

# human subjects' herald

A Publication of the Texas A&M University Human Subjects' Protection Program

Vol. 1, Issue 1



## Why Accreditation?

**For the past two years, the HSPP has been working toward receiving accreditation through the Association of Accreditation of Human Research Protection Program (AAHRPP).**

AAHRPP is a national non-profit organization that holds the highest standards regarding human subjects' protection. They will ensure that the HSPP at Texas A&M is effective, efficient and in compliance with federal regulations. Here are a few of the many advantages of being accredited:

- **Top standards and protections.** The federal regulations are broad in their ethics

requirements, so AAHRPP determines if programs are only meeting said requirements or if they have gone a step further in defining ethic requirements specific to their institution.

- **Quality Assurance.** Upon receiving accreditation, the HSPP will be given a gold accreditation seal. The seal represents a program whose records, forms and procedures were reviewed, not only for quantity and completeness, but absolute quality.

- **Efficiency and effectiveness.** The HSPP's policies and procedures will be reviewed to ensure they represent an efficient work environment and research process for investigators.

- **Competitive edge.** Sponsors, funding agencies and other members of the research community will recognize the preparation and level of commitment to excellence the HSPP has undergone. These sources will be

more likely to offer assistance and give their support to the HSPP.

- **Public trust.** Research participants can trust the HSPP with the knowledge it has voluntarily sought improvement for people like them. Participants can have faith that research approved by the Texas A&M IRB has been carefully reviewed and well constructed. They can feel more at ease about participating and more comfortable in contacting the IRB or HSPP with any concerns.

**Top Standards and Protections**

**Quality Assurance**

**Efficiency and Effectiveness**

**Competitive Edge**

**Public Trust**

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Visit us online at <http://researchcompliance.tamu.edu/irb>



# Growing Pains

**Summer brought lots of changes to our office.**

For starters, we moved! We packed up our files, said farewell to Research Park and relocated to the General Services Complex (GSC). We moved in May and have been loving our new digs ever since.

The General Services Complex is located at the corner of F and B Road and Agronomy Road – just down the street from the Wehner Building. Our parking lot is Lot 88, and requires a Texas A&M parking tag. Any DAY parking pass will work. Bus Route 06 (12th Man) runs to

our building as well. View Texas A&M bus schedules here.

Lot 88 also has 30 minute parking, as well as a pay lot, if you prefer to drive. We are on the third floor in Suite 3501. Whichever way you choose, come see us!

And if that isn't enough change for you... check out our website! We have updated it with new applications, application guides, Standard Operating Procedures (see page 4), Frequently Asked Questions, and more! Pay extra attention to the Information for Investigators section. As always, this section contains applications, consent documents and other helpful information pertinent to the review process.

**If my study personnel aren't listed as co-investigators, they don't have to take the human subjects' training.**

## **FALSE!**

Any member of the study team that has contact with human subjects is required to take the CITI course. The principal investigator (PI) is responsible for maintaining all training documentation for his/her study personnel. The IRB can ask to see documentation at any time.

Visit our website at <http://researchcompliance.tamu.edu/irb/trainreq> to access information about completing CITI.

**The HSPP and IRB are now located in the General Services Complex!**

## Did You Know?

There are 1,865 active research protocols involving human subjects at Texas A&M.

Review time for exempt and expedited review averages about three days.

95 percent of the research conducted at Texas A&M qualifies for exempt or expedited review.

Texas A&M actually has four IRBs!

IRB members are volunteers.

# Department Debut: Health and Kinesiology

***Diversity is not a new idea. All across the nation people are looking for ways to encourage diversity. But how do we get there? What makes it work? Why doesn't it work sometimes? That's what researchers like George Cunningham are trying to figure out.***

Cunningham, Texas A&M's chair of the Division of Sport Management and director of the Laboratory for Diversity in Sport, didn't always know he wanted to be a researcher.

"A long time ago I thought I wanted to be a coach, but I couldn't stand the recruiting aspect of it," Cunningham says.

Once he started his master's in kinesiology at Texas A&M, Cunningham took a research methods class as one of his course requirements. The class gave him a different take on sports management, which gave him insight as to what he wanted his own career to be. He initially worked with a colleague to figure out why women sports teams were more often coached by men instead of women.

That led him to complete his doctorate at Ohio State University. After spending a year



teaching at Indiana University, Cunningham returned to Aggieland in 2003 as an assistant professor. His primary interest has always been related to diversity. His research focuses on how diversity affects sport organizations, especially when involving minority groups. Cunningham found that people have bigger reactions and opinions to racial issues than gender issues, but nothing receives as much response in sports organization as sexual orientation issues.

Cunningham often collaborates with doctoral students in his studies. "It's really a learning environment about understanding what makes good research and how not to just take things at face value," Cunningham says.

Working as a team has allowed Cunningham to explore topics he wouldn't necessarily have researched on his own. His students have encouraged him to research topics such as sexual prejudice, sexual harassment in sports organizations and identity negotiations- for example, how a woman navigates her multiple identities, such as a partner, mother, athletic administrator, etc.

"Working with doctoral students is the most gratifying experience because you get to see them grow as researchers and as thinkers," Cunningham says.

In 2007, Cunningham took all that he's learned about diversity and wrote a textbook, *Diversity in Sport Organization*. He not only discusses the common issues of diversity, such as race and gender, but also expands to topics such as categorical effects of age, disability and obesity, relational diversity and legal aspects, just to name a few.

Cunningham's upcoming goal is to continue working with the NCAA to better understand the effects of diversity in the athletics context. His laboratory currently gives an award to the athletic department with the best diversity practices. Cunningham and his colleagues have visited departments to determine the best diversity practices.

"I enjoy advancing theory, but I hope to influence practice and policy as well," he says.

**Do you want to see your department featured in our newsletter? If so, give us a call or send us an email to share your ideas! We want to know about faculty, current research studies, research awards and stories from your own experience in research.**

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S E P T / O C T 2 0 0 8

# Proudly Introducing: Standard Operating Procedures

**Over the past year we have been documenting the HSPP's Standard Operating Procedures (SOP).**

"We" includes HSPP Staff, the HSPP Executive Committee and the IRB. It was a lot of work, but we finally got there.

All 60 SOP, each accompanied with its own set of supporting documents, have now been added to our website. Section 600: Investigator Responsibilities was created specifically to aide investigators in the IRB application process. By reading these SOP, investigators

can know what to expect from our office, even before they turn in their application.

One big change for this year — **investigators are now required to read Section 600 as part of their human subjects' training.** There will be a statement on the Signature Assurance Page of the Standard and Exempt Applications stating that the investigator has read the appropriate SOP.

HSPP staff has also been trained on every SOP to ensure that all investigators are given consistent information. Give us a call for help in determining how the SOP apply to your individual research needs!

## Section 600 Investigator Responsibilities

**HSPP 600-601: Study Design and Oversight**

**HSPP 600-602: Risk Minimization**

**HSPP 600-603: Application for Initial Review**

**HSPP 600-604: Amendment Applications**

**HSPP 600-605: Consent Process**

**HSPP 600-606: Investigator and Study Personnel Training**

**HSPP 600-607: Unanticipated Problems and Serious Adverse Events**

**HSPP 600-608: Protocol Deviations and Non-Compliance**

**HSPP 600-609: Continuing Review**

**HSPP 600-610: Completion Report**

## CITI Course, Part 2

**A question frequently asked of the HSPP staff is "Do you still accept the VPR and NIH Training?"**

The answer has always been yes, but as of January 1, 2009, only the Collaborative Institutional Training Initiative (CITI) course will be accepted.

CITI is the most accepted and used training course in the human subjects' research

world. It is thorough, practical and up-to-date, and we believe it will best prepare investigators at Texas A&M to conduct their research in an ethical manner.

If you have a current, approved study you do not have to complete CITI immediately. However, once you submit a new Initial or Continuing Review Application, you will be required to take the CITI course.

Also starting January 1st, the CITI refresher course will be implemented. It is very similar to the "regular" CITI course, but it is more condensed and has more complicated scenarios. The refresher course

will be required two years from the date of investigators' CITI course completion.

These are a lot of changes! We know that these new training steps will require more time for investigators, but we feel that these are the best steps towards complete compliance and protection for human subjects in research. Please let us know how we can make this adjustment easier.

*“We don’t have the power to change our*  
**CIRCUMSTANCES,**  
*but we can change the way we*  
**REACT.”**

## Inside the IRB: Linda Lekawski, DO

### *Growing up in a military family, Linda Lekawski is no stranger to change.*

Little did she know that the constant change in her childhood would prepare her for the challenging changes in her adult life.

“I never had any intention of going to medical school, but through my husband’s experience, I went. He was my inspiration.”

Lekawski first husband, Dr. Rodney Albert- a sociology researcher, was diagnosed with brain cancer at the young age of 34. After seeing him through chemotherapy, radiation and visiting the neurosurgeon, Lekawski thought of medical school seriously for the first time.

“I guess most science majors consider medicine at some point. I thought, well, I’ll just take the MCAT and see how I do. The rest is history,” she says.

After more encouragement from her mentor and family friend from the microbiology department at the University of North Texas (UNT), Lekawski started medical school at the UNT Health Science Center. She and Albert’s two children were ages three and seven at the time. Later that year, Albert passed away, but Lekawski continued with



her studies, with his inspiration serving as her guide.

“My years in medical school gave me a positive focus in a time in my life where I really needed it. We don’t have the power to change our circumstances, but we can change the way we react.”

Lekawski’s positive focus enabled her to serve as vice president of her medical class. After graduation in 1985, she quickly began working in private practice as a family doctor. A few years later, Lekawski heard of an opportunity as a staff physician at UNT, and she quickly applied.

“I thought, here’s a chance to use both of my career paths- teaching and medicine,” Lekawski says.

Lekawski’s position at UNT was the starting point for a prosperous career in university health. In 1993 she was recruited as the director of Student Health Services at Texas Women’s University (TWU). She also served as adjunct faculty in the colleges of occupational therapy and nursing.

The vice president of Student Affairs at TWU strongly encouraged faculty and staff to be involved with TWU’s academic mission. Lekawski sought ways to contribute,

and landed with the IRB. It was a different approach, but a joint effort in protecting the health and well-being of TWU’s students.

“I know how researchers feel when they get enthusiastic with their work. But you still need a guardian to ensure participants are cared for,” she says.

Lekawski came to Texas A&M as the director of Student Health Services in 2002 and was appointed to Texas A&M’s IRB in 2006. She can really identify with the research process as she has been involved at each level. She participated in psychology experiments as an undergraduate student at Oklahoma State, and later conducted research as a graduate assistant in microbiology. Now a member of the IRB, she is able to combine all her experiences and perspectives together.

“Your personal background helps you consider the questions you might have for researchers,” she says.

This past August, Lekawski retired as director of Student Health Services. However, her spirit of service still continues. She is now a library volunteer at Johnson Elementary School in Bryan, where two of her grandchildren attend. She also hopes to begin volunteering at the J. William Stark Galleries and is currently involved in the Texas A&M Women’s Club programs. Lekawski will continue to serve on the IRB, representing the Bryan/College Station community.

“It’s a very important committee because it makes sure we respect the people who participate in research.”

# Human Subjects' Protection Program

750 Agronomy Rd.  
Suite 3501  
College Station, TX  
77843-1186

Mailstop: 1186

**(979) 458-4067**

Fax:  
**(979) 862-3671**

researchcompliance.tamu.edu

**Program Coordinator**  
Melissa McIlhane

**Compliance Specialists**  
Hannah Butcher  
Lindsay Newcomer

**Student Workers**  
Amy Giles  
Jordan Jones  
Erin Stautzenberger



## From the Mailbag:

**Q. What should I complete for my continuing review?**

**A. There are three things:**

1. A completed continuing review application, with appropriate signatures.
2. A signed conflict of interest statement.
3. If you are still in the DATA COLLECTION STAGE, you must submit any consent documents you plan to continue using so that they may be reviewed and stamped for use in the coming year. Be sure the copies you submit are "clean" copies, meaning the version that is not signed by any participants or date stamped.

**Q. Are surveys always exempt?**

**A. Definitely Not!**

We do receive many surveys that are exempt, but there is no universal distinction- it depends on the nature of the questions and whether it is anonymous. For example, a survey on suicidal tendencies for college freshmen would NEVER be exempt because it is such a sensitive subject. A confidential survey is only exempt if the information could be released publicly without causing any harm. A good rule of thumb to ask yourself – if the participant's survey responses were in the newspaper, could it cause him/her harm? If there is a possibility of any harm to the subject's criminal or civil liability, or if there could be damage to his/her financial standing, employability or reputation, the study CANNOT be exempt.

**Q. Do I submit an amendment for ALL changes?**

**A. YES!**

Any change to an approved/exempt study must be approved/exempted via an amendment before the change is implemented. For example, if Joe wants to make his IRB approved survey a little shorter, he must submit an amendment showing which questions he wants to delete. He could not use the shorter survey until he received his amendment approval letter.

Here are common scenarios needing an amendment:

- Title change
- Decreased compensation for participants
- Change from a consent form to an information sheet
- Change in funding agreement
- Change in recruitment flyer format (font size, color, etc.)
- Change in protocol procedures
- Addition of co-investigator
- Change in method of recruitment
- Modification of consent script
- Change in location of research

More information on amendments can be found in HSPP SOP 300-308. All SOP are published on the HSPP website.

## Dates to Remember

### SEPTEMBER

- 9/3: IRB Meeting  
9/10: Submission due for 10/1 Meeting  
9/17: IRB Meeting  
9/24: Submission due for 10/15 Meeting

### OCTOBER

- 10/1: IRB Meeting  
10/9: Refresher Presentation  
10/15: IRB Meeting  
Submission due for 11/13 Meeting