Research ethics and the functions of consent

By Dr Monique Jonas

In ‘The Interpretation of Dreams’, Freud suggests that the symbols our dreams contain are ones that serve multiple representational purposes. Whether or not Freud is right about this, a similar claim may be made about the most prominent and most deeply embedded devices within ethical theory and practice. Consent offers a case in point.

It is commonly observed that a number of central ethical goals are served through the practice of seeking (and obtaining) valid consent for participation in research. Consent processes are intended to preserve and advance the autonomy of individuals with respect to research participation. They also offer a means by which researchers can demonstrate their respect for prospective participants. In turn, consent processes contribute to a relationship of trust between researchers and participants, and help to establish the trustworthiness of research as an enterprise more generally. Consent is also thought to be a vehicle for protecting and promoting the welfare of prospective participants, on the grounds that individuals are the most reliable adjudicators of their own interests (and, where this is not the case, that the costs of interference can be greater than the risks interference aims to avert). It may also be speculated that requirements to obtain valid consent incentivise the adoption of research designs that present the most favourable risk-benefit profile to participants. If this speculation is borne out, consent processes support the welfare as well as the autonomy of prospective participants in a number of ways, and make a substantial contribution to the maintenance of that crucial lubricant of research involving humans, trust.

Consent processes carry a substantial ethical load, but it is often held that autonomy interests are their most crucial cargo. On many accounts, the primary purpose of consent processes is to respect the autonomy of participants. Trust and welfare are depicted as notable but secondary justifications for a process the primary value of which lies with autonomy.

In research (as in other spheres, sexual relationships) valid consent is taken to render permissible practices that would otherwise be impermissible. This reflects the claim that autonomous individuals may expose themselves to risks that it would be wrong for others to impose upon them. But consent must have specific qualities to possess this transformative power. Consent can only render an action permissible if it is valid. A valid consent is given voluntarily, on the basis of sufficient information and by one who is competent. The requirements for sufficient information and competence reflect the thought that only consents that are the product of genuine understanding, made in the absence of controlling influences, are representations of a person's autonomous will.

The requirement to provide sufficient information and the requirement to ensure understanding might speak to the same ultimate goal, but they are not the same thing. The requirements each places upon investigators vary significantly, and a substantial body of research findings suggests that conventional approaches to informing participants may systematically fail to actually produce levels of understanding that would validate consent.

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This evidence has emerged from research in a variety of contexts. There is a large literature suggesting that consenting participants in randomised controlled trials frequently do not recognise randomisation as a feature of the trial design, and that those who do identify randomisation may nevertheless fail to grasp the fact that their treatment is determined by random allocation. This is the case even when information has been provided according to best practice. Interestingly, some researchers attribute the problems in understanding randomisation to deep and misleading cues within the research environment (the similarities between research and therapeutic environments lead participants to read therapeutic intent into the research), and to an underlying conviction amongst some participants that randomisation is an ethically unjustifiable and scientifically unnecessary feature of research. Their trust in researchers leads some participants to rationalise away information that points to a practice that is at odds with their own convictions.

Other research suggests that even seasoned researchers can fail to register and process crucial information when consenting to participate in research with which they are unfamiliar. Jill Fisher documents this in relation to qualitative research with members of research teams responsible for the consent process. Fisher observes that risks that lay outside her participants’ expertise often went unnoticed at the time at which consent was offered. Although the relevant information had been supplied, assumptions that participants made presented an obstacle to its use in their deliberations.

If seemingly robust consent processes do not reliably produce the understanding that is taken to validate consent, researchers, and ethics committees, are faced with a problem. Should the current approach to consent remain, despite its limited ability to serve the autonomy of participants, should more exacting consent processes be instituted or do we need to rethink the role of consent?

Some cast doubt upon the prospect of addressing the causes of the problem through overhauling consent processes or imposing demands such as demonstrations of participant understanding prior to admission to a study. The costs of such measures may be prohibitive. It is also possible that the cues emanating from very demanding consent processes could themselves undermine understanding (perhaps encouraging participants to overestimate the risks of participation).

Thinking about what information participants receive may help in assessing the scale of this problem and determining how to respond to it. For instance, we can distinguish between information which must be understood in order for agreement to count as consent, and information that serves to improve the quality of consent. Tom Walker claims that requirements to obtain consent generate a need to ensure that information of the first type has been understood, but that information that improves the quality of consent may simply be provided.

But even this approach may impair research employing methodologies such as randomisation. In the case of a randomised controlled trial (RCT) of a new therapeutic agent, random allocation is a core feature of the research proposition. Consent that isn’t based on an understanding of random assignment is not truly consent to participate in an RCT.

It may be possible to alleviate the problem by removing barriers to understanding. There has been much work done on how to present information more comprehensibly, although research suggests such efforts are unlikely to generate significantly better rates of understanding. Affecting deeper changes in the research environment may facilitate better understanding, for instance measures could be taken to erase the strong therapeutic resonances around research, but these may be costly and unlikely to have an impact in the short-term.

Given the apparently limited usefulness of consent processes as devices for serving autonomy, we need to consider two things: are consent processes worth retaining and, if research is not rendered permissible by consent as a signal of autonomous authorisation, can it be rendered permissible in some other way?

These questions deliver us back to the full ethical load borne by consent. Respect for autonomy is not the only goal consent advances. It also serves welfare, trust and demonstration of respect. These goals justify our continued efforts to honestly inform prospective participants, to enable choices based on understanding, and to involve competent individuals in research only with consent. Although many participants in research will understand the research proposition well enough to offer valid consent, some will not, so we must ensure that research is justifiable without relying upon respect for autonomy. Researchers and ethics committees have crucial roles to play beyond the examination of consent forms and processes, in ensuring that research can be justified through reference to a full range of ethical considerations.

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Sourcing survey respondents via the internet

By Associate Professor R Hugh Morton

This article summarises a paper I presented at the Australasian Ethics Network Conference, 16-17 February 2012 in Brisbane.

Sourcing survey respondents via the internet (with minor variations) has formed part of a number of ethics applications submitted to Massey University Human Ethics Committee (MUHEC) over the last few years. MUHEC, like other ethics committees upholds the usual ethical principles; privacy and confidentiality, minimisation of the risk of harm, informed voluntary consent, respect for culture/gender/ethnicity/…, etc. Principles of research adequacy also arise, such as whether study design makes it possible to achieve the stated goals and whether the validity of the approach has been established. It is here that this particular issue manifests.

A session at this conference was devoted to “ePrivacy and eResearch”. This field is new and emerging and the presentations were wide-ranging and informative. One in particular discussed using Facebook to source respondents via the internet. The applicant located a number of such sites, requesting survey terms, there appears to be no (or at least a non-verifiable) sampling frame. In the absence of such an assurance, it is both unclear whether the research goals are achievable and clear that validity is compromised. With this in mind, the following examples illustrate MUHEC’s experiences.

Example A: An investigation of the emotional status and behaviour of New Zealand teens (13-16 year olds). Information about the study and a link to the questionnaire were placed on publicly accessible teen and youth websites, and in teen magazines. When questioned on the issue, the applicant responded that: she was familiar with teens; she had worked as a teen social worker; she knew the websites and in teen magazines. It is my belief that sourcing respondents via the internet is likely to become more frequent, and ethics committees will increasingly need to think about how to deal with consequential issues like validity.

The basic question is: When the internet is used as a source of respondents for research, to what degree are researchers assured (and can they assure ethics committees) that respondents actually belong to the targeted population? In sample survey terms, there appears to be no (or at least a non-verifiable) sampling frame. In the absence of such an assurance, it is both unclear whether the research goals are achievable and clear that validity is compromised. With this in mind, the following examples illustrate MUHEC’s experiences.

Example A: An investigation of the emotional status and behaviour of New Zealand teens (13-16 year olds). Information about the study and a link to the questionnaire were placed on publicly accessible teen and youth websites, and in teen magazines. When questioned on the issue, the applicant responded that: she was familiar with teens; she had worked as a teen social worker; she knew the websites they tended to visit and the magazines they tended to read; and that she knew what she was doing.

Example B: An investigation of the experiences of young New Zealand people (16-25 year olds) using self-harm internet discussion groups or message boards. The applicant located a number of such sites, requesting

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Ethics Summer Studentships 2011/12

Six students were awarded HRC Ethics Summer Studentships in 2011/12. The purpose of the studentship is to enable a student to train during the summer break with a research team and have the opportunity to explore ethical issues that face New Zealand. Below is the overview of each project that received funding.

Robert Cole - University of Otago, Dunedin

Supervisor: Professor Gareth Jones - University of Otago, Dunedin

Should national antenatal screening for Down’s syndrome be publicly funded and provided for all pregnancies?

In 2010 a publicly funded screening programme for detecting Down’s syndrome (DS) pregnancies was introduced in New Zealand. If detected, DS is deemed a sufficient reason for termination. Some groups are opposed to the new framework feeling it stigmatises those with DS. Indeed, persons with DS lead lives with a level of subjective well-being and value similar to the non-DS population. This paper explores whether the provision of such services is justified for DS.

Frédéric Dichtel - University of Waikato

Supervisor: Dr Carol C Barber – University of Waikato

Informed consent in practice: How do New Zealand parents make decisions about the use of stimulant medication for children with ADHD?

Attention Deficit Hyperactivity Disorder (ADHD) is a developmental disorder that affects between 40,000 and 80,000 children in New Zealand. The most common treatment for this disorder is stimulant medication, but the decision to put a child on this medication can be difficult and fraught with stress for parents. This decision-making process, which involves giving or refusing informed consent to the medical treatment, is the subject of this research.

Robert Hunt - The University of Auckland

Supervisor: Associate Professor Tim Dare - The University of Auckland

Co-supervisor: Associate Professor Katrina Sharples - University of Otago, Dunedin

Reviewing the Health Research Council of New Zealand Data Monitoring Core Committee (DMCC)

The aim of the project is to gather data on the nine clinical trials which the DMCC has (as of December 2011) overseen to completion. From the data the investigator has aimed to give an account of the committee’s relatively short history, and to identify themes in its activities, including the more successful and problematic elements, in order to inform the direction of future development of the DMCC, and perhaps of other similar organisations.

Philip McKibbin - The University of Auckland

Supervisor: Associate Professor Tim Dare - The University of Auckland

Randomised comparison of two approaches to providing patients with information on clinical trials - The informed consent study

Informed consent is the process by which a person agrees to participate in a trial. This paper has described the process by which a booklet is developed to ensure that it complies with New Zealand and international regulatory requirements, and that it would effectively inform participants of their rights and other relevant information.

During the course of developing the booklet, a randomised controlled trial was undertaken to assess the use of a booklet and short trial-specific informed consent form on the informed consent process. The results of the trial suggest that the use of a booklet significantly improves the process – by enhancing both comprehension and recall.
Ketamine provides an efficient and economical way to perform painful procedures in paediatric practice without the use of general anaesthesia. However, ketamine has also been associated with non-physiological events or “emergence phenomena,” which are less well understood, particularly in children. Current understandings of the potential for non-physiological risk and harm in paediatric populations are vague. The aim of this study is to apply an ethical framework to examine the benefits and harm of ketamine use particularly related to vulnerable paediatric populations and the implications this has for children’s rights, autonomy, best interest and informed consent.

Maeve Payne-Harker - University of Otago, Dunedin
Supervisor: Dr Jing Bao Nie - University of Otago, Dunedin
Co-supervisor: Dr Grant Gillet - University of Otago, Dunedin

The ethical equivalence of withholding and withdrawing care in terminally ill patients

Withholding and withdrawing care is widespread in the setting of critical and terminal illness. Currently, both procedures are held to be ethically equivalent, based on the concept of medical futility. The researcher argues that the concept of futility fails to take into account issues such as uncertainty and the risk of unacceptable badness. In its place the researcher proposes a new concept around which decisions could be based, the concept of a “duty of care”. Given the need to discharge the duty of care, the researcher proposes that withholding and withdrawing care are not morally equivalent, and should not be considered as such.

A new system of Health and Disability Ethics Committees

Effective 1 July 2012, there is a new system of Health and Disability Ethics Committees (HDECs). Below are the three main changes:

1. The procedural rules for the HDECs are guided by the new standard operating procedures (SOPs). These SOPs provide rules and guidance on:
   - the role of HDECs;
   - the types of study that require HDEC review;
   - the application process for HDEC review;
   - the processes of the two review pathways: full and expedited review;
   - the decisions open to HDECs and the timeframes within which they must be made and communicated;
   - the statutory role of HDECs under the Accident Compensation Act 2001;
   - how certain decisions of HDECs may be challenged, and by whom;
   - the distinct role of localities in addressing the local research governance issues that may result from the conduct of study within them;
   - when amendments to approved studies themselves require HDEC review;
   - post-approval processes, and
   - the process for HDECs review of an organisation’s arrangements for establishing and managing a tissue bank.

2. Four new HDECs have been established under section 11 of the New Zealand Public Health and Disability Act 2000. They are: Northern A HDEC, Northern B HDEC, Central HDEC and Southern HDEC. Their function is to secure the benefits of health and disability research by checking that it meets or exceeds established ethical standards contained in Ethical Guidelines for Observational Studies and Ethical Guidelines for Interventional Studies. These HDECs are approved by the HRC Ethics Committee to provide independent ethical assessment of HRC-funded research.

3. Researchers can submit application to HDECs electronically through online forms.

For details of the SOPs, terms of reference, online form and meeting dates, please go to the website for HDECs: http://www.ethics.health.govt.nz/.

For information on the ethical standards, please go to the website of the National Ethics Advisory Committee: http://www.neac.health.govt.nz/.
membership from their controllers so she could enter into discussions with other members to source her data. In response to our concerns she replied: “research shows that online exchanges are often more truthful than people think”. She recognised it would be impossible to verify for example, the age of respondents, but said she would seek contextual assurance by asking for example whether and when the respondent had left school.

Example C: A study about out of control sexual behaviour amongst New Zealanders over the age of 18. Recruitment was via a national press release which included information about the study and a link to a private web page. When questioned the applicant agreed that the degree of assurance regarding sampled versus targeted population could not be ascertained, but felt that under eighteens were no more at risk from this website than from what may arise from other freely available websites.

Example D: A study of the aspirations of “at risk” 16-18 year old New Zealand school pupils. An advertisement and invitation to respond was inserted on the Facebook pages of all those members whose stated profile matched the target group. A link was then provided to those who responded. When our concerns were raised the applicant replied only that MUHEC did not understand (or at least had misunderstood) how Facebook worked, though admitting that addressing a population online is recognised as controversial.

Example E: A study addressing introspection and emotional maturity during adolescence amongst 13-18 year olds attending New Zealand schools. The recruitment method was identical to the previous example. When questioned, the applicant provided Facebook’s Statement of Rights and Responsibilities which clearly indicates no assurances or authentication regarding the stated profiles of Facebook members; then claiming that Facebook is increasingly regarded as a valid method of advertising.

There are two common themes running through these examples. One is that applicants (and presumably in some cases also their academic supervisors and/or sponsors) do not appear to regard the issue seriously enough to address it directly (if at all). The second is that the subject matters may all be regarded as sensitive in nature. This raises an issue of increased, unknown or unpredictable risk, which when dealing with sensitive issues is always an important consideration. A recent incident highlights what can happen.

In the broadest of details, respondents to a study on self-harm (not Example B) were sought through the internet. A person who did not meet the inclusion criteria did nevertheless participate, believing that the information provided could be useful. The respondent allegedly suffered a traumatic experience part-way through the survey, being so traumatised that they were unable to exit despite there being exit buttons on every page. The trauma allegedly continued for some time thereafter. Complaints against the researchers have arisen. Whilst it is clear that this could happen to those respondents who do meet the inclusion criteria, it is equally clear that this event was easily preventable.

I conclude that in sourcing respondents via the internet: there is obvious uncertainty regarding targeted vs. sampled population; the validity of the research may be compromised to an unknown degree; there is a reluctance to acknowledge or address the issues directly; there is an apparent willingness to proceed nevertheless; and, that there are additional and unknown risks.

So what does MUHEC do? This issue is by no means finally resolved and we currently adopt the following procedures: we will continue to raise these issues for applicants to address; we strongly advise applicants to discuss any consequent limitations in appropriate sections of their reports; and we consider that if applicants (and their supervisors/sponsors) accept these limitations, they should not necessarily prevent ethical approval.

R Hugh Morton is an Associate Professor of Sport Science and Biostatistics at Massey University, Palmerston North. He is a graduate of Rhodes, Wales and Cambridge Universities and has been a member of MUHEC for five years. The opinions expressed are my own, and do not necessarily represent the views of MUHEC or the HRC.