Australian Government
Department of Health, Disability and Ageing
National Health and Medical Research Council

Frequently asked questions on the consideration of sex, gender, variations of sex characteristics and sexual orientation (the Variables) in health and medical research

Rationale

Why must applicants for NHMRC and MRFF funding consider and integrate, where relevant, the Variables in their proposed research?

Sex, gender, variations of sex characteristics and sexual orientation (the Variables) can influence a person's experience of health and illness. This includes the medical conditions they develop, symptoms they experience, treatments and quality of care they receive, disease progression and outcomes, their responses to treatments and their engagement with, and experience of, the health system.

Historically (and continuing in many cases) limited consideration of the Variables has led to many population groups being underrepresented in health and medical research, leading to gaps in the evidence base that informs our health care system. In addition, consideration of the Variables is fundamental to high quality research that is rigorous, transparent, and widely applicable. Considering the Variables at all stages of every research project will help to address research gaps and produce equitable, accurate and high-quality evidence that can improve health outcomes for all people in Australia.

For more information, refer to the *Statement on Sex, Gender, Variations of Sex Characteristics and Sexual Orientation in Health and Medical Research*.

Who will benefit from integrating the Variables in research?

Appropriate consideration and integration of the relevant Variables in health and medical research will benefit all people in Australia. This includes those who have

historically (and continuing in many cases) been underrepresented in research, e.g. cisgender women and sex- and gender-diverse people. It also includes men where their experience of health and disease differ and may have been understudied. In addition, integrating the Variables also provides researchers with opportunities for new discoveries and innovation.

Why are you prioritising sex, gender, variations of sex characteristics and sexual orientation over other diversity characteristics?

The need to understand how other diversity characteristics affect health outcomes, and how they intersect with the Variables is recognised. Researchers are encouraged to consider the relevance of other intersectional factors in their projects, where relevant. Additional data collection could be needed to understand factors such as age, cultural and linguistic diversity, socio-economic status, abilities, and geography, and how these factors intersect with the Variables in relation to your research question. The requirement to consider the Variables is an important step towards more inclusive, rigorous and representative research that will encourage researchers to begin thinking about diversity and inclusion more broadly and build capacity to conduct meaningful intersectional analysis.

What about trans, non-binary people, people with innate variations of sex characteristics and people with diverse sexual orientations?

Trans and non-binary people, people with innate variations of sex characteristics and people with diverse sexual orientations in research have been historically underrepresented or excluded from research, resulting in gaps in the evidence base on medical conditions and appropriate treatments for these population groups. Increased effective, safe and sensitive inclusion of trans and non-binary people, people with innate variations of sex characteristics and people with diverse sexual orientations in research is encouraged. Researchers are also encouraged to consider their inclusion criteria to ensure that trans and non-binary people, people with innate variations of sex characteristics and people with diverse sexual orientations are not intentionally or unintentionally excluded on the basis of their gender identity, sex characteristics and sexual orientation.

Application

How do I know which Variables I should integrate in my research?

Researchers must consider the Variables at all stages of every research project. When one of the Variables is relevant to a research question, it is expected that researchers

integrate it in the proposed research, where appropriate. Consideration of the Variables is important throughout the research pipeline. Integration of the Variables into basic science research can improve rigour and reproducibility, as well as providing opportunity for new discoveries and innovation. In clinical, public health and health services research, accounting for the Variables can improve the applicability of research findings, support health equity and ensure that health care can be tailored to meet the needs of all populations.

For some research projects, there may be no need to address all or any of the Variables. For example, sex may be the only Variable relevant to basic science research involving cells and animals. While for clinical, public health and health services research involving human participants, all Variables are potentially relevant for integration in the research. Researchers should examine the existing literature to determine what is known about the Variables in relation to their research question and where there might be gaps to address. The *Statement on Sex, Gender, Variations of Sex Characteristics and Sexual Orientation in Health and Medical Research* includes prompts for different types of research, including basic science, to consider the Variables by research life-cycle stage.

What if none of the Variables are relevant to my proposed research?

Assessors will be looking for evidence that applicants have carefully considered and integrated, where relevant, the Variables as part of the proposed research. If you deem that none of the Variables are relevant/appropriate to integrate into your proposed research, you must provide a scientifically sound and evidence-based justification in your application. Assessors will consider whether this justification is scientifically sound and evidence-based when scoring the application against the relevant assessment criteria for the grant opportunity.

When, and in which grant opportunities, is the new requirement being introduced?

The requirement to account for the Variables in applications is being introduced in relevant NHMRC and MRFF grant opportunities that open for applications from **1 January 2026**. The requirement is **not being applied retrospectively to any grant opportunities that opened for applications in 2025,** even if the deadline for application submission and/or peer review occurs in 2026. The new requirement will apply to most NHMRC and MRFF grant opportunities. To determine if the new requirement applies in a particular grant opportunity, refer to the grant opportunity guidelines on GrantConnect.

What do I need to include in my application about the Variables?

Refer to the 'Implementation of sex, gender, variations of sex characteristics and sexual orientation in the grant program resource' for more information. Applicants should also refer to the relevant grant opportunity guidelines available on GrantConnect.

What information on the Variables do I provide in the application form question compared to the grant proposal?

In the free text response to the question on the Variables in the application form, applicants must address all the Variables. For any Variables that are not being integrated in the proposed research, applicants must provide a justification for this. For any Variables that are being integrated, applicants must summarise how they are being integrated in the proposed research.

In the grant proposal, applicants must detail how the relevant Variables, if any, are being integrated in the proposed research. Applicants should provide sufficient information for reviewers to assess the appropriateness of how the relevant Variables are being integrated in the proposed research.

What support is there for researchers to improve consideration of the Variables in their research?

There are resources available to support researchers to consider and appropriately integrate the Variables, where relevant, in their research. The *Statement on Sex, Gender, Variations of Sex Characteristics and Sexual Orientation in Health and Medical Research* provides key definitions and better practice prompts throughout the research cycle. The 'Implementation of sex, gender, variations of sex characteristics and sexual orientation additional resources document' provides links to a range of resources on integrating the Variables in health and medical research. NHMRC and the Department of Health, Disability and Ageing held a webinar on this topic in late 2025. See the related webinar page for more information.

How do I respond to the question if I am studying a condition that solely or predominantly occurs in one sex?

If your research is focused on a condition that solely or predominantly occurs in one sex, sex will inherently be a factor that you will be considering throughout all the stages of your proposed research. As a result, it would be expected that you will respond 'Yes' to whether sex is being integrated in the proposed research. If you are proposing a single-sex study, you will need to describe and explain the rationale for this in the free text response. For studies involving human participants, you will still

need to consider if gender, variations of sex characteristics and sexual orientation are relevant and will be integrated into the proposed research.

Does my study need to be powered to detect differences by a Variable for me to say the Variable is integrated in my research?

Not always. It depends on the role of the Variable in your study. To say you have integrated one of the Variables in your research you need to have:

- reviewed the literature and prior data for that Variable in your area of study
- selected a justified target distribution of cells/subjects/participants by the Variable
- a plan to appropriately collect data on the Variable
- a plan to appropriately analyse and report data by the Variable.

If the Variable is not central to your main hypothesis (exploratory), your study does not need to be powered to detect differences related to that Variable to meet the above criteria for integration. You still need to use an appropriate analysis approach that incorporates the Variable, rather than only 'controlling' for it. For example, where appropriate, you could test for a statistical interaction in an ANOVA or regression. If the study is not powered to detect differences related to the Variable, state this clearly as a limitation when reporting the results. If your study includes an *a priori* hypothesis about differences related to the Variable, it should be appropriately powered to test those differences.

Assessment

How will information on the Variables in applications be assessed?

Refer to the 'Implementation of sex, gender, variations of sex characteristic and sexual orientation in the grant program resource' for more information. Applicants should also refer to the relevant grant opportunity guidelines and peer review guidelines on GrantConnect.

What are valid justifications for not integrating one or more of the Variables?

Applicants must provide a scientifically sound and evidence-based justification(s) when not integrating one or more of the Variables in the proposed research. Valid justifications will vary depending on the research question and design of the project. Some justifications that may be considered for your research project include (but are not limited to):

- that the research is investigating the mechanisms of purely molecular interactions (for example, when investigating protein-protein interactions) or microorganisms
- that the research is using cells or tissues for which the sex cannot be ascertained (and other Variables do not apply)
- it is basic science research not involving human participants, (from the analysis of single cells to preclinical models) and thus gender, and most likely variations of sex characteristics and sexual orientation, are not relevant Variables
- that the research is using secondary data where access to data about the Variables has been predetermined by the limitations of the dataset (for example, when using databases or tissue banks which have not collected this data).

Other evidence-based justifications for not integrating one or more of the Variables may be relevant to your research and will be considered as part of the assessment process.

What are valid justifications for focusing on a specific population group for one or more of the Variables?

In some instances, there may be a scientifically sound and evidence-based justification for focusing on a single research population group for one or more of the Variables. This will be considered by assessors when scoring the application against the assessment criteria. There are some cases where research that focuses on a single population group may be appropriate, including:

- research on conditions or experiences/mechanisms that are specific to a single population group
- research aimed at redressing historic bias, and/or gaps in the evidence base for a particular population group
- research where the availability of only acutely small sample sizes mean that data are only available on a single population group (for example, participants with rare conditions or limited samples held in tissue banks).

Other evidence-based justifications for conducting research that is specific to a single population group will be considered as part of the assessment process.

In most cases, the following will not be sufficient justification for focusing on a single population group:

- prior work, including pilot studies, has only accounted for a single population group, with no evidence-based justification for doing so

- generic and unsubstantiated statement that a population group is inherently more variable, including hormone variability in female subjects/participants across the oestrous cycle or life course*
- pre-clinical researchers do not currently know the sex of the cells, tissues and/or animals used, but it is possible to find this out.

*There is a common misconception that female animals are difficult to study because of hormonal variations in the menstrual cycle. Meta-analysis research looking at experimental data from mice and rats found that both males and females display hormonal variability, and female variability does not affect study outcomes any more than in males.[1, 2, 3, 4]

Does the new requirement relate to how the Variables are represented within the research team?

While including individuals from diverse population groups based on the Variables within a research team is an important consideration, the new requirement only relates to the integration of the Variables within the proposed research. It is not relevant to discuss the composition of the research team in response to the question on the Variables in the application form.

However, it may be relevant to describe the diversity of the research team in other parts of the application to address other assessment criteria (refer to the relevant grant opportunity guidelines).

Methods

How do you define and distinguish between sex, gender, variations of sex characteristics and sexual orientation in research?

The consistent use of the definitions for the Variables in the Australian Bureau of Statistics' (ABS) Standard for Sex, Gender, Variations of Sex Characteristics and Sexual Orientation 2020 (ABS 2020 Standard) is encouraged. It is important to understand the distinctions between these variables, use the appropriate terminology and classifications, and avoid conflating terms. Broad use of the ABS 2020 Standard will support inclusive, consistent and comparable data collection and analysis across research projects. Terminology relating to the Variables is strongly contested, particularly terminology to describe gender identity and intersex variations. Researchers are encouraged to be cognisant of any community sensitivities and integrate them into their research as appropriate to maximise community participation and benefit.

How do I collect accurate and reproducible data on the Variables from human participants in a sensitive and ethical manner?

The approach to data collection/measuring the Variables should be selected in the context of the research study and population/s included and be justifiable in terms of being accurate, precise and inclusive. We encourage use of the ABS 2020 Standard and associated guidance on data collection and analysis by researchers in research projects. The ABS 2020 Standard is designed to collect demographic information on the Variables and its broad use will support inclusive, consistent and comparable data collection and analysis across research projects. However, there are other recommended approaches to measuring the Variables and there will be circumstances where the ABS 2020 Standard may not be suitable.

One example of this is when working with certain cultural groups, who may have different understandings of the Variables, or use different terms in their description. Researchers are encouraged to be cognisant of any community sensitivities and integrate them into their data collection as appropriate to maximise community participation and benefit.

There will be other occasions where the ABS 2020 Standard may not provide sufficient information on the Variables to answer the research question the project will address. Researchers are encouraged to collect demographic information, and to then use other best practice data collection methods to collect further information on factors that are relevant to their project.

This may include information such as:

- sex characteristics, such as chromosomes, hormone levels or anatomical features
- reproductive information, such as history of pregnancies or breastfeeding
- changes in gender identity over time or history of gender-affirming care
- societal gendered norms or expectations
- sexual behaviour, sexual identity or sexual attraction.

Whichever approach to data collection/measuring the Variables is selected, this should be described and justified within grant applications and any resulting research outputs/publications. Researchers must continue to adhere to existing legislation and guidance about research data collection, including the *Privacy Act 1988*, *National Statement on Ethical Conduct in Human Research* and *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities*. Further information on critically examining different approaches to data collection/measuring gender and sex in health research is available as part of the Canadian Institute of Health Research's Meet the Methods series.

What are some of the complexities of integrating the Variables in my research?

The Variables are complex and can influence health via different mechanisms. You may need to account for these specifics in your research. This could include information on:

- sex characteristics, such as chromosomes, hormone levels or anatomical features
- reproductive information, such as history of pregnancies or breastfeeding
- changes in gender identity over time or history of gender-affirming care
- societal gendered norms or expectations
- sexual behaviour, sexual identity or sexual attraction.

Do I have to include equal numbers of males and females (sex)/men and women (gender) in my research?

The appropriateness of the target distribution of cells, tissues, animals and/or human participants by the relevant Variables depends on the question(s) your research proposal seeks to answer. Although a balanced design to support the delivery of high-quality research is encouraged, a particular target distribution of subjects/participants on the basis of the relevant Variables is not expected. Researchers should consider and justify what a suitable distribution of research participants/subjects by the relevant Variables is to answer their research question(s).

In some studies, it may be more appropriate for the target distribution by the relevant Variables to be proportionally representative of the split in the general population, the population with the disease/condition of interest, or a target population within the disease/condition population. It also may be necessary to oversample certain populations for statistical purposes. It is recognised that in practice it is not always possible to recruit specific numbers of people from certain population groups. Nonetheless, researchers should describe the strategies they will use to proactively recruit and retain under-represented groups relevant to their research area and where appropriate, proportionally representative of the target population. These may include cis women and girls, trans and gender diverse people, people with innate variations of sex characteristics and people with diverse sexual orientations.

How do I appropriately incorporate the relevant Variables into my research analysis plan?

It is expected that the proposed research analysis plan will take the relevant Variables into account. Employing appropriate and rigorous analysis methods enables accurate and strongly supported conclusions to be reached about the Variables. One study

found that in a sample of papers published in 2019, 70% of claimed sex-specific effects were not supported by valid statistical approaches.[5]

Due to the large variety of research questions, experimental designs and data types in NHMRC and MRFF research proposals, it is not possible to be prescriptive about what constitutes an appropriate analysis plan in terms of integrating the relevant Variables. Whether the analysis plan adequately and appropriately integrates the relevant Variables will be considered by assessors. It is not an expectation that every study is sufficiently powered and has an analysis approach that enables detection of small differences based on the Variables. Applicants are encouraged to seek statistical support when developing their analysis plan to integrate the relevant Variables.

Will researchers need to increase the number of research subjects/participants when integrating the relevant Variables in their research?

Integrating the relevant Variables does not necessarily need to lead to an increase in sample sizes. The size of samples should be designed to answer the research question and should be tailored to the study type. The aim is that the findings will be more representative of the general population and large differences in population groups based on the relevant Variables can be observed. Even where findings are not statistically significant – either due to there being no true difference or an inadequate sample size to detect a difference – reporting of data and findings by the relevant Variables is essential for supporting subsequent meta-analyses, which may generate significant findings. Applicants are encouraged to seek statistical support when designing their research to integrate the Variables.

In terms of animal studies, including more than one population group by the relevant Variable does not necessarily require an increase in sample size to maintain statistical power. The general advice is to design your experiments as you normally would but then change half the animals to include the other sex. The number of animals used must be the minimum necessary to satisfy good statistical design, ensure the results are valid, robust and relevant, and achieve the proposed project aims(s). The use of too few animals may invalidate the results obtained from the study. Applicants are encouraged to seek statistical support when designing their research to integrate the Variables.

Will there be increased research costs associated with integrating the relevant Variables?

It is acknowledged that researchers may be concerned about increased study costs resulting from integrating the relevant Variables into their research. Researchers may

be able to integrate the relevant Variables appropriately without incurring additional costs. Where there are additional costs associated with appropriately integrating the relevant Variables, these can be justified by the benefits in terms of increased research quality and rigour. Where applicable, applicants are encouraged to include costs associated with appropriately integrating the Variables in their research, if the costs comply with the rules for eligible expenditure described in the grant opportunity guidelines.

References

[1] Prendergast, B.J., K.G. Onishi, and I. Zucker, Female mice liberated for inclusion in neuroscience and biomedical research. Neuroscience & Biobehavioral Reviews, 2014. 40: p. 1-5.

[2] Becker, J.B., B.J. Prendergast, and J.W. Liang, Female rats are not more variable than male rats: a meta-analysis of neuroscience studies. Biology of sex differences, 2016. 7(1): p. 1-7.

[3] Zajitschek, S.R., et al., Sexual dimorphism in trait variability and its eco-evolutionary and statistical implications. elife, 2020. 9: p. e63170.

[4] Kaluve, A.M., J.T. Le, and B.M. Graham, Female rodents are not more variable than male rodents: A meta-analysis of preclinical studies of fear and anxiety. Neuroscience & Biobehavioral Reviews, 2022: p. 104962.

[5] Yesenia Garcia-Sifuentes, Donna L Maney, Reporting and misreporting of sex differences in the biological sciences. ELife, 2021. 10:e70817.