

NSTSCCE

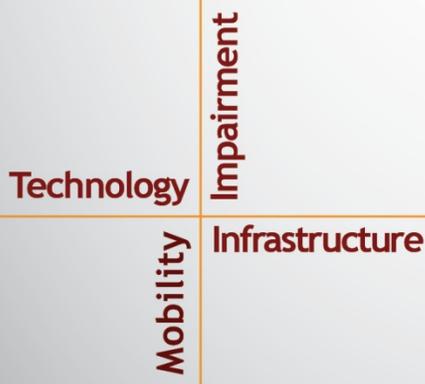
National Surface Transportation
Safety Center for Excellence

Data Sharing Across Borders

Current Status

Suzanne Lee • Jon Hankey

Submitted: May 28, 2020



Housed at the Virginia Tech Transportation Institute
3500 Transportation Research Plaza • Blacksburg, Virginia 24061

ACKNOWLEDGMENTS

The authors of this report would like to acknowledge the support of the stakeholders of the National Surface Transportation Safety Center for Excellence (NSTSCE): Tom Dingus from the Virginia Tech Transportation Institute, John Capp from General Motors Corporation, Lincoln Cobb from the Federal Highway Administration, Chris Hayes from Travelers Insurance, Martin Walker from the Federal Motor Carrier Safety Administration, and Cathy McGhee from the Virginia Department of Transportation and the Virginia Transportation Research Council.

The NSTSCE stakeholders have jointly funded this research for the purpose of developing and disseminating advanced transportation safety techniques and innovations.

The Government and others acting on its behalf shall have unlimited rights to obtain, reproduce, publish or otherwise use the data developed in the performance of this cooperative agreement pursuant to 49 CFR Part 19.36.

EXECUTIVE SUMMARY

This report is the culmination of several years of Virginia Tech Transportation Institute (VTTI) involvement in international collaborations in the field of transportation research. The sponsor of this report, the National Surface Transportation Safety Center for Excellence (NSTSCE) at VTTI, has also sponsored five biennial editions of the International Symposium on Naturalistic Driving Research (2008–2016). This has allowed VTTI researchers to host and network with like-minded researchers from several other countries. Throughout this time span, the playing field in data sharing has changed frequently and rapidly. This report outlines current regulations, cultural and language challenges, and trust issues. The report ends with current guidance to researchers wishing to engage in international transportation research (not only sharing data, but also collecting and storing data).

Key takeaways include the following:

- Plan ahead! The most successful large-scale data sharing projects begin planning years ahead of data collection, and involve a great deal of pre-data collection collaboration (e.g., the Second Strategic Highway Research Program [SHRP 2] Naturalistic Driving Study [NDS] and the European Field Operational Test Networking and Data Sharing Support [FOT-Net]).
- Current resources should be consulted immediately prior to preparation of consent documents and protocols to be used in other countries. However, once you have an approved protocol, it should remain valid even if the rules change later.
- Be sure to search out the most current information related to the country of interest. Many countries have both general laws, policies, or guidelines (hereafter referred to as guidance) for the collection of human subjects data and additional guidance related to the storage and further use of human subjects data. In some cases, this guidance matches very closely with U.S. regulations, while in other cases it is can be more or less restrictive.
- Trust plays a large role in these collaborative efforts. Trust is a dynamic and fluid concept when it comes to cultural differences and privacy of data. Mistrust can arise between researchers, between researchers and participants, between researchers and oversight agencies, and between participants and oversight agencies. Researchers should establish professional relationships that foster trust, should research the potential trust issues ahead of time, and should be aware of current events in the countries of interest.
- Researchers are encouraged to read resources such as *Culture Matters: International Research Collaboration in a Changing World–Summary of a Workshop* (Sloan and Alper, 2014) prior to beginning work. This reference provides many examples and considerations to help researchers think through the issues.
- The Common Rule governing research with human subjects in the United States took effect on January 21, 2019. The revision clarified that the use of pre-existing non-identifying data is not human subjects research, which could make data sharing easier for certain large datasets.

TABLE OF CONTENTS

CHAPTER 1. DATA SHARING ACROSS BORDERS: CURRENT STATUS	1
INTRODUCTION	1
CHAPTER 2. REGULATORY ISSUES	3
HUMAN SUBJECTS REGULATIONS	3
ACCESS FOR LEGAL PURPOSES	5
OTHER RELEVANT LAWS	6
SPECIAL NOTES ON THE REVISED COMMON RULE	7
SPECIAL NOTES ON EU GENERAL DATA PROTECTION REGULATION (GDPR)	8
CHAPTER 3. LANGUAGE, CULTURAL, AND TRUST BARRIERS	9
LANGUAGE BARRIERS.....	9
CULTURAL BARRIERS	10
TRUST BARRIERS	11
CHAPTER 4. DATA CATEGORIES.....	13
IDENTIFIABLE DATA	13
DATA PROVENANCE.....	13
CHAPTER 5. GUIDELINES FOR VTTI RESEARCHERS.....	15
CHAPTER 6. KEY TAKEAWAYS	17
REFERENCES AND FURTHER READING.....	19

LIST OF ABBREVIATIONS

ANPR	advance notice of proposed rulemaking
BAC	blood alcohol content
CF	consent form
CFR	Code of Federal Regulations
CoC	Certificate of Confidentiality
DHHS	Department of Health and Human Services
DSA	data sharing agreement
FOT-Net	Field Operational Test Networking and Data Sharing Support
FWA	Federalwide assurance
GPS	Global Positioning System
IP	intellectual property
IRB	institutional review board
NAS	National Academies of Science
NDS	naturalistic driving study
NIH	National Institutes of Health
NPR	notice of proposed rulemaking
OHRP	Office for Human Research Protections
PI	principal investigator
PII	personally identifiable information
SHRP 2	Second Strategic Highway Research Program
UNESCO	United Nations Educational, Scientific and Cultural Organization
WHO	World Health Organization
VT	Virginia Tech
VTTI	Virginia Tech Transportation Institute

CHAPTER 1. DATA SHARING ACROSS BORDERS: CURRENT STATUS

INTRODUCTION

Traffic crashes continue to be a leading cause of death in countries around the world, with an average global loss of life of 1.25 million people per year (World Health Organization, 2017). Researchers, practitioners, legislators, and law enforcement continually search for ways to reduce deaths and injuries using the three E's of education, enforcement, and engineering. This report focuses on the engineering aspect by focusing on data and how it can be shared legally and ethically. In this era of "big data," researchers are looking to maximize use of existing data rather than to collect new data (Sloan and Alper, 2014). If possible, naturalistic driving study (NDS) data should be made available to researchers from other countries to help improve driving safety and reduce traffic crashes in these countries. This may prove to be especially useful for countries unable to mount such studies due to limited resources (more than 90% of deaths occur in middle- and low-income nations; World Health Organization, 2017). In some cases, the international community has the ability to collect naturalistic data but not the tools for storage and use. This project investigated the current state of law, culture, and trust issues relating to sharing human subjects data internationally. Despite the lessons learned and progress made over the several-year course of this project, many challenges remain before cross-border data sharing can be fully implemented or its promise realized.

Over the past several years, the Virginia Tech Transportation Institute (VTTI) has worked to assess and address issues associated with data sharing across borders as it collaborates with other institutions in data collection and analysis efforts. Issues to be addressed include the fact that not all countries have the equivalent of the institutional review board (IRB). Researchers from countries without such institutional protections should be trained in the issues and safeguards corresponding to the use of naturalistic data. Researchers should be made familiar with the terms of the original consent forms signed by research participants. Language and cultural barriers surrounding human subjects' protection issues may be a larger impediment to cross-border data sharing than the relatively minor differences in driving habits and behaviors.

The Office for Human Research Protections (OHRP; part of the U.S. Department of Health and Human Services) annually assembles and publishes *The Compilation of International Human Research Protections* (hereto after referred to as the Compilation). The publication contains a section about international policy (through the United Nations Educational, Scientific and Cultural Organization [UNESCO]) and a country-by-country guide. Links are provided in six categories: general; drugs and devices; privacy/data protection; human biological materials; genetics; and embryos, stem cells, and cloning. This National Surface Transportation Safety Center for Excellence (NSTSCE) project focused on the general and privacy/data protection areas. The past several years' worth of these compilations were used during the course of this project (most recently, Department of Health and Human Services, 2013, 2014, 2015, 2017).

Several countries were initially selected for review (i.e., countries in which naturalistic driving studies [NDSs] have been conducted, are currently being conducted, or where such studies are being planned). VTTI has ongoing relationships with numerous international collaborators for projects involving data collection, data storage, or data access in or between different countries. Not counting the United States, these currently include Canada, Australia, Sweden, China,

Germany, Japan, South Korea, Switzerland, Italy, and Great Britain. If you include individuals registered as Qualified Researchers on the Second Strategic Highway Research Program (SHRP 2) NDS InSight website, the number is even higher.

This report covers not just the sharing of existing data but also provides guidance on the collection of data with collaborators from other countries. Several VTTI researchers are currently involved in conducting NDSs in other countries (Canada with two studies, China, and Australia). Their involvement ranges from guidance and consulting to active data collection. There have also been several data use licenses executed with institutions from other countries (these are international researchers requesting access to data managed by VTTI). This report is designed to summarize the lessons learned from these data collection and data sharing collaborations and to provide guidance for future collaborations. During the course of this project, the principal investigator (PI) developed a brief “best practices” document for use during these situations, and the best practices information has been incorporated into this report. This report also offers practical advice on how to best conduct international research projects so that the Virginia Tech (VT) IRB will allow VTTI researchers access to the resulting data. Guidance is also provided on data access requests originating from other countries where VTTI is managing the data access process.

This report is organized into the following chapters:

1. Introduction
2. Regulatory Issues
3. Language, Cultural, and Trust Barriers (including privacy expectations)
4. Data Categories
5. Guidelines for VTTI Researchers
6. Key Takeaways

CHAPTER 2. REGULATORY ISSUES

Regulatory issues uncovered in the course of this project fall into three broad categories: human subjects regulations, policy, and guidance; access to the data by the legal system for legal purposes; and other relevant laws (such as privacy laws).

HUMAN SUBJECTS REGULATIONS

Review of the OHRP compilations over the past several years reveals several important points. First, some countries provide human subjects protections via regulation and law, while others use policy or guidance. The researchers who will be collaborating should have a basic understanding of the framework of one another's human subjects protections. Regulation versus guidance can have an impact on how research misconduct is handled (e.g., does the host country have any enforcement capability in the case of misconduct?). For example, the United States operates under federal regulation (Title 45 of the Code of Federal Regulations [CFR] Part 46; a major revision was implemented in early 2019). Canada works under a policy statement (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, 2010). Australia has issued a national statement (Australian Research Council, National Health and Medical Research Council, and Universities Australia, 2018). In the United States, offending institutions can have their entire research programs suspended, while sanctions may be less severe in other countries.

Second, not every country has regulation, policy, or guidance regarding human subjects protections, but almost all developed countries do, and more countries are becoming active in this arena every year (e.g., the 2017 Compilation added a separate section for the Middle Eastern countries for the first time). Even for those countries that do provide guidance, there can be large variation in the amount of guidance provided. Some countries may have detailed national standards for the formation and operation of IRBs, while others may rely on the institutions themselves to translate guidance into local policy. For some countries, regulation, policy, and guidance may apply only to human subjects research performed under government contracts. For other countries, it may apply to all research conducted at institutions that accept government funding. For still other countries, it may apply to all human subjects research, no matter the source of the funding. Some countries regulate in the area of medical research, but not other human subjects research (due to clinical trial abuses that have occurred in countries with lax regulations; see an example from September 3, 2017, at http://www.santafenewmexican.com/news/health_and_science/offshore-human-testing-of-herpes-vaccine-stokes-debate-over-u/article_1d6e277b-b031-5af0-9e84-128775e4c038.html; Taylor, 2017). Researchers should familiarize themselves with the subtleties of the laws or policy applicable to the research being proposed and the country(ies) in which it will be conducted.

Third, the regulations, policy, and guidance change over time, which is why the OHRP updates the Compilation annually. During the course of this project, the OHRP proposed (and later implemented) significant changes to U.S. regulations. This process began in 2011 with an advance notice of proposed rulemaking (ANPR). OHRP incorporated comments and suggestions resulting from the ANPR and in 2015 issued a notice of proposed rulemaking (NPR). In January 2017, the OHRP issued the final update to the Federal Policy for the Protection of Human

Subjects (the Common Rule) with the update taking effect in January 2019 (OHRP, 2017). The changes are intended to simplify processes for low-risk research, reduce administrative burden, improve protections for higher-risk research, and clarify the human subjects requirements for biospecimens and identifying data. The changes could impact how NDS data are shared and to what degree subsequent use of data has to undergo IRB review. Researchers should be aware of how recently the relevant regulations or policies have been updated and whether there are revisions underway that could impact the eventual process of providing access to the data. The information provided by OHRP identifies the most important changes for transportation researchers (annotations by the PI of this project are included in square brackets):

- The requirement for consent forms to provide potential research subjects with a better understanding of a project's scope, including its risks and benefits, so they can make a more fully informed decision about whether to participate. [Important change for participants in NDSs who may be at significant legal risk due to their participation.]
- Requirements, in many cases, to use a single institutional review board (IRB) for multi-institutional research studies. [May simplify conducting multi-site naturalistic driving studies such as SHRP 2, which started with eight involved IRBs and ended with six after two institutions agreed to rely on the VT IRB.]
- For studies on stored identifiable data or identifiable biospecimens, researchers will have the option of relying on broad consent obtained for future research as an alternative to seeking IRB approval to waive the consent requirement. [The consent for future use of identifiable data language in a driving study consent form could allow broad future use without having to rely on using the waiver language.]
- Clarification that, in most cases, secondary use of de-identified data collected from humans is not human subjects research [most institutions will require investigators to submit a determination request to formalize the decision].
- The establishment of new exempt categories of research based on the level of risk they pose to participants. For example, to reduce unnecessary regulatory burden and allow IRBs to focus their attention on higher risk studies, there is a new exemption for secondary research involving identifiable private information if the research is regulated by and participants protected under the HIPAA rules. [Some types of transportation research that are now in the expedited category may now move to the exempt category.]
- Removal of the requirement to conduct continuing review of ongoing research studies in certain instances where such review does little to protect subjects. [Studies using existing data may no longer be required to submit continuing review applications.] (OHRP, 2017)

Fourth, a lot of countries are represented in the Compilation, but many of them do not have English translations of their materials. In many cases, there are links that open a Web page; in other cases, the link opens a Word or PDF document. In cases where an English translation is not readily available, extensive Web searches have failed to disclose English-language translations of the relevant material. To take China as an example, a brief overview of the scope is available in English, but the remaining materials are not translated. Collaborating researchers need to ensure that they truly understand the requirements for each country and the implications for the research project.

ACCESS FOR LEGAL PURPOSES

In the United States, researchers who are collecting data related to possible illegal activities can apply for a Certificate of Confidentiality (CoC) from the National Institutes of Health (NIH). The purpose of the CoC is to encourage participation in research that will benefit society, but which may put participating individuals at legal risk as a result of their participation. Driving research definitely puts people at legal risk as a result of their participation because it often captures evidence of at-fault behavior that would not have been captured except for the data collection systems installed on their vehicles. The CoC policy was recently updated (as of October 1, 2017) to automatically issue certificates to all research funded by the NIH. Per the newly designed CoC website, “CoCs protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations. *NIH funded researchers are automatically issued a CoC through their award.* Other Department of Health and Human Services (DHHS) agencies issue CoCs to researchers they fund. Researchers not funded by HHS can continue to apply to NIH or the FDA as appropriate to request a CoC for HHS-mission relevant research” (NIH, 2017a). (Emphasis added; note that NIH has funded NDSs in the past, particularly in the teen driving area).

Updated CoC guidance has also been issued for research funded by other federal agencies (such as the U.S. Department of Transportation; NIH, 2017b). Key points relating to transportation studies include:

Certificates of confidentiality are only issued for research projects that are:

- Collecting or using identifiable, sensitive information
- On a topic that is within the HHS health related research mission
- Storing the research information collected or used in the US

Research in which identifiable, sensitive information is collected or used, including research that:

- Meets the definition of human subjects research, including exempt research in which subjects can be identified...
- Involves any other information that might identify a person (NIH, 2017b)

Almost every naturalistic driving research study conducted in the United States to date would meet all of these requirements (an exception would be a study focused on the usability of an infotainment system without a direct link to safety outcomes).

In the past (and under the previous rules), many NDSs applied for and received CoCs, while others were denied. Recently (and prior to the new guidance), several NDSs have been denied the CoC. The most common reason is that the research topic is not “within the HHS health related research mission.” In cases with direct links to one of the NIH institutes, such as teen driving research, alcohol driving risk research, drugged driving risk research, and elderly driver research, the CoC was often granted, while in general data collection cases, the CoC was often denied. Time will tell whether the new guidance provides for more consistent administration of the CoC.

It is a common misperception in the NDS research community that a CoC protects all of the data from legal proceedings. However, the truth is that the CoC protects identifying information (such as the name of someone enrolled in a study about illegal drug use) but not the necessarily the data collected during the study. In NDS research, some of the data are also identifying information (most commonly, face video and Global Positioning System [GPS] traces) and thus when granted, the CoC also protects some classes of data. The CoC does not protect the non-identifying data. However, such data are considered to be of little legal use without the identifying piece to link it to a participant.

Other countries typically do not have similar mechanisms. In NDS studies without a CoC (both in the United States and in other countries), participants should be fully informed of the legal risks before they enroll. In some countries, researchers may have an ethical obligation to notify the appropriate authorities of the existence of evidence. Researchers should be aware of the relevant laws regarding legal access to identifying information or data so that participants can be correctly informed.

One final and important point regarding the CoC is that the law establishing the protection is a United States law, and so only covers data collected within the United States. Moreover, for non-HHS agencies and funders, the research data must then be stored in the United States to maintain that protection. In other words, NDS research data that include identifying information and are protected under a CoC cannot be stored in another country. If data are to be collected within the United States, but with the intent to have a copy of the data (including identifying data) stored outside of the United States, then the researchers should not apply for a CoC.

OTHER RELEVANT LAWS

In most countries, there may be other laws that are also applicable, and researchers should be familiar with these. For example, in some studies it may be necessary to record continuous audio, but in many countries it is illegal to record conversations without a person's consent. There may be very restrictive privacy laws which dictate how images of unconsented pedestrians can be used in research. Within the United States, the laws for audio recording vary between states. Some states require consent from both parties before a conversation can be recorded, while others require consent from only one party. A similar situation exists in Canada between provinces. Within the United States, there are a plethora of federal laws regarding personally identifiable information (PII). Other nations have a similar set of laws to contend with. In some countries, a general federal privacy law takes precedence over laws relating to human subjects research protections. In Europe, the Data Protection Directive mandates that "collecting and processing the personal data of individuals is only legitimate in one of the following circumstances laid down by Article 7 of the Directive: Where the individual concerned, (the 'data subject'), has **unambiguously given his or her consent**, after being adequately informed" (original emphasis; European Union, 2017). This means that collection of forward video in a naturalistic driving study may be prohibited in some cases because pedestrians and other incidental identifiable road users have not consented to the collection of the data. Conversations with European researchers indicate that these rules may be interpreted differently in different European Union (EU) nations. There is additional information on European regulation later in this section.

The U.S. General Services Administration maintains a website that provides a list of privacy laws and regulations at <http://www.gsa.gov/portal/content/104250>. For convenience, this list is reproduced below.

- [The Privacy Act of 1974 \(5 U.S.C. 552a\)](#)
- [Department of Justice guidance on the Privacy Act](#)
- [Clinger-Cohen Act of 1996, also known as the Information Technology Management Reform Act](#) (beginning on page 495 of the PDF found at this link)
- [Computer and Fraud Abuse Act of 1986](#)
- [Computer Matching and Privacy Protection Act of 1988](#)
- [E-Government Act of 2002 \(E-GOV\)](#)
- [Federal Information Security Management Act \(FISMA\) of 2014](#)
- [Records Management](#)
- [Paperwork Reduction Act \(PRA\) of 1995](#)
- [Rehabilitation Act of 1998 Section 508](#)
- [OMB Circular No. A-130, Appendix I, Managing Information as a Strategic Resource](#)
- [\(M-03-22\) Memorandum for Heads of Executive Departments and Agencies, OMB Guidance for Implementing the Privacy Provisions of E-Government Act of 2002](#)

SPECIAL NOTES ON THE REVISED COMMON RULE

The Common Rule governing research with human subjects in the United States was revised in 2017, and took effect on January 21, 2019 (three of the new provisions were allowed to be adopted in July 2018, but Virginia Tech decided against early adoption). None of the changes are especially relevant for this report. The revision did clarify that the use of pre-existing non-identifying data is not human subjects research, which could make data sharing easier for certain large datasets. There are no references to international research within the regulation itself, but the introductory material states that:

The change proposed by the NPRM would apply only to U.S.-conducted portions of studies because the flexibility to make use of local IRB reviews at international sites should be maintained. It might be difficult for an IRB in the United States to adequately evaluate local conditions in a foreign country that could play an important role in the ethical evaluation of the study. (page 60 at <https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf>, accessed on October 25, 2019)

The EU has introduced changes that do impact US researchers, and these are discussed next.

SPECIAL NOTES ON EU GENERAL DATA PROTECTION REGULATION (GDPR)

In May 2018, the GDPR was implemented in the EU. This privacy regulation has a significant impact on researchers from other countries outside the EU collecting data from EU citizens or within EU countries, or accessing personal data from these countries. Although it is still early, most educational opportunities (e.g., webinars) related to this topic recommend that the investigators and IRB office obtain legal counsel before proceeding with these types of projects (collecting or using data from the EU). With time and enough cases, clear guidance might become available for IRBs and investigators such that legal counsel is rarely required.

Arguably the biggest change to the regulatory landscape of data privacy comes with the extended jurisdiction of the GDPR, as it applies to all companies processing the personal data of data subjects residing in the Union, regardless of the company's location. Previously, territorial applicability of the directive was ambiguous and referred to data process 'in context of an establishment'. This topic has arisen in a number of high profile court cases. GDPR makes its applicability very clear – it applies to the processing of personal data by controllers and processors in the EU, regardless of whether the processing takes place in the EU or not. The GDPR also applies to the processing of personal data of data subjects in the EU by a controller or processor not established in the EU, where the activities relate to: offering goods or services to EU citizens (irrespective of whether payment is required) and *the monitoring of behaviour that takes place within the EU* [emphasis added]. Non-EU businesses processing the data of EU citizens also have to appoint a representative in the EU. (<https://eugdpr.org/the-regulation/>, accessed on October 25, 2019)

The most recent guidance on data privacy legislation around the world can be found at: <https://www.consumersinternational.org/media/155133/gdpr-briefing.pdf> (accessed on October 25, 2019). The bottom line is that this field has seen rapid change during the years this project was active, and will continue to change in the coming years.

CHAPTER 3. LANGUAGE, CULTURAL, AND TRUST BARRIERS

LANGUAGE BARRIERS

As mentioned in discussing the regulatory documents, language issues can provide barriers to international research. Even after researchers have gotten past the daunting task of understanding the current relevant laws applicable to the countries where the data will be collected, stored, and analyzed, other language issues can arise. Common examples include:

- The need for translations of consent forms. Who certifies that the two consent forms are equivalent (the one intended to be used by participants and the translation provided to an IRB in another country)?
- The need for translations of IRB or ethics board approval documents. This can be tricky as categories of research may be different across countries (e.g., Exempt versus Expedited and the criteria for each). Is someone available to compare the translation to the original to ensure accuracy?
- The need to ensure that collaborating researchers have a mutual understanding of the human subjects rules and regulations to be followed for the project. This can be especially difficult where cultures are quite different (to be discussed further later in this report). For example, “freely and voluntarily consenting to participate in a research project” may be interpreted differently in different countries. Language barriers can exacerbate existing cultural misunderstandings.
- The need to ensure that project personnel are adequately trained in the principles of human subjects protections. VTTI has encountered cases where researchers from other countries presented what they thought was an IRB training certificate, but was really a certificate for training in the use of animals in research. Someone whose grasp of another language is such that they do not really understand the underlying basic principles is unlikely to also understand the practical application of those principles to the research or data analysis being conducted. This can be especially difficult in academic fields with little human subjects experience. For example, there is a large interest in NDS data in fields such as civil engineering. Even for native English speakers in these fields, the process of obtaining IRB approval and completing a data use license may be a totally new experience. When this is compounded with language barriers, it may be very difficult for researchers to come to a mutual and adequate understanding of the required processes and protections.
- The need to ensure that the original research participants are provided access to someone who speaks their language or dialect, both during and after the study. Adverse events must be reported promptly and accurately, and there must be resources to allow for this at the local level.
- The need for researchers all across the world to be able to understand the conditions under which previous data were collected, and the conditions under which that data may be shared. For example, the SHRP 2 NDS was collected with a CoC and thus all

identifying data must remain stored in the United States. To have access to the identifying data from the SHRP 2 NDS, international researchers must be able to travel here. These conditions are all well-explained to researchers on the InSight website, and yet VTTI often gets requests for “all of the face video,” “all of the GPS data,” etc. Due to language barriers, it is often difficult to convey these concepts to international researchers. Likewise, these researchers may not be able to fully comprehend the terms of service of a website or the terms and conditions of a data use license.

- The need to have resources on hand to handle language barriers in setting up a visit to a secure data enclave, and then conducting output review after a secure data enclave visit. Visitors to the secure data enclaves are presented with a set of enclave policies that must be agreed to and signed before they can begin work. As they work, researchers often make notes (either in a spreadsheet or in a handwritten notebook). All such notes must be inspected before they can leave the enclave to ensure that no identifying data were included. (All de-identified output data must also be inspected, but this does not usually face a language barrier). Large research institutes can often provide these language services, while smaller entities may have difficulties with this requirement.

CULTURAL BARRIERS

In 2014 the National Academies of Science (NAS) hosted a workshop called *Culture Matters: International Research Collaboration in a Changing World* and reported the results in Sloan and Alper (2014). The panel and reporters summed up the issues elegantly and succinctly:

Challenges associated with language differences are perhaps most obvious when one thinks about culture; however, many other challenges come in to play as well when negotiating on a global scale. For example: How do differing cultural attitudes toward ownership of ideas and intellectual property (IP) affect cross-cultural partnerships? How is IP enforced? How is project risk assessed through different cultural lenses? Which country’s legal framework prevails when or if a project goes awry (beyond budget, timeline, etc.)? What happens when ideas about ethics and the conduct of research fail to align or harmonize across geographic boundaries? How does culture influence the wording/shaping/development of standards? What impact does culture have on a nation’s ability to innovate?

Ponder the influence of culture on multi-party, multi-country, possibly multi-disciplinary and/or multi-sector (government, universities, industry, other) partnership arrangements and the questions just keep coming. (Sloan and Alper, 2014, p. 8 of the PDF version)

Cultural differences are complex, even among seemingly similar countries (and even within areas of a single country). In driving research, this can be reflected in people’s regard for driving laws. In certain countries or regions within a country, traffic laws, signs, and devices may be seen as safety suggestions or as impedances to a goal (efficient arrival at a destination). In other countries or regions within a country, the same laws, signs, and devices may be taken much more seriously. A prime example is the push toward stricter and more uniform impaired driving laws. Even with the threat of losing federal highway funds, several states waited until the last possible moment to enact the original 0.10 blood alcohol content (BAC) limit. Other cultural differences can be seen in attitudes towards speeding and novice driver laws (including graduated driver’s licensing systems). These cultural attitudes are even reflected in the old adage of “Driving is a

privilege, not a right.” Many in the United States pay only lip service to that adage, while those in certain other countries truly believe it. Many researchers see marijuana legalization efforts as producing the next big cultural challenge in driving safety research.

Another consideration for cultural differences is in the interpretation of data collected in one country by researchers from another country. For example, a maneuver such as a rolling stop (with minimum speed less than 5 mph) may be coded as lawful driving by a researcher in one country, and as willful disregard for traffic laws by a researcher in another country. Traffic signs may also have different meanings in different countries, and the researcher who plans on using data from another country should have some understanding of that country’s traffic culture. The first author of this report has reviewed several scholarly papers where cultural misunderstandings resulted in erroneous conclusions or limited the generalizability of the results.

TRUST BARRIERS

No one likes being told they are not trusted, whether directly or indirectly. In the current world of big data hackers and data breaches, the words “trust” and “data” are rarely linked. In the years since this project started, we have had numerous national-level financial data breaches, as well as other news stories related to trust (e.g., the Facebook emotion study, the Edward Snowden case; see BBC News, 2014; Bower, 2014; Chow, 2014; Shahani, 2014). Mistrust can arise between collaborating researchers, between researchers and participants, between researchers and oversight agencies, and between participants and oversight agencies. Yet trust plays an essential role in these collaborative efforts. Trust is also a dynamic and fluid concept when it comes to cultural differences and privacy of data.

Some countries are leery of the United States’ oversight of data privacy and human subjects studies after the Edward Snowden and Facebook emotion study revelations. Other countries are wary of the U.S. Patriot Act and what it means in terms of privacy. Researchers often work on tablets and other mobile devices, and may not trust that they can travel into the United States without Border Patrol agents demanding that they unlock their devices and display data that should be held securely.

On the other hand, there may be countries for which the United States has little trust in that country’s ability to conduct studies and protect data. These mistrusts may be due to cultural expectations of privacy, cultural differences in what it means to provide informed consent, or even infrastructure capabilities to store and protect data in certain environments. News stories about widespread hacking of personal financial data may also foster a sense of distrust.

In some countries with poor human rights records, recruitment may be impeded because potential participants mistrust the government or scientists. This is true even in certain black communities in the American south because of past human subjects research abuses. Researchers should plan for additional time and resources where this may be the case.

The bottom line is that researchers should establish professional relationships that foster trust, and should research the potential trust issues ahead of time. Researchers should also try to stay aware of current events in the countries of interest. Researchers should feel free to have trust discussions with their colleagues. Finally, if trust cannot be established in the very early stages of

an international collaborative effort, it is better to abandon the project rather than face years' worth of adverse event reports, data breaches, and publishing rejections.

CHAPTER 4. DATA CATEGORIES

A final consideration is the type of data to be (or already) collected and shared. Different countries treat different types of data differently. For the purposes of this report, there are two broad categories of interest, with two levels in each category: data identifiability (identifying or not) and data provenance (original data versus summarized or derived data).

IDENTIFIABLE DATA

Identifiable human subjects data are held to a higher standard in the rules and regulations than non-identifying data. This is often referred to as PII (a government acronym meaning personally identifiable information). As a general rule, identifying data resulting from a human subjects research project should never be publicly shared. In some cases, low-risk identifying data (such as from a tightly controlled driving study on a test track) may be more freely (but still not publically) shared with explicit consent from participants. Identifying data from a naturalistic driving study are held to an even higher standard because participants cannot know ahead of time what type of data will be collected as they drive for months or even years. Some of the data may put them at legal risk, employment risk (especially in the case of professional drivers), and embarrassment. For teen drivers, such data exposure could put them at risk for years to come. Certain studies, such as those enrolling drivers who admit to using drugs such as marijuana, are held to the highest standard of protection. And once data are made public, they go “into the wild” and will exist in the datasphere for the indefinite future; thus, the need for extreme caution in using and sharing these data. In the field of driving research, the most common identifying data are face video and GPS coordinates (especially at the beginning and end of trips and those associated with crashes).

Non-identifying data are much easier to share. In many studies, they can be publically shared with the explicit consent of participants. In the case of studies with a large amount of data for a particular participant (such as the SHRP 2 NDS, where some participants were enrolled for more than 30 months), the IRBs begin to worry about future reidentification risk given big data techniques, machine learning algorithms, and merging with other existing publically available data sets. Small subsets of data, especially for participants with unusual characteristics, pose another issue. Fortunately, there are now a few transportation researchers with expertise in assessing reidentification risk who can be helpful in guiding the IRB and research team.

DATA PROVENANCE

Most NDS data sets include both original data and de-identified summary data. Original data are collected directly from the participant at enrollment, about the vehicle at installation, from each trip, and about crashes via post-crash interviews, etc. Original data include both identifying and non-identifying data. For the SHRP 2 NDS, all original data must be destroyed 30–40 years after data collection ended (depending on the type of data) and thus must be tracked. Only de-identified summary data may be kept indefinitely. In creating this requirement, the IRBs with oversight for this study expressed concern about future reidentification risk even for data currently considered non-identifying. It is unclear how IRBs will address this in the future since the revised regulations do not consider accessing and analyzing existing de-identified datasets to be human subjects research. The revised regulations do note that federal departments and

agencies shall consult with appropriate experts to reexamine the meaning of “identifiable private information” within 1 year of the revised Common Rule and regularly thereafter (at least every 4 years). These exercises may result in a new definition and description of data considered “identifiable private information.”

CHAPTER 5. GUIDELINES FOR VTTI RESEARCHERS

This research has provided some general guidelines that will be helpful to VTTI researchers who plan to engage in international collaborations that involve the collection and sharing of data. The guidelines can be easily adapted for other research organizations.

1. Become familiar with the relevant guidance in the country where data will be collected, and make sure your cooperating researchers are also familiar with the guidance. If they are not familiar with the guidance, make every effort to recruit someone to the team who is. If English translations are not available, hire an independent translator. Be certain that you are using the most recent regulation and guidance. For long-term projects, check the guidance periodically to ensure that you are up-to-date.
2. Make sure the guidance is, at a minimum, in accordance with the UNESCO Universal Declaration on Bioethics and Human Rights (UNESCO, 2005).
3. Investigate with your local IRB and the ethics board of the cooperating institution what sort of agreement will be reached regarding who will provide assurance of compliance with human subjects regulations or policies. If a Letter of Authorization will be needed (wherein one institution agrees to assure compliance for the entire study), check whether the international ethics board has a Federal Wide Assurance (FWA) number. Some overseas organizations do have an FWA and this is helpful in establishing such arrangements.
4. Make sure that the consent form fully informs the participants. Items that should be covered in the consent form to fully notify participants and facilitate the VT IRB review are:
 - a. Whether VTTI researchers are part of the research team.
 - b. Where the data will be stored. If they will be stored in the United States, specifically at VT, the consent form should say so.
 - c. Any risks that can be anticipated as a result of data being stored outside the country of origin.
 - d. Are there any requirements to warn participants of U.S. federal access to their identifying data? For example, in the Canada NDS, the research ethics board considered having VTTI include a statement to the effect that the Department of Homeland Security could access their data. There may also be issues in cases where vehicles travel across borders, violating either border crossing laws or the laws of the country they are traveling into.
 - e. For the original project, who will have access to the data, for what purposes, for how long, and under what conditions?
 - f. How PII will be stored and protected (e.g., name, contact information, face video, GPS coordinates of home and work)?
 - g. Whether and how the data will be shared with tertiary researchers (e.g., will data use agreements [DUAs] be required? Will additional ethics board [IRB] review be

required for each additional research project? Who will administer these processes for data stored at VT?).

- h. Whether the data are likely to be compared to or mingled with data from other studies.
 - i. Any legal privacy protections obtained (or guaranteed automatically) to protect their data, especially their PII. In the United States, many NDSs are covered by a CoC, but most other countries do not have an equivalent mechanism.
 - j. What are the contractual data rights imparted by the original contract? Are these data rights accurately reflected in the resulting IRB protocol and consent form? If not, be aware that the consent form will trump the contract. It is the PI's responsibility to ensure that these documents agree.
5. If VT will be holding data that may be subject to subpoena from other countries, it is likely that the VT legal department or Office of Risk Management would like to know this ahead of time, and it is *possible* that they may decline the risk (decline to hold the data). If the data are also stored in the originating country, that reduces the risk to VT, but if we are the only storage facility, risk to VT is increased.
6. Ask for advice and help from local and institutional human subjects personnel ahead of time. If the participant signs a defective consent form, it is likely that the VT IRB will not allow use of the data by VTTI researchers, even if the data are stored at VT. Local personnel can provide initial review and can consult with the VT IRB for difficult questions. Depending on your role in the study, it is possible that you will also need to obtain a VT IRB approval or a letter of authorization (ceding IRB authority to another IRB) before data collection begins; local personnel can also help sort this out.
7. Plan ahead of time to share data for any large-scale studies. Many times over the years the sponsor and PI have decided *a priori* that the data would not be shared with others, only to regret this decision a few years down the road when they wish to collaborate with others. Once participants have been told that the data will not be shared, there is no easy way to then share the data.

CHAPTER 6. KEY TAKEAWAYS

- Plan ahead! The most successful large-scale datasharing projects begin planning years ahead of data collection, and involve a great deal of pre-data collection collaboration (e.g., the SHRP 2 NDS [Dingus et al., 2015] and the European Field Operational Test Networking and Data Sharing Support [FOT-Net; Gellerman et al., 2017]). Even after years of discussion, planning, and collaboration, the key people in this field are still having a lot of in-depth conversations regarding data sharing when they happen to be at the same meeting (Figure 1).
- This field is changing rapidly and current resources should be consulted immediately prior to preparation of consent documents and protocols to be used in other countries. However, once you have an approved protocol, it should remain valid even if the rules change later. Be sure to search out the most current information related to the country of interest.
- The Common Rule governing research with human subjects in the United States took effect on January 21, 2019 . The revision clarified that the use of pre-existing non-identifying data is not human subjects research, which could make data sharing easier for certain large datasets.
- Many countries have both general laws/policies/guidelines for the collection of human subjects data and additional guidance related to the storage and further use of human subjects data. In some cases this guidance matches very closely with U.S. regulations, while in other cases it can be either more or less restrictive.
- Trust plays a large role in these collaborative efforts. Trust is a dynamic and fluid concept when it comes to cultural differences and privacy of data.
 - a. Some countries are leery of the United States' oversight of data privacy and human subjects studies after the Edward Snowden and Facebook emotion study revelations. Other countries are wary of the U.S. Patriot Act and what it means in terms of privacy.
 - b. There may be countries for which the United States has little trust in a country's ability to conduct studies and protect data. These mistrusts may be due to cultural expectations of privacy, cultural differences in what it means to provide informed consent, or even infrastructure capabilities to store and protect data in certain environments. News stories about widespread hacking of personal financial data may also foster a sense of distrust.
 - c. In some countries with poor human rights records, recruitment may be impeded because potential participants mistrust the government or scientists. Researchers should plan for additional time and resources where this may be the case.
 - d. Researchers should establish professional relationships that foster trust, and should research the potential trust issues ahead of time and be aware of current events in the countries of interest.

Researchers are encouraged to read resources such as *Culture Matters: International Research Collaboration in a Changing World—Summary of a Workshop* (Sloan and Alper, 2014) prior to beginning work. This reference (and there may be others as well) provides many additional examples and considerations to help researchers think through the issues.



Figure 1. Photo. Lee (US), Gellerman (EU), and Brach (US) encountering and plugging a data breach at the Madurodam, The Hague, The Netherlands, June 2017.

REFERENCES AND FURTHER READING

Note that all referenced materials are in the possession of the first author of this report and can be requested as needed.

Australian Research Council, National Health and Medical Research Council, and Universities Australia. (2018). *National statement on ethical conduct in human research*. Retrieved from <https://www.nhmrc.gov.au/guidelines-publications/e72>

BBC News. (2014, July 4). Official complaint filed over Facebook emotion study. Retrieved from <http://www.bbc.com/news/technology-28157889>

Bower, B. (2014, July 3). Main result of Facebook emotion study: Less trust in Facebook. *Science News*. Retrieved from <https://www.sciencenews.org/blog/scicurious/main-result-facebook-emotion-study-less-trust-facebook>

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. (2010, December). *Tri-Council policy statement: Ethical conduct for research involving humans*. Ottawa, Ontario, Canada: Interagency Secretariat on Research Ethics. Retrieved from http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf

Chow, D. (2014, July 4). Journal responds after controversial Facebook emotion study. CBS News. Retrieved from <http://www.cbsnews.com/news/controversial-facebook-emotion-study-journal-responds/>

Department of Health and Human Services. (2013). *International compilation of human research standards, 2013 edition (Word format)*. <http://www.hhs.gov/ohrp/international/>. Accessed on December 5, 2012.

Department of Health and Human Services. (2014). *International compilation of human research standards, 2014 edition (PDF format)*. Retrieved from <http://www.hhs.gov/ohrp/international/intlcompilation/2014intlcomp.pdf.pdf>. Accessed on November 21, 2014.

Department of Health and Human Services. (2015). *International compilation of human research standards, 2015 edition (Word format)*. Retrieved from <http://www.hhs.gov/ohrp/international/>. Accessed on October 2, 2015.

Department of Health and Human Services. (2017). *International compilation of human research standards, 2017 edition (PDF format)*. Retrieved from <https://www.hhs.gov/ohrp/sites/default/files/international-compilation-of-human-research-standards-2017.pdf>. Accessed on October 2, 2017.

Dingus, T. A., Hankey, J. M., Antin, J. F., Lee, S. E., Eichelberger, L., Stulce, K. E., McGraw, D., Perez, M., & Stowe, L. (2015). *Naturalistic Driving Study: Technical coordination and quality control (SHRP 2 Report S2-S06-RW-1)*. Washington, DC: Transportation Research Board of the National Academies. Retrieved from

- http://onlinepubs.trb.org/onlinepubs/shrp2/SHRP2_S2-S06-RW-1.pdf. Accessed October 3, 2017.
- European Union. (2017). Collecting and processing personal data: What is legal? Retrieved from http://ec.europa.eu/justice/data-protection/data-collection/legal/index_en.htm. Accessed on September 27, 2017.
- Gellerman, H., Svanberg, E., Kotiranta, R., Koskinen, S., Heineg, I., Val, C., Koskinen, S., Innamaa, S., Zlocki, A., & Bakker, J. (2017). *FOT-NET data: Data sharing framework* (Final Report Prepared for the FOT-Net Data Project: Field Operational Test Networking and Data Sharing Support. Funded by the European Union's Seventh Framework Programme, Information and Communication Technologies, Coordination and Support Action). Retrieved from <http://fot-net.eu/Documents/data-sharing-framework/>
- National Institutes of Health. (2015). *Certificates of confidentiality kiosk*. Retrieved from <https://grants.nih.gov/grants/policy/coc/index.htm>. Previous version accessed on October 5, 2015.
- National Institutes of Health. (2017a). *Notice of changes to NIH policy for issuing certificates of confidentiality* (NOT-OD-17-109). Retrieved from <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>. Accessed on October 2, 2017.
- National Institutes of Health. (2017b). *Certificates of confidentiality for research funded by non-HHS federal agencies*. Retrieved from <https://grants.nih.gov/policy/humansubjects/coc/who-can.htm#non-HHS%20agencies>. Accessed on April 3, 2019.
- Office for Human Research Protections. (2017). Final revisions to the Common Rule. Retrieved from <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html>. Accessed on January 20, 2017.
- Protection of Human Subjects, United State Code of Federal Regulations, 49 CFR part 46. Retrieved from <http://www.hhs.gov/ohrp/policy/ohrpreulations.pdf>. Accessed on October 5, 2015.
- Shahani, A. (2014, June 5). A year after Snowden, U.S. tech losing trust overseas. National Public Radio. Retrieved from <http://www.npr.org/blogs/alltechconsidered/2014/06/05/318770896/a-year-after-snowden-u-s-tech-losing-trust-overseas>
- Sloan, S. S., & Alper, J. (Rapporteurs). (2014). *Culture matters: International research collaboration in a changing world--Summary of a workshop*. Retrieved from <http://www.nap.edu/catalog/18849/culture-matters-international-research-collaboration-in-a-changing-world-summary>. Accessed on October 2, 2015.
- Taylor, M. (2017, September 3). Offshore human testing of herpes vaccine stokes debate over U.S. safety rules. *Santa Fe New Mexican*. Retrieved from

http://www.santafenewmexican.com/news/health_and_science/offshore-human-testing-of-herpes-vaccine-stokes-debate-over-u/article_1d6e277b-b031-5af0-9e84-128775e4c038.html

United Nations Educational, Scientific, and Cultural Organization. (2005). *Universal declaration on bioethics and human rights*. Retrieved from <http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/>. Accessed on November 21, 2014.

World Health Organization. (2017). Road traffic injuries fact sheet. Retrieved from <http://www.who.int/mediacentre/factsheets/fs358/en/>. Accessed on September 27, 2017.