Australian Genomics and the Australian Alliance for Indigenous Genomics Joint Consultation Response

On the Draft Quality Standards for Human Research Ethics Committees and their Host Institutions

May 8, 2025

Summary of key points

- The Draft Quality Standards include considerable procedural and operational detail, yet do not sufficiently address how to judge '*high quality ethics reviews'*.
- An update of the *National Statement of Ethical Conduct in Human Research* would be timely to support the Draft Quality Standards and address the gaps highlighted across several items and actions, such as for assessing quality of reviews and timeliness (Item 5.3).
- HRECs should be resourced to build capacity and capability for assessing emerging and complex research and technologies including genomics, artificial intelligence, Indigenous data sovereignty and machine learning. The composition and expertise of HRECs need to support '*high quality ethics reviews',* with holistic models of Indigenous representation, consumer involvement and governance advice, and ongoing relationships with subject matter experts that can be called upon as required.
- As the Australian Commission for Safety and Quality in Health Care (ACSQHC) is not responsible for the implementation and evaluation of the standards they create, a feedback mechanism is required to ensure standards are interpreted, implemented and evaluated in the way they were intended.
- Accrediting bodies must provide appropriate oversight to ensure quality and equity in HREC reviews. This should include increasing the number of Indigenous accreditation staff, improving the cultural and community knowledge of all accreditation staff, and including qualitative metrics for the assessment of evidence required for accreditation of host institutions or HRECs.
- HRECs and host institutions need to have transparent processes with clear policies, including for the assessment of low and negligible risk submissions. All ethics applications submitted to accredited HRECs and host institutions should be subject to preliminary review against national standardised criteria and timelines.
- A national training scheme needs to be developed and implemented for all HREC members to ensure consistency of training and education, improve the standardisation of reviews, and build trust between HRECs. Forums and workshops should be established to share best practice models and strengthen capacity and capability of HREC members across jurisdictions.
- Specialised HRECs, including Aboriginal HRECs, should be recognised for their unique role and expertise and should be resourced to meet the quality standards and supported to continue reviewing specialised research submissions.

Australian Genomics and the Australian Alliance for Indigenous Genomics Joint Consultation Response

On the Draft Quality Standards for Human Research Ethics Committees and their Host Institutions

April 17, 2025

The position of Australian Genomics and the Australian Alliance for Indigenous Genomics (ALIGN) on the Draft Quality Standards for Human Research Ethics Committees and their Host Institutions

- An update of the **National Statement** would be timely to support the Draft Quality Standards and address the gaps that have been highlighted.
- HRECs should be resourced to build capacity and capability for assessing emerging and complex research and technologies including genomics, artificial intelligence, Indigenous data sovereignty and machine learning.
- The Australian Commission for Safety and Quality in Health Care (ACSQHC) are not responsible for the implementation and evaluation of the standards they create. Therefore, a division exists between the entity that creates a standard and those entities that are responsible for implementing and evaluating a standard, creating inherent risks. A feedback mechanism is required to ensure standards are interpreted, implemented and evaluated in the way they were intended when created.

Australian Genomics

Australian Genomics[1] is an Australian Government initiative supporting genomic research and its translation into clinical practice. Through broad engagement and a national collaborative approach, Australian Genomics achieves two key objectives: to improve efficiency, reach and timeliness of genomic research projects, and to support Commonwealth, State and Territory health departments in the implementation of genomics research outcomes by refining and communicating evidence to inform policy development.

Australian Genomics engages with current and emerging government policy and priorities to identify gaps and opportunities, to support policy and action for integrating genomic technologies into the health system. By interfacing with consumers, government, industry and global genomics initiatives, Australian Genomics drives change and growth in the sector.

Australian Alliance for Indigenous Genomics (ALIGN)

The Australian Alliance for Indigenous Genomics (ALIGN)[2] is a national consortium, led by the Indigenous Genomics Group at The Kids Institute Australia and the Australian National University (ANU), in partnership with Aboriginal and Torres Strait Islander stakeholders, peak bodies and Communities, as well as research, clinical, industry and institutional partners from across Australia. ALIGN seeks to build and extend Indigenous leadership and involvement in genomic science, research, precision health care, data sciences, ethics, and Indigenous knowledge systems to reduce health inequality among Australia's First Peoples.

Aboriginal and Torres Strait Islander governance both underpins and leads ALIGN's work, and is instrumental in bringing forward the voices, values, and priorities of Aboriginal and Torres Strait Islander peoples, locally and nationally.

Responses to Consultation Survey questions

Trust and confidence in ethics review

6. Are there any other characteristics of high-quality ethics reviews that we have not identified?

We believe the opportunity to develop a truly high-quality set of standards has been missed. With only one new HREC registered since 2014, it seems impossible that HREC capacity could be keeping pace with the amount of research that requires review, and demand pressures may be compromising the quality of reviews. The Draft Quality Standards are largely procedural and structural and do not address how to judge '*high quality ethics reviews*'. Achieving the aim '*to address these concerns and enhance the consistency and efficiency of HREC review, to build reciprocal confidence in HREC approvals*' will consequently be difficult. While the Draft Quality Standards identify consistency and efficiency as markers of good quality ethics review (and both would be welcomed by researchers), these markers do not necessarily lead to '*high quality ethics reviews'.*

The National Statement currently does not align with many characteristics of what may constitute '*high quality ethics reviews'* as identified and described in the Draft Quality Standards. This is highlighted by the lack of a relevant National Statement paragraph for several items and actions (e.g. Item 5.3 and nearly every item under Action 6).

The minimum HREC membership and categories articulated in the National Statement must be also reviewed to address the existing recommendation for having one Aboriginal and/or Torres Strait Islander representative situated within the "Pastoral Care" category, as we believe that this is both inappropriate and ineffective. There is a need to consider and describe holistic models of Indigenous representation, consumer involvement, and governance advice within both the National Statement and Draft Quality Standards (for example establishing or linking in with Indigenous research advisory or governance committees to reduce the cultural burden of having only one Indigenous representative on a HREC). We have also detailed throughout our response to the different questions other ways in which "*high quality ethics reviews*" could be realised.

7. How do you suggest these characteristics could be assessed by an accrediting body?

We strongly recommend conducting a **review of the National Statement** to ensure that the Draft Quality Standards can support '*high quality ethics reviews'.* Otherwise, the scope and impact of the Draft Quality Standards will remain limited.

To provide appropriate oversight, particularly for quality and equity in HREC review, accrediting bodies should increase the number of Indigenous accreditation staff and increase the cultural and community knowledge of all accreditation staff to establish awareness and understanding of what to request and how to conduct an accreditation assessment, including being able to assess the evidence required from a host institution or HREC. Evaluation metrics and examples could include: demonstration by the host institution of how they have developed, fostered and maintained active

trusting relationships and partnerships with relevant community groups including Aboriginal and Torres Strait Islander health services, Communities, key stakeholders and advisory groups; and how these partnerships have informed cultural safety practice in the services they deliver, and the staff they employ. Increasing qualitative assessments (e.g. Interviews with participants and key stakeholders outside of the host institution or HREC) as part of an accreditation process would further enhance the quality of the assessment

Quality of an HREC

8. Are there any other features of a high-quality HREC that we have not listed?

The skills required to undertake scientific and ethical review are not entirely aligned, and consideration should be given to determine whether a committee constituted in accordance with the National Statement is best placed to provide scientific advice or whether a different body is needed. High quality HRECs have the ability and social conscience to create processes that reflect the needs and expectations of participants and community members, rather than stated expectations of external bodies.

A broad range of skills, knowledge, lived experiences and expertise is required within an HREC, and this often translates to having a large number of members who can be called upon to review applications and attend meetings. For a large and busy HREC this might require 20-30 professional and lay members, in addition to independent technical experts as required. Professional and lay reviewers should be able to review both high and low and negligible risk (LNR) research applications. A high quality HREC (and host institution) should also be able to demonstrate ongoing partnerships and regular engagement with consumer and community organisations to support assessment of research applications. HRECs should maintain relationships with subject matter experts and call upon this expertise as required, including for the review of research applications where specific cultural or technical specialisations are needed. However, inclusion of subject matter experts should add to and not diminish the structure and dynamics of the HREC.

HRECs and their host institutions should have transparent processes including clear policies and tools that are publicly available on the host institution or HREC websites. This should include processes for LNR submissions.

Continued professional development of all HREC members would also improve the quality of HREC reviews overall, and this should include training and upskilling to build expertise and understanding for emerging and complex research and technologies such as genomics, artificial intelligence, Indigenous data sovereignty and stewardship, machine learning etc.

Statistical knowledge can be limited in HREC members and this can lead to their reviewing and approving research applications where participant cohorts are structured around what ‘seems right’ or what can be achieved within the research budget rather than what is needed - an over or under enrolment of participants can therefore be overlooked. This could be addressed by supporting HREC members to develop a better understanding of statistical principles or host institutions supporting statistical experts contributing to HRECs pre-review or during review.

9. How would you suggest that these features could be assessed by an accrediting body?

In isolation, the accreditation and procedural focus of the Draft Quality Standards risks pushing research ethics even more towards a compliance/box ticking exercise than it already is and undermines any potential ethical value from the process.

We strongly recommend the development of both quantitative and qualitative criteria that assess evidence of community engagement in the development and delivery of HREC processes, and allowing more flexibility to enable processes derived from community input to eventually supersede criteria defined by external bodies. In being able to assess emerging and complex research and technologies, those agencies undertaking accreditation would need to build capacity and capability within their workforce, and access specialised subject matter experts as required.

However, accreditation alone may not be the only mechanism for achieving high quality ethics review and we suggest deploying existing or additional resources to provide adequate training to all HRECs (and not leaving this up to chronically underfunded institutions, who will deprioritise research ethics in the current environment).

10. Should it be a requirement for accreditation that institutions are required to perform a preliminary review for all applications submitted to their HREC?

Agree, but with caveats and more nuanced considerations described below.

11. Why / why not?

There needs to be clear and consistent processes for the assessment and review of all research applications, including LNR and high-risk applications. The criteria within the National Statement are still too subjective and pose a risk to many underserviced populations, such as Aboriginal and Torres Strait Islander peoples. The proposed Quality Standards need to be clearer on what is eligible for exemption from review.

There is currently a strong desire for HRECs to consider each project individually and this leads to a lack of standardisation. Often HRECs are resistant to taking on risk and ultimately suggest full review just to 'be safe'. These risk-averse tendencies, combined with insufficient understanding of relevant ethical and legal frameworks, are leading to unnecessary administration, and delays to research timelines, with no additional safety for participants.

However, it is beneficial to identify when an application lacks features that are necessary for efficient HREC review. Preliminary review should therefore be conducted for all applications submitted to accredited HRECs and host institutions, yet this review (and a benchmark for the time taken) should be standardised to ensure consistency between accredited HRECs and host institutions. Standardisation could be achieved by implementing a nationally coordinated preliminary review rubric against which applications could be vetted (with different considerations for specialty HRECs as required).

HRECs should also demonstrate sufficient capability and expertise to review all types of research (including for preliminary reviews). Training/up-skilling of existing members should be encouraged, and new members should be available to provide expertise and increased capability in areas of research where the HREC has historically had less experience.

12. What do you think would be the main advantages of accreditation for institutions and HRECs based outside of the healthcare system?

The main advantage of accreditation for institutions and HRECs (regardless of whether they are based inside or outside of the healthcare system) would be the reduced burden of review due to standardisation of assessment criteria, which will facilitate acceptance of review by all accredited HRECs.

13. Do you think that institutions and HRECs based outside of the healthcare system might not want to seek accreditation? Why?

Most accreditation systems have an annual cost associated with participation, and there will be additional costs associated with meeting accreditation requirements due to additional staff and resources being needed within the host institution and the research governance unit that supports the HREC. Smaller, non-health service HRECs (and their host institutions) that do not regularly review projects with patients or recruit via the health services may not seek accreditation. Host institutions will need to review current practices and service delivery models to ensure they are able to meet accreditation requirements, and any subsequent systems changes that will impact budgets.

Specialised HRECs

14. Can you suggest any other requirements to be fulfilled by specialist HRECs seeking accreditation? Please explain your answer.

Specialty HRECs will often be directed by factors outside of the National Statement in defining their processes, expectations for review documentation and ethical considerations for review. To acknowledge the differences in speciality HRECs there needs to be flexibility in the proposed Quality Standards so that their differences can be recognised. This could be implemented via (1) sub-accreditation of specialty HREC status, or (2) the option to self-nominate strategies and evidence to address actions when the specialty HRECs processes diverge from the Quality Standard expectations – this may be extremely pertinent for the registered Aboriginal HRECs. Additionally, specialty HRECs will need to demonstrate the technical and professional capacity of the HREC members to review the categories of submitted research applications within their specialty.

Clinical Trial Notification (CTN) and Clinical Trial Approval (CTA) Schemes

15. Should it be a requirement for clinical trials that are submitted under the CTN and CTA schemes to be reviewed by an accredited HREC that is hosted by an accredited institution?

Agree, but with certain caveats explained below.

16. Please give a reason for your answer.

There are significant and well-documented equity issues associated with lack of access to clinical trials for underserviced populations, including Aboriginal and Torres Strait Islander peoples. Review of clinical trial applications need to be restricted to suitably qualified, experienced and

accredited HRECs. Precision medicine clinical trials are increasing and require specialised clinical and research knowledge for assessment. As more diverse populations gain greater representation within the human genome or within newly developed pan-genomes, this knowledge needs to be translated to HREC members so that research applications can be assessed accurately and appropriately.

However, Aboriginal and Torres Strait Islander and other specialised HRECs should not be disadvantaged if accreditation is mandatory and they should be assessed for their cultural, Community, and specialised research knowledge and expertise, and the value this contributes to existing reviews and any future accreditation requirements. All HRECs should be resourced sufficiently to meet the accreditation standards and requirements.

Trust and confidence in ethics review

17. Can you suggest any other ways to build trust among accredited HRECs and host institutions and improve reciprocal confidence in ethics reviews?

Regular national workshops, forums and conferences should be convened to enable HREC members, co-ordinators and host institution representatives to discuss relevant human research ethics topics. These engagements would also facilitate the development of communities of practice that could help with establishing standardised review processes, building trust and improving reciprocal confidence in ethics reviews.

A national training scheme needs to be developed and implemented for all HREC members across all HRECs. This would ensure consistency of training and education for HREC members and would subsequently improve the standardisation of reviews and build trust between HRECs (Haas et al., 2019). We believe that this will limit re-review. Forums/workshops are suggested in the Draft Quality standards (page 41), however '*The format of the forums/workshops is to be determined in the future'* which leaves this statement open to uncertainty. These forums/workshops should be implemented as soon as possible to help build trust and improve reciprocal confidence. Best practice models and evaluation outcomes should be shared, and collaborative ethical deliberation events should be convened with review of case studies to allow benchmarking and knowledge transfer between HRECs, further strengthening capacity and capability of HREC members across all jurisdictions.

Paying external HREC members for their time

18. What do you think about paying external HREC members for their contribution to the HREC, beyond reimbursement for expenses such as parking?

Strongly agree.

19. Why / why not?

Payment of an honorarium aligns with existing best practice for community involvement, enables a more diverse community representation and reflects the value of HREC members' time and contributions (Involve Australia, Guidelines for Community Involvement in Genomic Research).[4] This can lead to a more diverse representation of the community participating in HRECs, by enabling individuals to apply for membership who may not otherwise be able to contribute.

Payment of honoraria may also help to achieve quorum, which can be difficult for HRECs if members cannot prioritise attending meetings. An institutional policy for engaging consumers and community groups should be mandatory and can be informed by utilising existing policies or examples (such as the Australian Genomics Community Member Honorarium Policy).[5]

20. If external HREC members were to be paid, should it be by a standard amount or at the institution's discretion?

The fee for payment of HREC members should be decided at the institution's discretion, however publication of a fee schedule range could be useful.

21. Are there any other issues associated with paying external HREC members?

There is a significant burden associated with meeting the needs of mainstream organisations and entities for some individuals and communities, for example for Aboriginal and Torres Strait Islander people in providing cultural knowledge and advice. Providing an appropriate honorarium or reimbursement reflects the value and appreciation of an individual's time and contributions. Institutions should ensure that a range of options are available in terms of preferred payment methods (e.g., direct transfer, gift card) and frequency of payment (e.g., quarterly, etc). Whilst institutional discretion is preferred, guidance on a range or minimum reimbursement amounts should be provided. However, as it should be up to the individual or community to decide if they will accept payment and each institutional policy should include an option to decline payment.

HREC members' conflicts of interest

22. For HRECs seeking accreditation, do you think that a national conflict of interest policy or additional guidance is needed to aid in the identification and management of members' conflicts of interest?

Agree.

23. Why / why not?

Accredited HRECs and host institutions need to develop and implement an appropriate conflict of interest policy. In addition, consideration should be given for developing national guidelines that can support HRECs with identifying and managing conflicts of interest, including conflicts of interest within research applications under review (e.g. being able to identify investigator conflicts of interest).

24. Should institutions seeking accreditation be required to provide training to HREC members about identifying and managing conflicts of interest?

Agree.

25. Please provide a reason for your answer.

Mandatory conflict of interest training would need to be flexible and provide a diverse range of scenarios that reflect where both implicit and explicit conflicts may arise. Host institutions could consider adapting and extending existing staff training to support capacity and capability of HREC members. If HRECs have not already implemented cultural safety training, this must be addressed. HRECs could also look at outsourcing appropriate education programs, utilising existing policies

and guidelines, and/or having a nominated contact person to address questions related to conflicts of interest.

26. Please indicate whether you agree or disagree with the following statements about institutional conflicts of interest for HRECs and their host institutions that are seeking accreditation:

The existing requirements in the National Statement are sufficient to address potential institutional conflicts of interest on HRECs.
Strongly agree.

For accreditation, institutions should be required to appoint an independent chairperson to the HREC.
Neither agree nor disagree.

Views from our contributors varied on whether institutions should be required to appoint an independent chairperson to the HREC. However, the appointment of a chairperson (internally or externally) should involve evaluation of demonstrated research and ethics experience, impartiality, and professionalism.

Accredited HRECs should be required to have a greater proportion of members from outside the host institution.
Neither agree nor disagree.

While most of our contributors agreed with this statement, some felt that this may place unrealistic pressure on smaller HRECs, which may impact their ability to function and remain viable. However, all professional reviewers (members) appointed to any HREC would need to demonstrate research and ethics knowledge and experience, along with additional professional or lived experience that would enhance the capability of the HREC.

Cultural safety

27. Do you think that institutions should be required to provide mandatory training in cultural safety and unconscious bias to their researchers, HREC members and administrative staff involved in ethics review?
Strongly agree.

28. How should institutions evaluate the effectiveness of their cultural safety training?
Considerations for evaluating the effectiveness of cultural safety training should include:

- whether the training was developed and/or delivered with an Indigenous partner or organisation; and
- whether the training has been both quantitatively and qualitatively evaluated internally and externally (e.g. with participants, Community members, Aboriginal organisations and health services that are involved in health service pathways and/or research), and if organisational change and cultural safety can be measured (e.g. how are new staff introduced to the cultural

safety training model and are staff appropriately asking and recording whether a patient or research participant is Indigenous?)

HRECs and host institutions should consider pre- and post- evaluation metrics based on implementation, e.g., number of Indigenous research applications assessed/approved, or case studies where applicable. However, it should be noted that these evaluations would currently be HREC-specific and may not address the nationally consistent approach that the Draft Quality Standards are aiming to achieve, particularly if institutions are undertaking different trainings and determining their own evaluation approaches. There could be potential for the development of a national cultural safety training resource to establish a baseline for training, and/or for introduction of national evaluation measures to assess the impacts of culturally safety training across institutions (for further details, see response to Question 46).

The Draft Quality Standards should provide guidance on the minimum level of cultural safety training required, and evaluation measures that can be implemented. However, care should be taken to ensure that undertaking mandatory cultural safety training does not become a benchmark activity to achieve accreditation. There needs to be broader evidence of institutional commitment to increasing cultural safety and reducing unconscious bias through a continuous program of work, organisational support and policies focused on implementing and evaluating practice and cultural change.

In addition to stand-alone cultural safety training, all HREC training should reflect on cultural safety considerations relevant to the subject matter (e.g. genomics training should link back to the principles of cultural safety and how this should be considered in the context of genomics research studies). Concepts from cultural safety training need to be reinforced to help members understand how to operationalise this training across all different scenarios. This includes HRECs considering how Indigenous values and knowledges can be incorporated into the HREC review process and having the capability and expertise to operationalise the "*AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research"*, and the NHMRC's "*Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders*."

Design of the accreditation scheme

29. Who do you think would be a suitable accrediting body? Please provide a reason for your answer.

The NHMRC could establish a Quality Assurance Programs division to focus specifically on quality improvement - not accreditation, compliance or procedural aspects. This would enable better integration of the accreditation system within the NHMRC as the entity that creates and maintains relevant national guidelines for human research and ethics implementation.

Although the Australian Commission on Safety and Quality in Health Care (ACSQHC) does not oversee the implementation and evaluation of the national health and safety standards, this is a role they could potentially consider. The division between the entity that create standards and entities that are responsible for implementing and evaluating standards in practice has inherent risks. At the very least, a feedback mechanism is required to ensure that the interpretation, implementation and evaluation of standards aligns with what was intended when they were initially developed.

30. Should accreditation visits be scheduled, to give the HREC and institution time to prepare, or should they be conducted at short notice (e.g. 24-48 hours' notice)?

Scheduled.

31. Please provide a reason for your answer.

The timeframe of notice given to HRECs and institutions for accreditation visits should depend on the veracity and scope of the audit process. For example, advanced notice periods should be provided where consumers or external stakeholders are to be interviewed. Scheduling will ensure that accreditation assessments, particularly qualitative assessments, are given sufficient notice for preparation, and that there are minimal impacts on external organisations and Communities in presenting/being available for interviews or providing written statements, etc.

Scheduled assessments will also better support institutions that do not have sufficient staff and resourcing to manage unscheduled assessments, in conjunction with existing workloads and activities, as they arise.

32. How long do you think an HREC's or an institution's accreditation status should be valid for?

Three (3) years. We also suggest that there should be an annual attestation from the HREC or host institution to demonstrate ongoing compliance with accreditation requirements.

Incorporating external feedback into the accreditation scheme

33. What do you think prospective research participants would want to know about the HREC that reviewed the research project?

Currently, the average research participant is unlikely to be aware of the role and responsibilities of a HREC, or HREC processes for research review. Research participants typically place their trust in the personnel (researchers and clinical staff) who they meet and interact with, or the organisation responsible for recruitment. Research participants want to know that the researchers and organisations involved in research are held accountable by external parties, if something goes wrong. This accountability can extend to HRECs.

We also believe that research participants would reasonably expect that HREC-approved research is safe and does not pose any significant or potential or unnecessary risks to the participants, and/or that all possible risks of participation are clearly articulated and mitigated within the research methodology and communicated clearly within participant specific documents such as the Patient Information and Consent Form.

Participants may also want to know that the research methodology is ethical, and that their best interests have been adequately considered and assessed by the HREC. The definitions and processes used by the HREC when determining whether research is safe, ethical, and the levels of risk, should be accessible via the host institution's website in clear and easy to understand language and formats. The Draft Quality Standards need to help reassure participants that reviews are standardised across HRECs, and that HRECs themselves are assessed and held accountable by some sort of accrediting body.

Therefore, we suggest that the Draft Quality Standards should specify that it is the responsibility of host institutions and HRECs to increase participant awareness and education around HRECs, including an understanding of roles and responsibilities, member composition, review processes etc.

34. What else do you think that participants expect from the ethics review process?

Additional expectations of participants may include:

- A contact person who is available for confidential discussions about any issues or concerns that the participant has at any stage.
- Having a transparent mechanism for complaints and appeals.
- A communication strategy to inform affected participants of the outcome of complaints.

35. Can you suggest any other ways that feedback from participants, researchers or the community could be incorporated into the proposed accreditation scheme?

Establishment of a Community Advisory Group (if there has not been one already established) for the development, implementation, and monitoring of the Draft Quality Standards and proposed accreditation scheme, with membership that reflects broad stakeholder representation. Stakeholder workshops should be hosted to facilitate targeted discussion and collaboration between researchers, participants, diverse community members, HREC members, coordinators, and host institution representatives, with the suggested Community Advisory Group acting as a centralised contact point for feedback.

Transparency

36. Should it be a requirement for accreditation that each HREC and its host institution make their contact details publicly available?

Agree.

37. Some HRECs publish details about their individual members, while others do not provide this information, citing privacy concerns. Do you think that transparency about the HREC's membership has any influence on its perceived quality?

We believe that it is not necessary to name HREC members to enhance perceptions of the quality of their ethics review and agree that publishing details about individual HREC members should remain optional due to privacy concerns, and to the potential risk of coercion if individual members were approached by research applicants. However, host institutions and HRECs should maintain transparency by publishing information on their ethics review processes, including detail on the diversity of experience and expertise held across their HREC members and external advisory groups or stakeholders.

Evaluation

38. Do you believe that the proposed Quality Standards address the relevant issues adequately?

Disagree.

39. Please give a reason for your answer.

As previously described, the Draft Quality Standards include considerable procedural and operational detail, but do not sufficiently address the issue of 'quality'. Further modifications should be made to clearly address the definition of 'quality' and articulate what this means in the context of ethics reviews. Detail should also be included to clarify the planned approaches for the implementation and evaluation of the Draft Quality Standards, including timelines.

Significant time and resources are currently being expended with study coordinators managing lengthy submissions and requirements associated with individual applications, and the Draft Quality Standards will not address this in their current form. It is imperative that the "future accreditation scheme" is implemented expeditiously once the Quality Standards are finalised, and that the National One Stop Shop with a centralised platform for ethics applications is progressed in parallel. The centralised platform could also be used to easily export performance measures of HRECs (which would align with strategies described on page 40 of the Draft Quality Standards).

40. How strongly do you agree with these statements?

Accreditation of an HREC and its host institution to the Quality Standards will increase my level of trust and confidence in their ethics reviews.
Disagree.

The proposed Quality Standards will lead to improvements in the ethics review process in Australia.
Disagree.

The proposed Quality Standards will lead to improvements in the conduct of human research in Australia.
Disagree.

Implementation of the proposed Quality Standards is likely to face challenges.
Strongly agree.

41. How likely are you to recommend the adoption of the proposed Quality Standards to others?

Somewhat unlikely.

42. Why / why not?

This will depend upon the structure and content of the final version of the proposed Quality Standards, including the extent to which stakeholder feedback throughout this consultation is incorporated. In its current form, we would not recommend adoption.

Without more thoroughly addressing the definition of 'quality' and associated processes, there remains a risk that the Draft Quality Standards may build a network of consistent, yet variable and/or poor-quality HREC reviews. Failure to address quality may also inhibit progress towards other key goals of the Draft Quality Standards, i.e. improving efficiency of HREC review, and building reciprocal confidence between HRECs. For the latter, ensuring there are robust quality standards and requirements for ethical research review will be integral to building reciprocal confidence between HRECs, particularly for research applications that require nuanced technical

and/or cultural expertise. We therefore strongly recommend modifying the Draft Quality Standards to better address 'quality' and include examples of quality-improvement drivers.

Additionally, it should be clarified whether the proposed accreditation system will become punitive to those organisations that do not obtain accreditation.

Our responses under Question 46 further highlight the issues that would prevent us from recommending the adoption of the Draft Quality Standards.

Additional questions

43. Have you ever taken part in a health or medical research study?

Not applicable.

44. Which of the following best describes where you are located?

Not applicable.

45. In which state or territory are you based?

Other not specified: National

46. If you have any additional feedback on the Quality Standards or the accreditation scheme, please provide it here. The information you have provided through this survey will help to improve the quality of ethics reviews in Australia, and improve their acceptability among institutions and HRECs.

Accreditation

The purpose of the proposed voluntary accreditation process appears to be solely focused on developing confidence in the review process when seeking multi-jurisdictional ethics approvals. However, we believe that this is a missed opportunity for improving the quality of review by all HRECs in Australia, and for addressing the existing lack of knowledge and experience of many HRECs in being able to confidently assess research applications that impact or ignore underserviced populations, or in areas of research where a lack of knowledge exists and has not been addressed through professional development of the HREC members (e.g. genomics, precision medicine, offshore specimen storage and data analyses by entities unknown).

Explanatory Notes (Page 20 – preceding Action 2 of the Draft Quality Standards)

There is an overarching theme in the Draft Quality Standards that points towards HREC membership becoming more professional, however, comments in the document such as *"increasing the ratio of internal vs. external HREC members"* indicate a desire to move towards a structure that would require more external volunteers to participate in HRECs. Increasing the ratio of external HREC members and appointing a chairperson who is external to the institution may make it harder to achieve consistency and implement the proposed Quality Standards. HREC participation is very time-intensive, and quality and consistency are both improved by having people that take on this role as part of their jobs either as a dedicated role (i.e. HREC chair) or organisational staff that contribute as part of their key performance indicators (KPIs) for support of organisational endeavours.

Selection and appointment of HREC members (Page 24 of the Draft Quality Standards)
There is a significant cultural burden associated with having only one member of the HREC being an Aboriginal or Torres Strait Islander person, or in contrast the risks associated with having no Indigenous representation at all. We suggest exploring more holistic models to support cultural representation and oversight of the issues within the assessment of research. For example, having the host institution establish or access an existing Indigenous advisory or governance committee to provide both ethical and cultural guidance and review on research ethics applications where Indigenous peoples are either well represented and considered in the research, or where the research could address existing health gaps or priorities that impact Aboriginal and Torres Strait Islander peoples but where this is lacking in the research application.

Item 5.3 - Timeliness (Page 40 of the Draft Quality Standards)
The level of complexity within a research ethics submission varies, therefore any benchmarking of 'timeliness' as a metric would need to address the different levels of complexity within an ethical review (i.e. student survey vs human embryo research). Without this consideration, HRECs could start rejecting more complex reviews due to the time required for review and feedback. Benchmarking of timeliness would also need to consider a "primary submission" versus "amendment" separately, as submission of amendments can be a reflection on researchers or projects rather than the HREC processes.

Cultural safety, respect, integrity (Page 43 of the Draft Quality Standards)
The current wording within the Draft Quality Standards states that *"Institutions should ensure that everyone involved in human research...practices cultural safety*" - we strongly recommend that "should" be replaced with "must".

There are no explanatory notes regarding the consultation processes that were undertaken to inform the development of the cultural safety recommendations within the Draft Quality Standards. If consultations with Aboriginal and Torres Strait Islander and other under-serviced populations and stakeholders were undertaken, how diverse they were, and would these consultations be considered "representative" of the many different populations within Australia including Aboriginal and Torres Strait Islander Communities and peoples that would be affected by the introduction and implementation of these proposed Quality Standards?

Referring to Item 6.1 (page 45 of the Draft Quality Standards), we believe that the strategies are insufficient to ensure cultural safety has been implemented effectively, and we strongly recommend the inclusion of decisive and measurable evaluation metrics to assess the effectiveness of cultural safety training beyond just "asking participants for feedback".

We recommend the inclusion of Communities, Aboriginal peak bodies and health service staff to evaluate how the host institution has built culturally appropriate and respectful relationships with these key stakeholders to inform their cultural safety training, culturally safe service delivery, and measurable increases in Aboriginal and Torres Strait Islander peoples engaging with their service and within research. This includes ensuring staff are asking patients and research participants whether they identify as an Aboriginal and/or Torress Strait person and to provide a respectful explanation for why they are being asked.

Quantitative and qualitative audits of this practice should be conducted by the host institution and demonstrated to the auditing entity. We do not understand the context for the point "*Appoint a relevant Cultural Liaison Officer...if appropriate.*" For what purpose? What is their role? Is one person adequate for the role within the host institution? The examples of evidence do not in any way measure impact and effect of cultural safety training and will fail to demonstrate a shift in the organisation toward culturally safe staff and do not measure whether experiences and events of discrimination and/or racism are increasing or decreasing as a result of cultural safety training.

General commentary of the Draft Quality Standards

We understand that the objective of the Draft Quality Standard is to operationalise the standards in a way that can be assessed in an accreditation system. This document does not outline the accreditation system itself but provides a standard that the accreditation system will be structured on. While the development of the accreditation system appears to be planned for a future phase, we emphasise that this system should be implemented as soon as possible.

We also raise the following questions to seek further information and clarification on how the Draft Quality Standards can support high quality ethics reviews:

- Does consistency equate to quality, and does quality address inequity?
- How will consistency be achieved and through what mechanisms?
- Is there a system of precedent that can be used to guide the development of the new Quality Standards?
- Do these Draft Quality Standards infer that HRECs should evolve to become regulatory bodies, rather than ethical deliberative bodies? If so, then that is fundamentally different to the role articulated in the National Statement.

References

1. https://www.australiangenomics.org.au
2. https://indigenousgenomics.com.au
3. Haas, M.A., Boughtwood, T.F., Quinn, M.C. and (2019), The ethics approval process for multisite research studies in Australia: changes sought by the Australian Genomics initiative. Med. J. Aust., 211: 440-4.e1. https://doi.org/10.5694/mja2.50397
4. Involve Australia, Guidelines for Community Involvement in Genomic Research, available from: https://www.australiangenomics.org.au/wp-content/uploads/2021/06/Involve-Australia_Guidelines-for-Community-Involvement-in-Genomic-Research-1.pdf.
5. Australian Genomics Community Member Honorarium Policy, available from: https://www.australiangenomics.org.au/wp-content/uploads/2021/06/AG-community-member-honorarium-policy_v4.docx