Senior Admin. Ofc. Research Services | 1035 | 742-3884 | jennifer.horn@ttu.edu |
| Randy Nix | Director, Environmental Health/Safety | 1090 | 742-3876 | randy.nix@ttu.edu |

Figure 2.
Number of active proposals in each college

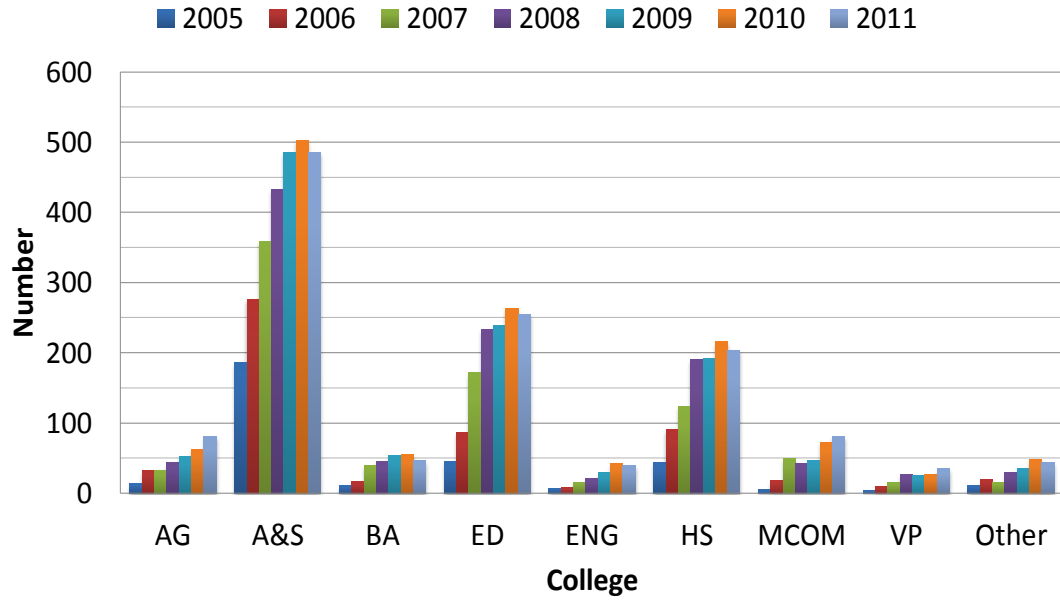


Figure 3.
Number of active proposals in departments in Arts & Sciences

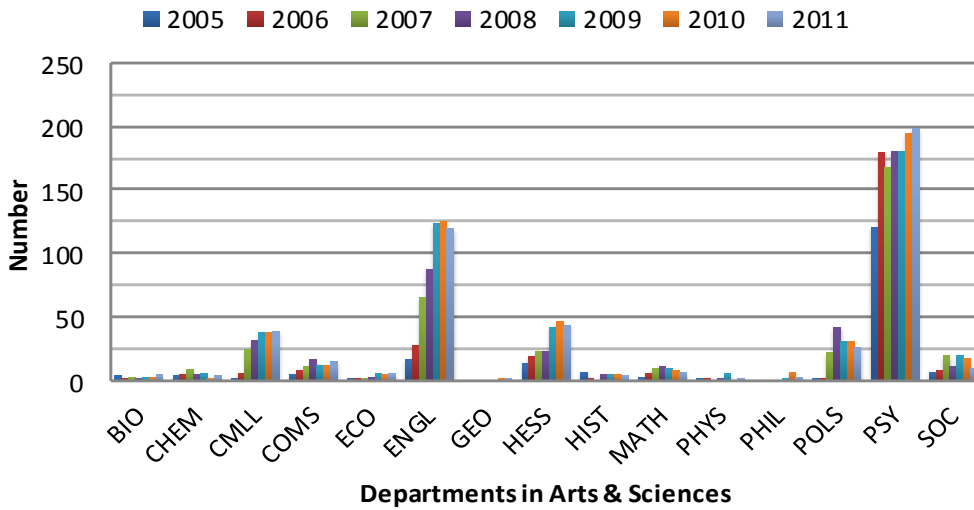


Figure 4.
Number of active proposals in divisions in Education and Human Sciences

