Consumers Health Forum of Australia

SUBMISSION

NHMRC Public Consultation on the National Statement on Ethical Conduct in Human Research Sections 4 and 5

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Consumers Health Forum of Australia (2020) *Submission to NHMRC Public Consultation on the National Statement on Ethical Conduct in Human Research Sections 4 and 5.* Canberra, Australia

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CONTENTS

Contents

Overview

The NHMRC proposed to include new and revised chapters in Section 4 and Section 5 of the National Statement on Ethical Conduct in Human Research, 2007 (updated 2018) (the National Statement). Developed by the Australian Health Ethics Committee (AHEC), the revised sections provide advice for both researchers and Human Research Ethics Committees (HRECs) addressing ethical considerations related to potentially vulnerable participants in research (Section 4) and research governance and ethics review (Section 5).

Under Section 13 of the National Health and Medical Research Council Act 1992, NHMRC was required to undertake public consultation prior to finalising its human research guidelines. NHMRC is keen to ensure that the Australian community has the best opportunity to participate in developing guidance on the ethical design, review and conduct of human research, and seeks your feedback on the proposed changes to the National Statement.

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers and those with an interest in health consumer affairs, including health based research. We have around 200 members reflecting a broad spectrum of organisations including state-based consumer peaks, condition-specific groups, volunteer patient groups, professional associations, Primary Health Networks (PHNs) and the research community.

We work in collaboration with our members, national partners and research collaborators to influence policy, programs and services to ensure they are in the consumer and community interest. In developing our submission we provided our members the opportunity to input into our responses and consulted with our 'Research and Data Special Interest Group', a group of nearly two-dozen everyday consumers with an interest in health research and data.

CHF is pleased to make this submission in response to the NHMRC Public Consultation on the National Statement on Ethical Conduct in Human Research Sections 4 and 5.

CHF Submission

1. Section 4 Feedback and Responses

REFERENCE	QUESTION
Introduction & Revised Chapter 4.1: Ethical issues in recruitment and involvement of vulnerable participants in research	
Introduction & Chapter 4.1	**1. Is the scope of Section 4 adequately defined and is the scope appropriate? If not, provide comment on the how the scope should be extended, reduced or re-defined.** Yes, we believe the scope is adequately defined and appropriate. We support the effort to highlight that vulnerability is related to individuals, not by group definition, and is on a continuum and is context specific.
Introduction & Chapter 4.1	**2. Do the enumerated chapters fully capture the issues that are within the scope of Section 4?** Yes
Introduction & Chapter 4.1	**3. Is the concept of vulnerability appropriately framed and described in the Introduction and in Chapter 4.1?** Broadly speaking, yes. The framing of the various aspects that can lead to as a factor contributing to vulnerability rather than automatically equalling someone being vulnerable is great. For example, a Person with a Disability may be vulnerable in the context of a research project with their disability contributing but the fact of them being a Person with a Disability does not automatically make them vulnerable. However, we believe one aspect of potential vulnerability that is perhaps not sufficiently explicitly addressed is that of 'Culturally and Linguistically Diverse" (CALD) backgrounds. We suggest the dot point: • social or economic disadvantages that constrain the exercise of self-determination, including those resulting from limited language skills, illiteracy or stigmatisation based on disclosed or perceived identity Be amended to articulate those CALD areas of vulnerabilities. The vulnerabilities related to language barriers than can prevent and impair participation. Similarly, it is possibly that LGBTIQA+ status may also not sufficiently clear as a potential characteristic contributor to possible vulnerabilities in research and should be listed as such in sub-section B of this part. We would also recommend an articulation of the fact that people with these vulnerabilities make up part of the real world population of Australia, so not only should they not be excluded for ethical reasons but they should be actively included in research to ensure the research data reflects the situation in the real world.
Introduction	In the draft revised Section 4, a dedicated chapter addressing ethical issues associated with research with Aboriginal and Torres Strait Islander people and communities has not been included (the current chapter 4.7 has been removed). Instead, we are proposing to address these issues in a revised Preamble to the National Statement, along with references to the NHMRC Indigenous research ethics guidelines and the new Australian Institute of Aboriginal and Torres Strait Islander

REFERENCE	QUESTION
	Studies (AIATSIS) guidelines/Code of Ethics (publication expected in 2020). This proposed approach has been taken in response to input from key stakeholders in this research sector and based on the rationale that this approach avoids reinforcing the association between (research with) Aboriginal and Torres Strait Islander peoples and the concept of vulnerability that underpins the draft revised Section 4. **4. Do you agree with the proposed approach to locate information and/or guidance on research with Aboriginal and Torres Strait Islander people and communities outside of Section 4? Why or why not?** Without seeing the revised Preamble, it is difficult to say with certainty that the proposed way of handling ATSI guidance on ethical research is appropriate and ideal. We agree that it is important to acknowledge the nuance and importance of ATSI involvement in ethical research, so specifically accounting for it in the Preamble on conjunction with the Section 4 Introduction guidance seems like an acceptable approach in concept. If Section 4 is revised slightly to include more explicit reference to the effect CALD factors can have on participant vulnerability.
Chapter 4.1, sub-section C	The use of a risk matrix, in graphic format, has been proposed for sub-section C of Chapter 4.1. This matrix can be used for risk assessment. **5. Should a risk matrix be included in Chapter 4.1 of the National Statement? Why or why not?** Yes, a risk matrix should be included. Is important for researchers to be reminded that risk is measured not just in terms of how *bad* an outcome is but how *likely* it is, with a highly-likely-but-less-"bad" risk needing mitigation as much as a very-bad-but-unlikely risk. A risk matrix effectively accomplishes this task. The risk matrix could be improved with a supplemental appendix of a 'worked exemplar' showing how the matrix used to identify, classify and then mitigate various risks for a research proposal in the Australian context.
Introduction & Chapter 4.1	**6. Provide any additional comments on the draft Introduction or Chapter 4.1 here.** We believe that it should be explicitly noted, likely as part of sub-section D, that the best way to ensure you have both correctly identified and mitigated potential risks for participants is to actively consult a*nd collaborate* with participants/participant representatives/advocates *early* in the research design stage. And that it is important to not simply do 'a box ticking exercise' where you design the whole research proposal yourself, ask for broader input at the end when it is too late to change any critical details and make generally superficial changes.
Revised Chapter 4.2: Participants in life stages that may give rise to vulnerability	
Chapter 4.2	The chapter on life stages only includes guidance addressing research involving persons with reproductive potential, pregnant persons, the foetus, persons who have carried a foetus and children and young people. Issues related to adulthood more generally are incorporated into other chapters. **7. Does the structure of Chapter 4.2 work as currently proposed? If not, why not and what modifications would be appropriate?**

REFERENCE	QUESTION
	From the introductory statement, there would be an expectation that there would be inclusion of older people and those at end of life with guidelines for their inclusion as participants in research. Including these people would give recognition of the diversity of life stages and the different needs of the aged population and research in addressing these needs. It may also be worth clarifying in the introduction section that the factors such as diminished capacity and frailty that may be erroneously linked to just older people should be considered as part of risk assessment in section 4.1.
Chapter 4.2, sub-section C	The sub-section of Chapter 4.2 on Children and Young People includes a statement that "the terms 'adolescent' and 'young adult' are not used … due to the diversity of meanings and age-ranges that different communities and cultural groups associate with these terms." **8. Does the decision not to use these terms raise any concerns for you? If so, what are these concerns?** We have no concerns. As articulated in the statement, the terminology used appears appropriate. The ethical issues of research involving 'children and young people' are appropriately articulated. **9. Can these concerns be alleviated by adding or modifying the content of Chapter 4.2? If yes, what modifications are appropriate?** N/A
Chapter 4.2, sub-section C	**10. Do you support the use of the concept/term 'assent' for research involving children and young people? If not, why not?** Yes, we broadly support it. It appears to be a good way to capture the importance of getting approval from the child/young person themselves in order to have ethical research while acknowledging that further consent is still legally needed by a parent or guardian with the emotional and mental maturity to understand the research in its entirety.
Chapter 4.2, sub-section C	**11. Is Figure 2 in sub-section C of Chapter 4.2 helpful? If not, why not?** Figure 2 helpful although it is unclear when to categorise a young person as falling into the bottom row. **12. Do you have any suggestions for how this table could be improved?** It may be redundant but making it clear that this table, we presume, only applies to people under the age of 18. Although potentially the assent-consent model could also be noted as a being useful guide for people over the age of 18 with legal recognition of impaired maturity and capacity to consent.
Chapter 4.2	**13. Provide any additional comments on Chapter 4.2 here.** We believe it is good that education institution bases research is included, point 30 on page 15, but note that potentially a broader range Government Departments should be

REFERENCE	QUESTION
	noted as relevant too e.g. Justice, Child Protection for research into 'children and young people' issues. Additionally, while the choice of juxta positioning the terms 'Assent' and 'Consent' was likely a deliberate one some consumers we consulted suggested that given these words were similar they may be easily confused and perhaps one should be changed. For example, referring to 'Support' or 'Agreement' from the child or young person rather than 'Assent'.
Revised Chapter 4.3: Life circumstances that may give rise to vulnerability	
Chapter 4.3, sub-section A	The sub-section on physical or mental ill-health includes reference to advance planning and advance directives. This inclusion is accompanied by a linkage to the 'scope of consent' categories in Chapter 2.2 (see 2.2.14) and advises that "advance directives may be project-specific, applicable to related future research ('extended') or broadly applicable to future research activities ('unspecified')." An alternative model might be to include reference to the use of advance directives, but limit their use to either the 'index project only' or to 'the index project and related future research only', i.e. excluding the use of advance directives for unspecified future research activities. **14. Do you support the inclusion of the use of advance directives in the National Statement? If not, why not?** Yes, we support the inclusion of advance directives to cover research participation. It seems a sensible way for people who may lose the ability to actively consider and consent what research they are and aren't willing to participate in to do so while they have the ability. This is a good idea. **15. If yes, do you support the framework proposed in sub-section A of Chapter 4.3?** Yes, we support it. Giving the patient the maximum scope for which to consider consenting or not-consenting is ideal. Artificially limiting their options and not letting them consider all the options would be a poor direction to take. **16. If yes to 14, but no to 15, do you support one of the alternatives proposed above in the introduction to these questions? If yes, which alternative do you support and why?** N/A
Chapter 4.3, sub-section A	In the sub-section on people who are seriously ill or unconscious, researchers and reviewers are advised to 'consider whether an independent person should make the initial approach and/or seek consent from a potential participant or from their guardian or authorised representative'. In addition to this category of participants (i.e. people who are seriously ill or unconscious), this guidance has also been provided in the Introduction to Chapter 4.3. **17. Is this guidance appropriate for research involving circumstances covered by Chapter 4.3, generally, and in the specific context described in the Introduction to this question, above? If not, why not?** This generally seems appropriate. However we would observe that the impairments to written and verbal communication noted in point 12 in regards to providing information to the potential participant also should be noted as applying to their ability to

REFERENCE	QUESTION
	mechanically complete the consent process and alternate mechanisms that the standard 'complete and sign a paper form' may need to be considered.
Chapter 4.3, sub-section A	The sub-section on emergency care research, intensive care research and research involving terminally ill participants includes a hierarchy of consent, waiver of the requirement for consent and approval of research without consent. This guidance replaces the guidance in current Chapter 4.4 of the National Statement, parts of which have been misunderstood and/or applied incorrectly: specifically, to support the practice of obtaining so-called delayed or deferred consent, which is not permitted under the National Statement. **18. Do you support the approach taken to the guidance in this sub-section? If not, why not and what alternative model would you suggest instead?** We generally support the hierarchy approach model of consent given in this guidance. However, given point 20 on page 23 we are not quite sure what exactly the 'deferred consent' or 'delayed consent' models are that the National Statement is explicitly not supporting so clarification there would be beneficial.
Chapter 4.3	**19. Provide any additional comments on Chapter 4.3 here.** This may be redundant but for people who are seriously ill or unconscious, it is likely worth articulating that research should a) ideally have a direct benefit for them as individuals in assisting with their condition and b) at a minimum not risk any worsening of condition or impairment of their recovery.
Revised Chapter 4.4: Research contexts that require additional consideration	
Chapter 4.4, sub-section B	Research conducted during natural disasters, armed conflict, public health crises or other emergencies is a new topic in this revision of the National Statement. It is also the subject of an array of guidelines and advice developed by international bodies, such as WHO[1], national governments, humanitarian organisations and the Nuffield Council on Bioethics[2] (UK). This guidance cannot all be replicated in the National Statement. **20. Do you think that the guidance provided in this sub-section is adequate and, if not, do you support the development of a separate guidance document to address this type of research?** This is beyond the area of CHFs expertise but as a general view, given the noted complexity of this area of research developing additional guidance documentation would likely be helpful to researchers and participants. **21. If you support a separate guidance document, do you think that this document should replace the guidance proposed in sub-section B or extend that guidance?** Again, this is beyond the scope of CHFs expertise but we would suggest 'extending' rather than 'replacing'.
Chapter 4.4	**22. Provide any additional comments on Chapter 4.4 here.**

[1] WHO guidance: https://www.who.int/ethics/publications/epidemics-emergencies-research/en/.
[2] Nuffield guidance: https://www.nuffieldbioethics.org/publications/research-in-global-health-emergencies/.

REFERENCE	QUESTION
	Point 2 on page 28 refers to "1.10 to 1.13" but is it not clear what precisely those items are. Additionally, the guidelines on page 31 start with number 15 but we believe it should start with 16 and have subsequent items renumbered. Links to other relevant documentation that researchers need to be aware of e.g. Government, Agencies could also be valuable, potentially as a curated appendix.
Other considerations	
Other	**23. Is there an area of research that is within the scope of Section 4 for which it does not provide adequate guidance? If so, what area and what guidance would you propose including?** N/A
Other	**24. If you have any other input that you would like to provide, please do so here.** N/A

2. Section 5 Feedback and Responses

REFERENCE	QUESTION
Revised Chapter 5.1: Governance responsibilities of institutions	
Chapter 5.1, guidelines 7-9	NHMRC is proposing that for research (a) that is to be conducted in Australia or with the participation of Australian residents, and (b) where an ethics review has been conducted in another country with an equivalent standard to the National Statement an ethics review in Australia may not be required. If this principle is accepted, then a corollary issue is what criteria would be applied to ensure that the standard that is relied upon is equivalent to the National Statement. **1. Is it appropriate for an institution to accept an external ethics review from a review body in another country when it is based on an international standard that is equivalent to the National Statement? If not, why not?** *Note: Stakeholders should be aware that the acceptance of one national ethics guideline or standard by another country is common practice internationally. For example, for those institutions conducting research using funds from the US government, the National Statement is accepted as an equivalent standard (to the Common Rule) by the United States under the Federal Wide Assurance (FWA) scheme operated by the U.S. Department of Health & Human Services Office for Human Research Protections. See www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html. Another example is the acceptance by some European countries of a review conducted in*

REFERENCE	QUESTION
	another EU member country, which, implicitly, is based on the acceptance of the adequacy of the standard used by the reviewing country. Yes, we believe this is appropriate. However, we would suggest some curated list be created and maintained by the NHMRC as to which countries have ethical review processes that meet the international standards and are acceptable substitutions for Australian ones. We also note that Guidelines No 3 (revised 5.1.2) should perhaps change the words 'satisfied' to 'ensure' to put a stronger onus on institutions to ensure that research they are responsible for is conducted ethically.
Chapter 5.1, guidelines 10--16	The existing National Statement risk categories ('greater than low risk', 'low risk', 'negligible risk' and 'eligible for exemption from review') have been modified. The proposed risk categories are 'moderate to high risk', 'minimal risk' and 'eligible for exemption from review'. **2. Do you agree with this change of risk categories? If not, why not?** *Note: If implemented, there will be consequential changes to the risk category definitions and guidelines in Chapter 2.1.* We believe that in theory the proposed new categories seem sensible and clearer than the current categories. However, without seeing the consequent changes to 2.1 and the research review/approval process, we can't give unconditional support to the proposed changes. For example, how it will be determined whether research proposals that formerly would be classified as negligible risk' would now be 'minimal risk' or 'eligible for exemption'.
Chapter 5.1, guidelines 15--17	The risk category 'eligible for exemption from review' has been expanded to include additional types of research. The expanded eligibility criteria are drawn from the recently revised US Common Rule criteria, with significant modifications. **3. Are the types of research proposed for revised guideline 16 appropriate and sufficient? If not, how should they be modified?** General this seems appropriate. However, there is some confusion as to how 'minimal risk' and 'eligible from exemption' are two separate categories but point 16a says that research with minimal risk may be eligible for exemption. We presume that the intention is that a 'minimal risk' research project won't satisfy any of the 16b categories while 'eligible for exemption' will, but that isn't completely clear. Otherwise they seem appropriate and sufficient.
Chapter 5.1, guideline 31 ***and*** **Chapter 5.2, guideline 48**	5.1.27 of the National Statement specifies that the Human Research Ethics Committee (HREC) terms of reference (ToRs) ***should*** be publicised. Revised guideline 31 states that an institution '***must*** set out and publicise' its ToRs. Additionally, revised guideline 48 in Chapter 5.2 states that standard operating procedures (SOPs) ***must*** be 'documented, implemented and publicised'.

REFERENCE	QUESTION
	The benefit of publicising ToRs and SOPs is that publication can assist users of an HREC, including non-affiliated researchers and institutions who are considering accepting an external HREC's ethics review, in obtaining access to information about institutional requirements and HREC operations. There are also some proposed changes to requirements for HREC ToRs and SOPs. **4. Are there any reasons why an institution would not be able to publish the revised HREC ToRs and/or SOPs on its website? If so, what are those reasons?** *Note: please distinguish between the publication of ToRs and SOPs within your response, if relevant.* N/A. CHF is not such an institution and while we can't envision reasons for institutions to not make such information public, we would defer to considering such reasons from them before having a firm position.
Chapter 5.1, guidelines 32-40	Some guidelines on minimum membership, additional members, pools of members and the requirements for diversity and expertise have either been added or modified. There are no new minimum membership categories proposed for HRECs; however, • the criteria that apply to some of the categories have been broadened • several ambiguities about attendance at HREC meetings and sources of expertise have been addressed, and • the requirement for gender balance is now for gender diversity, without reference to binary gender categories (i.e. 'male' and 'female'). **5. Do you have any concerns about the content of revised guidelines 32-40 or the way that they are expressed? If yes, describe your concerns and propose any alternatives or additional factors that may be appropriate to include.** We strongly support the need for diversity in HREC bodies and would suggest that the current guidelines (specifically 38, 39 and 40c) are too limited in what factors are considered (gender and external/internal) for the HREC membership pool. We would suggest professional diversity (e.g. inducing non-researcher/academic backgrounds), CALD diversity, queer/sexuality diversity, ability/disability diversity, spiritual/belief/religiosity diversity. While it is likely not possible to get a perfect and complete representation of the Australian community and its views onto all HRECs, they should still be factors HRECs aim to improve on and meet. **6. Do you think that further guidance should be provided at guideline 32(b) about the appropriate parameters for the type of experience that is optimal for candidates for appointment in this category? If yes, indicate what those parameters should be for these members.** Additional guidance as to what criteria can be used to help select HREC members would be beneficial however it is likely better suited as an appendix rather than within guideline 32(b) specifically. At this stage we are not sure how all the parameters could or should be defined but would welcome the opportunity to further input on such discussions.

REFERENCE	QUESTION
Chapter 5.1	**7. Provide any additional comments on revised Chapter 5.1 here.** N/A
Revised Chapter 5.2: Responsibilities of HRECs and other ethics review bodies	
Chapter 5.2	**8. Provide any comments on revised Chapter 5.2 here.** N/A
Revised Chapter 5.3: Responsibilities of researchers	
Chapter 5.3	The responsibilities of researchers described in the current Chapter 5.2 have been expanded and separated into a new chapter. **9. Do you have any concerns about the changes in revised Chapter 5.3? If so, what are they?** We have no concerns with the changes and believe they generally appear good. One possible addition would be adding in the responsibility for researchers to notify participants about the research results, publications and impacts; or at the minimum to give participants the option to choose to be notified about the results, publications and impacts of the research they participate in.
Chapter 5.3	**10. Provide any additional comments on the revised Chapter 5.3 here.** The last sentence in point 79 begins with 'A researchers. We suggest deleting the 'a'.
Revised Chapter 5.4: Monitoring	
Chapter 5.4	**11. Provide any comments on the revised Chapter 5.4 here.** The introduction refers to further resources available from the NHRMC and Department of Health. Ideally some linking to either those resource or a Hub of some sort where interested parties can find relevant collated resources should be included in 5.4. In the last sentence of the second paragraph of the introduction we would suggest that delegations be noted as 'appropriate' rather than 'necessary'.
Revised Chapter 5.5: Minimising duplication of ethics review	
Chapter 5.5, Introduction	The introduction and guidelines in revised Chapter 5.5 provide extensive clarification on the duplication of ethics review, including the imperative to minimise unnecessary duplication of ethics review (and project authorisation processes).

REFERENCE	QUESTION
and guidelines 96-99	**12. Do you have any concerns about the guidance in revised Chapter 5.5? If so, what are they?** We have no concerns.
Chapter 5.5, guideline 97	Although not prohibited previously, the revised guidelines now explicitly extend the principle of single ethics review to minimal risk research (i.e. research that does not require review by an HREC). **13. While application of revised guideline 97 will depend on the way that institutions manage the review of this research, do you have any concerns about this guidance?** We don't have any concerns. This seems sensible.
Chapter 5.5	**14. Provide any additional comments on revised Chapter 5.5 here.** The last paragraph of the introduction states "Ethics review and approval is not equivalent to and does not obviate the need for authorisation of research by institutions with a responsibility to oversee the research". From our reading of this section, and the draft Chapters as a whole, the distinction between "ethical approval" and "research authorisation" are not entirely clear. How the later should mechanically function, both in of itself and in relation to a HREC review process. Articulating this as part of the overall National Statement would be beneficial.
Revised Chapter 5.6: Disclosure of interests and management of conflicts of interest	
Chapter 5.6	**15. Provide any comments on revised Chapter 5.6 here.** The guidance all seems appropriate.
Revised Chapter 5.7: Complaints	
Chapter 5.7	The revised Chapter 5.7 directs those with complaints related to the conduct of research (as opposed to the review of research) to guidance provided in the *Australian Code for the Responsible Conduct of Research* and the *Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research.* Also, the term 'research misconduct' used in the current National Statement has been replaced with 'breaches of the Code', as per the 2018 Code. **16. Do you have any concerns about this approach used in revised Chapter 5.7? If so, what alternatives would you suggest?** We agree with the new approach of referring to them as "breaches of the Code' when alleged. Confirmed breaches could then be adjudicated to determine if there has been "misconduct". The label of misconduct can be quite damaging and should not be used in the investigative stage where complaints are being

REFERENCE	QUESTION
	resolved. However, there is still a place for the label "research misconduct" for some complaints when found to be unfortunately true so it should not be entirely removed. We would also recommend that some guidance should be produced about the penalties and consequences that exist for confirmed breaches of the Code and research misconduct.
Chapter 5.7	**17. Provide any additional comments on revised Chapter 5.7 here.** We would suggest some guidance be included about who needs to be notified and how about alleged breaches and the results of the investigation e.g. are participants told? When? By whom?
Revised Chapter 5.8: Accountability	
Chapter 5.8	**18. Provide any comments on revised Chapter 5.8 here.** The guidance seems appropriate.
Revised Section 2 / Glossary	
Chapter 2.1 and Glossary	If the changes to the categories for risk, as described at Question 3, above, are made, the definitions for these categories currently included in Chapter 2.1 and the Glossary will also need to change. **19. If you support these changes, do you have any suggestions for how 'moderate to high risk' and 'minimal risk' should be defined?** At this stage no but would welcome the opportunity to provide further consumer input as definitions are developed.
Glossary (and footnote in Chapter 5.1)	The definition of 'institution' has been modified and expanded in the draft revised Section 5. **20. Do you have any concerns about this definition? If so, do you have any alternative language to propose?** The definition seems appropriate, no concerns. Although we note that the 5.1 footnote's final sentence reads "It is recognised that not all institutions will have the infrastructure or resources necessary to perform all the functions that are attributed to institutions in Section 5". This reads as if there should be a follow-on sentence(s) that explains what should happen for the institutions in those circumstances to ensure research is conducted ethically. We would recommend guidance in that area be articulates.
General	
Additional comments	**21. Is there anything else that you would like to add to your comments on the content, format or useability of Section 5?**

REFERENCE	QUESTION
	From the consumers we conducted the following general points were raised: • Some consumers noted the consultation documents were very lengthy and difficult to parse, additional supporting materials to summarise key information and make it more accessible would have been beneficial. • Consumers noted that there should be an articulation of the ethical reasons and requirements, beyond any existing NHMRC or journal publisher rules and requirements, for taxpayer funded research through NHMRC grants should make their data, results and methods publicly accessible for independent analysis and further research. This needs particular focus in areas where companies/business are involved in the research, or can be spun off by parties involved in the research, to try make sure public funded data, results and methods don't become commercial-in-confidence and private-profit-generating. • Need a stronger articulation of the mechanisms that can assure the public that research is being conducted ethically and per the National Statement Guidelines. Having rules and regulations have no value if there is no certainty they are followed and enforced. Consumers suggest some sort of reliable, independent QA process that randomly audits NHMRC funded research and review it to make sure ethical processes are being followed. • Need an articulation about the reporting/publishing of "unsuccessful" research results, that is null-results research, as well as the more exciting "successful" research. Making the null-results research more publicly known is a critical part of the replicability of science plus in improving on methods by seeing all methods that have been used in the past, not just the "successful" ones.