



DRAFT PUBLIC CONSULTATION QUESTIONS FOR REVIEW OF NATIONAL STATEMENT SECTION 4

Thank you for the opportunity to comment on the Draft Public Consultation for Review of the National Statement on Ethical Conduct in Human Research. The Public Service Research Group at UNSW Canberra has a strong track record of research into public services in Australia and overseas, covering various aspects of public sector management, delivery of public services and user experiences. Our researchers focus on a range of population groups and public service programs across different service and sector contexts, including the Australian Public Service, the National Disability Insurance Scheme, Aboriginal health services, and women's services.

Many of the proposed changes contained in the draft document are minor, we therefore confine our comments to issues of terminology and associated ethics processes raised in Section 4.

We agree with the principle that vulnerability exists on a continuum and is context-specific. Vulnerability is, as the document points out, not a binary state nor a fixed characteristic of individuals or groups but is a matter of degree. A group of individuals, for example young people or people with disabilities, is not *necessarily* more vulnerable to harms than others and should not therefore be excluded from research on the basis of these characteristics alone. Such a focus encourages labelling as pointed out in the document.

Following from recent published research (Have 2015; Walker 2018) however, we prefer the terminology of marginalisation over vulnerability. Vulnerability tends to focus on the characteristics of individuals at the expense of sufficient attention to the social connections that shape human life, and experiences of exclusion and discrimination. Marginalisation, as a term, better highlights the social and systemic factors that diminish access afforded to individuals with particular personal characteristics.

We do not find the risk matrix - with its two axes of risk – increasing likelihood and increasing severity of harm –in Chapter 4.1 particularly useful. The matrix does not provide much guidance to researchers on how to use the framework to determine levels of risk nor determine strategies required to ameliorate them. As the matrix stands, it seems likely to push researchers into thinking in traditional ways about vulnerability, encouraging an assignment of risk status on the basis of personal characteristics alone. A strengths or asset based approach may provide a better framework for considering the range of supports required to assist individuals to achieve agency and self-determination in consent and research processes, and focus researchers' attention on how to support individuals in practical ways to facilitate their consent and participation in research.

We agree with the principle of assent and that young people and children benefit from knowing what will happen in the research and should be given an opportunity to express their interest as well as concerns and agreement to participate. Researchers are instructed to specify how an assessment of capacity to provide assent or consent will be made, including whether this will be on an individual or a group basis. However, we do not find Section 4.2C or the table provided (Figure 2, p18) particularly helpful in terms of providing guidance to researchers on how to make reasonable assessments on individuals' capacity to provide assent or consent. Our concern is for a 'tick box' approach to emerge that, albeit unintentionally, limits or reduces participants' ability to either assent or provide consent, particularly in the context of a group of potential participants.

We are concerned that there is not clear guidance regarding Australian Defence Force veterans. Currently, the DDVA Committee claims oversight for all research conducted on veterans as they claim that the group is vulnerable and that DDVA are the only Committee with the expertise to oversee research on this group. We would like it clearly noted to the NHMRC that this population group should not automatically be vulnerable and that unless DDVA are funding the research, then any HREC should be able to assess the research. If RECS needs further advice on this Dr Connor (HREAP A Convener is happy to oblige).

Overall, this review represents an opportunity to reform an onerous, one-size-fits-all approach to vulnerability / marginalisation. We would like to see a dialogue system formally introduced into the approval process so that participants, researchers and HRECs can discuss risk, inclusion and vulnerability as part of the process of application as opposed to assumptions being made on arbitrary grounds. Tolich and Fitzgerald (2006) have a model for this approach. Further reform is urgently needed to properly incorporate qualitative research methodologies and move the statement away from the bio-medical model (Connor et al, 2017; Wynn 2017) that stifles research.

Please contact Dr Karen Gardner via phone (0424247376) or on email (karen.gardner@unsw.edu.au) if you have any questions regarding our submission.

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