

Data and IRB Issues in International NDS

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We've Come a Long Way...

- At the last NDRS, we were talking theoretically
 - No international collaboration had occurred
- As you have heard, there are now numerous international NDS being conducted with VTTI and other US collaborators
 - Canada, China, Australia, ...
- Now we can focus on lessons learned (to date)

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Learning the Differences

- Regulation vs Policy/Guidance
 - In US, Institutional Review Boards operate under federal regulation
 - Due to Common Rule, almost all human subjects research in the US is reviewed by an IRB
 - In many other countries, human subjects research is guided by policy statements and guidance documents
- Terminology
 - IRB vs ethics board vs research ethics board

Things Can Change - Rapidly

- As stories break in the international news cycle, things can trickle down into the IRB world
 - Edward Snowden revelations → greater mistrust of anything relating to security of US data
 - Facebook experiment → greater mistrust of ability of US to properly govern the ethics of its researchers

Things Can Change - Rapidly

- U of Saskatchewan REB recently requested that we add a statement to our consent form regarding the Patriot Act and how it affects the vulnerability of even human subjects data held in the US
 - This was a repeat of an earlier request prior to various news stories
- We requested advice from our IRB, who consulted VT legal and VT IT → answer provided yesterday
 - Some validity to this claim
 - Suggested consent form wording provided related to human subjects data collected in other countries but stored in the US

Things Can Change - Rapidly

- The VTTI data servers are located in the USA and subject to US laws. The privacy of the information you provide is subject to the laws of those other jurisdictions. By participating in this study you acknowledge and agree that your information and data will be stored and accessed outside of Canada and may or may not receive the same level of privacy protection as if it were stored in Canada.

Cultural Expectations Matter

- Different expectations of privacy
- Different expectations of what it means to volunteer
- Different expectations of your duties as a citizen
 - Or as a good corporate employee
- Differences can affect risks to participants:
 - Driving laws
 - Safety culture
 - Driving culture

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What Should I Do?

- Use OHRP international website to become familiar with current laws/policy regarding human subjects
- Learn about your collaborators and their familiarity with human subjects work
 - Become familiar with cultural norms, driving laws, privacy laws, and expectations
- Make sure consent documents are explicit with regard to international aspects
 - Who will store the data and where
 - Who will have access to data – now and in the future
 - Any risks due to holding the data away from its country of origin

And... We Have a Long Way to Go

- Honor promises to participants
- Use data wisely
 - Avoid erosion of privacy protections
- Train future users of the data
 - Long life of NDS data → future users of currently collected NDS data may be children and infants now
 - As the international NDS community grows, we need to develop and propagate a culture of respect for human subjects, even for previously collected datasets
- Maintain access to IRB resources