DRAFT PUBLIC CONSULTATION QUESTIONS FOR REVIEW OF NATIONAL STATEMENT SECTION 4

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.** ACEM's view is that overall, the scope appears appropriate and adequately defined. ACEM is however concerned about the introduction to Chapter 4.1 that reads 'This Section provides guidance on research with participants who may be at high risk of research-related harms, burdens or wrongs, often described as vulnerable participants. It is ACEM's view that this statement is potentially demeaning to researchers and could be misinterpreted to imply that Human Research Ethics Committees (HRECs) are there to protect patients from researchers. It also perpetuates a myth that clinical research is inherently risky compared to routine clinical care. Many routinely used standard treatments in medicine are not based upon high quality evidence. Where there is uncertainty about efficacy/harms of treatment, or where there is variation in practice, patients are more protected in research where there is oversight and scrutiny of their care and outcomes than by receiving treatment outside of a research study. Moreover, by defining vulnerable participants as a product of research-related harms, burdens or wrongs, the statement diminishes the multifactorial drivers of vulnerability as considered on Page 4 of Draft Section 4. The role of a HREC is to ensure research is conducted in an ethical manner, which also incorporates justice, beneficence and respect for human beings. ACEM recommends the need to revise the description of vulnerable patients, both in the introduction to Chapter 4.1 and more generally throughout Draft Section 4.
Introduction & Chapter 4.1	**2. Do the enumerated chapters fully capture the issues that are within the scope of Section 4?**
Introduction & Chapter 4.1	**3. Is the concept of vulnerability appropriately framed and described in the Introduction and in Chapter 4.1?** ACEM considers that the concept of vulnerability as described in the Introduction and in Chapter 4.1 is reasonably well framed and welcomes the improvement on previous versions of the National Statement on Ethical Conduct. The description is clear and offers a good basis from which to consider possible sources of vulnerability. In addition to highlighting the potential for harm occurring to vulnerable people as research participants, ACEM believes there is a need to acknowledge the potential for harm due to routine practice variation and unproven standard treatments if barriers to recruitment into research remain for vulnerable groups. In many instances, the risk of research to participants is not due to the research *per se*, but rather the underlying condition leading to vulnerability (for example, critical illness) and the exposure to medical treatment in general. Rather than emphasise the role of HRECs and other review bodies first (Page 3, Paragraph 1), we suggest that it would be appropriate to initially document the researchers' responsibilities. If researchers give initial due consideration to 'vulnerability' this in turn will make the ethics review task both more straightforward and likely quicker.

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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 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?** ACEM supports the proposed approach and is pleased to see that Draft Section 4 recognises that vulnerable individuals or vulnerability exists on a continuum and is context-specific. Identifying as a member of the Aboriginal and Torres Strait Islander communities should not be associated with vulnerability. However, it is not clear whether the decision to locate information and/or guidance on research with Aboriginal and Torres Strait Islander people and communities outside of Section 4 was made following consultation with Aboriginal and Torres Strait Islander people. The proposed approach would carry significant weight if it has been decided through consultation and we recommend that if this is the case that this should be noted. ACEM recognizes that Indigenous communities have been the victim of poor research practices and recommends that this should be mentioned in Section 4 but with reference to the new AIATSIS guidelines. The proposed approach also mitigates the potential risk of misalignment with the AIATSIS guidelines. ACEM is however of the view that covering the ethics of research with Aboriginal and Torres Strait Islander people, in a preamble alone, is not adequate. Given the range of issues that should be taken into account, ACEM suggest that a separate chapter be considered. The AIATSIS Guidelines on working with indigenous people covers these complexities.
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?** ACEM's position is that the risk matrix presented in Figure 1 is not particularly insightful as it does not add to what is already included within the text and does not reflect the complexity of risk assessments. For example, severity and likelihood are only two dimensions; others that should be considered are possible impact: short and long term and mitigating factors. ACEM is concerned that the risk matrix graphic, as currently presented, could be misunderstood (for example, a high likelihood of harm is compensated for by low severity of that harm). We believe that it would be useful for both researchers and HRECs if Chapter 4.1, sub-section C included an example of an ethics application that has made an effective risk assessment (including how to address the risks).
Introduction & Chapter 4.1	**6. Provide any additional comments on the draft Introduction or Chapter 4.1 here.** It is ACEM's view that Guideline 3b, Chapter 4.1 (see below) appears contradictory to advice given later in section 4 on research in illness or emergency situations which may require enrolment under

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	next of kin or waiver of consent, for example, in situations including cardiac arrest and major trauma where the research intervention requires enrolment before the patient regains capacity. Chapter 4.1, Page 7, Guideline 3 b): *"*where an inability to consent is related to health status and is episodic or temporary, they should, where possible, delay recruitment into the research and seek consent when the potential participant is able to provide consent (see also 4.3.10)".
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 fetus, persons who have carried a fetus 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?** ACEM considers that the structure of Chapter 4.2 is appropriate.
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?** ACEM has no concerns with the decision to not use the terms 'adolescent' and 'young adult'. It is our view, that the rationale for not using the terms is clearly stated. We agree that the terms 'adolescent' and 'young adult' have a wide range of accepted definitions. **9. Can these concerns be alleviated by adding or modifying the content of Chapter 4.2? If yes, what modifications are appropriate?** As we do not have any concerns, this question has not been answered.
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?** ACEM supports the use of the term 'assent'. It is ACEM's view that the issue of 'dissent' (Page 14, lines 1-3) is difficult. Based on clinical experience, ACEM believes that most young people would have difficulty accepting any additional requirements of research without the possibility of personal gain.
Chapter 4.2, sub-section C	**11. Is Figure 2 in sub-section C of Chapter 4.2 helpful? If not, why not?** It is ACEM's view, that Figure 2 provides a useful overview. However, we recommend the addition of a comment regarding the need for documentation. Parent/guardian consent usually requires a signed Participant Information and Consent Form. Assent may (under many circumstances) be appropriately given with verbal permission to proceed. Requiring young people to sign a form may present an additional barrier while not providing any additional benefit. Given the potential for barriers, ACEM supports researcher documentation of verbal assent. **12. Do you have any suggestions for how this table could be improved?**

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	It is our view, that the table (Figure 2) could be improved by including an example of a child who is incapacitated and needs urgent treatment and where prospective consent is impractical.
Chapter 4.2	**13. Provide any additional comments on Chapter 4.2 here.** We have no additional comments.
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?** ACEM agrees with the inclusion of the use of advance directives in the National Statement. **15. If yes, do you support the framework proposed in sub-section A of Chapter 4.3?** ACEM supports the proposed framework in sub-section A of Chapter 4.3 and considers it will facilitate research directed at benefiting this population. **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?** Not applicable
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?** While, overall ACEM considers that the guidance provided is appropriate for research, it is ACEM's view that there are some circumstances where a patient who is unconscious for a prolonged period of time may be eligible for a trial, and a proxy decision-maker can be approached for prospective consent. In the context of research for emergency situations and/or critical illness, initial consent is impractical and will require a waiver. It is ACEM's position that the guidance provided in Chapter 4.3, sub-section A may be problematic if it makes the process of recruitment more complex and delays recruitment, for example in time critical emergency situations where treatment delay may be harmful. In time critical situations, the treating clinician is best placed to determine the patient's clinical treatment options. Where there is uncertainty and research is being undertaken to reduce this, clinician decision may be the ideal option. If the treating clinician is also involved in the research (for example as a named investigator on the HREC documentation), then a second practitioner may be required to confirm eligibility and appropriateness of enrolment for the patient for interventional clinical trials. The requirement for an

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	independent person to make the initial approach and/or seek consent from a potential participant, or from their guardian or authorised representative, will be unnecessarily burdensome for observational studies or comparative effectiveness trials of standard interventions. Indeed, it confers no protection for the prospective research participant and poses an obstacle which may deny the patient, the benefits of being a research participant. ACEM believes that a change in regulation is required to remove unnecessary obstacles for the conduct of clinical trials assessing the comparative effectiveness of standard interventions, especially where they pose negligible risk to participants. As discussed in response to Question 1, there is an assumption that research inherently confers risk to patients. Paradoxically, delivering routine standard treatments which are of unproven benefit, and possibly even harmful, exposes patients to greater risk of harm than enrolling them in research.
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?** ACEM welcomes the significant improvement in clarity in Chapter 4.3 from previous documents regarding emergency care research in time critical settings. There is clear recognition of the need for research to proceed without consent in time critical emergency settings with the criteria for these conditions to be met clearly set out. This is consistent with ACEM's position statement on research undertaken in Australian and New Zealand hospitals that involves participants highly dependent on medical care, who are unable to provide consent and require interventions with a time-critical element. ACEM also supports the pragmatic approach to supervised waivers, and variations to standard consent processes for the conduct of research in these situations. It is ACEM's position that the distinction that has been made between "deferred consent" and seeking consent to continue with the research is inappropriate. The process that has been termed "deferred consent" describes a situation where patients or families are explicitly explained risks/benefits of research participation; in situations where prospective consent is not possible for various reasons, detailed explanation, discussion, and documentation of such discussions is ethically appropriate. We disagree that the term delayed/deferred consent is unethical (Guideline 22) and consider that Guideline 22 contradicts both Guidelines 20 and 21 which describe the actual process that occurs with delayed consent. If a critically ill patient has been enrolled in a HREC approved research project under waiver of consent and then later regains capacity, there is typically a requirement to seek formal consent for both their previous and ongoing participation in the research. This is a form of delayed/deferred consent. We make no differentiation between point 21 "agreement to continue to participate" and what is termed "deferred consent" in Guideline 22 and deemed "not ethically permissible". Further to this, many research studies are observational and involve no deviations from usual practice and as such, Guideline 22 offers no justification for why delayed consent for low risk research is not ethical. As outlined in ACEM's position statement on time critical research, delays resulting from the pursuit of consent can result in preventable morbidity and avoidable mortality

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	and can obscure or reduce a beneficial treatment effect. It is our position that Guideline 22 is redundant and should be removed, as the intent is covered in other points (Guidelines 20 and21). The question of 'assent' in relation to children and young people was addressed in Chapter 4.2. Chapter 4.3 uses the term 'participant consent' but does not address 'assent'. It is ACEM's view that a consideration of assent in Chapter 4.3 would be of benefit, for example around advance directives (Guideline 6). In situations where informed consent may be problematic due to language and cultural barriers, the notion of assent may also be applicable. Question 18 refers to guidelines for emergency care research, intensive care research and research involving terminally ill participants (Page 22). ACEM recommends that the category of 'research involving terminally ill patients' be dealt with under a separate heading. ACEM is concerned about the use of the term 'precarity' (Chapter 4.2 sub-section C). Researchers may not be familiar with the term. People with Disability (sub-section B) and those living or working in institutional or community care settings (sub-section D) may also fit under "precarity" as outlined on pages 19 and 25 of Draft Section 4. It is ACEM's view that the inclusion of a definition of precarity in Chapter 4.3 is needed before addressing its links and experiences.
Chapter 4.3	**19. Provide any additional comments on Chapter 4.3 here.** ACEM believes that the guidance provided in Guideline 17 and Guideline 20 would be improved by the addition of the text in brackets (see below). This is particularly relevant for drug and alcohol or other sensitive research where the participant might not wish their presentation to be disclosed to their next of kin. • Chapter 4.3, Guideline 17 (Page 22): If obtaining consent from the participant or the participant's guardian or authorised representative is not practicable, [**or if contacting the participant's guardian or authorised representative would violate the participant's privacy**], then researchers should consider requesting a waiver of the requirement for consent (see 2.3.9-2.3.10). • Chapter 4.3, Guideline 20 (Page 23): If approval for research to proceed without consent has been granted and research has commenced, [**and if this would not violate the participant's privacy**], the participant and/or the participant's relatives and guardian or authorised representative should be informed as soon as reasonably possible of the participant's inclusion in the research and of the option to withdraw from it without any reduction in the quality of care that the participant is receiving. Guideline 19 (page 23) states that "Approval for research to proceed without consent can be granted by a HREC provided that it is satisfied that the following conditions have been met": It is not clear the difference between "research to proceed without consent" that can be granted by the HREC and not requesting a waiver of the requirement for consent as indicated in point h(ii) of Guideline 19. ACEM recommends that these specific circumstances are summarised and clarified. Guideline 21 (page 23) states "If the participant regains the capacity to make decisions regarding participation after the research has commenced, then the researchers should seek agreement from the participant that they are willing to continue to participate". ACEM considers that there is a need for caveats around Guideline 21. In drug and alcohol research, participants may not have regained their ability to consent prior to discharge, be accessible to researchers prior to discharge, or be contactable after discharge.

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	Attempting to contact a discharged patient raises the risk of privacy violation if communications are intercepted by family or occur when the participant is in the company of others. It is our view, that Guideline 21 should indicate: a. the reasonable steps that should be undertaken to contact a patient. b. if reasonable steps are taken and the patient is not contactable, whether the patient can remain included in the research.
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?** ACEM considers that the guidance included in Chapter 4.4, sub-section B is adequate and acknowledges that it helps to clarify a difficult issue. Optimally, the guidance should also mention language in addition to culture and specify the use of trained interpreters for both translations and in the conduct of research. It is our view that the guidance will be less accessible if in a separate guidance document. **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?** Not applicable
Chapter 4.4	**22. Provide any additional comments on Chapter 4.4 here.**
Other considerations	
Other	**23.**
Other	**24. If you have any other input that you would like to provide, please do so here.** It is ACEM's position that a nationally consistent approach to the regulatory requirements associated with consent would benefit research involving vulnerable participants. This would facilitate the conduct of multi-centre clinical trials. Consistent with the ACEM position statement on clinical research undertaken in Australian and New Zealand hospitals that involves participants highly dependent on medical care, who are unable to provide consent, ACEM supports the calls for special training or accreditation for Human Research Ethics Committees (HRECs) considering emergency care proposals. ACEM recommends that researchers working with children, young adults and vulnerable people should have a 'Working with Children and Vulnerable People' certificate. This is a minimum requirement in all organisations where people have direct contact with these groups of people.

[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/.

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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?** ACEM considers that it is 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. This is only if the rigour around ensuring that the international standards are adequate and are both transparent and defensible. Accepting an external ethics review promotes reciprocity and the efficient use of resources. Moreover, it facilitates international research collaboration and fosters international cooperation across jurisdictions. *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 another EU member country, which, implicitly, is based on the acceptance of the adequacy of the standard used by the reviewing country.*
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.* ACEM supports the proposed risk categories and welcomes the improvement in clarity.
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?**

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	ACEM believes that the types of research proposed for revised guideline 16 are 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'. 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?** ACEM recommends that consideration be given to: a) including in the ToRs or the SOPs, the complaints mechanisms for consumers, community members, or research participants. While complaints are covered in detail in Chapter 5.7, it is our view that they should also be considered in Section 5. b) specifying that HRECs are to be evaluated at specified and regular times. Draft Section 5 outlines the review of research projects but does not consider the actual HRECs themselves. *Note: please distinguish between the publication of ToRs and SOPs within your response, if relevant.*
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.** It is ACEM's view, that diversity relates to more than 'gender' and a broader approach should be taken. Such an approach would include references to age, ethnicity, religious and cultural affiliations. **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.**

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	ACEM recommends the specific inclusion of a First Nation voice in the membership of HRECs. We acknowledge that Guideline 32, page 6 of Draft Section 5 makes reference to members of an Aboriginal and/or Torres Strait Islander community but note that this is only in relation to a person who performs a pastoral care role in a community.
Chapter 5.1	**7. Provide any additional comments on revised Chapter 5.1 here.**
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.**
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?**
Chapter 5.3	**10. Provide any additional comments on the revised Chapter 5.3 here.**
Revised Chapter 5.4: Monitoring	
Chapter 5.4	**11. Provide any comments on the revised Chapter 5.4 here.**
Revised Chapter 5.5: Minimising duplication of ethics review	
Chapter 5.5, Introduction and guidelines 96-99	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). **12. Do you have any concerns about the guidance in revised Chapter 5.5? If so, what are they?**
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?**
Chapter 5.5	**14. Provide any additional comments on revised Chapter 5.5 here.**
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.**
Revised Chapter 5.7: Complaints	

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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?**
Chapter 5.7	**17. Provide any additional comments on revised Chapter 5.7 here.**
Revised Chapter 5.8: Accountability	
Chapter 5.8	**18. Provide any comments on revised Chapter 5.8 here.**
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?** ACEM recommends the need to define and outline 'potential risk' in the Introduction to Chapter 2.1: Risk and Benefit.
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?** ACEM has no concerns about the modified definition of 'Institution'.
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?**