# DATA USE AGREEMENTS

<table>
<thead>
<tr>
<th>Data Type</th>
<th>Is a DUA Required?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Human Data</td>
<td>No (but may be recommended)</td>
</tr>
<tr>
<td>De-identified Human Data</td>
<td>No (but may be recommended)</td>
</tr>
<tr>
<td>Limited Data Set</td>
<td>Yes</td>
</tr>
<tr>
<td>Human Data exceeding LDS</td>
<td>Yes</td>
</tr>
</tbody>
</table>

### Who signs the DUA?

The agreement needs to be set up as a contract between institutions and signed by an Authorized Official who is capable of binding the University to the terms. While NU PIs are often required to sign as “Read and Understood” they cannot sign on behalf of the University.

To set up a DUA, email the appropriate (inbound or outbound) Request Form to mta@northwestern.edu. Questions? please call (312)-503-0884.
One Success in Research Ethics

Published November 3, 2014 | By Julian Savulescu

Research ethics committees often behave unethically*. One example is their failure to understand the ethical basis for obtaining consent and the appropriate limitations. There is a simple rule – “get consent”. I discuss this in greater detail in Bioethics: Why Philosophy Is Essential to Progress, JME 40th Anniversary Issue.

But ethics is more complicated than this. It involves the weighing of different ethical reasons. Sometimes, those reasons can speak overall in favour of not obtaining consent in the way prescribed by various ethical guidelines. Deliberation is required. It is important to also consider the value of good research.

I was Chair of the Department of Human Services Victoria Ethics Committee between 1998-2002, I tried to improve various aspects of research review. You often don’t know if anything you do has any beneficial effect. But recently, Pam Snow came up to me after a lecture. I couldn’t remember her but she kindly told me her story. Here it is. I am relating it as a case study in how “deliberative” research ethics review can actually do some good. I asked her to put her thoughts in writing to show how ethicists can work with researchers to find a way to bring about a good outcome.

Dear Julian

It was nice to meet you this evening.

As per our chat, I wanted to acknowledge the very significant contribution you made in the early days of our research into the oral language skills of young people in the youth justice system.

By way of context, I’m qualified in both speech pathology and psychology, and back in the late 1990s was working in a child and adolescent mental health research role with a focus on drug and alcohol misuse. I had occasion to be thinking about “high risk” young people, and in considering the role of academic achievement/failure in this context, began to be interested in the contribution of expressive and receptive oral language skills, given that the transition to literacy draws heavily on a child’s underlying oral language skills. Obviously young offenders as a group typically do not successfully make the transition to literacy and so depart school early, with all the associated risks. For this reason, we wanted to examine the possible contribution that undiagnosed language disorders...
make to early academic disengagement in young people with other risks (dare, I say, after tonight’s presentation) of a bio-psycho-social nature.

My first challenge was to get a foot in the door with youth justice to gain access to a research sample. Happily this proved easier than I had expected, as I was fortunate to make contact with a regional manager you “got it” and was keen to support the first study. When I mentioned that my university ethics committee would require parent/guardian consent, however, her response was “well you can forget the study then”. Her argument (very reasonable and logical) was that many young people in youth justice have relationships with parents that are somewhere between non-existent and plain damaging. As you would realise, many young people enter youth justice via child protection, so this makes sense. I discussed this issue with the university ethics chair and was emphatically told that because this was “high risk” research (by virtue of it involving young offenders), and because the participants were, by definition, minors, I would indeed need parent/guardian consent.

I rang around to some academic ethics colleagues for some advice, and someone (whose name now escapes me) suggested that I speak to you, in your role as DHS Ethics Chair. To be honest, my unstated assumption was that DHS would be even more hard-line on this than the university and it hadn’t occurred to me that this would be productive. I recall a very reasonable conversation with you, in which you asked about the nature of the study (administering standardised measures of language skills) and associated risks (minimal) and you suggested that we should engage with youth justice key workers and ask them to act in loci parentis with respect to ensuring that the young person understood the ethics documents and the fact that participation was voluntary etc. The Youth Justice manager I was dealing with was delighted with this compromise and wrote a letter in support for the university ethics committee (as of course did you). Happily the university ethics committee ultimately accepted this compromise and the research proceeded.

We are now completing our 5th youth justice study and have clearly identified young offenders as a group that is high risk for unidentified language impairments (present in about 50%, in both community and custodial settings). We’ve also shown an association between language impairments and more complex patterns of offending and have written a lot about implications for restorative justice conferencing (a very verbal process), forensic interviewing, and counselling. A pilot cluster RCT focussing on improving teacher practices re language and literacy in early years classrooms in disadvantaged communities showed positive results, and an ARC Linkage-funded project is now taking that work to scale across 87 disadvantaged schools in Victoria. For the first time, we have a youth justice centre in Australia (Parkville in Melbourne) employing a Speech Pathologist – and moves are afoot to increase staffing there over time. Some of our papers are routinely used by youth justice sectors in training and induction packages for new staff, and we’re also in the process of conducting an intervention study in a custodial setting in NSW. I’m regularly asked to address justice and welfare audiences about this work and have also given a number of invited presentations to judicial colleges around Australia. Next week, I’m addressing the National Juvenile Defenders’ Summit in the USA, as a USA law professor at Madison has shown a real interest in this research and its implications for how young people are processed through the justice system.

So – I like to think that we’re having some modest impact, but am quite certain that this body of work would not have seen the light of day had we accepted the mandatory parental/guardian consent ruling that was initially applied. As I mentioned, the fact that we got that initial waiver has meant that successive ethics committees (university and justice) have followed suit. In 15 years, and 350+ young people, we’ve had no ethical incidents. Ironically, the degree of hidden impairment experienced by this group would have remained hidden had this not occurred – a far bigger ethical travesty I would think, than assessing young people’s language skills without their parents’ knowledge or consent.

For the record, here’s the key publications that have come out of this work:


http://blog.practicalethics.ox.ac.uk/2014/11/one-success-in-research-ethics/


Snow, P. C., Sanger, D.D. & Bryan, K. (2011). Listening to adolescents with speech, language and communication needs who are in contact with the youth justice system. In S. Roulstone, & S. McLeod, (Eds). Listening to children and young people with speech, language and communication needs (pp. 111-120). London: J&R Press.


http://blog.practicalethics.ox.ac.uk/2014/11/one-success-in-research-ethics/

Apologies that this is a bit more than a couple of paragraphs, but hopefully it covers the bases – please let me know if not.

Kind regards

*Pam*

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Posted in Julian Savulescu's Posts, Research Ethics

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http://blog.practicalethics.ox.ac.uk/2014/11/one-success-in-research-ethics/
Older people were less inclined to share anonymized health data, an NPR-Truven Health Analytics poll found. Americans, by and large, don't seem all that worried about what happens to the information in their medical records.

A NPR-Truven Health Analytics Health Poll found that data privacy didn't appear to bother most respondents. Privacy worries ran highest for information held by health insurers, but even then only 16 percent of people expressed concern.

Because we're nerds, we were curious to learn more about how Americans feel about sharing health data for research purposes. So we interviewed 3,010 people by cellphone, landline and online in December.

A majority of the people we asked said they would be willing to share information anonymously with health care researchers. Overall, 53 percent said that would be OK and 47 percent said no.

But the proportion of people willing to share information for research purposes was 15 percentage points lower than when we asked the same question in August and found that 68 percent were game. Why the change? Part of it could be that when we asked the first time around the question came after others on the use of electronic medical records by doctors, employers, insurers and hospitals. The context might have affected how people responded.

It could also reflect heightened sensitivity about data security. "Over the last quarter, major privacy breaches have been a hot topic in American culture – from leaked pictures of celebrities to the extensive Sony hack," says Dr. Michael Taylor, chief medical officer at Truven Health Analytics. "We don't know whether it's a temporary response influenced by these or other factors, but Americans may be more protective of the information they are willing to share electronically."

There was some variation in the latest poll among people who expressed a willingness to share anonymized data. Sixty-one percent of adults younger than 35 were fine with the idea compared with only 43 percent of people 65 and older.

The possible topics of research didn't matter much to people who said they were willing to share. Every category — ranging from safety issues to reining in health costs — scored support from at least 90 percent of the potential sharers.
And most people didn't seem to care who would be using the data, whether they would be researchers in government, universities, drug companies or consulting firms. Comfort with these researchers ran between 87 and 92 percent. Support for university professors varied more than that for other categories. Ninety-five percent of sharing-inclined people under 35 were OK with giving anonymized data to professors compared with just 74 percent of people 65 and older. The overall margin for error for the poll is plus or minus 1.8 percentage points. You can find the full set of questions and responses here and the findings from previous NPR-Truven Health Analytics Health Polls here.
Thirteen Questions for an IRB to Ask When Evaluating Risk

By Dennis J. Mazur and Norman M. Goldfarb

Assessing risk is a fundamental institutional review board (IRB) responsibility. To reach the right conclusion about risk, IRBs must first ask the right questions, since risk is a complicated matter in clinical research. Risks have two main components: severity and probability. Severe, high-probability risks are of major concern. Even unlikely severe risks are of concern, precisely because they are rare events, so less is understood about them. Study participants will also want to understand risk of relatively minor severity, e.g., temporary confusion, disorientation and nausea. Other combinations of severity and probability also need to be sorted out by the IRB. Assessing the severity and probability of risks is challenging — after all, we’re talking about research — but IRBs must do the best they can under the circumstances.

When IRB members talk about risks, they need a vocabulary to discuss the risks. Objective, quantitative descriptors, e.g., “a likelihood of 10%” or “one week in the hospital” are best, but are seldom available. In most cases, only qualitative descriptors, such as “unlikely” or “severe” are at hand. If such descriptors are used, they should be defined as precisely as possible (e.g., “unlikely” might mean “a 1-10 chance out of 1,000”), since such terms mean different things to different people. The description of the risk is also important, e.g., “stroke” or “stroke that might cause irreparable physical or cognitive damage.”

Risk and uncertainty are two different concepts. The existence of a risk implies both severity and probability. To the extent these statements are imprecise, there is uncertainty. For practical purposes, there is always some level of uncertainty, so the question is whether there is enough certainty. It is much easier to assess risks for which the severity and probability are well-known. If both parameters are very uncertain for a Phase III study, and the IRB has reason to be concerned, the study drug or device might not be ready for Phase III testing.

The 13 Questions

When assessing the risk of a study, the IRB should ask the following questions:

1. **What are the risks?** Mental or physical injury to the study participant is an obvious concern, but are there also, for example, privacy risks, or risks to others, such as family members or study team members? IRBs should not assume that the absence of known risks means there are no risks. Even with an approved drug or device, very rare risks might not become apparent until many thousands of patients have been treated. Thus, even apparently safe studies should have some scientific merit to be approved.

2. **How well understood are the severity and probability of each risk?** For example, how much is known about the pertinent physiology? Do previous studies provide adequate information on the risks? Can information be extrapolated from other drugs or devices in the same class? How are the researchers assessing the risks of a newly developed drug (with a new mechanism of action) that has barely been tested on human research subjects?

3. **Does the IRB have adequate expertise to objectively assess the risks?** If the expertise of the Board members is insufficient, can outside experts, other IRBs, or
federal regulators provide advice? Does the IRB need to hear a pro/con discussion among experts?

4. **Is the IRB able to assess risk in an objective and unbiased manner?** An expert’s bias can be caused by a conflict of interest, a particular past experience, or simply by his or her attitude toward risk in general — “better safe than sorry” or “nothing ventured, nothing gained.”

5. **Do the potential benefits to study participants and generalizable knowledge justify taking the risks?** Potential benefits have their own significances and probabilities. If participating in a study might, in fact, benefit study participants, how does the consent form explain the potential benefits? Not disclosing potential benefits is a disservice to potential participants.

6. **Will potential study participants understand the risks?** Are the risks accurately described in non-technical language? Are the risk descriptors quantitative, qualitative or absent? Are the real risks obscured by a cloud of unlikely or inconsequential risks? Does the consent form understate the risks? On the other hand, erring on the side of overstatement does not help if it unduly frightens potential participants from enrolling in the study.

7. **What treatment options do study subjects have outside the study?** Is the risk/benefit ratio of standard-of-care treatment higher or lower than the study treatment? Does the study’s informed consent form adequately explain the pros and cons of clinical treatment versus research participation?

8. **Does the protocol minimize the risk to each participant and to the study population as a whole?** For example, is liver enzyme, genomic and other testing adequate to screen out vulnerable participants? Does the consent form adequately explain any limitations in screening out participants subject to particular risks?

9. **Who in the potential study population is vulnerable to the risk?** Excluding vulnerable patients from research participation may protect them, but it interferes with creating generalizable knowledge.

10. **When does the risk occur?** If it occurs within an hour of treatment, subjects should be kept for observation. If it occurs within a day of treatment, a call the next day makes sense. If it might occur after months or years, a monitoring plan should be created.

11. **If harm occurs, how will it be identified?** What is the impact on the study participant if it is not identified in a timely manner?

12. **If harm occurs, how will it be handled?** What suffering, cost and inconvenience will the study participant experience? Who will perform the treatment? Will treatment provide a cure? How will it be determined whether the harm was caused by the study? Who will pay for the treatment? Will any compensation be paid for the injury to the study participant? By whom? Who

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**Example Risks for IRB Members to Consider**

As an exercise, draft consent form language that explains the following severe but rare risks:

- Malignant hyperthermia
- Neuroleptic malignant syndrome
- Tardive dyskinesia

Should each consent form have the same explanation?
13. **Taken as a whole, are the risks acceptable?** Is there a single risk that is unacceptable or a set of risks that, in aggregate, are unacceptable? What is it about the unacceptable risks that make them unacceptable?

**Conclusion**

Asking the right questions is half-way to getting the right answers. With the 13 questions above, IRBs can discuss the risk of clinical studies in a structured way that is likely to draw out the real risks and assess their significance.

**Author**


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