RESEARCH INTEGRITY NEWS

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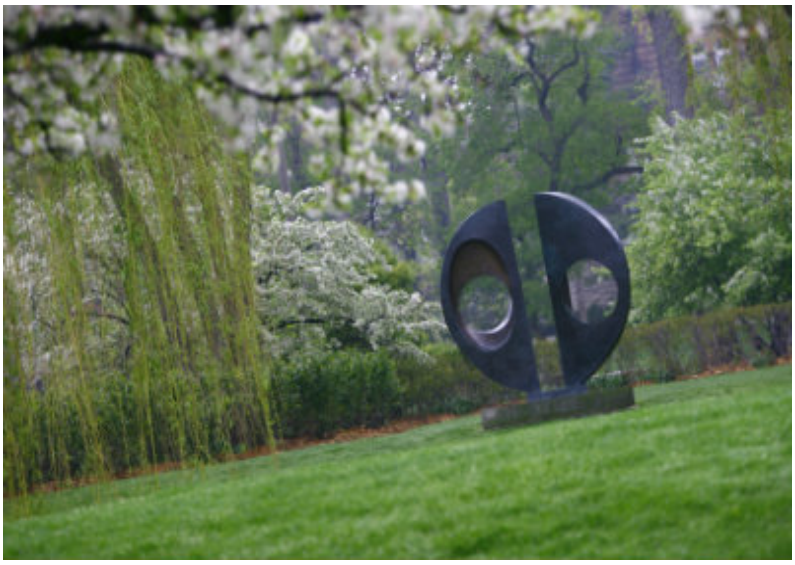

ORI Mission:

- Identifying compliance risks in our research practices and communicating those risks to the research community;
- Partnering with the research community in innovative and effective ways to minimize and manage research risks;
- Educating the research community with respect to appropriate business practices related to the conduct of research at Northwestern University; and
- Monitoring and correcting non-compliance in accordance with University and federal guidelines.

ORI Staff

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Groundbreaking Cell Line Brings Ethical Considerations to the Frontline: Formal Agreement between Lacks Family and NIH Regarding Use of HeLa Cell Genome

The HeLa cell, a cell type widely used in research, has been identified as originating from the cervical cancer cells of Henrietta Lacks, an African-American woman whose cancer cells were removed from a tumor biopsy in 1951 at Johns Hopkins Hospital. As was customary at the time, Ms. Lacks did not consent to the use of her cells, nor was she even aware her cells were to be used for research. While the HeLa cell has been used in countless medical and research advances, its use and origination has shone a spotlight on the ethical dilemmas in research, such as consent. In addition to not obtaining proper consent from Ms. Lacks, researchers later released Ms. Lacks' medical records for publication and performed research on the Lacks family without obtaining consent.

Another consent issue arose for the Lacks' family in March 2013 when a team of German researchers published a paper sequencing the HeLa genome. This detailed account of HeLa DNA violated the Lacks' privacy, providing others the ability to identify the Lacks' family disease risk. The paper was initially pulled, but is currently available for public viewing per the recent agreement entered into between the National Institutes of Health (NIH) and Lacks family outlining how the HeLa genome data can be accessed.

According to the agreement between the NIH and the Lacks family, HeLa genome data will be stored in the NIH Genotypes and Phenotypes database. Researchers who agree to abide by the HeLa Genome Data Use Agreement will be able to apply for access to the HeLa genome sequence data.

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Did You Know?

Did you know that PIs are responsible for retaining research data for a minimum of 3 years after the project's financial report has been submitted? http://www.research.northwestern.edu/policies/documents/research_data.pdf However, PIs engaging in human subject research are also required to retain signed consent documents, IRB correspondence, approvals and research records for at least 7 years (or for the contractually specified time) after the completion and termination of the study. http://irb.northwestern.edu/sites/default/files/documents/northwesternhsppolicyv53.pdf

Did you know that NUCATS launched a new Clinical Research Coordinator (CRC) Basic Training Live Course? http://www.nucats.northwestern.edu/education-career-development/research-support-staff-training/clinical-research-coordinator-basic-training/crc-basic-training-live.html

Did you know that last month was the opening of the new Center for Clinical Research (CCR), a program of the NUCATS Institute? The CCR is designed to help researchers address their study needs. http://www.nucats.northwestern.edu/resources-services/research-study-support/center-clinical-research/index.html

Introducing Lauran Qualkenbush….

1) What is your title at Northwestern?

I'm the Director of the Office for Research Integrity and I'm also the Research Integrity Officer for Northwestern.

2) What does that mean?

I am responsible for promoting ORI's mission of research integrity through both proactive and reactive measures. This includes investigating research misconduct and looking for ways to better serve our entire research community and help them understand what they need to do.

3) What is one thing you want people to know about what you do here?

ORI is here to help, not just when you have problems. If you don't know where to go, call us and we'll help you figure it out! Northwestern is complicated and even after being here so long, it is not always clear where to find answers, so let us know how we can help!

4) How long have you been at Northwestern?

I have been at Northwestern for over 12 years and originally started in the IRB Office.

5) What did you do before you came to NU?

I was a clinical research coordinator at the University of Chicago.

6) Where is your home town?

Cleveland, Ohio and yes, I LOVE ALL Cleveland sports teams!!!

7) What is your favorite flavor of ice cream?

All ice cream is my favorite but I really like Ben and Jerry's Phish Food and peanut butter cup blizzards!

8) What is your favorite thing to do outside of work?

I enjoy taking pictures, spending time with my family, being outside and tending to our garden.

9) What is your favorite yearly Chicago event?

I enjoy anything with fireworks or the zoo lights - it's magical!

European Commission Research Integrity Seminar in Brussels

The European Institute of Public Administration Consortium (EIPA) for the European Commission invited ORI's Director, Lauran Qualkenbush to present at its research ethics and integrity seminar in Brussels, Belgium on July 12, 2013. The European Commission is an institution, or branch, of the European Union (EU), representing the EU's interests by proposing legislation and verifying that legislation is appropriately applied by the EU member countries. They also provide research funding to European countries, similar to the NIH and NSF in the US. The purpose of the seminar was to discuss the importance of safeguarding research integrity, a particularly poignant topic in the European research landscape given the recent highly publicized Stapel research misconduct case. http://www.nytimes.com/2013/04/28/magazine/diederik-stapels-audacious-academic-fraud.html?pagewanted=all&_r=0. The seminar was attended by members of the European Commission, the Research Executive Agency and the European Research Council.

Lauran, the sole representative from the United States, was asked to discuss the U.S. experience regarding implementing and facilitating research misconduct regulations, policies and procedures. As you may know, in the US, the Office of Science and Technology Policy (OSTP) requires all federal agencies supporting intramural or extramural research to implement a federal research misconduct policy. Institutions receiving funding from the federal agencies must comply with these various policies and regulations for reviewing and reporting alleged research misconduct. The EU, however, has taken a proactive approach by implementing the European Code of Conduct for Research Integrity. The Code provides principles and guidelines to follow when conducting research, which EU member countries rely upon when self-regulating its researchers.

In light of recent serious misconduct cases, the Commission is looking at implementing guidelines or standard policies for dealing with research misconduct to cover all participating EU countries which currently have their own separate methods, some more formal than others. Lauran believes that there are great opportunities to collaborate and improve how things are done at Northwestern University and in the United States. "It was such a great experience for me to see how differently things are approached in the various countries throughout the EU. I was extremely impressed with how well financial compliance is proactively monitored for all awards through various policies and procedures within the Commission. I'm looking forward to fostering a partnership with our European counterparts because it is clear to me that we both have so much to learn from each other."

Research Administration Upcoming Training

This four-session seminar is geared toward research administrators and staff involved in research administration, and anyone who wants to learn about NU's research administration process, policies, and procedures. This is a great educational opportunity for staff new to research, or experienced staff who would like a refresher in certain areas. Representatives from departments throughout NU will be on hand to present and answer questions. This is a great chance to network with others in NU's research community!

The next seminar will next take place September 24th, 26th, October 3rd, and 5th from 9:00 a.m.-12:30 p.m. on the Evanston campus (Chambers Hall, lower level classroom). To register, email nu-ori@northwestern.edu.

EthicsPoint is a third party vendor that allows you to confidentially raise ethical concerns, ask questions, and/or report activities that may involve misconduct or violations of Northwestern University policy. For more information visit the website at:

www.northwestern.edu/ethics

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NORTHWESTERN UNIVERSITY

HeLa cell genome…

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In addition, the agreement includes that two of the Lacks family members will serve on a panel to review proposals for access to the genome sequence data, and researchers will be expected to deposit their data into a database for future data sharing through the NIH. Furthermore, researchers who use or generate genomic data will be asked to acknowledge the Lacks family in their publications.

The NIH recognizes that labs could reproduce the genomic sequence from HeLa cells without following the policy outlined in their agreement. Because the Lacks family has endured numerous ethical transgressions over the years prior to the formulation of human subject protection regulations, the NIH is strongly encouraging compliance with the policy to allow the Lacks some protection and autonomy over the identified data. Current policy does allow researchers to sequence genetic data without the knowledge or permission of the subject, as long as the subject is de-identified to the researcher.

The story of Henrietta Lacks and her infamous cells have brought much attention to the use of human tissue and materials and the rights of the human subject. Much has changed since her cells were collected, but that being said, we still have to remember that doing research with human subjects, including research with human tissue or data is a privilege. It is critical for researchers to uphold the highest ethical standards and remember that the tissue or data that is used belonged to someone and we need to treat it with the highest level of respect and confidentiality possible. Just because we don't physically see a subject, doesn't mean they don't care about what happens with their tissue and data.

http://www.nih.gov/news/health/aug2013/nih-07.htm

http://rebeccaskloot.com/faq/#questions-lacks

Most people say that it is the intellect which makes a great scientist. They are wrong; it is character."

–Albert Einstein