

SPECIAL EDITION!

RESEARCH IN A GLOBAL CONTEXT

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 Special Edition



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Compliance Companion is a
 quarterly publication from the
 Research Integrity Program.
 Comments and feedback are
 welcome at ori@louisville.edu

Intercultural Competence: An Ethical Approach to Research

Elizabeth Langston, Ph.D.
 Assistant Research Integrity Specialist

The forces of globalization have been at work for a very long time, but have finally reached a point where the average person in Louisville, Kentucky, can personally notice the effects of it in their daily lives, for better or worse. A person may rise in the morning, put on an outfit made in Turkey, grab a box of sushi from a Mexican immigrant working behind the counter at the grocery store deli for lunch, join a phone meeting for work over Skype with partners in Brazil, then collapse in front of the television in the evening to watch a Bollywood movie or catch upon the Spanish soaps. From the American side, globalization is about expand-



ing markets and economic growth, access to things and places once considered culturally and geographically distant, having the world at your doorstep. (Continued on page 4)

The America Invents Act: Harmonizing US Law with International Practice

Laura Zanewicz, Assistant Research Integrity Specialist

If you ask a patent attorney, there have been some very interesting revisions recently in regards to patent laws. This past September, President Obama signed the America Invents Act (AIA). This is the most significant overhaul to the United States' Patent Act since 1952. This reform intends to speed up the patent process to help businesses bring their inventions to market sooner, thus creating new business and jobs. This article will briefly describe some of the key elements of the AIA.

The AIA will harmonize the US patent process with the rest of the world. Before this change, the United States was on a 'first to invent' system, in which the date of the invention determined the rights to the patent. With the AIA, the US has now moved to the 'first to file' system, in which the date of filing determines the priority. Furthermore, the USPTO has set up new processes in which to speed up the sharing of this information to other patent offices (Continued on page 2)

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The America Invents Act: Harmonizing US Law with International Practice

(Continued from page 1)

around the world in an effort to increase efficiency and speed. This synchronicity will make the process for entrepreneurs to protect their Intellectual Property (IP) in the United States and abroad more efficient and diminish the current headache due to the differences in patent laws. This provision is scheduled to take effect on March 16, 2013.

Additionally, the AIA establishes a fast track option for patent processing. Currently, the average wait time in the system is almost 3 years. This new fast track option for processing will reduce that to 12 months or less. Because patent ownership is extremely critical when searching for venture capital or angel investment in the technology and/or business, speeding up this process will open the door to entrepreneurs to potential funding earlier than the current standards.

One contributor to the long wait time mentioned above has been the patent application backlog. During the Obama administration, the patent application backlog was reduced by almost a 100,000, even though there was an increase in filings. The AIA has provided additional resources that will aid the United States Patent and Trademark Office (USPTO) to continue to decrease the number of patent applications within the backlog, primarily by giving the office more direct control over the setting and usage of patent filing fees.

If you have questions, please contact the University of Louisville, Office of Technology Transfer. Thinker@louisville.edu or 852-2965.

References and for more information:

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The White House. Office of the Press Secretary. *President Obama Signs America Invents Act, Overhauling the Patent System to Stimulate Economic Growth, and Announces New Steps to Help Entrepreneurs Create Jobs*. The White House. 16 Sept. 2011. Web. 05 Oct. 2011. <<http://www.whitehouse.gov/the-press-office/2011/09/16/president-obama-signs-america-invents-act-overhauling-patent-system-stim>>.

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Compliance 101: **Uncle Sam (and UofL) Wants YOU...** ***Not to Break Export Control Laws!***

Contributed by William A. Metcalf, J.D.
Director of Export and Secure Research Compliance



Are you traveling outside the U.S. for University business or for a class?

University of Louisville faculty, staff, and students commonly travel internationally with their laptops, cell phones, GPS, PDAs, and other electronic devices loaded with information and software (“Devices”). Although taking Devices to international destinations seems routine, individuals doing so may be “exporting” the Device for purposes of the U.S. export control laws. Such “exports” may require a license from the U.S. government.

Most international travel with Devices will not require a license. However, UofL travelers should be familiar with the applicable export control regulations and strive to comply, because violations can result in the imposition of criminal sanctions and heavy civil penalties. The Director of Export and Secure Research Compliance is available to assist travelers in ascertaining compliance requirements. His contact information is provided below.

Travelers are likely to require an export license to bring a Device outside the United States if:

- They are traveling to a country that has been embargoed by the U.S. Department of Treasury (Cuba, Iran, Myanmar (Burma), N. Korea, Syria or Sudan);
- The Device holds certain encryption software, either commercially available or research-generated;
- The Device contains unpublished data or other information relating to items or materials on one of the technology control lists established by the U.S. government (an example of such information would be blueprints of laboratory equipment that could be used to create toxic materials). Note that the need for an export license would probably not apply to data and information which result from fundamental research: basic and applied research typically associated with academia;
- The Device is designed for use or application with technologies associated with satellites, spacecraft or technologies with a military use, or the Device contains information or software designed for use or application with such technologies; or
- The Device could be used in the development of weapons.

While a license may be required, certain exemptions to the licensing requirements may be available for Devices taken outside the country for professional or personal uses. The exemptions are fact specific and require individual analysis.

In addition to becoming familiar with applicable export control requirements, UofL travelers should note that any international travel with a Device may result in the disclosure of personal and proprietary information installed on the Device. In some countries, custom officials may examine information contained in Devices or seize Devices. Travel in and out of the U.S. is no exception. Homeland Security personnel may inspect information contained in a traveler’s Device or seize the Device. In fact, on April 21, 2008, the Ninth Circuit Court of Appeals ruled that U.S. customs has the right to inspect your laptop as you go through border security, including at U.S. airports. The
(Continued on page 4)

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Intercultural Competence

(Continued from page 1)

From virtually every other perspective, the picture is less clear. For many, globalization often looks like little more than an overwhelming, and often unwelcome, flood of American material culture; or about opportunities to migrate to other countries for better economic opportunity, then sending earnings back home to join the massive flow of remittances from fellow citizens working outside the country, as well. To others, it's about multinational corporations, the World Wide Web, and American hegemony.

In the world of academic medical research at the University of Louisville, globalization likewise has more than one meaning. It might mean a large population of foreign students and fellows, submitting papers to international conferences and scientific journals, or the diffusion of information and technology across borders; but it could also mean the conduct of research and clinical trials abroad, local patients and subjects who are not fluent in standard English, and awkward citizenship restrictions on lab personnel, among many other possibilities. Each of these dimensions of the globalization experience in research is fraught with questions of power—with not only opportunities for personal growth and shared scientific progress, but also with the potential for exploitation of vulnerable people and communities.

Much of the conflict that can and does arise in the course of academic research in the international context may be traced to a simple lack of intercultural competence. Examples abound, unfortunately. From the fairly benign case of a researcher doing his ethical best to obtain signed informed consent forms from individuals to participate in a research study, but not being linguistically prepared to manage the oral aspects of the consent process; to the more grave case of a researcher intentionally selecting a research site where oversight is lax in order to avoid having to navigate unfamiliar or time-consuming institutional processes.

Many resources exist to aid those considering research abroad, or struggling with cultural or linguistic challenges in a local research setting, and the Research Integrity Program can help connect you to some of those resources. However, the most important thing to remember is that some things really are universal—like treating others the way you would want to be treated. No translation necessary.

Compliance 101: Export Compliance

(Continued from page 3)

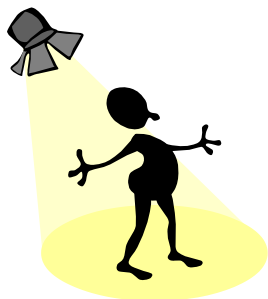
court dismissed concerns regarding any privacy or First Amendment rights holding that “reasonable suspicion of any crime or wrongdoing is not needed for customs officials to search a laptop or other personal electronic storage devices at the border.”

So what does this mean and what should you do? Prepare your laptop before leaving the U.S. by taking the following precautions:

- Remove export-controlled information, technical data, and software from your laptop prior to leaving the U.S.
- Use a “shredder” program to erase the information you do not want to share so that it cannot be recovered.
- Do not take the only copy of data or information you cannot afford to lose.
- Generally, if you don't need it, don't take it with you.

This information is designed to provide only general guidance on a complex issue. If you think you might need a license or need to rely on exclusion, or if you have any questions or need more detailed information about this topic, please contact:

William A. Metcalf, J.D., Director of Export and Secure Research Compliance
Phone: 502-852-1708, or email: will.metcalf@louisville.edu.



Compliance Spotlight

Science as a Bridge Between Cultures: An Interview with Dr. Yang Liu on the Responsible Conduct of Research in China and the U.S.

Elizabeth Langston, Ph.D.

For at least one UofL post-doctoral fellow from China, science is able to cross all barriers between the cultures of China and the US. In a recent interview, Dr. Yang Liu, a post-doctoral associate in the Speed School Department of Industrial Engineering, reviewed issues in the responsible conduct of research and the ways in which key aspects of research integrity—such as mentorship, plagiarism, and conflict of interest—are thought about and managed in his home country.

Mentorship is considered one of the most effective methods for training researchers in the responsible conduct of research, as well as being crucial to the career prospects of trainees. The nature and productivity of such relationships varies widely, and is certainly one area highly influenced by social factors, such as culture or gender, even more so than by institutional or academic factors. In his graduate studies at the University of Kentucky, Liu chose his Ph.D. advisor early on, based in large part on their shared nationality and alma mater in China. He focused his research on the interests of his advisor, rather than selecting an advisor solely based on his own research interests. Although Dr. Liu recognized this was not necessarily standard practice in the US, he stated that he firmly believes that a good mentoring relationship is one of the keys to success. He noted that other students who choose mentors based on shared research interests alone sometimes fail to graduate, especially when that personal relationship between mentor and student turns out to be less than optimal.

Despite Dr. Liu's years studying and working in the US, he indicates that an academic position outside the US is still very attractive to him. As he points out, most Americans assume that he, as well as other international scholars, wishes to stay in the US permanently, but, according to Liu, the job market in China is better right now than it is in the US. Nevertheless, he expects that the academic environment will be similar to the one here. As he says, "I think publishing papers is the first priority in my field in every country." In fact, the Chinese academic system may even put more pressure on young scholars. For example, many Chinese universities offer particular short term contracts in their overseas talent programs, which specify a certain number of papers to be published in a select few journals within the contract term. If that publishing requirement is not met, the employment contract may be terminated, or the salary dramatically cut.

Such high pressure tempts many to take shortcuts or, even, to plagiarize. Plagiarism is a contentious issue around the world, especially with cultural differences surrounding the concept of intellectual property, language hurdles in international journals, and divergent attitudes toward the publishing process. Because of the great number of Chinese scholars involved in research today, one often hears of such problems in the Chinese academic community. A recent article by Yuehong Zhang, a Chinese academic, found that up to one third of all academic articles submitted to one major Chinese journal had been plagiarized. However, efforts are being made to curb the practice, as the government is serious about its intentions to aggressively promote research for the country's development. Dr. Liu cited a recent case that has been buzzing in the Chinese blogosphere about an academic who plagiarized a graduate student's thesis and published it, and was subsequently fired when the discovery was made public. (*Continued on page 6*)

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Don't miss the upcoming PRIM&R Webinar:

When the Stakes are High: Managing Communication and Public Opinion in Research Settings

Hosted by Research Integrity

Tuesday, October 18th, 2011

1:00pm -2:30

K-Wing Bldg 2035

RSVP to emlang02@louisville.edu

Compliance Spotlight: China

(Continued from page 5)

While many aspects of research ethics and training appear to be shared, there are some other notable differences. For example, Liu pointed out that attitudes toward conflict of interest are quite different in China. The disclosure of potential financial conflicts is often not required in China, and Liu reports that such relationships are generally considered acceptable. While such ties are less visible, there remains an awareness that a scholar's work might sometimes be influenced by their personal business ties. However, influence does not automatically equate to misconduct, nor does it in the US, where the point of disclosure of financial interest is to find ways to mitigate possible influence, or to remove the suggestion of it by publicly acknowledging the relationship.

As Liu says, "Everywhere science is the same, and the pressure is high on academics." He concludes that, despite different experiences with research and regulation, both countries share similar perspectives on most major issues about the responsible conduct of research.

References:

"Chinese journal finds 31% of submissions plagiarized" Yuehong Zhang *Nature* 467, 153 (09 September 2010).

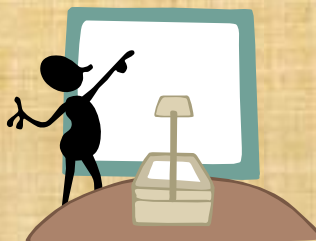
"New Threads," <http://www.xys.org/>, a well-known website blocked in China, set up by an independent Chinese person dedicated to routing out cases of academic misconduct.

FYI

CITI has added two new training modules that address risk and research with vulnerable communities: *Avoiding Group Harm: US Research Perspectives*, as well as a second module geared toward research in international settings. UofL is registered for both, and they should be available to you when you log in to CITI training.

Contact 852-2454 if you need assistance.

Did you miss these RCR training seminars?



Slides from the following webinars are now available:

- *International Research: Applying Ethical Principles and Research Guidelines in Global Settings*
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ETHICAL CONSIDERATIONS: A CASE STUDY



*Family Involvement in Informed Consent**

Author: Emily E. Anderson

You are the principal investigator of a study on postpartum depression that will include in-depth open-ended interviews with women who are recent immigrants from Mexico (have immigrated within the past 10 years) and first generation Mexican-American women who have been diagnosed with moderate postpartum depression. The informed consent process and all interviews will be conducted in Spanish by a Latina co-investigator who is a 2nd generation Mexican-American and has extensive experience working with this population in research and outreach settings.

The interview will include sensitive questions regarding depression, anxiety, confusion, suicidal ideation, and thoughts about motherhood. However, the sensitivity of the research topic does not seem to be a major barrier to recruiting participants. Approximately 20 women have responded to flyers that have been placed in a community mental health clinic, but only 3 have been enrolled. In many cases, after the study has been explained and participants are asked to sign the consent form, many have said either, "I have to ask my husband first before I sign anything" and then do not return to the clinic with the signed form, or, "I don't think my husband would like me to participate in this study." When asked why, many participants (especially the more recent immigrants) remarked that generally they do not sign any forms without first discussing the matter with their spouses. Several potential participants also mentioned that because the topic involves not just themselves but their child and family, they do not feel comfortable excluding their husbands from the decision.

Should you (and if so, to what extent) involve husbands in the informed consent process?

***Case reprinted from the Ethics in Mental Health Research (EMHR) website. Cases were developed by the Albert Gnaegi for Health Care Ethics at Saint Louis University in collaboration with the Missouri Institute of Mental Health with funding from the National Institutes of Health, the US Office of Research Integrity, and the National Institute of Mental Health (James DuBois, Principal Investigator).*

<http://www.emhr.net/index.php?mact=caseStudies,cntnt01,default,0&cntnt01what=studie&cntnt01alias=Family-Involvement-in-Informed-Consent&cntnt01returnid=64>

A great many people think they are thinking when they are merely rearranging prejudices.

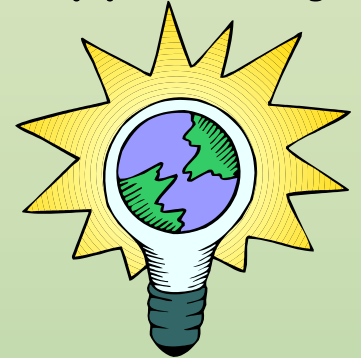
– William James



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