DRAFT PUBLIC CONSULTATION QUESTIONS FOR REVIEW OF NATIONAL STATEMENT SECTION 5

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?** • Yes, it is appropriate, especially with increasing international efforts in data sharing for precision medicine and genomic research initiatives. • In relation to the later guideline 21, reviewing bodies will need guidance on equivalency of review will be determined and whether acceptance of external international review should be granted. The Global Alliance for Genomics and Health Ethics Review Recognition Policy outlines standards upon which to measure equivalency of review by, and may be worth consideration by the NHMRC. • This will rely on transparency of other countries' review boards on their review procedures. • If equivalency of review is determined on a case by case basis, this could prove slower than submitting the project again for local review. A list of internationally recognised review bodies be developed and added to with each new instance of acceptance, allowing subsequent projects reviewed by those bodies to be accepted without delay. *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?** • Reducing to three categories should result in a less complicated framework for ethical review.

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	• The 'moderate to high risk' may alarm participants involved in research if they become aware of the categorisation – suggest an alternative that avoids the use of the term 'high risk'. (see also response to Q19). *Note: If implemented, there will be consequential changes to the risk category definitions and guidelines in Chapter 2.1.*
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?** • It is constructive to see more detailed guidelines on the kinds of research that can be exempt from ethical review in this updated version of Chapter 5 (cf previous sections 5.1.22-23 and 2.1.7). However, this raises some potential concerns: b)i. May encourage researchers to submit proposals purposely targeted to the 'exempt from review' category where re-identification of individuals to feedback results that may be important health information will not be done (to expedite review processes). This may result in participants potentially missing out on important health information, experiencing the benefits of research participation. b)ii. May encourage researchers to continue to favour broad, unspecified consent models, where there is mounting evidence of the benefits of greater control over the use of biological samples and data for research participants. • Should c read "is restricted to surveys, interviews, or observations of public behaviour…"?
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?** • As researchers, we cannot see any reasons why a HREC could not publish its ToRs or SOPs on its website. These may be helpful to researchers to decide whether a HREC is appropriate to review a specific project. Transparency around SOPs for timely consideration of applications, the

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	process for review of external applications, notification of decisions to researchers and monitoring of research (guideline 48) would be of interest to researchers. • Noting that in the preparation of this response we were able to access the ToRs for the HREC we use online. We have had a 5-year relationship with this HREC and have not previously had a need to find their ToRs. *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.** • In addition to gender diversity, HRECs should be aiming to achieve cultural/ethnic diversity, given the multicultural nature of Australian society. • If HRECs are not able to approve research involving Indigenous people they should be transparent about this and be knowledgeable enough to provide information to researchers on how to seek such approvals. • NHMRC should reconsider the relevance of a "minister of religion" or "chaplain" as a member of an HREC, given that the 2016 census revealed that 30% Australians reported "no religion" and is "rising fast". **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.** • Some examples could be provided here, though we would consider HRECs quite adept in identifying such individuals since they have been a long-standing part of the HREC membership.
Chapter 5.1	**7. Provide any additional comments on revised Chapter 5.1 here.** • There are several statements that would benefit from expanded guidelines to HRECs, whether through the National Statement or other supporting guidelines. HRECs should be supported to use their data history on the management of previous

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	applications to determine their alignment with, and report with transparency on, the following guidelines: • "the workload of the HREC does not compromise the quality and timeliness of ethics review." (Guidelines 28 and 30) • "committee decisions are transparent, consistent, and promptly communicated" (Guideline 28) • "review processes and procedures do not cause unnecessary delay" (Guideline 28)
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.** • Addition to guideline 60 would be useful, on the requirement or not for ethical review of patient engagement materials, such as the information on participant-facing websites or other sources of information for participants. • Where HRECs and Governance systems mandate the use of online portals for submission of applications and amendments, the reviewing bodies should make assurances that their online systems are working to a minimum viable standard at all times. • Guidance and standards on the research project investigators (PIs/AIs) who need to be approved at the HREC-level and those that only need site governance-level approval or noting on a delegation log would be useful.
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?
	• Just a couple of typos:
	  • Guideline 77 "is" should be "are"
	  • Guideline 79 "researchers" should be "researcher"

Chapter 5.3	**10. Provide any additional comments on the revised Chapter 5.3 here.** N/A
Revised Chapter 5.4: Monitoring	

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Chapter 5.4	**11. Provide any comments on the revised Chapter 5.4 here.** • Guideline 86b seems to suggest that only project changes that alter the level of risk for participants or are significant changes to the execution of the project require the submission of amendments to the HREC. Our understanding is that ALL amendments to the project should be submitted for approval, not restricted to those in guideline 86b. If this is the case, clarifying this guideline would be important, including if there are any changes to projects that are exempt from being submitted as amendments.
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?** In general, we believe it would be useful to include both ethical review and governance processes in the introduction section. This is particularly important in the current environment of research is across multiple institutes, meaning that there is a high number of site-specific assessment (SSAs) being submitted based on a single HREC review.
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 agree in principal with this guideline. We are assuming this also includes governance processes. However, we note that for large-scale national projects there is still a need to submit the same project to multiple HRECs due to the NMA (2013) not encompassing all HRECs. For example, separate HREC applications for a national program would have to be made for Tasmania, South Australian, Western Australia, two regions of the Northern Territories and the states that have entered agreement (Victoria/New South Wales/Queensland). It is envisaged that more states and HRECs joining the NMA in the future will aid in increasing the efficiency of the ethics and governance process.
Chapter 5.5	**14. Provide any additional comments on revised Chapter 5.5 here.** We would encourage an expansion of the NMA, which relates to guidelines 96-98. As proposed by Haas et al., (2019), the establishment of an overarching national HREC was recommended. We note that 98d and 98e are particularly important to decrease duplication of ethical review. As suggested previously, a single national online system for ethical review would aid in administration of ethics and governance generally.
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.**

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	It may be useful to provide an example of a conflict of interest. For example, there may be a conflict between the responsibilities of a researcher in a study, who is also a treating clinician of participants in the same study.
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?** A practical and suitable example of an independent assessor would be useful If the complaint is made at a local site level, what mechanisms are in place to flex this complaint back to the respective governing HREC (eg via collation of Annual RGO or HREC reports)
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.** Guideline 112 – suggest inclusion of MRFF funding.
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?** We suggest using the wording 'moderate risk and above' rather than 'moderate to high risk'. This is due to the possible negative connotations of 'high risk'.
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?** As mentioned in the latter half of the definition of an institution, I would be useful to provide options for alterative arrangements where an institute does not have the ability to perform all functions attributed to an institution.
General	

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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?** In general, some clarity around the different processes during ethical and governance review would be beneficial. We also make two additional points concerning limiting duplication during both the ethical review and governance review: • There is no direct mention of the National Mutual Acceptance (NMA) system, 2013, to facilitate single site review of multi-centre research to avoid multiple HREC reviews. If an HREC is participating in and certified under NMA, there should be guidelines on communicating the details of that participation to researchers. • There is no direct mention of a harmonization of electronic systems to track ethics and governance submission and approvals. Currently there are *ad hoc* systems, depending on the state (eg RGS in WA, REGIS in NSW, ERM in QLD, VIC and research GEMS in SA). Although these points may be beyond the scope and detail of the guidelines, based on practical experience (see also Haas et al., 2019, *Med J Aust* 211, 440-444) we believe there is a need to address in some capacity.