

human subjects'

herald

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Collaborative Compliance

Research is governed by many federal laws, state laws and even by institutional policy.

While the Human Subjects' Protection Program (HSPP) and the Institutional Review Board (IRB) are responsible for ensuring compliance with only a very small number of applicable rules and regulations, it is always our goal to encourage compliance with rules and regulations outside of our direct purview.

In this spirit, the HSPP is implementing a new procedure designed to facilitate collaboration with the Office of Biosafety. The Office of Biosafety and the Institutional Biosafety Committee (IBC) provide oversight to researchers conducting research with biohazards.

Research involving human cell lines and tissues, among other agents (see <http://biosafety.tamu.edu/>) must be reviewed and approved by the IBC before initiation. These items may qualify as human subject research as well, depending on if the investigator is involved in data collection, if the specimens are deidentified, and so forth.

With the new procedure, once the HSPP/IRB gives an approval or exemption to a study calling for the use of biohazards, the IBC will be notified of the project title and the contact information for the investigator. The IBC will then follow up as necessary to ensure studies are compliant with IBC requirements. The HSPP/IRB will still grant approval/exemptions with the provision that the investigator must also gain approval from the IBC prior to beginning work involving biohazards.

The Office of Biosafety is located in the General Services Complex (next to the HSPP Office) and can be reached at Biosafety@tamu.edu or by phone at 862-4549. IBC applications and more information about what constitutes the need for IBC approval can be found on the Office of Biosafety website: <http://biosafety.tamu.edu/>.

Biohazards include:

- **Pathogens and potential pathogens of humans, animals or plants**
- **Materials potentially containing human pathogens (including human blood, tissue, and cell lines; non-human primate blood, tissue, and cell lines)**
- **Recombinant DNA (and RNA) including creation or use of transgenic plants and animals**

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



Conducting International Research Gets Easier

The Human Subjects' Protection Program (HSPP) and Institutional Review Board (IRB) require investigators conducting research internationally to submit a letter of cultural evaluation for their protocol procedures from an expert on the local culture of their study. The reason for this is to provide a cultural review of the study in addition to a typical IRB review.

The HSPP's standard operating procedures were written with American cultural norms and public policies in mind, which are often quite different from those of other countries. In order to minimize risks to participants, the HSPP/IRB must consider how cultural differences could impact participants in other countries, or place them at more risk of harm or undue influence.

For example, in some countries, paying subjects any amount of money for participating could be considered coercive, whereas

appropriate amounts of compensation are not necessarily coercive in America. The consent process may significantly change as well when working internationally. Most investigators conducting research in the United States approach participants one on one to obtain their consent (as well as when obtaining documentation of consent), in efforts to allow maximum privacy. But in other countries, it may be offensive to approach people individually—the investigator may receive a better response and may appear less intimidating by inviting people to participate in a group setting.

These are the kind of exceptions that an expert could detail or explain in an evaluation letter. The HSPP/IRB wants to be flexible with investigators and allow for the best study procedures specific to each culture.

A letter of support has always been required with international research, but the HSPP recently created Guidelines for Cultural Evaluation to make the process easier. While there are not specific requirements for the letter, this list gives experts a better idea of what the HSPP/IRB needs to know and understand prior to making a review decision.

The expert may be a current resident of the culture or may live outside the culture, but has exceptional knowledge of the culture's customs, public policies, history and so forth. In most cases, the expert cannot be a part of the research team.

To learn more about the requirements of submitting a human subject research study internationally, see HSPP 600-611: Conducting International Research.

Department Debut: Marketing

Karen Winterich, Ph.D.

When someone uses the term “marketing,” what comes to mind?

Stereotypes of big businesses, snazzy slogans and expensive advertising are at the top of the list. But marketing cannot be limited to one certain segment or size of the marketplace. Sometimes it is found on a small scale as well.

“Marketing is behind every business and organization. If no one knows about you, you can’t get their business,” says Mays Business School’s assistant professor of marketing, Karen Winterich.

Winterich first became interested in marketing when she was a teenager working at a local supermarket in her hometown of Mifflintown, PA. With a population of nearly 1,000 residents, grocery store customers were anything but strangers to Winterich. She became curious about the different buying patterns of customers she had known for years.

“Do they use coupons? Do they shop sales? Why do they do what they do?” Winterich says. “I became very interested in the ‘why’ of things.”

This curiosity led Winterich to pursue a doctorate in marketing and to conduct numerous research studies on emotions and

consumer behavior. One of these studies looked at the relationship between positive emotions and consumption. Participants were given pretzels to eat while completing a survey and writing measure for the experiment.

The results for this study showed that participants who felt happy at the time of the experiment tended to consume more pretzels, as they were in a celebratory and indulgent state. Whereas participants who felt hopeful rather than happy, were more future focused and tended to consume fewer snacks. Other studies have tested the relationship between negative emotions and consumption, but this was one of the first studies to explore the effects of specific positive emotions on consumption.

The consumption study, like much of Winterich’s research, was facilitated through the Marketing Subject Pool. The Marketing Subject Pool is an HSPP-approved recruitment method that offers students the opportunity to gain their needed research credit (or extra credit) for a marketing class by participating as a subject in a research study.

Creating a subject pool for the marketing department was a major project Winterich took on shortly after arriving to Texas A&M. She worked closely with colleague Kelly Haws

to ensure the subject pool procedures were safe for participants.

“We used to think about it as ‘how will we do this?’ But now it’s ‘what would we have done without it?’” Winterich says.

Winterich and Haws collaborated with Carnegie Mellon University, the University of South Carolina and the psychology department and HSPP at Texas A&M to set up the subject pool. Although the purpose and topic of each study may differ, the Marketing Subject Pool uses the same standard recruitment procedures each time. Winterich and her colleagues visit marketing classes each semester and explain the option of participating in marketing research.

“The hardest part of setting up the subject pool is figuring out how the pieces fit together. The key is being patient. You can’t get it up and running in one week. Research is a learning process, and doing a subject pool is a learning process too.”

Winterich plans to continue using the Marketing Subject Pool for her new projects as well, which specifically focus on how consumers’ morality affects their charitable giving and feelings of disgust. She and Haws also have hopes of creating a second subject pool for Mays, which may be composed of Texas A&M staff.



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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“One of the great things about
TEACHING *is getting to*
HELP STUDENTS
with the IRB process.”

Inside the IRB: Jean Brender, R.N., Ph.D.

“What’s exciting about the IRB is that it brings together all kinds of backgrounds and expertise.”

“We have a really good mix in our Texas A&M IRB,” says Jean Brender, professor of epidemiology at the Texas A&M Health Science Center School of Rural Public Health.

When Brender joined the IRB at Texas A&M in 2007, she brought her own distinct background and expertise and a consistent theme of helping others. She started her career as a nurse, working specifically in an acute coronary care unit as well as the emergency room. She received a master’s in nursing and a doctorate in epidemiology from the University of Washington. Along the way, she also taught nursing at Washington State University’s Intercollegiate School of Nursing.

“Nursing provides a great background for both epidemiology and the IRB because you work directly with patients in public health and health care settings,” Brender says.

Brender spent over 10 years with the Texas Department of State Health Services (DSHS), where she served on their IRB and was a program and division director



for the environmental and occupational epidemiology programs. She also taught graduate level epidemiology courses in a health services research program at Texas State University for six years. She joined the School of Rural Public Health at the Texas A&M Health Science Center in 2005 to teach in an accredited school of public health as well as spend more time conducting research. However, she stays in contact with many colleagues from the Texas DSHS—some of whom are currently collaborating with her on research projects and publications.

“It was at DSHS that I really gained an understanding of confidentiality, specifically through IRB review of studies regarding HIV. We tend to think of the IRB as protecting against physical harm, but it must protect subjects from

economic, social and psychological harms as well.”

Most of Brender’s research has focused on the relationship between environmental exposure and birth defects. She first became interested in causes of birth defects at the Texas DSHS while investigating several reported clusters of birth defects in Texas.

One of Brender’s current projects combines all aspects of her former research projects together. This NIH-funded four-year project looks at the separate and combined effects of prenatal exposures to nitrosatable drugs, drinking water nitrates and food nitrates and nitrites on risk for birth defects. The study involves collaborators from the School of Rural Public Health, Texas A&M Department of Biological and Agricultural Engineering, Boston University, University of Iowa, University of Arkansas for Medical Sciences and the Texas DSHS.

Brender has dedicated much of her career to students—through advising and teaching various topics in epidemiology and public health. She has served as chair or committee member on over 20 thesis committees and has mentored several students as authors and co-authors on journal publications.

“One of the great things about teaching is getting to help students with the IRB process,” Brender says. “The IRB not only helps protect human subjects in research, but also can potentially save the researcher a lot of grief. Researchers can regard IRBs as a help in the research process.”

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From the Mailbag:

Q. Does the HSPP Refresher Presentation take longer than the online Collaborative Institutional Training Initiative (CITI) refresher course?

A. The HSPP Refresher Presentation and the online CITI refresher course both take approximately one hour to complete. The advantage of attending the HSPP Refresher Presentation is that it includes information about the actual IRB process at Texas A&M. The presentation itself will last about 45 minutes and include time for a Q&A session. All HSPP Refresher Presentation dates are posted on the HSPP/IRB website here.

Q. Do I submit an Information Sheet or a Consent Form?

A. The purpose of the consent form and information sheet is the same: they both outline the information necessary for participants to make an informed decision as to whether or not to participate in a research study. The design and procedures of an investigator's study will play a key role in determining which consent document would be more appropriate.

If the study qualifies for an exemption, a consent form is not necessary, and an information sheet may be used. Studies that qualify for expedited or full board review are required by federal

law to obtain documentation of consent, as well as provide specific details to participants. These specific requirements are provided in the consent form template on the HSPP website. Investigators must include all of the elements on the consent form template unless they qualify for a waiver of consent or documentation of consent.

If a waiver of consent or documentation of consent is granted, investigators may use an information sheet, or an alternative. For more detail, read "Understanding Consent with Exempt Research" and "Which Waiver do I Use?"

Q. I took the CITI course from another university. Do I have to do it again for Texas A&M purposes?

A. Many institutions have made CITI their training provider because it offers top-notch information regarding research compliance. However, institutions will vary on which specific modules they require for training completion. Investigators who completed the CITI course with an institution other than Texas A&M must submit the specific CITI modules they have completed to the HSPP Office. The compliance coordinator can authorize a training substitution if the modules taken for another institution are the same or similar as those required at Texas A&M.

If the modules are the same as the Texas A&M course, the investigator will not have to take an additional CITI course. But if the modules differ, the investigator will have to take some or all of the Texas A&M CITI course.

Dates to Remember

MAY

- 5/19:** *Refresher Presentation at 9:30 a.m., GSC, Room 101C
- 5/25:** HSPP Office CLOSED for Memorial Day
- 5/27:** Submission due for 6/17 IRB meeting

JUNE / JULY

- 6/24:** Submission due for 7/15 IRB meeting
- 7/3:** HSPP Office CLOSED for Independence Day
- 7/8:** *Refresher Presentation at 9:30 a.m., GSC, Room 101C
- 7/29:** Submission due for 8/19 IRB meeting

**Please RSVP to Lnewcomer@tamu.edu if you are interested in attending.*