



# **Statement on Sex, Gender, Variations of Sex Characteristics and Sexual Orientation in Health and Medical Research**

**Submission to NHMRC and MRFF  
Consultation**

**15 December 2023**



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## Introduction

Women’s Health Victoria (WHV) welcomed the opportunity to provide feedback to the public consultation on the [Development of a joint National Health and Medical Research Council \(NHMRC\)/Medical Research Future Fund \(MRFF\) Statement on sex, gender, variations of sex characteristics and sexual orientation in health and medical research](#) in December 2023.

The consultation sought feedback on the [draft Statement](#) from the community and stakeholders, including research, industry, consumers, health services and philanthropy.

The Statement addresses the inclusion of sex, gender, variations of sex characteristics and sexual orientation at all stages of health and medical research, including prioritisation and research question setting, conduct, data collection, analysis, reporting, translation and implementation.

Note: This submission was originally made as a response to an online survey, and has been reformatted, including section headings for ease of navigation. Due to character limitations imposed for survey answers, country-specific examples included in Question 30 were not able to be submitted. Questions 1 to 25 (containing details of the submitting organisation) are omitted.

# Survey responses

## Q26. What benefits should the Statement achieve?

Women's Health Victoria (WHV) commends the MRFF and NHMRC for taking action to improve inclusion and consideration of sex, gender, variations of sex and sexual orientation ('the Variables') in health and medical research.

WHV believes the Statement should:

- Improve understanding in the research sector of why consideration of sex, gender, variations of sex characteristics and sexual orientation throughout the design, conduct, analysis, reporting, translation and implementation of medical research is crucial to improving health equity and outcomes in Australia,
- Build the capacity of the research sector to routinely consider 'the Variables' as part of rigorous scientific research,
- Increase preclinical and clinical research output that considers the Variables and contribute to closing the significant gaps in research and understanding of women's and gender diverse people's health due to the historical lack of inclusion of the Variables in health and medical research. This includes building a better understanding of health problems (from prevention through to treatment and recovery) in these populations, as well as a greater understanding of how the Variables impact health outcomes,
- Contribute to more effective interventions at all points along the spectrum of prevention, early intervention, response and recovery, for people of all genders,
- WHV also supports the following recommendations on what the Statement should achieve from the George Institute for Global Health:
  - The Statement should provide clear guidance to the research sector on when, why and how to implement sex, gender, variations of sex characteristics and sexual orientation into health and medical research.
  - The Statement should unify the research sector by creating common understanding of the value of incorporating sex, gender and diversity analysis into research (i.e., closing evidence-gaps including understanding causes of disease, prevention and treatment; bringing Australia in line with North America and Europe<sup>1</sup>).

## Q27. Do the [Vision and Purpose of the Statement](#) align with the benefits you identified in the previous question? If not, how can this alignment be improved?

Women's Health Victoria (WHV) urges the MRFF/NMHC to clearly state that sex and gender considerations are expected in medical research. We endorse the George Institute for Global Health's recommendation for the Vision to be edited to read: "To improve health

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<sup>1</sup> The Sex and Gender Sensitive Research Call to Action Group (2020) Sex and gender in health research: updating policy to reflect evidence. *Medical Journal of Australia*. 202(2): 57-62. Available from: [URL](#)

outcomes for all Australians by ensuring that sex, gender, variations of sex characteristics and sexual orientation are routinely considered in health and medical research”.

While WHV supports the Vision and Purpose of the Statement, we are concerned that the statement’s language (‘improving’, ‘promoting’, ‘encouraging’) is too weak to effect real change to health and medical research design. We urge the MRFF/NHMRC to strengthen the language and ambition of the Statement by:

- requiring ‘consideration of sex, gender, variations of sex characteristics and sexual orientation throughout the design, conduct, analysis, reporting, translation and implementation of all research’ (this should include requiring female cell lines in exploratory research); and
- mandating the ‘inclusion of cisgender and trans women and men, non-binary people, people with innate variations of sex characteristics and people with diverse sexual orientations in research, particularly where they have been historically underrepresented or excluded’, and analysis thereof, as a requirement/condition of research funding (or to demonstrate why this is not applicable).

**Q28. Is the guidance provided in the ‘What better practice looks like’ section (pages 8-12) suitable? If not, what could be added or removed to strengthen the section?**

WHV welcomes the introduction of this guidance on ‘What better practice looks like’ in medical research. The list of questions is comprehensive and importantly, places emphasis on partnering with individuals with lived experience at each phase of the research cycle. However, this section would benefit from further detail regarding how questions should be applied, and expectations for reporting answers. It is also critical that the Statement make clear that these questions should be applied to all medical research, even when the relevance of sex and gender is unknown at the time of study design.

Further guidance should be included in the Statement to support meaningful incorporation of the questions in medical research. The current framework provides a foundation but would be strengthened by including examples and explanations that facilitate a more nuanced understanding of how considerations should be addressed. For those without prior experience incorporating sex and/ or gender in research, the importance, meaning and application of some of the questions may be unclear. For example, questions that prompt researchers to consider the safety requirements of women and gender diverse participants would be more effective if they included further detail on what these requirements may be and how they may differ to those applicable to other populations.

Further guidance is also needed regarding how answers to these questions should be reported, including requirements for their inclusion in grant applications. The Canadian Institutes of Health Research requires all applicants to respond to mandatory questions about sex and gender when applying for grants, awards and fellowships<sup>2</sup>. WHV recommends that similar mechanisms for accountability and oversight are implemented in Australia to ensure that the Variables are consistently incorporated in government-funded research.

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<sup>2</sup> CIHR (2023) Health research training at CIHR: training tools. Canadian Institutes of Health Research, Ottawa. Available from: [URL](#)

## **Q29. What do researchers, research organisations, consumers, etc. need to implement the Statement?**

Both training and funding are required to support researchers and research organisations to effectively implement the Statement.

Comprehensive training is required to educate researchers and clinicians on the importance of considering sex and gender in research, and how to incorporate these considerations in different types of studies. While the Statement provides a list of questions to prompt integration of sex and gender in research, it is important that researchers understand why these should be addressed, and how they should be applied effectively at each stage of the research cycle. Instruction in undertaking robust sex and gender analysis and reporting is also critical. This training will be required to enhance the rigour, comparability and applicability of results.

The Canadian Institutes of Health Research currently provides online training modules on integrating sex and gender in biomedical research for scientists and peer reviewers<sup>3</sup>. We recommend that the NHMRC and MRFF similarly provide online training to support the Statement's implementation in Australia.

Furthermore, provision of sufficient grant funding to facilitate the inclusion of sex and gender analysis in medical research is important. Implementing a thorough examination of sex and gender differences requires additional resources to enable representative sample sizes, support the recruitment of women and gender diverse participants, and address specific barriers to participation that these groups may face. For example, as women bear a disproportionate share of caring and other responsibilities, they are less likely to have time to participate in medical research than men<sup>4</sup>. Funders should develop a funding pool to cover these additional costs, for example to provide childcare to research participants where needed.

Funding is also required to support analysis, interpretation and translation of sex and gender-disaggregated data. Including these analyses adds complexity to study designs and demands specialized expertise, which contributes to additional expenses. Funding should be allocated to build this expertise and support training of researchers in how to effectively undertake research that incorporates sex and gender.

## **Q30. Is there anything you would like to raise that is not otherwise captured by these questions?**

It does not appear that this Statement will be accompanied by any measures that would enforce integration of gender and sex considerations in research or incentivise researchers to study female and gender diverse populations. Consequently, it is unlikely that the Statement will have much impact on improving the representation of women and gender diverse people in health and medical research. Indeed, where medical journals have previously subscribed to sex and gender guidelines, and have encouraged but not enforced their use, integration of these variables has largely not occurred. A study that reviewed the

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<sup>3</sup> CIHR. IRSC (2023) Sex and gender training modules. Canadian Institutes of Health Research. Institute of Gender and Health, Ottawa. Available from: [URL](#)

<sup>4</sup> Leslie K (2020) Why are women ignored by medical research? *Pursuit (University of Melbourne)*. (Mar 7): 1 webpage. Available from: [URL](#)

10 leading journals in Australia found that sex and gender were poorly incorporated into Australian medical research publications, and this was not improved by journals endorsing the International Committee of Medical Journal Editors guidelines<sup>5</sup>.

Policies that mandate the consideration of sex and gender are necessary to ensure these are incorporated in all government-funded health and medical research. A growing number of countries have introduced such policies for competitive research grants<sup>6</sup> and have subsequently seen a significant increase in publications that include sex and gender perspectives. For example, the introduction of legislation in the United States that requires the inclusion of women in clinical research and sex as a biological variable in pre-clinical research as a condition of funding has led to an increase in reporting of sex-specific results in peer reviewed literature and increased women's participation as research subjects in trials funded by the US National Institutes of Health<sup>7</sup>.

Australia now lags behind North America and Europe, both in terms of research output that considers sex and gender as key determinants of health, and policies to address this issue<sup>8</sup>. As government entities, it is incumbent on the MRFF and NHMRC to lead the way in requiring the inclusion of sex and gender in Australian medical research and ensuring that studies on health conditions that affect people of all sexes and genders are no longer conducted predominantly in men.

To address the under-representation of women and gender diverse participants in Australian health research, it is critical that the MRFF and NHMRC implement policies that require all medical studies include the following elements as a pre-requisite for government funding (or demonstrate why these are not applicable):

- an appropriate sample size of women participants
- trans and gender diverse participants where possible
- female cell lines and animals in preclinical research
- disaggregation and analysis of results by sex and gender in reporting

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<sup>5</sup> Hallam L, Vassallo A, Hallam C, Thompson K, Shanthosh J, Chappell L, et al. (2023) Sex and gender reporting in Australian health and medical research publications. *Australian and New Zealand Journal of Public Health*. 47(1):1-6. Available from: [URL](#)

<sup>6</sup> Swannell C (2019) Sex and gender health research: Australia lags behind. *Medical Journal of Australia Media Release*. (Nov 25): 1-2. Available from: [URL](#)

<sup>7</sup> Johnson J, Sharman Z, Vissandjée B, Stewart D (2014) Does a change in health research funding policy related to the integration of sex and gender have an impact? *PLoS One*. 9(6): 1-8. Available from: [URL](#)

<sup>8</sup> Swannell C (2019) Sex and gender health research: Australia lags behind. *Medical Journal of Australia Media Release*. (Nov 25): 1-2. Available from: [URL](#)