A place for opt-out consent in the National statement on ethical conduct in human research

In most human research, potential participants are provided with detailed information so that they can make a fully informed choice about whether to participate in the project. The requirement for explicit consent reflects the value that our society places on individual autonomy.

The National statement on ethical conduct in human research 2007 (updated December 2013) (National Statement; http://www.nhmrc.gov.au/files_nhmrc/publications/attachments/e72_national_statement_131211.pdf) currently qualifies the need for explicit consent by allowing human research ethics committees (HRECs) to approve limited disclosure for low-risk research where no practical alternative exists and the potential benefits of the research justify it. An example is research that involves observing people’s behaviour, where disclosing the nature of the research may change the behaviour being studied.

The other option offered to HRECs is to allow the requirement for obtaining explicit consent to be waived. A common example is analysis of the data from population disease registries, which may contain thousands of people. The research must be low risk, of significant benefit to the population, and on a scale where it is impractical to obtain consent from such large numbers of people. Often the data are de-identified and the privacy of those whose data are used in a study is adequately protected.

Currently, the National Statement neither includes nor specifically excludes what is commonly called opt-out consent. Opt-out consent is when, following the dissemination of information about a research project, consent of the participants is presumed unless an individual actively withdraws consent. I am not arguing that this is an alternative to explicit consent; rather, it is an option that sits between explicit consent and a waiver of consent if it satisfies the principles of ethical conduct of research that are the basis of the National Statement.

Some would argue that opt-out consent better balances autonomy with research, because it demands a stronger intention not to participate, as withdrawal requires action, whereas opting in inflates non-consent. Like waiving the requirement for consent, approvals to use opt-out consent must ensure appropriate respect for potential participants, define the spectrum of activities for which participants could be recruited or their information accessed, and protect individual privacy.

Although the term “opt-out consent” has been challenged because the consent is only presumed, I use it here because the term is commonly used and generally understood. It certainly allows more autonomy than a waiver for obtaining consent altogether. The National Statement gives no guidance on approaches that can be used to recruit individuals or to access information that has been collected for non-research activities but later becomes useful for research. Researchers in specific areas such as epidemiology have lobbied the National Health and Medical Research Council to allow opt-out consent. Individual ethics committees have been approving the option in specific circumstances. This has prompted the suggested revision to the National Statement, which was open for public consultation in May 2013.

Granting opt-out consent requires that information about the process be provided to populations. For example, information about what is collected in clinical registries may be communicated by a brochure. A media announcement about a research project using the data may be used. A quality improvement program in a hospital may be notified to patients in their admissions packages. Some jurisdictions, such as South Australia, have a Code of Fair Information Practice, which gives guidance about providing such information.

Unlike explicit consent, there is no guarantee that each individual has read the information. Even with explicit consent the adequacy of the information given has been questioned since recall of this information has been found to be poor. It is often participant anxiety about the underlying disease necessitating the trial that prevents assimilation of information at the time it is provided.

What type of research would be a candidate for opt-out consent? As more data are stored digitally, there will be increasing options to interrogate and link large databases to inform clinical practice and answer research questions. Opt-out consent could apply where research or the maintenance and improvement of health care standards would not be possible or would be critically compromised without it. An opt-out approach or even opt-out consent by proxy by parents or guardians would be an important option in epidemiological studies where it is not practical to obtain explicit consent. For example, an investigator monitoring the possible effect of an occupational exposure may wish to obtain access to health records collected some years previously where it may be difficult to trace ex-workers to obtain explicit consent. Advertisements in the press notifying the intention of the researchers, coupled with a procedure for individuals to opt out, may be seen as preferable to the use of a waiver in such a situation by investigators and HRECs. Individual health data would be de-identified in reporting results to ensure privacy.

Another example is clinical quality registries that collect and analyse information from groups of patients with the aim of enhancing the quality of care. For example, they monitor the effectiveness of treatment, safety of drugs, or compliance with clinical guidelines. Opt-out consent is currently used by three-quarters of the clinical registries in Australia. These registries must collect individually identifiable or reversibly anonymous information on individuals so they can track individuals whose treatment may span several institutions, and allow follow-up after hospital discharge to ascertain outcomes of the cohort.

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accuracy of the outcome depends on the completeness of the sample.

In both of these examples, population-based research relies for its accuracy on obtaining as complete as possible acquisition of the population being studied. Research on explicit consent in such situations shows that it is generally associated with a recruitment rate of 30%–50%. It is highly likely that with this level of recruitment, the participants will be unrepresentative of the whole population, and the data therefore will have little credibility for quality improvement, benchmarking or policymaking; or worse, may lead to inappropriate conclusions and actions. In contrast, the Victorian State Trauma Registry, with over 15,000 people, uses opt-out consent and has a high recruitment with a less than 0.5% patient withdrawal rate. A randomised trial in Australia comparing opt-in with opt-out parental consent for childhood vaccine safety surveillance using data linkage is ongoing.

Registries benefit individuals by providing them with information about outcomes of their diseases and allowing them to benchmark outcomes with other jurisdictions. There is not just a benefit to the community or to researchers at the expense of some individuals who may not have exercised their autonomy in decision making. The establishment of clinical registries not intended for research does not require the approval of an HREC. However, the data may subsequently prove valuable for research and an opt-out approach may be sought. It would therefore be prudent to apply for opt-out consent at the establishment of such data collections. This aligns with the Australian Commission on Safety and Quality in Health Care principles for clinical quality registries.

Further, situations will arise where it is possible to combine waiver and opt-out consent — for example, a research study wanting to use information from a tissue bank or registry may apply opt-out consent to those still contactable and a waiver for the others.

Because explicit consent is the ideal, there must be strict criteria against which HRECs judge requests for opt-out consent. The bioethical literature contains examples where opt-out consent may be acceptable. The proposed revisions to the National Statement suggest that the research should be low risk, result in substantial public benefit and require near-to-complete participation — compare this with many clinical trials that require certain numbers to enrol but can tolerate refusals. There must be a reasonable strategy to widely disseminate plain language but comprehensive and accurate information about the research project and a mechanism for potential participants to obtain further information or to opt out. There must be strict procedures in place to ensure the privacy of an individual’s information as stated under s 95A of the Privacy Act 1988 (Cwlth), both during the study and in subsequent reporting of results. Individuals should not be identifiable in reporting population results.

My personal communications with consumer groups revealed that privacy is not the overriding concern of consumers, who expect that data about their disease will be used for the good of those to come. A survey of cancer patients about the uses of their personal data for research revealed no majority position, and confusion, or perhaps lack of concern, over the distinction between identified and de-identified data. There was more concern about who uses the data. There are patient groups likely to be more sensitive to the use of their health information, such as with mental illness or sexual health, but strict procedures to ensure the individual’s privacy apply to all.

Explicit consent remains the most desirable method of obtaining consent. The option for opt-out consent would provide ethical review bodies with an additional tool to apply to types of low-risk research that result in important benefits to the community, but only if near-to-complete participation is achieved. Ethical review bodies would be responsible for interpreting the general guidance provided by the National Statement and for applying it to specific research proposals.

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