

## Is the principle of autonomy a sound-enough basis for consent?

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One of the key issues that human research ethics committees (HRECs) commonly focus on is ensuring that the participant consent obtained for research is appropriate and sufficient. The *Australian National Statement on Ethical Conduct in Human Research* (National Health and Medical Research Council, 2007) provides a strong outline (NS 2.2) concerning informed consent and a detailed list (NS 2.2.6) of the information that should be provided to participants before they make a decision whether or not to participate in a research project involving them or their data.

In common with much of the scholarship on consent and autonomy (See e.g. Dworkin, 1988) the *National Statement* bases consent in the principle of respect for humans – and, notably, human autonomy. Respect in the *National Statement* can be seen as having four aspects, expressed in general within the Introduction to Section 1 and in particular within paragraphs 1.10-1.13.

- Recognising the intrinsic value of a human being, including due regard for “the welfare, beliefs, perceptions, customs, and cultural heritage, both individual and collective, of those involved in research”. (NS 1.10)
- Respect for the privacy, confidentiality and cultural sensitivities of participants and their communities. (NS 1.11)
- Respect for the capacity of people to make their own decisions. (NS 1.12)
- Providing appropriate protections or empowerment for those who may be ‘unable to make their own decisions or have diminished capacity to do so’. (NS 1.13)

As respect for autonomy (limited here to the capacity to for people to make their own decisions) is evident only in paragraph 1.12 it can be inferred that respect for humans encompasses more than respect for autonomy alone. However it is respect for autonomy that is the primary influence on informed consent, a position that goes back at least to the Belmont Report (1979) and all editions of Beauchamp and Childress’s *Principles of Biomedical Ethics* (1977-2009) .

In this paper we reflect on consent. In particular we focus on informed consent and its reliance on autonomy, and ask why informed consent is needed. The intention is to open a discussion rather than provide solutions to some of the problems that arise with consent and autonomy.

Most of us are familiar with government, organisations or companies retaining and using our (often personal) information. In most instances they are relatively free to utilise information about us so long as they abide by appropriate privacy provisions.<sup>1</sup> Indeed, in some instances we would be worried if an organisation (such as a bank or medical practice) did not share and manage our personal information (at least within the organisation) such that all relevant staff have access to pertinent information about us and are able to provide reliable and consistent service across that organisation. We are accustomed to some of this information being shared between organisations (e.g. banks being required to give the taxation department access to customer account details). We are also becoming more aware of the kinds of information available about us in other contexts – e.g. information on the internet, on mobile phones and electronic devices, information from our commercial transactions and the like, and how this may be accessed and used by others (See e.g. Ferguson, 2013).

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<sup>1</sup> e.g. The Australian National Privacy Principles in the Privacy Act 1988 (Cth) s 3. It is noted that in 2014, after this paper was written, the Australian Privacy Principles (APPs) replaced the National Privacy Principles and Information Privacy Principles

Much data about such things as our buying preferences, our relationships and other aspects of our lives formerly thought to be private are gathered by commercial organisations that are not governed by the same restrictions as those governing research by academic institutions. Supermarkets and online retailers, for example, use information about our shopping habits to target us with personalised advertising, vouchers and offers. Those who shop online may notice that web pages frequently include advertisements for products related to those they have bought recently. Supermarkets have detailed data available through loyalty programs and in addition they track shopping docket, use of credit/debit cards and other information on spending habits. Based on significant research with sophisticated methodologies, supermarkets and online vendors can come to understand what each individual is likely to purchase and can provide individual incentives such as personalised special offers. Race, occupation, relationship status, age, family details are all crucial for tracking individuals, and in other contexts may be viewed as private or sensitive information, yet this sensitive information is relatively simple to obtain. Research by large commercial operations into our buying habits, our viewing habits and so on is achieved without the kind of approvals or consent usually required in a university, hospital or clinical trial research context. Despite the lack of fully-informed consent from those whose information is collected, we should neither assume that the methodological approaches and processes are simple nor that the consequences are benign. Commercial research of the type just described poses ethical risks: it lacks transparency (no consent is sought and results are not published) and as a consequence there is little understanding by individuals of what is being done with their data, by whom, how and to what ends. In addition, corporations acquire property rights over data from individuals, rights that may serve to place a burden on those whose data are acquired.

In Australia, enormous amounts of data are collected by governments and corporations – often without consent. Much of the data are stored on computer systems which may be located or backed up in other jurisdictions or even in other countries, thus potentially weakening privacy and legal protections that may be in place within a particular national jurisdiction. We may have some notion that our personal data are being collected, however consent for government or corporations to collect data about us is often weak, at best, and most citizens probably remain unaware of how much data is collected, of what type, where it is stored and either what is done with it or what *can* be done with it.

But what is meant by consent? In the Commonwealth *Privacy Act (1988, s.6(1))* the term ‘consent’ is defined as ‘express consent or implied consent’: it is not further explained or expanded. However, further explanation comes from the Office of the Australian Information Commissioner (OIC) which explains consent as

voluntary agreement to some act, practice or purpose. It has two elements: knowledge of the matter agreed to, and voluntary agreement. Consent can be express or implied. Express consent is given explicitly, either orally or in writing. Implied consent arises where consent may reasonably be inferred in the circumstances from the conduct of the individual and the organisation. Consent is invalid if there is extreme pressure or coercion.

Only a competent individual can give consent although an organisation can ordinarily assume capacity unless there is something to alert it otherwise. Competence means that individuals are capable of understanding issues based on reasoned judgements and communicating their decisions. The general law about competence and incapacity will apply to the issue of consent.(Office of the Federal Privacy Commissioner, 2001)

Capacity (or competence – the terms are equivalent in Australian law)(Victorian Law Reform Commission, 2012 p. 99) is necessary for consent. The *Guidelines on Privacy in the Private Health Sector (Office of the Federal Privacy Commissioner, 2001a)*, for example, identifies the elements of

consent as: consent must be voluntary; consent must be informed (the individual must know what they are agreeing to) and; the individual must have the capacity to provide consent.

The *National Statement* says, in part,

the requirement for consent... has the following conditions: consent should be a voluntary choice, and should be based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.

The process of communicating information to participants and seeking their consent should not be merely a matter of satisfying a formal requirement. The aim is mutual understanding between researchers and participants (Para 2.2.4)... No person should be subject to coercion or pressure in deciding whether to participate (2.2.9)

The principle of respect for autonomy underpins the idea of consent in the *National Statement* (1.12) and capacity underpins consent at law. The terms capacity and autonomy do not describe exactly the same things, but are near synonyms. As the Victorian Law Reform Commission notes:

Capacity is a legal concept that describes the level of intellectual functioning a person requires to make and accept responsibility for important decisions that often have legal consequences. Capacity is linked to the significant value of respect for autonomy, which is 'the authority to make decisions of practical importance to one's life, for one's own reasons, whatever those reasons might be'.

Autonomous people are presumed to have the necessary level of intellectual functioning, as well as the right, to make their own decisions. Medical ethicists Tom Beauchamp and James Childress suggest that while: autonomy and competence differ in meaning (autonomy meaning self-governance; competence meaning the ability to perform a task or range of tasks) the criteria of the autonomous person and of the competent person are strikingly similar." (Victorian Law Reform Commission, 2012 Paras 7.11, 7.12 )

So, consent based on respect for autonomy will look the same as consent based on capacity (competence). Whatever its basis, if such consent is so important that it is required of all publicly-funded research in Australia (and similarly in many other countries) why is it not also required of data-gathering by governments and private commercial research? Under the Commonwealth *Privacy Act (Commonwealth of Australia, 1988)*, the gathering of specified data by Australian governments does not require consent from the people of Australia, but the Act puts in place National Privacy Principles as protection for those whose data are collected. However apart from the National Privacy Principles (in particular the limited effects of Section 95, 95A which deal with releasing information for medical and other health research and 95AA which allows disclosure of genetic information in some circumstances) and the Therapeutic Goods Administration's (2000) version of guidance on good clinical practice, the issue of what should govern private research is unresolved. If the primary reason for constraining research is to protect the public, we might conclude that either private research should be conducted under the same constraints as those governing academic research, or the constraints on all research need to be re-assessed.

In the research context, we are familiar with the concept that a participant should be able to consent, or not, to everything asked of them. Such consent commonly comes in a number of forms:

**Explicit or opt-in consent.** This is probably the most common form of consent sought. Generally this involves some written or verbal information about the proposed research, a being provided to a potential participant. The information needs to furnish enough information to enable an informed, voluntary choice whether or not to participate in the research. This approach to consent is usually

considered the best as it most clearly demonstrates adherence to the value of respect for human beings and their autonomy. But should the emphasis be on respect for humans or on respect for autonomy? The *National Statement* – in common with the Belmont Report (1979) and Beauchamp and Childress (2009) – opts for respecting autonomy and defines it as ‘the capacity to determine one’s own life and make one’s own decisions’ (p.11). It bases respect for autonomy on their being intrinsic value in humans, value that ‘must inform all interactions between people’. Intrinsic value is itself a problematic notion within moral philosophy but that is not the only issue at play in this small section of the *National Statement*. It says that ‘respect goes further than this’ and also ‘involves providing protection for those with diminished or no autonomy’ (p.11). If it is autonomy that is to be respected, rather than persons (as some bioethicists would have it) what is the moral basis for us being required to protect those with no capacity to determine their lives and make their own decisions? There are other issues related to autonomy, which will be canvassed later.....

Opt-in consent assumes that potential participants have been given sufficient information about the proposed research to enable them to weigh up the risks and benefits for themselves and to reach an informed judgment whether or not to participate. One difficulty is that sometimes this process can provide too much or too-detailed information to participants who are then unable to understand sufficiently what is to be done by whom, to whom, when and where – and they are unable to determine for themselves what the risks are (Steinsbekk & Solberg, 2011 p. 237). It may also be the case that there is too much information for the research purpose in that it can corrupt the research design. In this case there is a tension between respecting autonomy and subverting the research itself.

**Enduring consent.** Enduring consent is probably best understood as a modification of informed consent. It most commonly applies to data in biobanks and databanks and is also known as open or broad consent (See e.g. Sutrop, 2011). Here the participant effectively agrees to their information being stored for unstated future use. There may be constraints on the use, such as having to seek ethics approval before interrogating the data or accessing tissue samples, but such consent is by its nature not informed consent. It is related in many cases to waiving the requirement for consent.

**Implied consent.** This is applied to many, usually anonymous, surveys where completing a survey and pressing the ‘submit’ button on a website is taken to be consent. However, participation is likely to take place without adequate information being provided to potential participants.

**Opt-out consent.** This commonly involves providing information to participants on the basis of which they can choose to decline to participate or stop participating. In research involving this people are participants unless they act to stop their participation. At the time of writing the *National Statement* did not include an opt-out approach to consent but public consultation was undertaken in 2012 to solicit responses to a suggestion to include an opt-out approach for “some low and negligible risk research, particularly for information which is to be stored or is already stored in a databank” (National Health and Medical Research Council, 2012).<sup>2</sup> Under an opt-out approach people (or, more specifically, their data) will be included in research unless they communicate a choice not to. Opt-out consent is often used for gathering large – often benign – data sets, surveys and for large population studies. Such consent is also sometimes used when an entire group is part of a study and when the ethical risks are low. The opt-out approach may be considered ethically contentious. There is a risk that participation in research will occur without the understanding or desire of those from

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<sup>2</sup> It is noted that in March 2014, after this paper was presented, Chapter 2.3 of the *National Statement* was updated to include guidance on the use of an opt-out approach. The NHMRC’s advice on the change notes that the approach is limited to low-risk studies and must be used in a manner consistent with the whole of the *National Statement*, notably paragraphs 2.2.19 and 2.2.20 (<http://www.nhmrc.gov.au/health-ethics/human-research-ethics/inclusion-advice-opt-out-approach-national-statement-ethical-con>).

whom the data are to be obtained. Opt-out consent also forces people to make a decision that they would ordinarily not have to make: that is, they are in the study unless they make a decision not to be. Such consent is considered methodologically important where entire populations need to be sampled but it is less rigorous and offers less protection of a potential participant's autonomy than other forms. Opt-out consent, while still requiring that sufficient information is made available to potential participants, is unable to ensure that a prospective participant has been individually given and has considered the information about the research in detail before participating. Members of the public are likely to benefit from innovations generated by large population studies and that may be used as a justification, but this requires a departure from the presumption that respect for individual autonomy is the most important element. The public benefits from large population studies and the like and, because an individual stands to benefit, it may be thought that he or she has an obligation to contribute to such studies. However, if participation in a study is predicated on such an *obligation* this would be an inversion of the common view that the primary concern of consent is protection of an individual's assumed *right* to control what happens to him or her and his/her personal information.

**Waiver of consent.** The term 'waiver' usually implies that a person has reached a deliberate decision to relinquish their right to consent; and this is the case in many instances, for example where a donation of tissue or data is made and the person consents to enabling the tissue or data to be provided to other researchers for as yet unknown research. The *National Statement* extends the idea of 'waiver' to allow a Human Research Ethics Committee to approve some kinds of research where no express consent has been sought. Only an HREC may approve research using personal information in medical research where this is obtained through such a process (National Health and Medical Research Council, 2007 para 2.3.5).

A waiver of consent is effectively in place for the use of human tissue acquired as the by-product of surgery or the leftovers from routine diagnostic services such as blood samples and biopsy tissue because the law is not clear on the issue. As the Australian Law Reform Commission notes: "At present, Australian legislation does not address the property status of genetic samples. Instead, the legal status of genetic samples is governed by the common law. However, the common law position on property rights in human tissue samples is not well developed, and there is no clear judicial statement on the issue" (Australian Law Reform Commission, 2003 s20.10). Use of such tissue is excluded from the Australian human tissue Acts. It is not clear to what extent people are aware that their tissue may be used for research without consent.

**Other models.** There are also some models that can combine different consent formats. A parent may, for instance, sign a generic or standing consent for their child to be involved in school-based research (NS 4.2.10); and the student later be asked to opt-in to or opt-out of a particular study, in their own right, without further reference to a parent - whether or not the parents are informed about the specific study. In some cases consent may be given by a competent proxy<sup>3</sup> or needs to be witnessed by a competent person to ensure that consent is based on clear understanding of what will happen in the research. In other cases consent may be provided communally and affirmed individually (e.g. in some villages where the head person gives overarching consent and individual affirmation is sought only due to HREC requirements).

HRECs commonly consider the quality and impact of the consent and also other factors such as the ability of participants to withdraw from the study and any limitations to withdrawal (e.g. it is no longer possible to withdraw once data have been anonymised or collated).

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<sup>3</sup> In Western Australia the Guardianship and Administration Act limits this proxy approval to cases where the risks are low

## Autonomy

HRECs assume that people generally have autonomy and base their protection of participants, in part at least, on the idea of respect for autonomy. But what is autonomy? A closer examination reveals that it is not as simple as defined by the *National Statement* – ‘the capacity to determine one’s own life and make one’s own decisions’ (p.11). Is autonomy limited to control over one’s body? How far does or should such control extend? Does it include potential as well as capacity? Newborns do not yet have the capacity to determine their lives and make decisions, yet. In terms Aristotle might use (See e.g. Aristotle, 2013), newborns (in the normal way of things) have the *potential* to determine their lives and make decisions, but not the *actuality* of being able to do so. And what of people in a permanent vegetative state? They may have *had* the capacity to determine their own lives, but perhaps no longer do. Does their lack of capacity of autonomy mean that they should no longer be treated as morally considerable? If they are morally considerable but lack the potential and the actuality of autonomy, then autonomy alone is not a sufficient basis on which to make ethically-defensible decisions about humans.

Autonomy is a cornerstone of consent, however it is important to distinguish different uses of the concept of autonomy. Current discourse around autonomy focuses centrally on personal autonomy (Buss, 2013), or on autonomy as a personal right where autonomy is construed principally in terms of having control over one’s life and what happens to one’s body. As noted earlier it is also sometimes used to denote a capacity, but a capacity for what? One candidate is a capacity for moral agency, but this is seldom made explicit. Sometimes it denotes possession of a moral right that imposes obligations on others. Today it is commonly understood in terms of decision-making rights and duties whereby my (presumed) right to make decisions about myself imposes an obligation on others at least to respect that right. This further assumes that we have a form of ownership over ourselves and our lives but leaves open the question of what the basis or origin of the right might be. If we unpack the concept of autonomy, different traditions of thought about this concept are revealed and we might ask: to which of these senses of autonomy does the *National Statement* refer?

1. Autonomy is essentially the idea of sovereignty over oneself, self-governance or self-determination. The ancient Greeks applied the term to city states – communities able to make autonomous political and economic decisions. This idea of autonomy as self-governance assumes there is a domain (i.e. myself) over which I rule. Commonly, accounts of autonomy in this tradition invoke community or political values. In such an account, it would be wrong to interfere with my sovereignty (i.e. to do something to me without my consent) as this is morally equivalent to invading a sovereign state. In medicine, this view is often used to provide a positive ethic of consent, namely that where consent is obtained a medical treatment, even if it might invade the sovereignty of the person, can be undertaken; i.e. it provides a mechanism for authorising a treating doctor to do something which could otherwise be wrong (e.g. assault). However, as Walker (2013) points out, when this model is applied to research ‘the requirement to defer to the rightful authority and obtain their decision before acting does not in itself require that one provide them with information about things like the consequences of what is to be done (p.393). In other words, respect for autonomy does not necessarily require fully informed consent.
2. Autonomy as self-governance or self-determination may well require that we have some capacity to control the values or desires that move us to action and are able to subject them to rational scrutiny – in other words, that we have the ability to assess critically our desires and values and to modify actions through the lens of critical reflection. Yet we all commonly make decisions without being (fully) informed about the potential ramifications or risks of our decisions – even assuming that it is possible to be fully informed at all. This does not mean that there is a case for withholding information; simply that a judgment needs to be

made about what information, if any, might be relevant or sufficient for a person to make an ethically-informed and prudent decision whether or not to participate in research.

3. At least since the time of Kant (in the late 18<sup>th</sup> century) the idea of autonomy has commonly been applied to individual persons. Kant argued that as rational agents we have a *will* that is autonomous such that “we may think of a person as free when bound only by her own will and not by the will of another” and where “The authority of the principles binding her will ... comes from the fact that she willed them.” (Johnson, 2012). This idea of the right to make autonomous judgments about ourselves is the idea which Beauchamp and Childress (2009) employed in their seminal work *Principles of Biomedical Ethics*. In this account, an individual’s consent is essentially an expression of an autonomous choice or judgment. The researcher’s responsibility is to respect that choice i.e. to decide what needs to be done, ethically, in response to the individual’s choice. The rights approach has some merit, but can be coercive in that when a right is asserted it is frequently accompanied by a claim that others have specific obligations to the person with the asserted right.
4. It can be argued that this view of autonomy does not necessarily require informed consent, so long as we respect the individual and do not undermine any autonomous choices that individual has made. The problem with this view of consent is that it provides no guidance where someone does not make or express an autonomous choice. Some people may be happy to allow things to happen to them or their data without feeling that they need to provide autonomous consent; others may not be so happy – but the researchers would never know.
5. Autonomy based in ethical claims is another approach. HRECs commonly ask whether potential research participants have an in-principle capacity to provide their consent, e.g. applied to young people or people suffering from conditions such as mental illness or addictions. However, it is not necessarily the case that there is a requirement to seek informed consent or that the individual needs (or wants) to provide their informed consent. There are many instances where we may (without withholding information) ask for consent to be given even if the specific risks are relatively unknown. Respect for autonomy requires that we at least accept an individual’s decisions even if these are made without what would be considered adequate information. “The problem with the idea that informed consent is required in order to respect autonomous choices ... stems from the fact that such requirement is silent about our obligations where someone has not made an autonomous choice”(Walker, 2013 p.390).

Given the above, why do we need fully informed consent as the standard for research? Autonomy is often cited as the primary reason, but it is difficult to argue this case on the basis of the principle of autonomy alone.

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