



Australian Government

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

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# Vision

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Improved health outcomes for all people in Australia by ensuring the evidence-base that informs our health care system considers sex, gender, variations of sex characteristics and sexual orientation.

## Key messages

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- The National Health and Medical Research Council (NHMRC) and the Department of Health and Aged Care, responsible for implementation of the Medical Research Future Fund (MRFF), have released a joint Statement on Sex, Gender, Variations of Sex Characteristics and Sexual Orientation in Health and Medical Research (the Statement) as a commitment to:
  - health equity, acknowledging that every person in Australia has the right to be included in safe, high quality research that informs our health care
  - supporting everyone in the community to have a role in research, acknowledging that better partnerships between consumers, researchers, clinicians, and other research stakeholders ultimately leads to better health outcomes
  - strongly encouraging all research funded through the NHMRC and MRFF to:
    - consider sex, gender, variations of sex characteristics and sexual orientation at all stages of every research project
    - use consistent definitions and classifications (the Australian Bureau of Statistics 2020 Standard)
- We appreciate that we will need to work with, and support the sector to implement the Statement over time.

## Purpose

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The purpose of the Statement on Sex, Gender, Variations of Sex Characteristics and Sexual Orientation in Health and Medical Research (the Statement) is to improve health outcomes by:

- improving knowledge of research gaps related to historical underrepresentation of sex, gender, variations of sex characteristics and sexual orientation in various research fields and topics,
- improving consideration of sex, gender, variations of sex characteristics and sexual orientation throughout the design, conduct, analysis, reporting, translation and implementation of all research,
- promoting increased 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,
- promoting effective, sensitive and safe involvement of people with lived experience in all stages of research projects,
- encouraging more effective partnerships between consumers, researchers, clinicians, and other research stakeholders.

These practices aim to ensure that health and medical research produces an evidence-base that is relevant to all people in Australia.

In reading and using this Statement, it is important to note the following:

- The term ‘the Variables’ will be used in some instances in the Statement as an abbreviation of the term ‘sex, gender, variations of sex characteristics and sexual orientation’.
- The intention of this Statement is not to increase the pool of researchers who focus only on the Variables but that *all* researchers applying for, and in receipt of, NHMRC and/or MRFF grant funding will consider the Variables in research question setting, design, conduct, analysis, reporting, translation and implementation.
- While consideration of the Variables is encouraged in all research, particular consideration and sensitivity should be given to these variables where there is existing evidence or reason to believe there will be differences or specific influencing factors due to these variables.
- While the Statement is focused on the Variables, it is acknowledged research operates within a larger intersectional framework, including cultural and linguistic diversity, age, socio-economic status, abilities, and geography, that impacts equitable health outcomes.

## Background

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Health and medical research provides the evidence base to inform Australia’s health care. Including people from all sex, gender, variations of sex characteristics and sexual orientation population and communities in research is primarily an issue of human rights and health equity, and providing higher quality, and safer health care for all people in Australia. Inclusive research is research that is safe, sensitive and effective; will provide critical data to improve understanding of health gaps and solutions; uses funding to support broad application of research across all population and community groups; and will lead to more inclusive, safe and appropriate health care and health outcomes.

Promotion of research that is inclusive of sex, gender, variations in sex characteristics and sexual orientation is now being recognised and put into practice by public funding agencies around the world.<sup>1</sup> This complements the increasing recognition of the need for consumer involvement and co-design in research projects to produce outcomes that are both priorities for and usable by patients, consumers, clinicians and other stakeholders. These approaches are based on the appreciation that the best way to design research for groups of high unmet need is to meaningfully engage with these groups and to work in partnership, harnessing their lived experience, to understand their needs and priorities throughout the research lifecycle. Effective partnerships are at the core of this work. Every part of the research community has a role to play in improving practices.

It is important to acknowledge that inclusion and effective partnerships have not always been the norm. Historically, the limited consideration of sex, gender, variations of sex characteristics and sexual orientation in health and medical research has led to many population groups being excluded or discouraged from research participation, or made invisible in research findings<sup>2</sup>, or has led to inappropriate and/or harmful health care<sup>3</sup>, lack of consideration in health and public policy, and/or continued discrimination. The populations who have been, and still are, impacted by these practices vary based on the research area, and include cisgender and trans women and men, non-binary people, people with variations of sex characteristics and people with diverse sexual orientations. However, it is also important to acknowledge that some historical exclusion from research was due to safety concerns. For example, the exclusion of pregnant people<sup>4</sup> and women<sup>5</sup> from clinical trials was intended to avoid foetal harm. It is now acknowledged that it is important to ensure that all populations can be safely and meaningfully included in research to support targeted health care and equitable health outcomes.

Safe involvement in research for any individual or population includes ensuring that effective physical, emotional and psychological safeguards are in place at all stages of the research project. For example, ensuring that:

- research teams have strong capacity and capabilities in safely and sensitively involving people with lived experience,
- individuals and population groups with lived experience are meaningfully and effectively involved in prioritisation, design and conduct of research that impacts them or has the potential to impact them,
- individuals are provided the information they need to make informed decisions about consenting to participate in research,
- the research team recognises the human rights of people with lived experience, including the right to bodily integrity, and
- support for confidentiality, health and wellbeing of research partners and participants is demonstrated.

The Statement is an opportunity to learn from past practices and apply them in a modern Australian context, to improve research practice and create better evidence and ultimately better health care for all. It has been developed by NHMRC and the Department of Health and Aged Care, responsible for implementation of the MRFF, following both targeted and public consultation processes. The Statement complements a range of existing NHMRC and MRFF guidance namely the:

<sup>1</sup> L Hunt, MW Nielsen and L Schiebinger, 'A framework for sex, gender, and diversity analysis in research', *Science*, 2022, 377(6614):1492-1495, DOI: 10.1126/science.abp9775.

<sup>2</sup> M Carman, C Farrugia, A Bourne, J Power and S Rosenberg, *Research Matters: How many people are LGBTIQ?* [PDF 104KB], Rainbow Health Victoria, 2020, accessed 24 August 2023; M Carpenter, *Researching intersex populations*, Intersex Human Rights Australia website, 2023, accessed 24 August 2023.

<sup>3</sup> I Zucker and BJ Prendergast, 'Sex differences in pharmacokinetics predict adverse drug reactions in women', *Biology of Sex Differences*, 2020, 11(32), doi:10.1186/s13293-020-00308-5; M Frommer, J Howell, E Santow, S Cochrane and B Alston, *Ensuring health and bodily integrity: towards a human rights approach for people born with variations in sex characteristics*, Australian Human Rights Commission, Australian Government, 2021, accessed 26 September 2023.

<sup>4</sup> R van der Graaf, ISE van der Zande ISE, HM den Ruijter, MA Oudijk, JJM van Delden, K Oude Rengerink and RHH Groenwold, 'Fair inclusion of pregnant women in clinical trials: an integrated scientific and ethical approach', *Trials*, 2018, 19(1):78, doi:10.1186/s13063-017-2402-9.

<sup>5</sup> A Yakerson, 'Women in clinical trials: a review of policy development and health equity in the Canadian context', *International Journal for Equity in Health*, 2019, 18(56), doi.org/10.1186/s12939-019-0954-x.

- [Australian Code for the Responsible Conduct of Research](#)
- [National Statement on Ethical Conduct in Human Research](#)
- [Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities](#)
- [Principles for consumer involvement in research funded by the Medical Research Future Fund](#)
- [Statement on consumer and community involvement in health and medical research](#)
- [Australian code for the care and use of animals for scientific purposes](#)
- [NHMRC's Research Quality Strategy.](#)

NHMRC and the Department of Health and Aged Care will work with the sector over time to establish improved consideration and increased 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 through each organisation's respective granting processes. Researchers and their supporting stakeholders are encouraged to reflect and start doing what they can now, to improve consideration of the Variables in their research.

It is acknowledged that effectively introducing and embedding this work is a challenge requiring support and action from all stakeholders across all levels of government, research funding organisations, research organisations, ethics committees, researchers, local health networks, non-government organisations, groups of high unmet need, patients, consumers, clinicians and health service providers.

## Definitions and use of the ABS 2020 Standard

The Australian Bureau of Statistics' (ABS) [Standard for Sex, Gender, Variations of Sex Characteristics and Sexual Orientation 2020](#)<sup>6</sup> (ABS 2020 Standard) standardises the collection and dissemination of statistical data.

The Standard identifies four variables with associated definitions that each present different statistical standards across a diverse and wide-ranging population:

- Sex
- Gender
- Variations of Sex Characteristics
- Sexual Orientation.

It is important to understand the distinctions between these variables, use the appropriate terminology and classifications, and avoid conflating terms. The ABS website provides a full [glossary](#) of terms. Importantly, the ABS 2020 Standard also provides detailed guidance on how to collect and analyse data on these variables, including, for example, directions on how to use a two-step method to identify cisgender and trans participants.

Broad use of the ABS 2020 Standard will support inclusive, consistent and comparable data collection and analysis across research projects. This will (1) provide valuable information about all population groups to inform the translation and implementation of research into health care, services and policies that support the differing needs of people across society, and (2) reduce research waste by allowing data from smaller studies to be interoperable, reused and/or contribute to a broader evidence base as appropriate.

The ABS 2020 Standard and definitions below have been developed by the ABS in consultation with Australian stakeholders. We encourage use of the ABS 2020 Standard and associated guidance on data collection and analysis by researchers in all

<sup>6</sup> Australian Bureau of Statistics (ABS). Standard for Sex, Gender, Variations of Sex Characteristics and Sexual Orientation Variables. ABS, Canberra, 2021.

research projects. However, we acknowledge that there may be circumstances where another best practice framework may be more appropriate or necessary, such as when conducting global clinical trials or with particular cultural groups.

## Sex

A person's sex is based upon their sex characteristics, such as their chromosomes, hormones, and reproductive organs. While typically based upon the sex characteristics observed and recorded at birth or infancy, a person's reported sex can change over the course of their lifetime and may differ from their sex recorded at birth.

## Gender

Gender is a social and cultural concept. It is about social and cultural differences in identity, expression and experience as a man, woman, or non-binary person. Non-binary is an umbrella term describing gender identities that are not exclusively male or female.

Gender includes the following concepts:

- Gender identity is about who a person feels themselves to be.
- Gender expression is the way a person expresses their gender. A person's gender expression may also vary depending on the context, for instance expressing different genders at work and home.
- Gender experience describes a person's alignment with the sex recorded for them at birth, i.e. a cis experience or a trans experience.

Responses to a gender question may reflect a combination of gender identity, expression and/or experience. In statistical collections, gender may be reported in terms of a person's felt or lived gender, as well as how that person is perceived by others, depending on whether information on gender is based on self-reported data or done by proxy.

**Cisgender (Cis):** The cisgender (cis) experience of gender is defined for persons whose gender is the same as the sex that was recorded for them at birth.

**Trans and gender diverse (trans):** The trans and gender diverse (trans) experience of gender is defined for persons whose gender is different to the sex that was recorded for them at birth.

**Non-binary:** Non-binary is an umbrella term describing gender identities that are not exclusively male or female.

## Variations of sex characteristics

Variations of sex characteristics refers to people with innate genetic, hormonal, or physical sex characteristics that do not conform to medical norms for female or male bodies. It refers to a wide spectrum of variations to genitals, hormones, chromosomes and/or reproductive organs.

Other umbrella terms used to describe being born with variations of sex characteristics are intersex or Differences/Disorders of Sex Development (DSD).

As outlined in the ABS 2020 Standard, it is important to note that many variations of sex characteristics are not evident at birth, and people may not be aware they were born with a variation of sex characteristics until puberty or later in life. It is also possible that a person may never know that they were born with a variation of sex characteristics. There is no singular experience or identity for people born with variations of sex characteristics.

## Sexual orientation

Sexual orientation is an umbrella concept that encapsulates:

- sexual identity (how a person thinks of their sexuality and the terms they identify with)
- attraction (romantic or sexual interest in another person)
- behaviour (sexual behaviour).

Responses to a sexual orientation question are a subjective view of oneself and can change over the course of a person's lifetime and in different contexts. An individual could respond differently to questions on either sexual identity, attraction or behaviour. There are a number of ways in which someone might define their sexual identity and attraction to others. Common examples include heterosexual, gay, lesbian, and bisexual.<sup>7</sup>

## Data collection and analysis

Researchers should refer to the ABS 2020 Standard for guidance on best practice data collection and analysis for all variables. For example,

1. Depending on the research project, asking for a person's sex at time of completing a survey, may be more relevant than asking for sex recorded at birth. Alternatively, a 'two-step method' in which responses to the sex recorded at birth and gender questions are cross-classified may be more appropriate for deriving cisgender and trans and gender diverse classification.
2. Inclusion of 'Another term' as a third response option for the sex at birth question can enhance data quality, however, it should not be used as a count of people who have variations of sex characteristics. Many variations of sex characteristics are not evident at birth, and people may not be aware they were born with a variation of sex characteristics until puberty or later in life. The inclusion of born with a variation of sex characteristics or intersex as a response option in a sex question, alongside male and female, is not capable of generating reliable or consistent results in measuring this population, and perpetuates the misconception that intersex people are neither male nor female.

## What better practice looks like

In order to support researchers, research organisations and other stakeholders to give effect to this Statement, the Variables should be considered in all NHMRC and/or MRFF funded research. Table 1 provides prompts to guide this consideration.

Due to the extensive diversity of research projects, this guidance will not cover every scenario. For some research projects there may be no need to address all or any of the Variables in the research. In these cases, researchers should be able to demonstrate that the Variables have been considered and be able to articulate strong justification as to why they do not need to be addressed. In other projects, some but not all prompts listed below may be relevant.

For example, basic science research can currently only address potential sex differences. In addition, basic science research spans from the analysis of single cells to pre-clinical models and therefore a study may or may not have a specific research population group. As a result some of the questions in the table below will not be relevant for this research area.

All researchers are asked to consider these questions to understand and address gaps in their current consideration of the Variables.

<sup>7</sup> Definitions taken from: Australian Bureau of Statistics (ABS) Standard for Sex, Gender, Variations of Sex Characteristics and Sexual Orientation Variables, ABS, Canberra, 2020.

**Table 1.** Prompts for considering sex, gender, variations of sex characteristics and sexual orientation (the Variables) by research life-cycle stage.

<b>Question Setting</b>	Are the Variables being considered when reviewing the literature?
	Has previous basic science research included both male and female cells or animals?
	Has previous basic science research considered sex differences?
	How are the Variables used and defined in the literature and how does this compare to current standards?
	Are historical gaps understood and acknowledged?
	Are there known health inequities based on any of the Variables?
	Has previous research considered the Variables in its inclusion of research participants?
	Has previous research considered the Variables in the research design, conduct, analysis and reporting?
	Has previous research considered intersectional factors (e.g. cultural and linguistic diversity, age, socio-economic status, abilities, geography) alongside the Variables?
	Are the Variables being considered when defining the population group/s of interest?
	Which population group/s will this research seek to include and benefit? Refer to each Variable.
	If any population group/s are being excluded, or research is focusing on a specific subgroup, is this justified?
	Are people with lived experience and other stakeholders being involved effectively, safely and sensitively in developing the research question?
	Does the research team have expertise to involve the proposed research population group/s effectively, safely and sensitively?
	Are all potential stakeholders being considered? These may include: <ul style="list-style-type: none"> <li>• groups of high unmet need</li> <li>• patients</li> <li>• consumers</li> <li>• community organisations and/or consumer representative groups</li> <li>• clinicians and healthcare professionals</li> <li>• policy makers</li> <li>• industry, including pharmaceutical or medical device manufacturers</li> <li>• clinical guideline developers</li> <li>• other researchers/stakeholders along the research pipeline.</li> </ul>
	Are the voices and priorities of people with lived experience and other relevant stakeholders being valued and included?
	Is this research a priority for the proposed research population group/s?
	Are the Variables considered in the final research question?
	In basic science research, is the potential for sex differences being considered in the development of the final research question?
	<b>Design</b>
Are there knowledge gaps about sex differences in preclinical research that may impact the research design?	
Are there biases or data gaps related to the Variables that may impact the research design?	
Do any reference values being used in the research design account for the Variables?	
Is the research team partnering with people with lived experience, including the various research population group/s, and other stakeholders to co-design the research?	

	Does the design include realistic timelines and budgets to support effective, safe and sensitive engagement with co-design partners?
	Does the design consider the Variables when defining and planning to recruit eligible participants or study eligible subjects?
	In basic science research are male and female cells or animals included in research by default unless appropriately justified?
	Is there appropriate representation of the impacted population/s across the health condition being studied?
	Are there evidence-based and scientifically sound justifications for the groups included and excluded?
	Are eligibility criteria regarding the Variables as inclusive as possible while aligning with the research question?
	Are other eligibility criteria, such as age or pregnancy, that may impact who can be recruited to the study being considered?
	Is a recruitment plan being co-designed with the research population group/s?
	Will an analysis be conducted based on the Variables?
	Is the analysis plan being developed with a statistician?
	Is the required sample size of all population or animal groups being determined?
	If the research aims to detect differences between groups, will the study be powered to do so?
	Do any groups need to be oversampled to achieve appropriate study power?
	Are other relevant factors or outcomes that may vary based on the Variables being considered in the design?
	Could the sex-specific behaviours or housing needs of animals be relevant to the study?
	Are specific sex characteristics, physiological or anatomical features, gender, expressions, experience, roles or norms or sexual behaviours relevant to the study?
	Are there any relevant outcomes that may vary based on the Variables that should be measured?
	Are there any intersectional factors that should be considered?
	Are the Variables being considered when designing data collection methods?
	Are appropriate experimental data collection methods being determined for preclinical research?
	Can suppliers of cells or animals provide any relevant data, such as donor sex or chromosomal information?
	Will the ABS 2020 Standard be used to collect data on the Variables?
	If not, is there an appropriate justification, such as that the study includes a global clinical trial that uses a different standard?
	Are the research population group/s being consulted to design best practice data collection for other factors or outcomes of interest?
	Are the Variables being considered when designing research using existing data sources?
	How was existing data on the Variables originally collected?
	How can limitations in the existing data, such as only sex being collected, or only binary gender without being able to further identify cisgender and trans men and women, be accounted for?
	Are the implications of using existing data as a proxy for any of the Variables being considered?
	Are other NHMRC and MRFF codes, guidance and consumer statements being considered?
<b>Conduct</b>	Is the research being conducted in alignment with the research design?
	Does the research team have appropriate expertise and capacity to conduct the research?
	Is the research being conducted in effective, safe and respectful partnership with the research population group/s?

	Does the conduct support the recruitment of participants representative of the research population group/s?
	Are the eligibility criteria clearly articulated?
	Do the eligibility criteria use inclusive language that enables all potential participants to see themselves in the research, such as replacing 'women with ovarian cancer' with 'people with ovarian cancer, including, cis women, trans men, non-binary people'?
	Is the communication to potential participants appropriate and sensitive?
	If there are co-design partner/s, are they involved in participant recruitment, for example working to overcome recruitment barriers?
	Are individuals being provided the information and support they need to make informed decisions about consenting to participate in research?
	Is fit-for-purpose data collection on the Variables and other factors being conducted?
	Is the ABS 2020 Standard and associated guidance being used to collect data on the Variables? If not, is there an appropriate justification?
	Does the conduct involve effective, safe and respectful engagement with participants and/or stakeholders involved in the original research design, including people with lived experience?
	Is respect for the human rights, confidentiality, health and wellbeing of participants demonstrated?
	Is a supportive environment being provided, respectful of the needs and wishes of those with lived experience?
	Is plain language used and relevant training and information provided?
	Are sufficient numbers of participants/stakeholders included to allow for multiple voices and peer support?
	Are roles and responsibilities clearly defined and agreed?
<b>Analysis</b>	Is the analysis scientifically sound?
	Are appropriate statistical methods being used?
	In basic science research, is scientifically sound analysis and interpretation of sex being supported?
	Is the ABS 2020 Standard and associated guidance being used to analyse data on the Variables? If not, is there an appropriate justification?
	If powered to do so, are differences between groups or effects based on the Variables being analysed?
	If the sample size of a group was insufficient, are other analysis options and their implications being considered, such as excluding or merging groups?
	Is intra-group variation being analysed?
<b>Reporting</b>	Are the terms sex, gender, variations of sex characteristics and sexual orientation being used appropriately and not conflated?
	Are the literature and community knowledge the study is based on being included in reporting?
	Are biases or gaps in previous research being acknowledged?
	Are the research methods being described transparently and justified?
	Are the approaches to consideration of the Variables in study design, eligibility criteria, recruitment, data collection and analysis being reported?
	Are all results relevant to the Variables being reported?
	Is the sex of subjects in pre-clinical research being described, using appropriate terminology for cells and animals?
	In basic science research, are the results on any analyses of sex, including null results being reported?
	Are participant demographics being reported using appropriate terminology, aligned with the ABS 2020 Standard where possible?
	Are actual versus planned recruitment numbers for research population group/s being reported?

	Are the results of any analyses regarding the Variables, including null results, being included?
	Are disaggregated results by the Variables being reported for contribution to larger studies or meta-analyses?
	Is participant confidentiality and anonymity, including that participants from small population groups could be more readily identifiable, being considered in the reporting?
	Are the results being appropriately interpreted and implications of the research for people with lived experience and other stakeholders being discussed?
	Is reporting inclusive, safe, appropriate, valid and rigorous?
	Is every effort being made to ensure that interpretation of the results does not perpetuate or create harmful messaging, stereotypes, discriminative practices, or rhetoric?
	Does the discussion acknowledge heterogeneity within groups, including intersectional factors?
	Are results about the Variables being contextualised, including their relevance for translation, clinical practice, health service design or health policy?
	Are any limitations around consideration of the Variables being discussed, such as recruitment targets not being met, gender data only being reported as a cisgender binary, or an animal model only being available in one sex?
<b>Translation and Implementation</b>	Are the results being widely disseminated?
	Are stakeholders, including the research population group/s, being updated on relevant outcomes?
	Is the research being shared with institutions and departments that focus on any of the Variables or included research population group/s?
	Can findings be used for the minimisation of health inequities based on the Variables or other intersectional factors?
	Can findings be used to inform targeted, fit-for-purpose health interventions, care, services and policies?
	Can findings support improved health outcomes for groups of high unmet need?
	Are relevant policy makers and healthcare professionals being informed of the results?

## Further support, tools and resources

Embedding sex, gender, variations of sex characteristics and sexual orientation considerations in research requires a range of supports, tools and resources. As mentioned above, the Statement will be implemented over time in consultation with the sector. Other tools and resources will be linked from the [Statement webpage](#).