

# AH&MRC HREC Submission

Invitation to provide feedback on the Policy Directive: Ethical & Scientific Review of Human Research in

NSW PHOs

23<sup>rd</sup> September 2019

## SUMMARY

- The AH&MRC HREC would like to thank the Ministry of Health, Office of Health and Medical Research for the opportunity to comment on the discussion paper relating to the review of Policy Directive PD2010\_055.
- The AH&MRC Human Research Ethics Committee considers that the proposed amendments relating to the review of research that impacts Aboriginal and Torres Strait Islander people in the Policy Directive discussion paper are not consistent with the requirements of the National Health and Medical Research Council, and its guiding documents The National Statement on Ethical Conduct in Human Research (2007, updated 2018) and the Ethical Conduct in research with Aboriginal and Torres Strait Islander Peoples and Communities (2018).
- The AH&MRC Human Research Ethics Committee (HREC) is best placed to review Aboriginal health research proposals in New South Wales. Aboriginal health research is complex not only because of the cultural protocols that must be adhered to, but also because Aboriginal health research spans a range of disciplines. To ensure this research is adequately reviewed, the HREC must adhere to the National Ethical guidelines documents. The AH&MRC HREC has a range of cultural skills, knowledge and experience that supports the review of proposals, ensuring the highest quality of Aboriginal health research in New South Wales.
- The AH&MRC HREC is currently funded by the Ministry of Health to provide expert advice on the ethical requirements of Aboriginal health research and the policies which support the review of such research. For this reason, the AH&MRC HREC does not understand why the Office of Health and Medical Research has declined to include content proposed by the AH&MRC HREC and supplied to the Office of Health and Medical Research on the 7<sup>th</sup> February 2018.
- Consistent with the National Ethical guiding documents and the funding contract expectations of the Ministry of Health, it is the AH&MRC HREC position that the content provided to the Office of Health and Medical Research on the 7<sup>th</sup> of February 2018 be the final content provided in the revision of Policy Directive PD2010\_055.

## THE NATIONAL ETHICAL GUIDELINES:

The National Health & Medical Research Council (NHMRC) sets out the requirements for ethical review of research proposals. These requirements are outlined in the *National Statement on Ethical Conduct in Human Research* (2007 updated 2018) and further guidance on the specific requirements of Aboriginal and Torres Strait Islander research is available in the document *Ethical Conduct in research with Aboriginal and Torres Strait Islander Peoples and communities* (2018). The AH&MRC HREC is a fully constituted HREC, registered under the NHMRC and applies these guidelines to all applications that it reviews.



It is also noted in the National Statement 1.10 that *Respect for human beings is recognition of their intrinsic value. In human research, this recognition includes abiding by the values of research merit and integrity, justice and beneficence. Respect also requires having due regard for the welfare, beliefs, perceptions, customs and cultural heritage, both individual and collective, of those involved in research.* This is also featured in the NHMRC guidelines specific to Aboriginal and Torres Strait Islander health research that state under Reciprocity demonstrating reciprocity involves:

*“Providing evidence of a capacity-building or capacity-strengthening development plan that describes how Aboriginal and Torres Strait Islander people and communities will benefit from the project directly (e.g. training, development or infrastructure) and indirectly (e.g. broader social, economic or political strategies at a local or jurisdictional level). (pg. 8)”*

The discussion paper the Ministry has provided outlining that capacity building options should be identified “where possible” is inconsistent with the current requirements of the National Guidelines on ethical conduct, which were updated in 2018.

4.7.7 of the National Statement states

*“The benefits from research should include the enhancement or establishment of capabilities, opportunities or research outcomes that advance the interests of Aboriginal and Torres Strait Islander Peoples. (pg. 78)”*

#### **THE AH&MRC HUMAN RESEARCH ETHICS COMMITTEE:**

A role of the AH&MRC Human Research Ethics Committee (HREC) is considering applications for ethical approval and to ensure that the projects represent the views and interests of Aboriginal people across New South Wales. The AH&MRC HREC deals with not only ensuring that research is conducted in an ethical manner, but that research is also undertaken with Aboriginal people in a **culturally appropriate** manner. This means that there is community consultation at all levels and that the project is designed with the Aboriginal community. This is reflected in the AH&MRC HREC requirement of the Five Key Principles document which all researchers submitting to this HREC must complete. Further, the membership of the AH&MRC HREC, with representation across a number of communities, disciplines, skill-sets and life experiences places the AH&MRC HREC as the most suitable HREC to determine whether or not research may affect the health and wellbeing of Aboriginal people and communities.

The National Statement Chapter 4.7 in the introduction section outlines that research which involves Aboriginal and Torres Strait Islander people must be reviewed and approved by a Human Research Ethics Committee. The introduction further states that the HREC assessment must include advice from:

- People who have networks with Aboriginal and Torres Strait Islander Peoples and/or knowledge of research with Aboriginal and Torres Strait Islander Peoples; and
- People familiar with the culture and practices of the Aboriginal and Torres Strait Islander people with whom participation in the research will be discussed.

The AH&MRC HREC is the only HREC in New South Wales with the extensive membership required to adequately address research proposals affecting Aboriginal people across New South Wales. The AH&MRC HREC is supported by a diverse membership from Aboriginal communities across the state. In addition to the NHMRC minimum membership, the AH&MRC HREC has members with expertise in Alcohol and Other Drugs, Comprehensive Primary Health Care service delivery from both a local and state-wide level, Justice Health, Public Health, Clinical Trials and a range of Aboriginal Elders who are intimately across the various cultural protocols that exist in New South Wales. This allows the AH&MRC HREC to consider applications at

both a state-wide level and local level, with members being able to make comment on the cultural intricacies of research both with Aboriginal people and communities, and across a wide range of disciplines.

#### **AH&MRC HREC REQUESTED CONTENT 2018:**

The AH&MRC HREC is currently funded by the Ministry of Health to provide expert advice on the requirements for ethical review of Aboriginal health research, specifically in respect to the Ministry of Health Policy Directives that relate to health research. As such, It is disappointing to note that in the discussion paper, the Research Ethics and Governance Unit of the Office of Health and Medical Research has declined to include all changes originally requested by the AH&MRC HREC on 7<sup>th</sup> of February 2018. The content provided was as follows:

#### **5.2 Research that may affect the health and wellbeing of Aboriginal people and communities**

In accordance with the NHMRC National Statement (relevant sections identified after each criteria) approval from the Aboriginal Health and Medical Research Council (AH&MRC) Human Research Ethics Committee is required where the research project involves research in, or concerning, NSW and any one of the following applies:

- The experience of Aboriginal people is an explicit focus of all or part of the research (4.7.6 b);
- Data collection is explicitly directed at Aboriginal people (4.7.6 b);
- Aboriginal peoples, as a group, are to be examined in the results (4.7.6 b);
- The information has an impact on one or more Aboriginal communities; or
- Aboriginal health funds are a source of funding.
- Aboriginal people are known, or are likely, to be significantly over-represented in the group being studied (e.g. compared to the 3.4% of the total NSW population) or Aboriginal peoples, as a group, are to be examined at any stage in the research' (4.7.6 a).

One of AH&MRC HREC's major criteria in assessing an application is to ensure that there is Aboriginal community involvement in, and control over, the research. Investigators will need to show evidence that they have the support of each local Aboriginal Community Controlled Health Service (ACCHS) or an alternative appropriate Aboriginal organisation, subject to the agreement of the HREC, where the research is being conducted. Researchers are asked to demonstrate that meaningful consultation has occurred and that where possible researchers are undertaking capacity building activities. The AH&MRC HREC reviews applications from the perspective of the impact on Aboriginal people. The review is required in addition to review by a lead or local HREC.

The AH&MRC HREC accepts applications at any stage in their progress through another HREC.

Each investigator can decide whether they will seek AH&MRC Ethics Committee approval before submitting to other HRECs, or after approval by other HRECs, or simultaneously.

Further information is available from:

<https://www.ahmrc.org.au/ethics-research/ethics/>

The National Statement on Ethical Conduct in Human Research and the Ethical Conduct in research with Aboriginal and Torres Strait Islander people were both updated in 2018 and current versions of these documents reflect that the inclusion of capacity building activities in research projects within the space need to be included in the project.

This aligns with the national statement section 4.7.2 which states

*“There should be evidence of support for the research project from relevant Aboriginal and Torres Strait Islander communities or groups and the research methodology should engage with their social and cultural practices.” (pg. 78.)*

#### **AH&MRC HREC REQUESTED CONTENT 2019:**

It is the position of the AH&MRC HREC that the content provided in the discussion paper on the 12th of September 2019 under *Section 4.2 Research that may affect the health and wellbeing of Aboriginal people and communities* is insufficient and ambiguous on the requirements for AH&MRC HREC and in which instances the Ministry supports these reviews.

Not only is it essential that the policy directive be clear in relation to the requirement for researchers to seek AH&MRC HREC approval when undertaking research relating to Aboriginal people, communities and organisations in a New South Wales Public Health Organisation, it is also important that it aligns with both the National Statement and the *Ethical Conduct in research with Aboriginal and Torres Strait Islander Peoples and communities (2018)*.

Nationally, there are only three states that have an Aboriginal Community Controlled Human Research Ethics Committee. Of those three states, New South Wales receives the largest number of submissions, many of which are from Ministry of Health. The ongoing relationship between the Office of Health and Medical Research and the AH&MRC HREC is essential to ensuring the high quality of Aboriginal Health Research in New South Wales. This relationship is supported by Policy Directive PD2010\_055, giving all parties a platform to guide their scope. A detailed description within PD2010\_055 and how it relates to the requirement for submission to the AH&MRC HREC will assist researchers in self-identifying if/when this review is required. It will also assist the AH&MRC HREC staff and the Office of Health and Medical Research staff in reinforcing the same message, decreasing in the delays caused by researchers not understanding this requirement.

It is for these reasons that the AH&MRC HREC requests the content provided by the AH&MRC HREC on the 7<sup>th</sup> of February 2018 (which has been amended below to reflect currency with the guidelines) be the content presented in its entirety in the amended version of PD2010\_055.

#### **5.3 Research that may affect the health and wellbeing of Aboriginal people and communities**

In accordance with the NHMRC National Statement (relevant sections identified after each criteria) approval from the Aboriginal Health and Medical Research Council (AH&MRC) Human Research Ethics Committee is required where the research project involves research in, or concerning, NSW and any one of the following applies:

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The AH&MRC HREC reviews applications from the perspective of the impact on Aboriginal people. The review is required in addition to review by a lead or local HREC.

The AH&MRC HREC accepts applications at any stage in their progress through another HREC.

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**CONTACT DETAILS:**

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