Research on Humans

Nicholas Tonti-Filippini
John Paul II Institute for Marriage and Family
Melbourne, Australia

In modern society we are often asked to participate in research. Most often it takes the form of market research for which the purpose of gaining information is entirely commercial or political and may even be exploitative, intending to use or even sell your contact details and information about you to target you with advertising.

Most people are aware of the nature of market research though not all may be aware of the privacy implications of personal details being made more widely available to others for commercial purposes. Commercial phone surveys that ask for personal details such as age and income are an obvious risk.

Generally there is little regulation of market research compared to the extent of regulation that exists for scientific research. The difference presumably is that commercial research is known for what it is, there are no common good expectations and you participate at your own risk.

However people participate in scientific research in a spirit of altruism willing to increase human knowledge for the sake of the common good. To protect their vulnerability, scientific research on human subjects, in developed countries at least, is required to be approved by an ethics committee meeting specified standards and required to abide by a published code of ethics.

In recent times there has been much more focus on the relationship between researchers and research participants with greater requirements on the researchers to inform the participants of the results of the research. In genetic research, for instance, there are requirements that information that is discovered that is relevant to the health of participants and their relatives must be offered to them.

Generally, participation in research requires consent, though ethics committees can waive the obligation for low risk research where it would be difficult to make the contact to obtain the consent, such as epidemiological research involving large numbers and where there is no need to identify participants.

The current system of ethics committee review developed after the atrocities of the Nazi era, though it should be born in mind that the atrocities in the name of science were not restricted to Nazi Germany. In the first half of the twentieth century most western countries permitted harmful research on people who were developmentally disabled, had mental illness, or were prisoners or in the military. Many jurisdictions, including the UK and many US States, adopted eugenic laws that provided for compulsory sterilization of those with cognitive disabilities.

The need to inform participants and obtain consent, to have independent ethics review, and not to place participants at significant risk became a priority in reaction to the atrocities. Researchers and ethics committees are required to uphold respect for the person which requires recognition of the intrinsic worth or value of the person, including their body and hence their safety. It also includes recognition that participation in research is voluntary and based on sufficient information about, and adequate understanding of, both the proposed research and the implications of participation in it.

Research on people who cannot consent is only permitted where the risk is low and consent is given by someone who has legal authority to represent their interests.

Children pose a significant difficulty as their capacity to understand and give consent is emerging. Different levels of maturity and of the corresponding capacity to be involved in the decision include:

a) Infants, who are unable to take part in discussion about the research and its effects;
b) Young children, who are able to understand some relevant information and take part in limited discussion about the research, but whose consent is not required;
c) Young people of developing maturity, who are able to understand the relevant information but whose relative immaturity means that they remain vulnerable - the consent of these young people is required, but is not sufficient to authorise research; and
d) Young people who are mature enough to understand and consent, and are not vulnerable through immaturity in ways that warrant additional consent from a parent or guardian.[1]

Research involving children and young people raises particular ethical concerns about:

a) Their capacity to understand what the research entails, and therefore whether their consent to participate is sufficient for their participation;
b) Possible coercion by parents, peers, researchers or others to participate in research; and
c) Conflicting values and interests of parents and children.[2]

Ethics committees should limit research on children to circumstances where:

a) Iit is likely to advance knowledge about the health or welfare of, or other matters relevant to, children and young people; or
b) Children's or young people's participation is indispensable to the conduct of the research; and

[1] National Health and Medical Research Council *National Statement on Ethical Conduct of Human Research* Australian Government, Canberra 2007, Ch. 4.2
[2] Ibid.

c) There is no reason to believe that such participation is contrary to that child's or young person's best interest.[3]

Research involving people in dependent relationships, such as doctor and patient, teacher and student or employer and employee, are problematic because the participant may not be entirely free to refuse. Special precautions are required in those circumstances usually involving an independent third party in the consent process

Payment for research is an area that is highly problematic. Where the promise of payment of compensation for taking a risk leads to a decision that is motivated by that promise of payment, a participant's decision would not meet the basic requirement of respect for the person. The promise of payment can lead participants to accept risks that exceed ethical acceptability, especially in early phase clinical trials. It can also lead researchers to consider risk of harm to be part of the deal so that less care may be taken for those who are paid to participate.

The assessment of payment for participation in research should take into account:

a) that there is a moral difference between taking a risk for an altruistic reason, and taking a risk in order to receive payment;
b) that a person might reasonably take risks in the hope of medical research being of benefit to the community, but not for the purpose of receiving payment for taking those risks;
c) that those who are economically disadvantaged might be exploited if payment were such that it provided what, in effect, would be a perverse incentive to take risks that they would otherwise not take, for example, payment that is greater than the current minimum wage; and
d) that payment for a person's time and services is similar in some ways to employment, and employers have ethical (and legal) obligations for the safety of their employees, for example:
    - compliance with relevant occupational health and safety laws•
    - informing participants that they need to retain receipts and declare • payments in income tax returns
    - determining if the payment is likely to affect any government benefits • the participant may be receiving, eg students, pensioners, and people who are unemployed.

It is particularly important therefore that ethics committees carefully assess whether or not any payment to participants is payment for risking discomfort or harm or compensation for discomfort or actual harm done.[4]

One of the functions that ethics committees have is to ensure that research is properly designed and likely to achieve its aims. If you are asked to participate in bona fide

[3] Ibid.

[4] National Health and Medical Research Council *Using the national statement 1: Payments to participants in research, particularly clinical trials* Australian Government, Canberra 2007 Accessed from: http://www.nhmrc.gov.au/_files_nhmrc/file/health_ethics/hrecs/reference/using_the_national_statement.pdf

research, then you should receive a clear statement of the goals, design and method and what your participation involves, and which ethics committee approved it and the contact details of the committee so that you can check.