



Australian Government
Australian Institute of
Health and Welfare



Ms Gayle Milnes
National Data Commissioner
Office of the National Data Commissioner
One Canberra Avenue
Forrest ACT 2603

Dear Ms Milnes

Submission to the Data Availability and Transparency Code 2022 – Consultation

The Australian Institute of Health and Welfare (AIHW) welcomes the opportunity to provide a submission to the Office of the National Data Commissioner (ONDC) on the draft Data Availability and Transparency Code 2022 (the Code).

The AIHW is an independent statutory Australian Government agency producing authoritative and accessible information and statistics to inform and support better policy and service delivery decisions, leading to better health and wellbeing for all Australians. As an information agency, the AIHW relies upon strong data governance to perform its functions effectively and maintain a trusted reputation amongst its many data suppliers, data users and stakeholders.

The attached AIHW submission on the Code is guided by questions set out in the ONDC consultation paper.

We trust that you find this information useful. Should the ONDC have any queries about the information provided, or wish to seek additional information from the AIHW, please contact Michael Frost, Data Governance Group on [REDACTED]

Yours sincerely

[REDACTED]
Rob Heferen
Chief Executive Officer
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Attachment 1: AIHW Responses to Data Code Consultation Paper questions

Consultation questions – Project principle: project reasonably expected to serve the public interest

1. Is the approach to weigh arguments for and against the project serving the public interest appropriate? If not, how else could entities assess whether a project for the purpose of informing government policy and programs, or research and development, serves the public interest?
2. If yes to the above are the requirements of what entities must do, to weigh up arguments for and against the project serving the public interest, clear and unambiguous, and is this list proper and pragmatic? In your response, please provide reasons.

The AIHW believes the public interest approach is pragmatic, albeit subjective to an extent. It can be difficult to quantify risks and benefits for projects and therefore reach a rational assessment in some cases.

For example, desirability can be a very subjective notion in this context as these may differ between parties. Assessing commercial benefits against public interest can also be extremely complex. Similarly, public interest or benefit may also not be immediately apparent, for example, until after research is complete. Therefore, there may be benefit in providing greater scope for 'expected' public benefit.

The DAT Act involves sharing data more broadly than for 'medical research'.

However, there is a risk the current draft Data Code increases administrative effort for entities that apply similar but different criteria and tests to data sharing for research purposes. For example, a Human Research Ethics Committee (HREC) must apply the public interest criteria at Section 3.3. of the ['Guidelines approved under Section 95 of the Privacy Act 1988'](#) (Section 95 Guidelines) where a project falls within the meaning of 'medical research' as defined in the *Privacy Act 1988*. This means that organisations that require a waiver to collect, use or share/disclose those data will be required to apply two tests to the same sharing arrangement. There is a certain amount of consistency/overlap between the two tests, but they are not the same.

To reduce this risk, we suggest the Section 95 Guidelines be recognised in the Data Code, for example by waiving application of the proposed criteria at **s6(4)** of the draft Data Code in circumstances where the Section 95 Guidelines have already been or will be applied. The Section 95 Guidelines have been operating for many years, are established under the *Privacy Act 1988*, and have a particular focus on balancing the public interest in the research and the public interest in the protection of privacy in the research context.

If alignment is not possible, it would be helpful if the Data Code could clarify the relationship between 'research and development' and 'medical research'. This would help to avoid any doubt about which best practice criteria and tests (including standards of consent, waiver criteria and public interest tests) should apply to a proposed data sharing project that involves the sharing of personal information for purposes that could be described as 'medical research'.

Ideally, there would be no inconsistent outcomes if an entity applied the proposed criteria at **s6(4)** of the draft Data Code compared to if the entity applied the current criteria at Section 3.3 of the Section 95 Guidelines. This alignment is essential where a proposed 'research and

development' project also happens to fall within the meaning of 'medical research' as defined in the *Privacy Act 1988*.

The above should not be interpreted as the AIHW saying the principles and standards that apply to medical research should apply for all research or all sharing of personal information occurring for 'research and development' under the DATA scheme, as that is for the ONDC to decide. We simply suggest that there be express recognition of other current criteria and tests established by legislation within the Data Code.

3. Is the list of projects that do not serve the public interest able to be practically applied? What, if any, further guidance is required to support entities consider when a project does not serve the public interest?

4. Are the notes contained in this section helpful, and would this section benefit from other illustrative examples provided as notes? If yes, what examples and under which subsections?

The AIHW believes the list can be practically applied and the examples can be helpful. However, examples of a project that is 'merely of interest to the public' and which 'exclusively serves commercial interest' would be useful to assist with interpretation of **s6(5)** of the draft Data Code.

Notwithstanding, from a public perception viewpoint, '*merely* of interest to the public' [emphasis added] might be perceived negatively. Additionally, this could be taken to include projects that don't have an immediate applied use. If the intention is to exclude salacious-type interest, then similarly to paragraphs (b) and (c), (d) could read, for example, 'the project is of interest to the public, but does not serve the public interest', or 'the project is of general interest, but does not serve the public'.

The question of whether a project 'exclusively services commercial interest' can be subjective and greater clarity/guidance here could be beneficial.

Consultation questions – Project principle: applicable processes relating to ethics

5. Under the draft data code, entities must have regard to **any** process of ethics applicable. Do you have any comments about this approach?

6. Is the note provided to assist entities identify ethics processes helpful? Why, or why not?

There is a risk that **s7(1)** of the draft Data Code may enable avoidance of requirements under the [National Statement on Ethical Conduct in Human Research](#) (the National Statement).

The intent is to avoid duplicative processes where multiple ethical reviews may be required. Avoiding duplication is a good idea, however, some ethical review requirements may bring to bear a specific competency or expertise on a given proposal for data sharing and these should not be avoided. This might include, for example, ethical review by an Indigenous HREC where research involves or affects Aboriginal or Torres Strait Islander people.

s7(2) acknowledges that entities can undertake additional ethics processes, but this is permissible and implies that they can choose not to do so.

The note at **s7(1)** of the draft Data Code could clarify that ethics processes based on law should always be considered and an informed decision be made on whether the sharing of data satisfies ethical requirements.

The second sentence of the same note may also be improved by using the word 'humans' instead of 'individuals'.

Another worthwhile consideration is that, while Public Sector custodians are likely to be aware of applicable ethics processes relevant to their data, users may not necessarily be so aware.

Consultation questions – People principle: conflicts of interest

7. Are the requirements of this element of the people principle clear and unambiguous? What, if any, further details or guidance could assist?

8. Is the example provided under this section helpful? Why, or why not?

Sections 8 and 9 of the draft Data Code mention 'appropriately' managing conflicts of interest. An example of de-identifying data before sharing is given but other risk mitigation strategies would be helpful to add here.

The conflict of interest example is also quite limited and assumes the data contain identified information and the recipient recognises a named individual. This is probably the most obvious of conflicts. Guidance to entities in the code on more nuanced circumstances would be useful. For example, the types of matters raised in 10(4) are also relevant here.

Further, more clarity about how affiliations such as sponsorships, scholarships or participation in talent programs can create conflict of interest – through an example might help with interpretation.

Consultation questions – People principle: appropriate persons

9. Are the attributes, qualifications and affiliations listed in this section appropriate and easy to understand?

10. Would this section of the draft data code benefit from other illustrative examples provided as a note? If yes, what examples and under which subsections?

The AIHW believes this section is appropriate and easily understood.

However, **Section 10** of the draft Data Code mentions security clearances but does not mention other strategies such as requiring the signing of non-disclosure agreements (which may be embedded in the actual sharing agreement). These can improve the level of trust in an appropriate person.

The AIHW also believes that the Data Code should include some requirement to declare sanctions or any prior involvement in relation to data breaches, including where affiliations may have been a factor. This level of transparency regarding prior issues and how they have dealt with them will serve to build public trust.

Overall, the examples are clear, but comments raised on questions 7 and 8 above would apply here.

Consultation questions – Setting principle: reasonable security standards

11. Is this section adequate in clarifying what are reasonable standards?

12. Would this section benefit from an illustrative example provided as a note? If yes, what are some proposed examples?

Overall, the AIHW notes that the Data Code reiterates the importance of meeting Commonwealth standards for security.

The AIHW believes that this section is mostly adequate. However, it may be beneficial to include prescriptive guidance in some circumstances (i.e. what are the minimum requirements).

For example, it may be beneficial to cover risks proposed by method of access in circumstances with 2-way data flows.

The security standards that may be required for a given proposal can also intersect with the output principle. For example, in certain circumstances, the systems used to hold and analyse data will be required to have audit trail capabilities or output vetting arrangements. The Data Code could usefully provide some examples of the kinds of arrangements that may be necessary, depending on the nature of the data in question. Illustrative examples would also be useful in setting expectations for different data sharing scenarios. Given the scope of the DATA Scheme, at least one example should include linked Commonwealth data.

Consultation question – Data principle: appropriate protection – whether data should be altered

13. In practice, this element of the data principle, the privacy protections, and three data services set out in the Act, all work together to provide a framework to appropriately protect data. ONDC acknowledges there is a need to strike the right balance between taking a layered approach and not making the DATA Scheme too complex. Could the draft data code be improved to better assist entities apply this element of the data principle?

On subsections (2) and (3), the key objective of protecting the data is to manage privacy risks i.e. (re)identification and attributes. The Privacy Commissioner's guidance on this is in the public domain (see: [De-identification and the Privacy Act](#)), yet the key focus is on data reduction. This section of the Data Code could be strengthened by noting that the risks to be managed are re-identification and attribute disclosure risk.

We also recommend emphasising the need for proportionate protections commensurate with the context of use and accompanying risks might help. For example, for a Commonwealth agency sharing data with expert users such as the ABS or AIHW, it would be counterproductive to alter the data. Therefore, data should only be altered where it does not meet the scope or aim of the project.

Consultation question – Data principle: appropriate protection - data sharing must be reasonably necessary

14. Is the 'reasonable person' test adequate in this section? If not, how could this section be improved to allow the entities to test whether the data proposed to be shared, collected and used is reasonably necessary to achieve the data sharing purpose?

The AIHW believes an example here will help as these situations could be quite complex. Some guidance around providing justification for data requested may assist the application of this test.

Consultation question – Output principle

15. In practice, the output principle requires entities to agree how the accredited user will use shared data. Overall, how could the draft data code be improved to best assist entities apply the output principle?

The output principle as described in the Data Code does not explicitly cover the requirement for output vetting. The AIHW recommends the Data Code highlight the importance of ensuring that the risk of re-identification or attribute disclosure through the output should be minimised. Further, it should also provide more clarity on where this obligation lies. These are risks that should be mitigated under the output principle.

Consultation questions - Privacy protections

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?

There are existing requirements and tests to assess whether consent requirements have been met (Chapter 2.2 of the National Statement) and whether the requirement for consent may be waived for a given project (Chapter 2.3 of the National Statement; Guidelines under s. 95 of the Privacy Act). The APP Guidelines also provide guidance on these matters.

To reduce administrative burden and risks of non-compliance arising from similar but not identical tests (for example, another criterion in the s.95 Guidelines is that there will be scientific defects in the medical research if it was not conducted in the manner proposed), we recommend the ONDC recognise the NHMRC's principles and standards in these sections of the Data Code. For example by:

- waiving application of the proposed criteria at **s15** and **s16** of the draft Data Code in circumstances where NHMRC principles and standards have already been or will be applied (for example, following ethical review by a HREC or other relevant review body) or
- aligning the tests with existing requirements or
- even better, cross-referencing them.

The AIHW believes the NHMRC waiver of consent guidelines can complement the Data Code. It is important to understand how the contemporary advice in the Data Code relates to the NHMRC approach to consent, and if there are any additional requirements these should be articulated.

The ONDC should, in any case, check that there would be no inconsistent outcomes if an entity applied the proposed criteria at **s15** and **s16** of the draft Data Code compared to if the entity applied the current criteria at Chapter 2.2 and Chapter 2.3 of the National Statement.

There should be greater clarity on where custodians are permitted to delegate obligations to other bodies or committees to make informed decisions. For example, an ethics committee with diverse membership could provide more balanced views in considering whether consent is to be sought, or more broadly whether data sharing would satisfy the five principles.

Further, considerations of administrative burden and other general points raised in our response to Question 1 apply here.

17. Is this part of the draft data code adequate in providing further clarification for what considerations should be taken into account when determining whether it is necessary to share personal information to properly deliver a government service? How could this section be improved?

The AIHW believes an example here may help interpretation.

18. Does this part of the draft data code provide an adequate list of factors for data custodians to consider when determining whether the public interest justifies the sharing of personal information without consent? Would this section benefit from an example provided in a note, and if so, can you suggest one?

The word 'must' should be replaced with 'may' at **s18(4)** of the draft Data Code. Otherwise, the 'other relevant considerations' should be included in the list at s. 18(3) of the draft Code.

Sharing information about vulnerable cohorts of the population such as people in nursing homes or people with compromised immune systems to enable prompt administrative emergency response in natural disaster situations (such as bushfires or floods) or outbreaks of Covid-19 like epidemics could be provided as examples in a note. Data sharing considerations for within and across health services and cross jurisdictions will be impacted by the need to promote best practice and continuity of care.

Further, general points raised in our response to Question 1 apply here.

Consultation questions - Data sharing agreements

19. Should the data sharing agreement include any additional details about the designated individual who is a foreign national?

The AIHW believes that it will be safer to include relevant additional details given geo-political sensitivities with certain nations.

An additional consideration is where the designated individual might access data from. For example, where remote access is possible from countries other than Australia.

Consultation questions - Miscellaneous

20. This part of the draft data code is informed by the list prescribed in section 130 of the Act. Is this an appropriate approach, and are there any additional details that should be provided to the Commissioner outside of that list?

To avoid the risk of administrative burden mentioned at Question 1, the reporting required by **s21** of the Data Code should recognise the annual reporting that is already required by the '[Guidelines approved under Section 95 of the Privacy Act 1988](#)' (Section 95 Guidelines).

Annual reports to NHMRC cover the following information about each waiver of consent granted by the AIHW Ethics Committee:

- which matters were relevant in establishing that the public interest in the research proposal outweighed, to a substantial degree, the public interest in the protection of privacy,
- the name of the Commonwealth agency/ies from which the personal information was sought,

- the data items that were sought from the Commonwealth agency and approved,
- the number or range of records involved.

We recommend the ONDC waive the requirement for reporting under **s21** of the draft Data Code in circumstances where reporting to the NHMRC under the s. 95 Guidelines has already been or will be undertaken for a given data sharing project.

The same general points raised in Question 1 apply here.

21. Is the 31 July an appropriate deadline for data custodians to provide information and assistance to the Commissioner to prepare for the annual report?

The AIHW believes any deadline should balance the reporting and administrative burden placed on data custodians against the benefits of transmitting this in a timely manner. Consideration should be put on how this information can be periodically provided to the ONDC either automatically as part of regular operations of the DATA Scheme or as an addendum that poses minimal burden on custodians (for example, through the Dataplace platform).

Consultation question - Potential additions to the data code

22. What additional topics could the data code include to assist the establishment or integrity of the DATA Scheme?

Other additional topics

For the integrity of the DATA Scheme, additional topics could be included in the Data Code to assist entities understand any ONDC requirements:

- where the same entity is acting in more than one role as Data Custodian and/or accredited Data Service Provider and/or accredited Data User
- regarding notifying ONDC of a non-personal data breach under s30 of the DAT Act.

Collect a copy of the data

Additionally, **s10 (3)(b)** of the DAT Act states 'For the purposes of this Act, if an entity provides another entity with access to data... the entity to which access is provided is taken to collect a copy of the data'

The intention of this clause is unclear. For example, is it intended to signal the need to ensure legal authority to receive data is in place before engaging in sharing? Alternatively, could this clause be interpreted to imply that where access is provided to data in a secure environment, where the data cannot be removed without authorisation by the data custodian for example, that the user has been 'taken to collect a copy', thus negating the protections of the secure environment.

Consistency with Privacy Act

It would also be helpful to expand on how an entity determines if the sharing of data under the DAT Act 'is consistent with' the *Privacy Act 1988*. The interpretation here can be contentious.

For example, does it mean that all action must be compliant with the Privacy Act and, if it is, then the DAT Act permits sharing of personal information provided the DAT Act provisions for doing so are also met? e.g. where a waiver is obtained for sharing data without consent.

Alternatively, does it mean that if, for example a waiver *could have been* obtained, the sharing is authorised by the DAT Act, subject to meeting the Act provisions for doing so?

Considerations around priority population groups

The Data Code does not currently describe the impact or sensitivities and additional consultation required for Indigenous data governance or considerations required for priority population groups who may be under-reported or misrepresented. If this is out of scope for the current phase, plans for future consultation should be noted.