Response to the draft NHMRC/MRFF Statement on Sex, Gender, Variations of Sex Characteristics and Sexual Orientation in Health and Medical Research

**Key issues**

1. The draft NHMRC/MRFF Statement draws heavily on the Australian Bureau of Statistics (2021) *Standard for Data Collection on Sex, Gender, Variations of Sex Characteristics, and Sexual Orientation* (ABS Standard). The ABS Standard is an appropriate starting point. However, it is crucial to recognise that it was not developed with health and medical research as a focus. In addition, the reference group for the development of the Standard did not include a single women’s or women’s health research organisation meaning the needs of women are not fully appreciated or reflected in the ABS Standard. The ABS Standard has good elements, but it is crucial that the NHMRC/MRFF Statement appropriately define each of the variables and provides specific guidance on data collection for use in health and medical research.
2. The draft NHMRC/MRFF Statement does not emphasise the importance of collection of accurate data on the variables of sex, gender identity, variation of sex characteristics and sexual orientation (including sexual identity, sexual attraction and sexual behaviour) as part of the Vision and Purpose and throughout the document.
3. The draft NHMRC/MRFF Statement does not disaggregate the three aspects of sexual orientation identified by the ABS Standard: sexual identity, sexual attraction, and sexual behaviour. These are all relevant for data collection in health and medical research.
4. The draft NHMRC/MRFF Statement uses the term ‘gender’ to mean ‘gender identity’, even though it is well recognised that ‘gender’ is often understood to mean ‘sex’ and this confusion of concepts is a problem in health and medical research.
5. The draft NHMRC/MRFF Statement is not explicit about the nature and problem of the female data gap in research, and does not use the word ‘women’ in a sexed meaning, thereby obscuring the phenomenon itself and the sexism underlying it.
6. The draft NHMRC/MRFF Statement recommends that researchers should use desexed language in study recruitment and, for example, not use the term ‘women’ in a sexed meaning but rather uses phrases such as ‘people with ovarian cancer.’ It does not consider how desexed language might reduce inclusivity, increase confusion, dehumanise, or alienate potential study participants.
7. The draft NHMRC/MRFF Statement does not recognise that not everyone applies the concept of gender identity to themselves or would say they have a gender identity.
8. The draft NHMRC/MRFF Statement lacks any acknowledgement of gender as the social and cultural expectations of the sexes and the relevance of this in health and medical research.
9. The draft NHMRC/MRFF Statement does not recognise that data on sex is being lost due to the prioritisation and replacement of gender identity over sex in data collection. It does not contain any text describing the consequences of loss of data on sex, particular for women and children, or guidance on when data on sex should be collected.
10. The draft NHMRC/MRFF Statement includes a definition of sex that is partially based on characteristics that can be changed, and therefore it supports the idea that biological sex can be changed. It also contains text suggesting that this is the case. It does not consider how this idea is harming the health of individuals, introducing errors into Australia’s health data sets and undermining research.
11. The draft NHMRC/MRFF Statement recommends involvement of stakeholders in research design but does not recognise the need to weigh potentially conflicting views and does not consider the need to provide primacy to the protection of data integrity and accuracy.

**Key recommendations**

1. The NHMRC/MRFF Statement should emphasise the importance of collecting accurate data on sex, gender identity, variations of sex characteristics, sexual identity, sexual attraction, and sexual behaviour where it is appropriate and beneficial to do so.
2. The NHMRC/MRFF Statement should highlight the female data gap, the sexist nature of this gap, and the importance of accurate collection of data on and disaggregation by sex in order that the female data gap be addressed. **There is need for the NHMRC/MRFF to take leadership and ensure that data on sex as a biological variable continues to be considered in research and is not replaced by legal sex, self-reported sex, or gender identity.**
3. The NHMRC/MRFF Statement should use the term ‘women’ in a sexed sense to mean ‘adult female person’ throughout.
4. The NHMRC/MRFF Statement should include guidance for researchers on when data on sex should be collected. We argue that that would be in any circumstance where physiological/anatomical differences between the sexes or gender (meaning social expectations of the sexes) may be relevant. It should be specified that this includes any circumstances where women’s reproductive capacity (ability to become pregnant) or reproductive work (pregnancy, birth, breastfeeding, or care of infants) may be relevant.
5. The NHMRC/MRFF Statement should use a scientific definition of sex that is applicable to humans and animals and should reserve the terms ‘male’ and ‘female’ for referring to the sexes.
6. The NHMRC/MRFF Statement should recognise and acknowledge that not everyone applies the concept of gender identity to themselves and provide guidance on data collection on lack of gender identity.
7. The NHMRC/MRFF Statement should disaggregate the three aspects of sexual orientation, namely sexual identity, sexual attraction and sexual behaviour, because each of these can be important to health research, health policy, health communication, and healthcare provision. Clear definitions of sexual identity, sexual attraction, and sexual behaviour should also be provided in the Statement.
8. The NHMRC/MRFF Statement should recognise that sexed language is, in most instances, the most inclusive language form, but should also support the use of desexed/gender identity-prioritising language for specific purposes such as in research focussed on transgender and gender diverse people.
9. The NHMRC/MRFF should build upon the ABS Standard and develop its own standard for data collection on these variables, tailored specifically for health and medical researchers.
10. The NHMRC/MRFF Statement should provide guidance to researchers on how to negotiate a balance between what stakeholders want and the need to ensure inclusion of relevant variables and ensure data quality on sex, gender identity, sexual identity, sexual attraction and sexual behaviour.
11. **What benefits should the statement achieve?**

The NHMRC/MRFF Statement should promote and facilitate accurate collection of data on sex, gender identity, variations of sex characteristics, sexual identity, sexual attraction and sexual behaviour where it is appropriate and beneficial to do so. Accurate data collection on these variables is vitally important, and this should be explicitly stated in the Vision and Purpose of the NHMRC/MRFF Statement and elsewhere. There should be disaggregation of the different aspects of sexual orientation (i.e. sexual identity, sexual attraction, and sexual behaviour, as described in the ABS Standard (Australian Bureau of Statistics, 2021), because each of these is important for health research, health policy, health communication and healthcare. We explain why this is necessary later (in response to Question 2).

1. **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?**

The Vision of the draft NHMRC/MRFF Statement is:

*‘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.’* *(page 3)*

The draft Vision is partially aligned with what we believe the NHMRC/MRFF Statement should seek to achieve. However, we suggest that the Vision should emphasise the importance of collecting accurate data on these variables. We believe this is necessary because, as we share later (in response to Question 3 and elsewhere), there is evidence that data collection on these variables is increasingly inaccurate. The Vision should also make it clear that data should be collected on these variables when it is appropriate and beneficial to do so.

We are particularly concerned about an evident loss of data on sex that is occurring in research in Australia and internationally and we believe that the NHMRC/MRFF Statement should specifically address this. We discuss this later (in response to Question 3). We also recommend that, throughout the Statement, ‘gender identity’ rather than ‘gender’ be referred to, in order to reduce confusion and improve data quality. We explain why this should be the case later (in response to Question 3).

We suggest that the Vision be reworded to:

*‘Improved health outcomes for all people in Australia by ensuring the evidence-base that informs our health care system appropriately includes* ***and considers accurate*** *data on sex,* ***gender identity****, variations of sex characteristics,* ***sexual identity, sexual attraction, and sexual behaviour.***

The Purpose in the draft NHMRC/MRFF Statement is:

*‘To improve health outcomes by:*

1. *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,*
2. *improving consideration of sex, gender, variations of sex characteristics and sexual orientation throughout the design, conduct, analysis, reporting, translation and implementation of all research,*
3. *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,*
4. *promoting effective, sensitive and safe involvement of people with lived experience in all stages of research projects,*
5. *encouraging more effective partnerships between consumers, researchers, clinicians, and other research stakeholders.’ (page 4, numbers added by us)*

We agree that points 4 and 5 are appropriate inclusions in the Purpose of the draft NHMRC/MRFF Statement.

We regard the intent of points 1, 2 and 3 of the Purpose as appropriate, but we recommend that additional text be added, and other wording changes be made.

Regarding points 1 and 2, we recommend that the variable of sexual orientation be disaggregated and the different aspects of sexual orientation, namely sexual identity, sexual attraction and sexual behaviour (Australian Bureau of Statistics, 2021), be specified, because each of these can be important to health research, health policy, health communication, and healthcare provision. These variables should be included by researchers when appropriate to the research question at hand and not used when this information is irrelevant to the investigation.

It has long been known that it should not be assumed that these aspects of sexual orientation are aligned with one another. Importantly in relation to sexual health, an individual's sexual behaviour may be different from what their stated sexual identity would suggest. For example, in male prisons, it is not uncommon for men to state that they are heterosexual but to engage in sex with other men (Ricciardelli et al., 2016).

Furthermore, recent changes in people's understanding and conceptualisation of sexual orientation have occurred, that make disaggregation in data collection more broadly necessary. Researchers need to be aware that the increasing cultural salience of the concept of gender identity means that some people, when asked their sexual orientation, report their sexual identity based on their gender identity and not on their biological sex.

The relatively new understanding of sexual orientation as being related to gender identity and not biological sex means that being gay/lesbian/homosexual is increasingly understood to mean being same gender identity attracted (not same sex attracted); and being straight/heterosexual is increasingly understood to mean being opposite gender identity attracted (not opposite sex attracted). In practice, this can mean that someone who is biologically male but has a gender identity of woman, and is sexually attracted to biological females, may state a sexual identity as a lesbian/homosexual. Their partner may similarly identify as a lesbian. Furthermore, a biological male who has a gender identity of woman and is sexually attracted to biological males may identify their sexual orientation as straight/heterosexual, despite engaging in sex with other males. As a final example, someone who is biologically female but has a gender identity of man, and is sexually attracted to biological males, may identify as gay/homosexual and state that they are a man who has sex with men. This has enormous ramifications for particular areas of research, and healthcare, especially those related to sexual health and pregnancy.

This gender identity-based understanding of sexual orientation is increasingly being prioritised, including in legislation. For example, the recent Western Australian review of anti-discrimination law recommended a definition of sexual orientation that was gender identity-based rather than sex-based, stating that, ‘*Sexual orientation should be defined as a person’s emotional, affectional and sexual attraction to, or intimate or sexual relations with, persons of a different gender or the same gender or more than one gender’* (Law Reform Commission of Western Australia, 2022, p.12).

Consequently, research that simply collects data on sexual identity as a single variable cannot validly be used to consider issues related to sexual behaviour. Furthermore, valid data on a sex-based understanding of sexual orientation cannot be collected via a simple question on sexual orientation. We direct you to a recent Australian paper that addresses in detail some of the complexities related to data collection on sexual identity, sexual attraction, and sexual behaviour (Mooney-Somers et al., 2023). We refer again to the issue of collection of data on sexual identity, sexual attraction, and sexual behaviour later (in response to Question 3) when discussing the suitability of the recommended questions from the ABS Standard.

The importance of accurate data collection on sexual behaviour was exemplified in the recent mpox (monkeypox) epidemic, where both sex and sexual behaviour were critical risk factors. According to the World Health Organization, 96.3% of individuals who were infected with mpox in this epidemic were male, and 85% of these males had engaged in sex with other males (World Health Organization, 2023). Females were rarely infected with mpox and, when they were, their experience was very different from that of males. This was shown in a study considering mpox in ‘women and non-binary people,’ a mixed sex group consisting of female people (of unspecified gender identities) as well as male people with a gender identity of ‘woman’ (Thornhill et al., 2022). The epidemiological and clinical characteristics of mpox were shown in this research to be vastly different between the sexes, including: number of sexual partners, involvement in sex for payment, concurrent HIV infection, probable mode of transmission, rates of initial misdiagnosis and vaccination, where diagnosed, location of lesions, presence of pregnancy and whether they were caregivers of children (Thornhill et al., 2022). However, these differences could only be demonstrated because accurate data on sex and sexual behaviour was collected.

However, in Australia and elsewhere, confusion between sex, gender identity, sexual identity, sexual attraction, and sexual behaviour was evident in both intervention design and health communication regarding mpox. For example, the ACT Government stated that, *‘Based on current experience in Australia and internationally, people at highest risk from mpox are gay, bisexual or other men who have sex with men (GBMSM).’* This statement is accurate if a sexed definition of ‘men’ (meaning male person) is used. However, eligibility criteria for vaccination indicated that ACT Health was not using a sexed definition of men but instead a gender identity-based definition. Their guidance stated that vaccination was available for *‘Sexually active men (cis and trans) who are gay, bisexual or have sex with other men’ and ‘Partners of the people above.’* This policy decision, which applied a gender-identity based definition of men (by referring to ‘cis and trans’ men), reflects a misapplication of the evidence and a muddling of sex and gender identity. It included people who were not at risk (trans men who are biologically female) and excluded people who were at risk (biological males who identity as women and who have sex with other males).

The potential seriousness of this confusion of sex, gender identity, and sexual behaviour in the context of a disease epidemic is very concerning. Such confusion has great potential for adverse health consequences at a population and individual health level. We recognise that this is a fraught area, and that respect for identity is extremely important in health communication. However, we highlight the mpox experience to illustrate how vital it is to accurately collect data on sex and sexual behaviour in research, and for these concepts to be appropriately applied in health policy and healthcare. We also note that those individuals most likely adversely impacted by confusion, such as that described here, are those with diverse gender and sexual identities. Thus, ensuring accurate data collection on sex and sexual behaviour should be considered vital to increasing understanding of the experiences and health needs of such people.

We therefore suggest that additions be made to points 1 and 2 of the Purpose of the NHMRC/MRFF Statement, so that they read:

‘***Identifying and reducing*** *research gaps related to historical* ***and ongoing*** *underrepresentation of sex,* ***gender identity****, variations of sex characteristics,* ***sexual identity, sexual attraction, and sexual behaviour*** *in various research fields and topics’*

*‘Improving consideration of sex,* ***gender identity****, variations of sex characteristics,* ***sexual identity, sexual attraction, and sexual behaviour*** *throughout the design, conduct, analysis, reporting, translation and implementation of all research’*

In addition, clear definitions of sexual identity, sexual attraction and sexual behaviour should be provided in the NHMRC/MRFF Statement, and sexual orientation should be disaggregated throughout the whole Statement.

Regarding point 3 of the Purpose, we believe that the wording ‘*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’* is highly inappropriate. We say this for two reasons. First, it does not address sex discrimination against women in the form of the historical and continuing lack of inclusion of female people and female states, conditions, and experiences in research. This lack of inclusion impacts all female people, irrespective of gender identity, and so is experienced by transgender men and female non-binary people.

The adverse impact on women and children when women, including pregnant and breastfeeding women, are excluded from medical and other research, is well-established and significant. For example, despite advocacy from the Coalition for Advancement of Maternal Therapeutics (Coalition for Advancement of Maternal Therapeutics, 2020), COVID-19 vaccine trials did not include pregnant or breastfeeding women (Van Spall, 2021). The result was that hundreds of millions of pregnant and breastfeeding women were required to make decisions on receiving a COVID-19 vaccine in the absence of research showing safety. In some contexts, women were forced (at least for a time) out of their employment or had to choose between breastfeeding and their employment, because government policy meant they could not be vaccinated in line with work requirements while pregnant or breastfeeding (Hare & Womersley, 2021).

More broadly, the lack of inclusion of women in research has resulted in a ‘female data gap’ that is evident not just in medicine, but across the breadth of human experience and has a profound negative impact on women and by extension, children (Criado-Perez, 2019). The historical and ongoing lack of inclusion of women in research, including because of their reproductive capacity, is because of their sex and a result of sexism. This should be made clear in the NHMRC/MRFF Statement.

We argue therefore that the NHMRC/MRFF Statement should use the word ‘women’ in point 3 of the Purpose, as a sexed term meaning ‘adult female people.’ Furthermore, the term ‘women’ in this sexed meaning should be used throughout the Statement when the need to ensure appropriate inclusion of female people in research is being discussed. The Statement should also include a clear definition of the term ‘women,’ to make it clear that it includes all adult female individuals, including those who experience a gender identity meaning that they identify as a trans man or non-binary person. To do otherwise makes sexism against women invisible in the Statement and obscures the importance of addressing the female data gap.

The second problem with point 3 of the Purpose is that it ascribes the concept of gender identity universally, including to women who do not have a transgender identification, through the use of the term ‘cis women.’ What constitutes gender identity is a matter of debate and conjecture (Gheaus, 2023). However, gender identity is universally understood to be something internal to the individual that can only be self-determined and declared, never imposed. It needs to be recognised that some women do not apply the concept of gender identity to themselves, and object to the gender identity of ‘woman’ and the descriptor of ‘cis,’ being applied to them (Karleen D. Gribble et al., 2023; Welford, 2021). Those who so object include women from culturally and linguistically diverse (CALD) backgrounds, who may be unfamiliar with the concept of gender identity (Kowaliw, 2020). Alternatively, women from CALD backgrounds may have an understanding of the concept of gender identity and see its imposition upon them as culturally imperialistic (Gribble et al., 2022). Some of us have received or heard of complaints of cultural imperialism and neo-colonialism by people from non-Western countries who have been required to apply the concept of gender identity to themselves, for example in filling out a survey.

Detransitioned women (a very marginalised group of women who once identified as transgender, but no longer do so) are also amongst those who may reject gender identity and associated concepts, having experienced them as unhelpful or even harmful (Alleva, 2022; Karleen D. Gribble et al., 2023).

As previously indicated, sexual orientation should be disaggregated into its three components (sexual identity, sexual attraction, and sexual behaviour).

We therefore suggest that Point 3 of the Purpose should be reworded to say:

*‘promoting increased inclusion of* ***women, transgender and non-binary people****, people with innate variations of sex characteristics and people with* ***diverse sexual identities, sexual attractions and sexual behaviours*** *in research, particularly where they have been historically underrepresented or excluded.’*

An additional point should be added to the Purpose. This point should address the need to collect **accurate** data on these variables. We suggest that this point should say, ***‘improving the accuracy of data collection on sex, gender identity, variations of sex characteristics, sexual identity, sexual attraction, and sexual behaviour.’***

The importance of accurate data collection on these variables should be referred to and emphasised throughout the NHMRC/MRFF Statement.

1. **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?**

Some aspects of the better practice guidance are not suitable. We argue that the following questions in Table 1 (underlined for emphasis) should be changed or removed.

*Are specific sex characteristics, physiological or anatomical features, gender, expressions, experience, roles or norms or sexual behaviours relevant to the study? (page 10, Design stage)*

This question does not clearly delineate the differences between sex, sex characteristics or variations, gender (social expectations of the sexes), gender identity, sexual identity, sexual attraction, and sexual behaviours.

We suggest that this question be reworded to state, ***‘Are sex, sex characteristics or variations, gender identity, gender expression, sexual identity, sexual attraction, or sexual behaviours of individuals relevant to the study? Is gender (social expectations of the sexes) relevant to the study?***

*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?* *(page 10, Design stage]*

This question does not allow for the existence of individuals who do not apply the concept of gender identity to themselves. It also does not recognise that that there a problem with data on sex not being accurately collected and recorded in research and in Australia’s health data sets and elsewhere. We suggest that this question be reworded to state, ***‘How can limitations in the existing data, such as only sex or only gender identity being collected, or inaccurate collection of data on sex or gender identity (including no provision for non-binary gender identity and no provision for gender identity not being applicable) be accounted for?’***

*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’?* (page 11, Conduct stage)

This question prompt proposes that study language should be desexed, that is terms that refer to the sexes should be avoided. This question prompt will not increase inclusivity, but rather will decrease it, and may also compromise research quality.

There are numerous examples of desexed language causing inaccuracy and confusion. During the COVID-19 pandemic, the Australian Department of Health desexed its COVID-19 vaccine decision-making guide for pregnant and breastfeeding women. A switch from describing COVID-19 severity in pregnant *women* compared with non-pregnant *women* to describing COVID-19 severity in pregnant *people* compared with non-pregnant *people* meant that statistics reported were incorrect (Gribble et al., 2022). There have been numerous similar errors caused by using desexed language to compare pregnant people with non-pregnant people, including in many peer-reviewed publications (e.g. Delara & Sadarangani, 2022; Gupta & Arguello Perez, 2022; Jorgensen et al., 2022; Stebbings et al., 2021; Wu et al., 2020).

Sometimes, use of desexed language has meant it is not possible to identify the sex of ‘non-pregnant people.’ For example, a paper on telomere length in ‘pregnant and non-pregnant people’ did not report on the sex of the non-pregnant people (Panelli et al., 2022). Study participants were recruited via an obstetric and gynaecological service, but such services are sometimes used by post-operative trans women who are biologically male, so it remains unclear whether the comparison group was entirely female.

In public health communications, replacements for ‘women’ such as ‘anyone with a cervix’ can be reasonably predicted to present a barrier to understanding by women who have low literacy, low health literacy or low English proficiency. The Australian Department of Health National Cervical Screening Toolkit says to use ‘plain language rather than medical terms’ when discussing cervical cancer screening (Australian Department of Health, 2022). Nonetheless, the Queensland Department of Health now invites ‘persons with a cervix’ for cervical cancer screening in their health promotion materials (Queensland Health, 2022). This is despite research showing that poor understanding of cervical cancer screening is a major reason why, for example, immigrant women in Australia participate in cervical cancer screening programs at lower rates than Australian born women (Alam et al., 2021).

It also ignores the fact that low health literacy is a challenge in Australia’s Indigenous population. Indigenous women are less likely to be screened for cervical cancer (including specifically in Queensland (Whop et al., 2016)), more likely to develop cervical cancer, and more likely to die from cervical cancer than other women (Butler et al., 2020).

The same issues apply to research using similar terms in recruitment. As researchers, we are keenly aware that people who have lower levels of education and literacy are less likely to participate in research, particularly survey-based research. We believe that an expectation that desexed language is used in health and medical research, including in recruitment, will reduce participation of demographic groups who are already commonly underrepresented. That is, it will exclude people.

Desexed language steps away from the evidence-based health communication principle of plain language, reduces inclusivity, presents a barrier to healthcare provision and participation in research, and further disadvantages the most vulnerable sections of the population (Beauchamp et al., 2015; Choudhry et al., 2019; Rheault et al., 2021).

Alternatives to sexed terms for women are also often dehumanising. In 2022, the cover of an issue of *The Lancet* referred to women as ‘bodies with vaginas.’ Research funded by the Australian Government considered the experiences of Vanuatuan women with a disability regarding menstruation (Wilbur et al., 2021). The findings published in the *Lancet Western Pacific* highlighted the stigma associated with menstruation, but called the women who participated in the research ‘menstruators’ (Wilbur et al., 2021). There is no indication that study participants were asked if they agreed to be referred to by a stigmatised physiological process. We argue that the language used in this paper was unethical. In mass media, the ABC has referred to women as ‘vulva owners’ (Australian Broadcasting Corporation, 2022) and the SBS has defended (Morgan, 2017) *Teen Vogue* referring to women and girls as ‘non-prostate owners’ (Engle, 2019). Recently Johns Hopkins University redefined the words 'lesbian' and 'gay'. A lesbian was described as ‘a non-man attracted to non-men,’ while a gay man was described as ‘a man… attracted to other men.’ This definition was eventually withdrawn due to the uproar it received (Lavietes, 2023). It needs to be appreciated that many people find desexed language offensive; research from the USA with new low-income mothers showed that some objected to some desexed terms and would refuse to participate in surveys using these words (Kinney et al., 2023).

We argue that to encourage desexed language for use with general audiences will exclude and confuse some people and compromise data quality. We recognise and support that in some circumstances it may be appropriate to use desexed language. This might be, for example, if the research is predominantly recruiting people who identify as transgender. We point to the recently revised American Psychological Association's *Equity, Diversity, and Inclusion: Inclusive Language Guide* (American Psychological Association, 2023), which supports our position of tailoring language according to context. One way of managing this issue might be to have two versions of materials in some circumstances, one using sexed language and the other desexed or gender identity-based language.

We are concerned about which organisations and individuals were consulted to come to this recommendation to use desexed language. We also have concerns about the evidence-base used to inform this recommendation. It does not seem that experts in maternal and child health or women’s health were consulted or the evidence properly considered. This recommendation also goes against the later question prompt, *‘Is plain language used?’* We recommend that the question prompt advising use of desexed language is removed and is replaced with questions saying:

***Is plain and clear language used in participant recruitment materials, participant information sheets, and instruments such as surveys to enable individuals who have low literacy or language skills to participate?***

***Is language tailored to the target audiences for the study? May it be necessary to use more than one version of recruitment materials, participant information sheets, and instruments such as surveys to ensure that the language used is suitable for all who may wish to participate (for example, different languages or desexed language for transgender or gender diverse people?)***

*Is the ABS 2020 Standard and associated guidance being used to collect data on the Variables? If not, is there an appropriate justification? (p.10, Design stage)*

*Is the ABS 2020 Standard and associated guidance being used to analyse data on the Variables? If not, is there an appropriate justification? (p.11, Analysis stage)*

*Are participant demographics being reported using appropriate terminology, aligned with the ABS 2020 Standard where possible? (p.11, Reporting stage)*

These question prompts assume that the ABS Standard is wholly appropriate for use by health and medical researchers. As detailed below, we do not believe that the ABS Standard is appropriate for use by health and medical researchers in its entirety. The ABS Standard was not designed primarily to collect data for health and medical research. In addition, as revealed in administrative data released by the ABS, the reference group for the development of the Standard did not include a single women’s or women’s health research organisation meaning the needs of women are not fully appreciated or reflected in the ABS Standard. There have already been problems with the ABS Standard, and one of the questions included in the 2021 Census had to be withdrawn because it was shown to result in meaningless data (Australian Bureau of Statistics, 2022b). This suggests flaws in the development of the ABS Standard with inadequate testing and consideration of ramifications. We suggest that the ABS Standard is an appropriate starting point, but that NHMRC/MRFF should consider how it could be improved so that researchers and provide a Standard better supported for accurate collection of data on the variables of sex, gender identity, variations of sex development, sexual identity, sexual attraction and sexual behaviour in health and medical research.

Here we detail what we see as positive about the ABS Standard and what we see as problematic, and we make suggestions about how the NHMRC/MRFF should address data collection on the variables.

Sex

The ABS Standard provides a definition of sex as follows:

*‘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.’*

We note that the draft NHMRC/MRFF Statement also uses this definition. We believe this definition is inappropriate to be used by health and medical researchers for several reasons.

First, the definition in the ABS Standard is not an accurate definition of sex. Sex as a biological trait is not limited to humans and is defined by whether individuals produce small motile gametes (male) or large sessile gametes (female) (Goymann et al., 2023; Hilton & Wright, 2023). Individuals who do not produce gametes because they are too young, too old, or because of disease, surgery or developmental anomalies, still have a sex which is identified based on whether their bodies are on the developmental pathway to producing small motile or large sessile gametes (Goymann et al., 2023; Hilton & Wright, 2023). This distinct dichotomy in the size of female and male gametes is called ‘anisogamy’ and is a characteristic of all multicellular sexually reproducing animals, including humans. In mammals, whether an individual is on the developmental pathway of male or female is determined by their chromosomes and the SRY gene (Gilbert, 2000). However, this is not the case for all animals; for example, sex is determined by temperature in reptiles, and other mechanisms of sex determination exist in other animals (Gilbert, 2000; Goymann et al., 2023). Thus, reference to chromosomes as a determinant of sex is misleading. We believe that a definition of sex that applies across all multicellular animals, including humans, should be used by the NHMRC/MRFF. This is not just because health and medical researchers undertake research using animals and animal cell lines, but also for scientific consistency and to build confidence in the scientific integrity of Australian health and medical research.

Second, two of the characteristics which the ABS Standard says determine sex (hormones and reproductive organs) can be changed, supporting the increasingly held belief that people can change their sex. Hormone levels can be altered via use of medications, through disease, with age, or via gonadectomy. Reproductive organs can be removed via surgery. Using a definition of sex based on changeable characteristics supports the belief that an individual’s sex can be changed. For example, a recent article in *Medscape* argues that people who change their hormonal profile or have surgery have changed their ‘phenotypic sex’ (Brandt, 2023). The consequences of a definition of sex that supports the idea that people’s sex can change has serious negative ramifications for the health of individuals, the integrity of Australia’s health data sets and for the quality of research.

The health of individuals is placed at risk if they change their sex in their health records because they believe that surgical or hormonal mediated changes they have made to their body have actually changed their sex. This risk is heightened if they do not inform their healthcare providers. Those whose appearance is atypical for their sex, including those who are transgender and who have undertaken hormonal or surgical modifications to their body, are most at risk of harm if their sex is recorded incorrectly in their health records.

There are an increasing number of case studies published documenting how incorrect sex markers in health records or general lack of clarity regarding a transgender person’s sex have harmed their health. In the United States of America (USA), confusion in a hospital emergency department regarding a person’s sex resulted in a delayed diagnosis of pregnancy, labour, and a prolapsed umbilical cord, with the ultimate result being fetal death (Stroumsa et al., 2019). Again in the USA, a trans man who was seriously injured in a car accident was intubated for a protracted period of time with an endotracheal tube of a size typically used for males and generally considered too large for females. As a result, they experienced severe tracheal stenosis and required repeated procedures and surgeries over months (Lao & Crawley, 2020).

In the United Kingdom, results of testing for Kells antibodies in the blood of a pregnant trans man were initially incorrect because paternal rather than maternal testing was undertaken, as a result of the blood being incorrectly labelled as being from a male (Greenfield & Topper, 2021). This resulted in a significant delay in provision of specialist support. For trans men, being recorded as male in health records has been identified as a barrier to cervical cancer screening, as reminders may not be sent (Alison et al., 2021). Lack of participation in cervical cancer screening is strongly associated with cervical cancer diagnosis (Johnson et al., 2020).

The problem of inaccurate recording of sex for pathology testing is increasingly being recognised. The NSW LGBTIQ+ Health Strategy highlights this and describes the need for collection of accurate data on biological sex for pathology testing alongside gender identity (NSW Ministry of Health, 2022). The Strategy proposes that explanations be provided to staff and patients on why it is important that accurate data on sex be recorded in health records, stating that they are developing ‘*communications for community and staff to explain why sex assigned at birth matters for some pathology tests and is included on pathology request forms’* (NSW Ministry of Health, 2022, p.37).

Biological sex also matters in relation to safe and effective pharmacological treatment. The draft Statement notes that *'Historically, the limited consideration of sex … in health and medical research … or has led to inappropriate and/or harmful health care'* *(page 5).* The cited reference is Zucker & Prendergast (2020, p.1), which reported:

*‘Sex differences in pharmacokinetics [PK] strongly predict sex-specific ADRs [adverse drug reactions] for women but not men. This sex difference was not explained by sex differences in body weight. The absence of sex-stratified PK information in public records for hundreds of drugs raises the concern that sex differences in PK values are widespread and of clinical significance. The common practice of prescribing equal drug doses to women and men neglects sex differences in pharmacokinetics and dimorphisms in body weight, risks overmedication of women, and contributes to female-biased adverse drug reactions.’*

Rather than encouraging researchers to focus only on self-reported sex or legal sex, the NHMRC/MRFF Statement should explain why collection of accurate data on biological sex is important.

The idea that sex can be changed, and the resultant mis-recording of sex in health records, has compromised the integrity of Australia’s health data sets, including those of the Australian Institute for Health and Welfare (AIHW). For example, the 2021-22 AIHW Hospital Procedure Data Set records 67 adults as having undergone penis amputations: 15 females, 14 people whose sex was not reported (a designation noted by AIHW as sometimes being used for gend, and 38 males. It is reasonable to assume that all these people were biologically male. It is clear that, for some patients, the data that was provided to AIHW as representing their sex, instead reflected their gender identity or a self-belief that they had changed their sex via hormonal and/or surgical transition treatments. AIHW states on their website that even when their data is described as being in relation to sex it may not be. The AIHW website states that, *‘Most AIHW reports present results by whether people are male or female as this is what is recorded in the data collections. In many of these instances, male or female may refer to either sex or gender, depending on the data source. Most current data sources do not record sex and gender as separate concepts so it can be unclear which is the focus’* (Australian Institute for health and Welfare, n.d.).

Individuals are also likely being encouraged in the idea that they can change their sex through Services Australia processes which allow individuals to change their ‘gender’ in Medicare records on provision of *‘a statement from a Registered Medical Practitioner or Registered Psychologist verifying your gender’* (Services Australia, 2023).Given the importance of sex to health care provision, most people would assume that the use of ‘gender’ here is being used as a synoym for sex.

In the example of penis amputation, the mis-recording of sex can be identified because of the sex-specific nature of this procedure. However, such errors would be occurring, largely invisibly, across the whole of Australia’s health data sets. Such mis-recording of sex in health and other data sets has great potential to impede the ability of researchers to contribute to knowledge generation and health and social service provision. Indeed, amongst us are researchers who have also identified anomalies in research data sets where it appears that the sex of some individuals has been mis-recorded. This problem is likely to continue and worsen if action is not taken to ensure accurate collection of data on sex in the health system and in research.

The mis-recording of sex is a particular problem for any health or social condition where there is a large sex difference and a small number of one sex affected relative to the other. An example of a social situation where mis-recording of sex warps findings is regarding childhood sexual abuse. The vast majority of perpetrators of childhood sexual abuse are male, with female perpetrators being unusual (Gerke et al., 2020). This makes accurate recording of female offenders particularly important. In 2021, in the United Kingdom, it was reported that there had been an 84% increase in the number of women recorded as sexually abusing children (Fair Play for Women, 2021). However, it was not possible to determine if there truly had been an increase in female perpetrators because, amongst other reasons, police and court data collection had shifted from recording the biological sex of perpetrators to, in some instances, recording their gender identity or self-reported or legal sex (Fair Play for Women, 2021). It is entirely possible that there had been no increase in female perpetration of child sexual abuse but that the increase was simply a result of a mis-recording of a small percentage of male perpetrators as female. Mixed sex groupings in analysis of violent crime have made their way into peer-reviewed publications (e.g. McMillan et al., 2021) with, in at least one case, criticism of such grouping being suppressed (Phoenix, 2021). This cannot be of benefit to society.

The ABS definition is also problematic because it explicitly encourages the idea that an individual’s sex can change, stating, ‘*a person's reported sex can change over the course of their lifetime and may differ from their sex recorded at birth’* (p. 4). This statement is repeated in the draft NHMRC/MRFF Statement. The ABS Standard also states that*, ‘caution should also be exercised when comparing counts for sex recorded at birth and the sex of a person at the time of completing a survey, as a person's reported sex may change over the course of their lifetime’* (p. 5).

It is indeed possible for people in Australia to change their legal sex and, as already discussed, some people believe that their sex has actually changed, because of their new gender identity and/or medical treatments. Consequently, they may report their sex incorrectly even if they have not changed their legal sex.

We draw attention to the Sex and Gender Policies in Health and Medical Research Project, which is funded from a philanthropic source and is a collaboration of the Australian Human Rights Institute at the University of New South Wales and the George Institute for Global Health. Although this Project is framed as being about improving health and medical research and is reportedly going to be formally launched next year by the Assistant Minister for Health and Aging, it does not recognise sex as a biological variable. Rather, as described in the Project glossary, ‘*Sex for humans is a legal status, classified as either male or female in most jurisdictions, and which is typically presumed or observed at birth based on external sex characteristics. While typically based [on] these sex characteristics, a person’s sex can change over the course of their lifetime and may differ from their sex recorded at birth’* (Sex and Gender Policies in Health and Medical Research, 2021).

**There is need for the NHMRC/MRFF to take leadership and ensure that data on sex as a biological variable continues to be considered in research and is not replaced by legal sex, self-reported sex, or gender identity.**

The NHMRC/MRFF should recognise that collecting data on legal sex or self-reported sex instead of sex as a biological variable constitutes a loss of data on biological sex. This works against both closing the female data gap and data collection necessary for the ensuring the health and wellbeing of transgender and gender diverse people. The NHMRC/MRFF should not include a definition of sex in their Statement that suggests in any way that it is possible for sex as a biological variable to be changed. We cannot conceive of circumstances in health or medical research where it would be beneficial to ask someone for their legal sex or self-reported sex instead of their biological sex. We would argue that so called legal sex or self-reported sex where it is different from biological sex is simply another measure of gender identity. Thus, collecting data on sex as recorded at birth alongside current gender identity will gather the necessary information and will not result in a loss of data on sex.

The ABS Standard definition also suggests that the sex of infants is identified based on the sex characteristics listed (chromosomes, hormones, reproductive organs). This is misleading. Medical investigation to identify an infant’s chromosomal makeup does not occur unless an abnormality is suspected; similarly, hormones are not measured unless there is a medical indication to do so. Rather, the sex of infants is overwhelmingly easily identified based upon the appearance of their genitals. The exception is for infants with variations of sexual development, for whom further investigation may be required.

The NHMRC and MRFF, as healthcare organisations, must adopt a definition of sex that is based on biology, rather than legal considerations or gender identity. The definition should be fact-based and hence incontestable, as opposed to incorporating ideological positions that are not universally accepted. The NHMRC/MRFF Statement should make it clear that in terms of healthcare for the individual, a person’s biological sex, as identified before or at birth, sets up a specific developmental framework that remains over the person’s lifetime regardless of any medical interventions that may take place.

We suggest that the NHMRC/MRFF develop their own guidance on data collection on sex, and use a simple definition of sex that is applicable to humans and animals, such as, *‘Sex is biological trait that exists in all anisogamous sexually reproducing organisms. Identification of sex is principally based on the anatomy of reproductive organs which have evolved for the production of male or female gametes.’*

If desired, it can be noted that, although biological sex cannot be changed, legal sex can be changed, but where sex is relevant in health and medical research, data on biological sex should be collected.

The ABS Standard provides two questions for asking people what their sex is: 'Sex recorded at birth' and 'Sex'.

The first question format is:

*What was [your/Person's name/their] sex recorded at birth?*

*Please [tick/mark/select] one box.*

*☐ Male*

*☐ Female*

*☐ Another term (please specify)*

We support the use of this question in this format in health and medical research, and we believe that this question format provides the most accurate data on sex as a biological variable as sex recorded at birth is, but for rare exceptions, the same as biological sex.

As the ABS Standard notes, requesting an individual’s sex as recorded at birth assists in ensuring accurate answering, *‘As the terms sex and gender are often used interchangeably, a respondent might provide a gender response to a sex question. The sex recorded at birth question may reduce the number of gender responses to a sex question.*’ *(page 5)*

Notably, the ABS Standard emphasises the importance of sex recorded at birth stating:

*‘Sex recorded at birth refers to what was initially determined by sex characteristics observed at birth or infancy. This is an important indicator for statistical analysis in births and deaths, health statistics, calculating fertility rates and deriving counts for cis and trans populations.’ (Glossary)*

*‘Sex recorded at birth refers to what was determined by sex characteristics observed at birth or infancy. This is an important indicator for statistical analysis in births and deaths, health statistics, calculating fertility rates and deriving counts for cis and trans populations. A collection may instead ask for a person's sex at the time of completing a survey, rather than their sex recorded at birth. However, there are advantages of sex recorded at birth as the sex question and further data that can be derived when using sex recorded at birth as the sex question, as outlined below in Discussion on conceptual issues.’ (Sex section)*

The second question format on sex provided in the ABS Standard is:

*What is [your/Person's name/their] sex?*

*Please [tick/mark/select] one box.*

*☐ Male*

*☐ Female*

*☐ Another term (please specify)*

We do not support the use of this question in health and medical research because the quality of data collected will likely be lower than where participants are asked for their sex as recorded at birth. The ABS Standard makes it clear that this question is not intended to collect data on biological sex but ‘reported sex’; that is legal sex or self-reported sex. It notes that *‘a person's reported sex may change over the course of their lifetime’* and ‘*Trans people asked "what is your sex" would likely answer this question according to their gender identity.’* This measure therefore is not suitable for research where data on sex as a biological variable is needed. Using this question in preference to asking about sex as recorded at birth would likely disproportionately disadvantage transgender and gender diverse people through reducing the quality of data collected for this group.

However, we also propose that if research is being undertaken specifically considering the needs and experiences of transgender and gender diverse people that the following question be considered for use:

*What was [your/Person's name/their] sex as assigned at birth?*

*Please [tick/mark/select] one box.*

*☐ Male*

*☐ Female*

*☐ Another term (please specify)*

We propose this option because the phrase ‘sex as assigned at birth’ is supported and understood within the trans community and so such usage may increase data quality. However, this phrasing should not be generally used it may undermine the confidence in the research because it is not scientifically accurate to say that sex is assigned at birth.

Gender identity

The ABS Standard provides a definition of gender as follows:

*‘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 themself 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.*

The ABS definition disaggregates gender identity into the concepts of gender identity, gender expression, and gender experience. Although, as previously discussed, the concept of gender identity is contentious, with no single or settled definition, the conceptualisations provided in the ABS Standard are not uncommon.

The question format provided in the ABS Standard can only reasonably be interpreted as being in regard to gender identity:

*How [do/does] [you/Person's name/they] describe [your/their] gender?*

*Gender refers to current gender, which may be different to sex recorded at birth and may be different to what is indicated on legal documents.*

*Please [tick/mark/select] one box:*

*☐ Man or male*

*☐ Woman or female*

*☐ Non-binary*

*☐ [I/They] use a different term (please specify)*

*☐ Prefer not to answer*

This question uses the term ‘gender’ rather than ‘gender identity.’ We argue that the term ‘gender identity’ should be used in collection of data on this variable. The term ‘gender’ has long been and is still often used as a synonym for sex. The ABS Standard recognises this, saying *‘the terms sex and gender are sometimes used interchangeably.’* We suggest that using the term ‘gender identity’ (with a definition) would reduce the possibility that individuals will answer a question about gender identity with the sex, and would thereby improve data quality.

The question proposed by the ABS Standard also suggests that a third party can be asked about someone’s gender identity as it allows for the insertion of a person’s name. This interpretation is supported by text elsewhere in the ABS Standard, which states that, ‘*gender may be reported in terms of… how that person is perceived by others, depending on whether information on gender is based on self-reported data or done by proxy.’* As previously noted, it is understood that gender identity is internal to the individual. Although someone’s appearance may be visible to others, the meaning of that appearance as a gender expression cannot be determined by others. Therefore, we do not believe that data on gender identity should be collected from anyone other than the individual involved.

We also do not support the use of the terms ‘male; and ‘female’ in this question. As previously noted, there is confusion around the difference between sex and gender identity, amongst both researchers and members of the public, and applying ‘male’ and ‘female’ to gender identities assists in this confusion. Use of male and female to refer to gender identities may encourage people to answer a gender identity question with their sex, and likely also facilitates the mis-recording of sex in health records. As previously described, this presents a risk to the health of individuals and to the integrity of Australia’s health and social data sets. We argue that ‘male’ and ‘female’, the scientific terms describing the sexes of not only people but all anisogamous sexually reproducing organisms, should be reserved solely for use in a sexed meaning, for clarity and to ensure research and data quality. The ABS Standard uses ‘male’ and ‘female’ in a number of other places to describe gender identities. We are of the view that the NHMRC/MRFF should advocate generally for the terms male and female not to be used in any context in relation to gender identity because of the confusion this creates and the resultant negative impact on data quality.

The ABS Standard question for collection of data on gender identity is also inadequate because it lacks an answer option for those who do not apply the concept of gender identity to themselves. As previously described, gender identity is internal to the person and cannot be imposed by others. Thus, any question on gender identity should also include an option for people to indicate that they do not have a gender identity. This answer option could be:

*☐ I do not have a gender identity/ not applicable*

We suggest that research needs to be undertaken on how to collect accurate data on gender identity. It seems plausible that some people when asked about their gender identity think that they are being asked about their sex for a second time. If this is occurring, this data is not accurate and likely the number of people with gender identities is being over-reported.

The NHMRC/MRFF should also consider how best to collect data on change in gender identities over time, including for people who have at some time had a transgender identification but who have desisted or detransitioned. This appears to be a growing group about which very little is known but for whom there are likely current and future health needs and concerns that should be researched.

Variation of sex characteristics

The ABS Standard provides a definition of variations of sex characteristics as follows:

*‘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.’*

We support the use of this definition.

The ABS Standard notes that where collection of data on people with variations of sex characteristics is desired, this should be through a question separate from a question about sex. The question format for variations of sex characteristics provided in the ABS Standard is:

*Were you born with a variation of sex characteristics (sometimes called 'intersex' or 'DSD')?*

*Please [tick/mark/select] one box:*

*☐ Yes*

*☐ No*

*☐ Don’t know*

*☐ Prefer not to answer*

We support this question format for collecting data on variations of sex development (including asking separately from the sex question) in order to maximise the quality of data on this variable.

Sexual orientation

The ABS Standard provides this definition of 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).*

As already noted in this response, we recognise these components of sexual orientation, and we believe that it is necessary that researchers consider these components separately and collect accurate data on each where appropriate. We agree with this definition and disaggregation.

The ABS Standard also notes that, *‘An individual could respond differently to questions on either sexual identity, attraction or behaviour’.* However,it provides only one question format:

*How do you describe your sexual orientation?*

*Please [tick/mark/select] one box:*

*☐ Straight (heterosexual)*

*☐ Gay or lesbian*

*☐ Bisexual*

*☐ I use a different term (please specify)*

*☐ Don't know*

*☐ Prefer not to answer*

This question will only collect accurate data on sexual identity.

In addition, the classification and code structure provided for this question in the ABS Standard is not accurate for people who consider their sexual identity to be in relation to gender identity rather than sex.

Thus, although the ABS Standard question for sexual orientation can facilitate accurate information on sexual identity, neither sexual attraction nor sexual behaviour can be accurately inferred from answers to this question. We suggest that sexual orientation may be best measured in surveys or oral questions through inference, where data on biological sex is collected and where a question asking the person whether they are sexually attracted to males or females or both males and females is included.

*Are you sexually attracted to?*

*Please [tick/mark/select] one box.*

*☐ Males*

*☐ Females*

*☐ Males and females*

We do not suggest how questions on sexual behaviour might be collected, but instead we refer the NHMRC/MRFF to the paper by Mooney-Somers et al. (2023) for consideration of the complexities of data collection on sexual behaviour. As previously described, given the importance of sexual behaviour for research and healthcare provision, it is imperative that references to sexual orientation be disaggregated in the NHMRC/MRFF Statement, with guidance provided to researchers on data collection on sexual behaviour.

*Other comments on the better practice section*

In addition to these question prompts in the NHMRC/MRFF Statement, we recommend additional prompts related to ensuring quality data collection. We have observed that data collection on sex and gender identity, in particular, is commonly confused. Data on sex and gender identity is often sought in a single question, in which it is often unclear what variable is being considered. A question might ask, ‘What sex/gender best describes you?,’ with the answer options of ‘male,’ ‘female,’ ‘transgender,’ and ‘gender non-conforming.’ A question might be asked about gender or gender identity but with the scientific terms for the sexes of ‘male’ and ‘female’ provided as responses, making it unclear what information is wanted. A question on gender identity might be asked when sex is the most relevant variable.

As an example, the current Australian Government National Bowel Cancer Screening Program participant details form has the question, ‘What gender do you identify as?’ with the answers of ‘male’, ‘female’ and ‘other’ (Australian Government, n.d.). The Australian Department of Health has confirmed that this question is intended to collect data on the gender identity of participants. There is no question asking participants to state their sex. We argue that it is likely that most people would consider that this question is asking them for information on their sex, not only because of the answer options of ‘male’ and ‘female’, but also because it is difficult to understand why data on sex would not be relevant to a physical health condition like bowel cancer but gender identity would be. The loss of data on sex in the National Bowel Cancer Screening Program is concerning; but also the way that the question on gender identity is written guarantees that it is not collecting accurate data on this variable either.

As another example, we draw the attention of the NHMRC/MRFF to a question on sex which was a part of the ABS Standard from June 2021 until September 2023 (Australian Bureau of Statistics, 2021, 2022b). This question was used in the 2021 Australian Census and was:

*Is the person?*

*☐ Male*

*☐ Female*

*☐ Non-binary sex*

The option of indicating a ‘non-binary sex’ could be made singularly or in addition to male or female. Unsurprisingly, data on the non-binary sex response has been determined by the ABS not to provide useful information (Australian Bureau of Statistics, 2022a). But how it came to be asked in the first place is a serious matter that calls into question the process of developing the ABS Standard. This should be of concern to the NHMRC/MRFF and should give pause to the idea of recommending the ABS Standard wholesale to health and medical researchers.

Related to this issue, we draw the attention of the NHMRC/MRFF to the need to consider and weigh the views of stakeholders appropriately, keeping in mind the need to protect data integrity. It is unfortunately the case that there are instances where this weighing has not occurred and data quality has been seriously compromised. For example, the 2021 England and Wales decennial Census included a question on sex and a two-part question on gender identity. The question on gender identity was worded in line with guidance from and in consultation with transgender advocacy organisations, and it seems was not broadly tested for understandability or reliability (Biggs, 2023). The questions were, ‘*Is the gender you identify with the same as your sex registered at birth?’* If people answered ‘no’, they were then provided with an option to say what their gender identity was. This question was seemingly misunderstood by many people. When answers to the gender identity question were cross-checked with data on migration and English proficiency, it was seen that geographic areas with the highest percentage of people who were apparently transgender were those with high numbers of immigrants not proficient in English (Biggs, 2023). As Professor Michael Biggs from Oxford University describes, *‘Only 10% of all adults do not speak English as their main language, but they contributed 29% of the total number of transgender adults according to the Census’* (Biggs, 2023 p. 10). It seems that a once in a decade opportunity to collect accurate data on transgender people in the UK was missed as a result of this poorly constructed question. The question was what key stakeholders wanted but it is the transgender community who have been most disadvantaged by the poor formulation of the question. From an ethical standpoint, every question asked in a study or as a part of healthcare provision should produce data that is accurate and meaningful and usable. However, as seen with both the English and Australian Censuses, even national statistical authorities have struggled to construct questions on sex and gender identity that meet these basic ethical criteria.

Specifically, regarding sex, some transgender organisations and individuals may argue against the relevance of sex as a biological variable and argue against data collection on this variable. We point as an example to an editorial in the *British Medical Journal* in which authors recommend that, *‘questions about sex assigned at birth are abandoned’* (Alpert et al., 2021). Such views are not universally held by transgender people, as can be seen in a response to this editorial from the Gender Dysphoria Alliance, which stated that it was very important for transgender people to have their sex accurately recorded in their health records (Kimberly et al., 2021). Nonetheless, it is likely that, in some cases, transgender and gender diverse stakeholders may suggest that data on sex not be collected and this may compromise the quality of research and knowledge acquisition. This detriment applies to everyone, including transgender people. For example, a Canadian study on ‘pregnancy involvement’ and the mental and sexual health of transgender young people did not report data disaggregated by sex even though getting someone pregnant is very different from getting pregnant, severely limiting the usefulness of the research (Veale et al., 2016). It would not be surprising if lack of data collection on sex in this study was a result of stakeholder consultation.

Australian researchers would benefit from support, including in the form of question prompts in the NHMRC/MRFF Statement, on negotiating a balance between what stakeholders want and ensuring inclusion of relevant variables and data quality on sex, gender identity, sexual identity, sexual attraction and sexual behaviour.

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

Researchers need evidence-based guidance on how to collect data on sex, gender identity, variations of sex characteristics, sexual identity, sexual attraction and sexual behaviour, including detailed information on areas of complexity and sensitivity. Ethics committees require clear guidance in this respect. As explained above, the ABS Standard, including the definitions therein, is not appropriate in its entirety for use by health and medical researchers. The NHMRC/MRFF Statement should not advise researchers to use it. Instead, the NHMRC/MRFF should develop its own standard tailored specifically for health and medical researchers, drawing on and acknowledging the ABS Standard where appropriate.

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

It is very important that the NHMRC/MRFF Statement is conceptually sound and evidence-based and fit for purpose, because it will have a powerful influence on health and medical research in Australia, especially research funded by the Australian government.

The definitions provided in the draft NHMRC/MRFF Statement are from the ABS Standard. These should be edited to ensure accuracy, as previously described.

The NHMRC/MRFF Statement should refer throughout to ‘gender identity’ rather than ‘gender’ for reasons of clarity, as previously explained in relation to the ABS Standard.

The NHMRC/MRFF Statement should clearly recognise and acknowledge that not all people apply the concept of gender identity to themselves and others (and, for example, the population cannot simply be divided into ‘cis’ and ‘trans’).

The draft NHMRC/MRFF Statement suggests that there may be circumstances where asking for a person’s self-reported/legal sex may be more relevant than asking for their sex as a biological variable saying, *‘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’* (page 8). We accept that there may be research where it may be useful to collect data on both biological sex and self-reported or legal sex. However, we have not been able to identify health or medical research where it would be beneficial to collect data only on self-reported or legal sex, and not biological sex. If there is indeed such research, we recommend that the NHMRC/MRFF Statement describe the circumstances under which this would be the case.

The NHMRC/MRFF Statement should also recognise the importance of gender, meaning the social and cultural expectations of the sexes (Griffin et al., 2021). Because it is a social construct, gender varies from society to society, and can change over time (World Health Organization, n.d.), but it nonetheless powerfully impacts the health and wellbeing of individuals and populations. Gender in this meaning is linked to aspects of the female data gap (Criado-Perez, 2019), and for this reason should be considered in research. Thus, when gender as a social construct may be having an impact, data on sex must be collected in order to make this visible. To not do so, will in most circumstances, disproportionately adversely impact women and children.

The NHMRC/MRFF Statement should include guidance for researchers on when data on sex should be collected. We argue that this includes circumstances in which physiological factors that are different or gender (meaning social expectations of the sexes) may be relevant. This includes any circumstances where women’s reproductive capacity (ability to become pregnant) or reproductive work (pregnancy, birth, breastfeeding or care of infants) may be relevant, including workplace discrimination and career advancement. We draw the attention of the NHMRC/MRFF to the recent award of the Nobel Prize to Professor Claudia Goldin for her work which identified that women’s career disadvantage and the gender pay gap is predominantly a motherhood penalty (The Nobel Prize, 2023).

We would like to raise a particular concern regarding data collection in relation to sex and gender identity. Some universities have published guides for researchers discouraging collection of data on sex or suggesting that information on the sex of study participants be limited to medical research (e.g. Nicholas, 2021). We are also concerned that the quality and applicability of our research will decline if we are required by ethics committees to omit data collection on sex from our research, including social research. Progress on research into female-specific health issues is a recent change to the historical approach of extrapolate research on men to women or to not disaggregate by sex (Criado-Perez, 2019).

It is concerning to us that, in its own data collection, the NHMRC has effectively replaced data collection on sex with data collection on gender identity. The NHMRC Sapphire Profile previously asked researchers to simply state whether they were ‘male’ or ‘female.’ The field was labelled ‘gender’ but, because of the male/female response options offered, was understood (at least by us and we presume by many others) as being used as a synonym for sex (National Health and Medical Research Council, 2022). In 2023, the question was changed so that it explicitly asked researchers to state a gender identity, with the answer options reflecting this change (man, woman, and non-binary added) (National Health and Medical Research Council, 2022). Researchers’ profiles have been automatically mapped across to the new fields, without the researchers being given an opportunity to state that they do not have a gender identity or that such mapping would not accurately reflect their gender identity. This goes against the principle that gender identity is self-determined and should not be assumed. It also goes against the aim of 'improving consideration of sex' in point 2 of the Purpose of the NHMRC/MRFF Statement (page 4).

We urge the NHMRC/MRFF to explicitly and clearly collect data on both sex and gender identity for the organisation’s equality monitoring. Doing so would not only be in line with efforts to reduce the female data gap, but would also yield useful information on the intersection between sex and gender identity. For example, it is well established that the research careers of women are adversely impacted by motherhood (K.D. Gribble et al., 2023; Lutter & Schröder, 2020). Although some of this adverse impact may be a result of gendered expectations (i.e. sex stereotypes and sexism) (Toffoletti & Starr, 2016), the sexed biological processes of pregnancy, birth and breastfeeding are also factors (K.D. Gribble et al., 2023). Thus, it can be speculated that those with a non-binary gender identity who are female and give birth might have a research career path that is different in key ways from those who are male and will not become pregnant. However, this can only be confirmed if data on both sex and gender identity are accurately collected.

We appreciate that the desire to prioritise gender identity over sex in language and data collection comes from good intentions to support and include people who experience gender dysphoria and/or who identify as transgender. We support these intentions. However, we believe that many of the actions that are being taken, ostensibly to assist this group of people, but inappropriately prioritising their gender identity over their sex and confusing or reducing data collection, are also to their detriment. As discussed, this includes research regarding both their individual health and their health needs and experiences as a group. Evidence-based principles for health communication, indicating that targeted communications for those with needs that diverge from those of the broader population, should be applied (e.g. Carroll et al., 2023). Good intentions are not enough.

## References

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