

14 September 2022

## **Submission to Data Availability and Transparency Code 2022 – Consultation on draft instrument**

This submission relates to *Consultation Question 16*: “One of the objects of the Act is to enable the sharing of data consistently with the Privacy Act and appropriate safeguards. Does this part of the draft data code strike the right balance between holding data custodians accountable to seek consent, and providing data custodians with an exception to collect consent in circumstances where it is genuinely unreasonable or impracticable to seek consent? How could the draft data code be improved to achieve the right balance? For example, could the National Health and Medical Research Council waiver of consent guidelines be used here?”

The DAT Code aims to provide “proper and pragmatic guidance, so that entities are able to apply and comply with the principles and privacy protections”. In order to this it is critical that the DAT Code appropriately reflects the relevant principles and privacy protections, in a way that supports application and compliance. In particular, the Code should not differ from the relevant principles and privacy protections in what it requires.

**I am writing to convey my concerns that the part of the draft DAT Code relating to a waiver of consent does not appear to appropriately reflect the underpinning principles and privacy protections, in a way that would be likely to adversely affect public health.**

Population health research, including that using linked data, is life-saving and of major importance to improving health and health systems. Much of this research involves many thousands if not millions of individuals and depends heavily on the ability to waive requirements for consent, where appropriate.

Provision for waiving of the requirement for consent is standard in most international and national research ethics guidelines, with the most common criteria for this being:

- It is impracticable to obtain consent
- The collection, use and sharing of the data is low risk
- There is some public benefit or interest in the use of the data

The Australian Privacy Principle Guidelines, the section 95 Guidelines of the *Privacy Act 1988* and the National Statement on Ethical Conduct in Human Research all include these three elements as well as additional criteria.

The draft DAT Code appears to deviate materially from these three basic criteria, and where it is similar, there are differences in wording that would make it harder for entities to apply and comply with the relevant principles and privacy protections.

The main material difference is that the code states that ‘It is not unreasonable or impracticable to seek consent merely because the consent of a very large number of individuals needs to be sought’ (clauses 16 (3-4)). This is more stringent than the Australian Privacy Principle Guidelines and section 95 Guidelines and National Statement on Ethical Conduct in Human Research. It is also in direct opposition to the “pragmatic” nature of the Code. For example, obtaining consent for thousands, if not millions of people whose records

are used for data linkage projects, using privacy-preserving methods, *is* unreasonable and impractical. It undermines the code to state that it is not. It may also have the more serious effect of making it impossible to conduct population health research under the DAT Scheme.

In addition, in order to provide proper and pragmatic guidance, it would support application and compliance if the Code used the same wording as the Privacy Act guidelines.

The current wording is likely to cause confusion and inconsistency, as well as unnecessary barriers to data use, in that it will require those considering requests for waivers of consent for medical research (largely Human Research Ethics Committees) to interpret and apply multiple sets of guidance with differing wording and requirements. It will also hamper Data Custodians' ability to apply and comply with them.

Hence, the draft currently does not "strike the right balance between holding data custodians accountable to seek consent, and providing data custodians with an exception to collect consent in circumstances where it is genuinely unreasonable or impracticable to seek consent" and would be improved by making this part of the Code sufficiently consistent with the Act and the appropriate safeguards it seeks to reflect.

Yours faithfully,

A handwritten signature in black ink, appearing to be 'EBs', written in a cursive style.

Professor Emily Banks AM