

# **AAMRI Panel**

Final

Recommendations

# Introduction

The inspiration for this project is based on the fact that optimal health management must be based on knowledge, and with this new work we will be addressing the knowledge gap in the consideration of sex, sex characteristics, and sex and gender variables, in health and medical research.

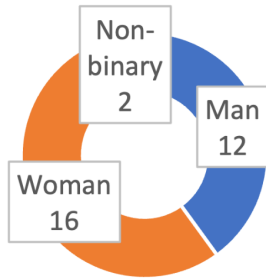
In recognition of this, in April 2023 AAMRI convened a Deliberative Panel of 30 individuals. The Panel was descriptively representative of AAMRI's member institute workforce:  
FIGURE 1 ON PANEL DEMOGRAPHICS

The Panel was tasked with creating a policy framework to enable AAMRI member institutes to comprehensively consider sex, sex characteristics, and sex and gender variables in health and medical research. Drawing on research conducted by the George Institute for Global Health and background information provided by AAMRI and UNSW Human Rights Institute, the Panel met over three days using a deliberative engagement process, in-person and online, facilitated by NewDemocracy and Gauge Consulting.

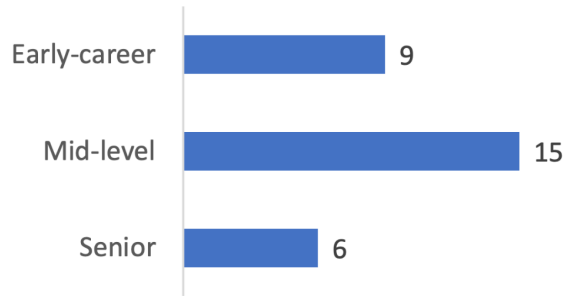
The Panel heard from a diverse range of experts and community stakeholders including those with lived and living experience, researchers, funding body representatives, MRI sector leadership and advocacy group representatives. Based on the Panel's deliberations, further insights were sought from additional stakeholders to better comprehend the full extent of the complexity of the project.

At the conclusion of the three days, the Panel found agreement on a policy framework encompassing four policy statements and recommended actions. The Panel endorsed that knowledge and consideration of the importance of sex, sex characteristics, and sex and gender variables in health and medical research is a prerequisite for conducting quality research, achieving meaningful results and translating meaningful outcomes. The endorsed framework provides the foundation for AAMRI to collaboratively implement these recommendations in partnership with the sector and broader community, recognising that this will be an evolving collaborative effort.

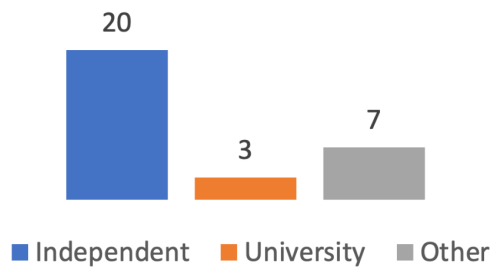
### Gender



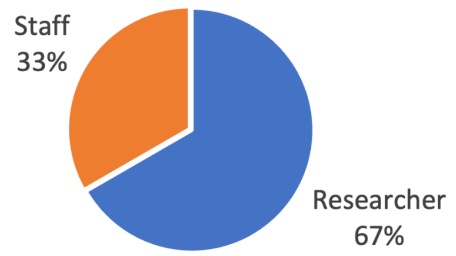
### Seniority



### Institute



### Role



## Recommendation 1

### Policy Statement:

AAMRI will advocate to MRIs and all sector stakeholders for visibility and awareness of the critical need for consideration of sex, sex characteristics, sex and gender variables in health and medical research (HMR). This is integral to quality and ethical research.

### Supporting Actions:

1. AAMRI will convene a representative (e.g AAMRI members, researchers, community bodies and those with lived experiences and funding bodies) working group to engage with the HMR sector in the development of a policy statement to embed the consideration of sex, sex characteristics and sex and gender variables in HMR (encompassing preclinical and clinical research - human, animal or models derived from either) as a critical part of research design including project development, experimental practice and trial and other study designs.
2. AAMRI will advocate to the NHMRC for the ongoing considerations of sex, sex characteristics and sex and gender variables in The Australian Code for the Responsible Conduct of Research and the National Statement on Ethical Conduct in Human Research (and any other pertinent documents from other peak bodies) and any associated training, resources and education.
3. AAMRI will advocate for the immediate expansion of funding to support projects and analyses that incorporate sex, sex characteristics, sex and gender variables, with the long-term expectation that this is included from the start of research development.
4. AAMRI will advocate to the HMR sector to include considerations of sex, sex characteristics and sex and gender variables as a mandatory part of research integrity training, adapting existing materials where appropriate.
5. AAMRI will advocate to Australian HMR Journals, Societies and funding bodies to ensure consideration of sex, sex characteristics and sex and gender variables is part of all standard assessment processes for manuscript review for publication, and for funding applications (including internal funding opportunities) and other research outputs.

## Recommendations 2 + 3

### Policy Statement:

AAMRI acknowledges that sex, sex characteristics and sex and gender variables are umbrella terms that have multiple unique and interrelated concepts that evolve in meaning and application; these applications vary across the breadth of health and medical research. We recognise that they are not static and that best practice would require ongoing participation by stakeholders and regular review.

AAMRI will commit to developing a robust mechanism to respond to ongoing change and complexity in the above by coordinating collaboration and co-design methods with relevant community leaders, those with lived experience, and research experts to revisit the definition/terminology/ontology and application of these terms in health and medical research on a regular basis.

### Supporting Actions:

1. AAMRI will facilitate a co-design process, bringing together community leaders, those with lived experience, peak bodies and research experts to agree to and disseminate updated terminology and application considerations. This group is to develop an accountability structure that establishes frequency of review.

- AAMRI to facilitate forming of an independent working group – receive advice from core community leaders and those with lived experience to develop terminology and inform best practice.
  - Invite participation from all interested parties for working groups (including institutes, researchers, community representatives, end-users)
  - Seek input from international and national experts (eg. CIHR, The George Institute partnership, community of practice researchers UNSW group) as well as funding bodies, as needed.

2. AAMRI to develop an Engagement and Advocacy Plan based on the outcomes of the Co-Design Process to link member organisations and the health and medical research sector with further information, case studies, and best practice guidelines to embed the use of sex, sex characteristics and sex and gender variables in research practice.

- AAMRI annual conference to include NHMRC/MRFF/ARC and other reps.
- Commit to making space for equity (eg. education talk, open forums/ GEDI award / research talks/case studies/working group outlines/project quality examples where its been carried out well)

3. AAMRI to encourage peer-to-peer learning to build capacity and collaboration related to the application of sex, sex characteristics and sex and gender variables in health and medical research.

- AAMRI to lobby for the regular review of ongoing policy cycle agreed upon so that

wording is reviewed and consultations/feedback is reignited at pre-planned intervals - determined by working groups.

4. AAMRI to endorse the outcomes of the process and encourage its uptake.

- Panel process and outcomes available and endorsed online by AAMRI
- Advocate for compliance by AAMRI institutes and local application of guidelines by ethics/peer review committees
- AAMRI to provide a list of appropriate third parties who can provide training and advice to all members of research institutes, not just researchers but also support staff.

## Recommendation 4

### Policy Statement:

AAMRI will advocate for appropriate inclusion of monitoring, benchmarking, and reporting mechanisms across its spheres of influence (such as members, universities, funding bodies, and journals) regarding sex, sex characteristics, and sex and gender variables in health and medical research applications, research conduct, and reporting of findings.

### Supporting Actions:

1. AAMRI should advocate to funding bodies, the NHMRC (in the context of national ethics and research integrity statements), and Australian journals to consider including sex, sex characteristics, and sex and gender variables as a requirement to ensure accountability for researchers when applying for, conducting, and reporting health and medical research.
2. AAMRI to encourage Australian health and medical journals to draw on international journals for examples of checklists (such as STROBE, SAGER, and ARRIVE) for including and reporting sex, sex characteristics, and sex and gender variables.
3. AAMRI should support MRIs and where relevant universities to establish capacity to monitor and evaluate how sex, sex characteristics, and sex and gender variables are monitored and reported in research conduct and outputs. This could include leveraging resources from members that already have this monitoring capability. AAMRI should encourage members that do have this capability to report this information in their annual reports. This could include reporting on the percentage of studies conducted that include sex, sex characteristics, and sex and gender variables.
4. AAMRI should evaluate which MRIs report on sex, sex characteristics, and sex and gender variables, communicate the outcomes, and facilitate a feedback process with MRIs. Based on the findings of AAMRI's evaluation, AAMRI should review and adjust how it can support MRIs to uptake reporting on inclusion of sex, sex characteristics, and sex and gender variables.
5. AAMRI can highlight best practice for monitoring, benchmarking, and reporting on sex, sex characteristics, and sex and gender variables in health and medical research. This could include highlighting and celebrating outstanding performing MRIs who do well at this in its general communications and at conferences.

## Recommendation 5

### Policy Statement:

There is currently a lack of knowledge of the application of sex, sex characteristics and sex and gender variables among researchers and the wider community, which acts as a barrier to high quality inclusive research. AAMRI will lead continued education efforts aimed at increasing knowledge and understanding of sex, sex characteristics and sex and gender variables in health and medical research to ensure sustained understanding of how and why to conduct high quality research.

### Supporting Actions:

- AAMRI will establish a working group to undertake a scoping exercise to understand what education materials exist among members and internationally and tailor them to use as appropriate
- AAMRI, through the working group, will curate a suite of existing educational resources, guiding tools, systems, and processes accessible from the AAMRI website, including:
  1. An online repository that houses resources which includes details of key contacts from the HMR and wider communities to provide advice on and education about sex, sex characteristics and sex and gender variables
  2. An education module for delivery to students and staff (e.g. during onboarding) at MRIs to educate about sex, sex characteristics and sex and gender variables (delivery modes may vary, however face-to-face is preferred)
  3. Resources targeted for the purpose of education and understanding within funding bodies, government, community groups, consumer advocates, and the media. These resources may also be available to the broader community.
- To disseminate the terminology resources on sex, sex characteristics and sex and gender variables developed through the co-design process articulated in Recommendation 2+3.
- AAMRI will partner with appropriate organisations and bodies (such as the George Institute, the CIHR or the NIH) to develop an accessible and useful suite of educational resources and programs, drawing on existing materials where appropriate.
  1. AAMRI will advocate to MRIs and build awareness in the broader HMR community, to make use of these resources at all levels including undergraduate and postgraduate students, ECRs through to senior researchers and leaders, to build researcher capacity and understanding around the consideration of sex, sex characteristics and sex and gender variables in research
  2. These education programs will include training on how inclusive or appropriate practices should be included in all stages of research (from



conceptualisation to translation), across different disciplines (clinical research, basic science, public health, health services, etc)

- The uptake and value of the online repository and educational resources will be periodically evaluated and updated, in consultation with the working group and other parties of interest as well as through feedback from end-users, to ensure ongoing relevance and utility.
- All AAMRI policy guidance around sex, sex characteristics and sex and gender variables will include an education piece
- AAMRI advocates that MRI stakeholders (e.g. funders, ethics, government) take action to increase knowledge and understanding around sex, sex characteristics and sex and gender variables in their sectors, including directing all queries to the AAMRI-auspiced online repository.