Waiver of Consent

Summary

The right to provide informed consent to involvement in research is of vital importance to respecting an individual's right to autonomy and dignity. However, in some research, consent may not be possible. This may be because of the age of records, a characteristic of the cohort or for some other reason. In these cases, researchers may request a HREC to consider waiving the requirement to seek consent. Though research without informed consent may appear to violate fundamental rights, when conducted with appropriate safeguards, it provides the opportunity for significant benefits to the public as well as specific groups who may not be able to provide consent. However, there is low public tolerance for the use of information or material without consent and doing so must be justifiable.

The *National Statement on Ethical Conduct in Human Research* (National Statement) provides a framework for a HREC to assess a project in order to determine if the waiver is appropriate, the merits and benefits are sufficient to justify waiving consent and that researchers have sufficient processes in place to protect participants' rights to privacy and confidentiality.

Figure 1
Section 2.3.10 of the National Statement

2.3.10 Before deciding to waive the requirement for consent (other than in the case of research aiming to expose illegal activity), an HREC or other review body must be satisfied that:

a) involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7, page 20) to participants;
b) the benefits from the research justify any risks of harm associated with not seeking consent;
c) it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records);
d) there is no known or likely reason for thinking that participants would not have consented if they had been asked;
e) there is sufficient protection of their privacy;
f) there is an adequate plan to protect the confidentiality of data;
g) in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media);
h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled;
i) the waiver is not prohibited by State, federal, or international law.

Firstly, there are two points regarding addressing Section 2.3.10 as a whole:

Each criterion must be substantively addressed. A common error is for applicants to reiterate the criterion i.e. in response to point 2.3.10a stating "This research is low risk" without providing a basis for that assertion. Responses that reflect due consideration of the criterion and the principles they reflect are far more likely to receive approval.

Another common error is the lack of recognition of indirect risks. The HREC is aware that access to data or samples that are surplus to clinical requirements is rarely likely to result in physical harm occurring. The HREC review most frequently considers risks which relate to the potential for privacy/confidentiality breaches and the subsequent potential for emotional distress amongst participants, public loss of faith in the integrity of the health service, damage to the hospital's reputation and the potential that members of the public may become disinclined to be completely forthcoming with health information as a result, even when relevant to their care.

Section 2.3.10a

"*Involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7, page 20) to participants"*

The criterion for low risk is, to paraphrase the National Statement, the potential for harms *greater than discomfort* to occur as a result of participation. This is not a particularly functional definition because discomfort is subjectively experienced; what may be innocuous to some may induce trauma in others. Each project and the experience of participants is considered holistically by the HREC. However, the following vignettes provides some potential cut offs for acceptance as low risk that may be illustrative:

The collection of a small amount of additional blood during a routine blood test may meet the criteria for low risk. However, a project which requires a study specific venepuncture would not be considered low risk.

A project involving photography would likely be eligible as low risk. However, a study proposing MRI scans would not, due to the potential for claustrophobia, the standard use of sedation in the event of distress and the imaging required to detect the presence of metal in the body.

The risk of projects that seek to collect data is typically dependent on the procedures in place to mitigate the risks to privacy or mismanagement.

Section 2.3.10b

"*the benefits from the research justify any risks of harm associated with not seeking consent"*

Beneficence is one of the primary principles upon which ethical research is founded. It requires that research should provide the potential for benefit over and above the potential harms or burdens or participation. Research may provide benefit in several ways: it may benefit participants or their community directly, lead to a clinical or service improvement, contribute important knowledge in a particular area, explore an unmet need and/or provide healthcare professionals with research experience.

A question which may help in addressing this criterion is: "*If I were asked to justify this approach to an individual involved, what case would I make for the study and the lack of informed consent?"*

Section 2.3.10c

"it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records)"

A task which is impracticable is not merely difficult or time consuming; it is *"Impossible in practice to do or carry out*." As such, those seeking a waiver should consider whether a

proposal is merely difficult or truly impracticable. There are several ways to address this criterion and some examples are provided below.

Propose a study wherein a legitimate attempt will be made to seek consent from all requisite participants and those who are unable to provide consent will be included. There may be issues with doing so discussed in Section 2.3.10d

A study requires the involvement of all, or a representative sample of all, eligible participants to avoid bias. For example, excluding those unable to consent would either make the study impossible or introduce bias e.g. deceased or incapacitated individuals may be such as a result of the condition being investigated, and their exclusion would deprive the research of their experience.

A project which seeks approval to collect data from a very large number of participants over a significant period of time such that significant numbers of the sample would likely have moved, died or changed contact information.

Recent changes impacting Section 2.3.10c

In 2020, an amendment was passed to the Guardian and Administration Act (GAA) which added wording regarding research participation for the first time. This created the foundation of a legally supported process by which a third-party could consent to research participation on behalf of another individual. As such, it is now important to consider whether consent from an individual, or a third-party research decision maker, is impracticable.

2.3.10d

"there is no known or likely reason for thinking that participants would not have consented if they had been asked;"

This is a notoriously difficult criterion to address because it is impossible to say, with any degree of certainty, what another person, or persons, would or would not have consented to had they been asked. The rationale for the inclusion in the National Statement is that participants should not be included in research that does not align with their values or it is unlikely they would have consented to. An example of this is the evidence to suggest that the public are less inclined to donate tier information or samples to commercial research without consent. The researchers should consider whether it is reasonable to believe, based on what is known about the cohort under investigation, that an individual would have consented to involvement.

This assertion may be supported by engaging with members of this cohort, consumer groups or groups who advocate on behalf of this community. Also, evidence from past studies of a high level of engagement in research by that community may also address this criterion.

2.3.10e

"there is sufficient protection of [participants'] privacy;"

Privacy is the right of an individual to control over how his or her personal information (or personal health information) is collected, used, and/or disclosed. In the context of research with consent, providing sufficient protection of privacy frequently involves the removal of personal information from data collected as soon as possible, or preferably, not collecting personal information at all. Where this is not possible, it must be clearly articulated when personal information is removed, whether the information is coped and re-identifiable, who will have access to the data in both identifiable and non-identifiable forms.

2.3.10f

"there is an adequate plan to protect the confidentiality of data;"

Confidentiality is the duty to ensure information is kept secret to the extent possible. In the context of research, this means limiting access to data only to those who are required to view or analyses it for the purpose of the research project proposed, secure storage and processes for management and destruction.

A note on the importance of Data Management in responding to 2.3.10e & 2.3.10f

Privacy and confidentiality (discussed in Section 2.3.10f are often inter-related and can both be addressed by an appropriately robust data management plan. Many universities have begun mandating the adoption of institutional data management plans in order to ensure data collections meet appropriately high standards and remain consistent. All data management plans from major WA tertiary institutions are accepted by the SCGOPHCG HREC. If researchers do not have access to one of these pre-existing plans, there are a number of resources available to develop one. The Digital Curation Centre provides a number of useful documents and tools to assist researchers including the DMPlans platform. Similarly, DMPTool provides similar support. Both are open source and free to use and while they are written to reflect the requirements of the UK and US respectively, the principles addressed within are internationally accepted.

2.3.10g

"in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media"

Returning the results of research to those who may receive benefit, and the public at large, is an important element of adhering to the principal of justice. Publication of the results of research in medical journals is not sufficient to meet this criterion as medical journals are not accessible to the general public both because of the often technical language used, and cost associated with accessing journals. Producing lay summaries of research to display around the hospital or for inclusion in material circulated amongst the community, on social media or via advocacy organisations are all acceptable methods of meeting this criterion.

2.3.10h

"the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled;"

While it is an important consideration, it is rare that research utilising a waiver of consent has the potential for direct commercialisation. In the event there is no potential for commercialisation, it is sufficient to state that this is the case. Where some financial benefit may arise from the research using data or samples collected using a waiver of consent, applicants should address how their use in the research will not deprive participants of financial benefit. The sale of data or samples to a commercial party would not be supported by the HREC.

2.3.10i

"the waiver is not prohibited by State, federal, or international law"

The HREC does not expect researchers to seek advice regarding the legal acceptability of the waiver of consent. An assurance that, so far as the applicant is aware, the waiver if not prohibited by law is generally sufficient. A component of the institutional (RGO) review is a consideration of the legality of the waiver in its specific context and the applicant will be notified if a waiver is not legally supported.

However, the collection and transfer of personal, or personal health, information outside of an organisation without consent may contravene the Commonwealth Privacy Act. In that case, an HREC is required to consider whether the purpose/s of the study are within the scope of the disclosure allowed within that Act. Where a project does involve this disclosure of personal information, the applicant should consider the Privacy Act and the relevant NHMRC guidance.

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