

Sex in Experimental Design

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Medical
Research
Council

Embedding Diversity in Research Design

Does research include all groups who have the potential to benefit from the findings?

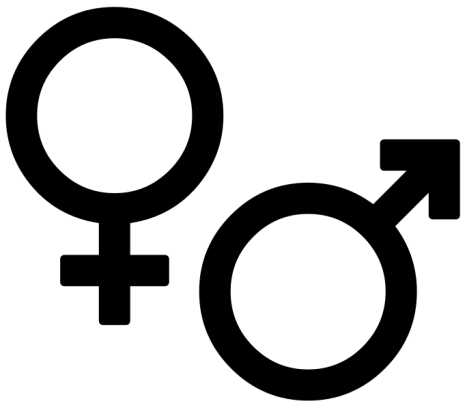
- Animal, cells and tissues, and human participant (population/data) research
- Including: sex/gender, ethnicity, age, socio-economic position (deprivation/equity), disability, + other

Defining Sex and Gender

Canadian
Institutes
of Health
Research:


Sex - a set of biological attributes in humans and animals that are associated with physical and physiological features including chromosomes, gene expression, hormone function and reproductive/sexual anatomy

Gender - the socially constructed roles, behaviours and identities of female, male and gender-diverse people



The SAGER Guidelines: Sex and Gender Matter

GENERAL PRINCIPLES



• Authors should use the terms sex and gender carefully in order to avoid confusing both terms.

• Where the subjects of research comprise organisms capable of differentiation by sex, the research should be designed and conducted in a way that can reveal sex-related differences in the results, even if these were not initially expected.

• Where subjects can also be differentiated by gender (shaped by social and cultural circumstances), the research should be conducted similarly at this additional level of distinction.

Policy and guidance development

Landscape review

- National and international health and biomedical research funders

Consultation

- Survey of MRC research community - animals, cells and tissues, human participant research – July 2021

Grants evaluation

- Review of all applications submitted May 2020

Working Group

- Animal research (& cells and tissues) – Sept 2021
- Human research - 27 May 2022

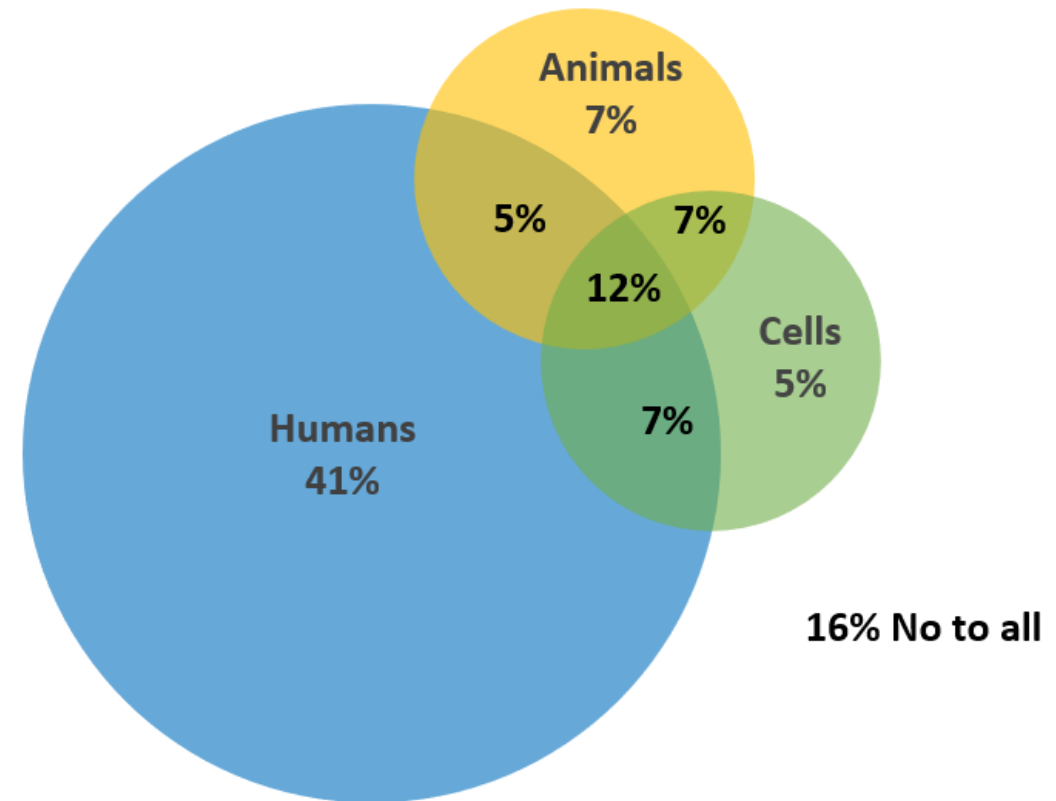
Implementation

- Policy launch for Inclusion of both sexes - March 2022

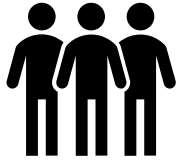
Survey: Diversity in research design and conduct

- Survey in July 2021 of MRC researchers, clinicians, wider research community
- Three sections – only responded to those relevant to their research
- ~800 respondents
- Animal section covered sex, age, reproductive status

Respondents by Research Area

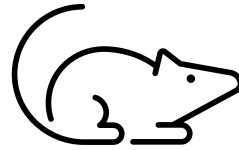


Top 3 benefits to considering diversity factors



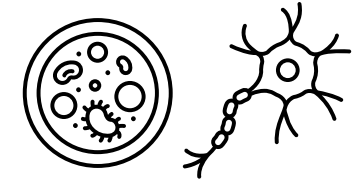
Humans

1. Relevance of findings (86%)
2. Avoiding bias (81%)
3. Reproducibility (41%)



Animals

1. Detecting sex specific results (66%)
2. Avoiding bias (63%)
3. Relevance to disease (54%)



Cells

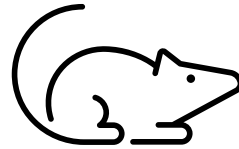
1. Translatability (61%)
2. Reproducibility (60%)
3. Novelty (51%)

Top 3 drawbacks to considering diversity



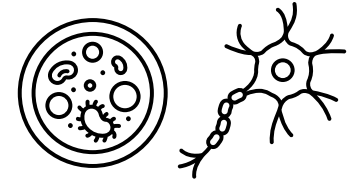
Humans

1. Difficulty of recruitment (56%)
2. Complexity of study design (87%)
3. Cost (42%)



Animals

1. Cost (63%)
2. Increase in animal use (3Rs principles) (52%)
3. Complexity of study design (49%)



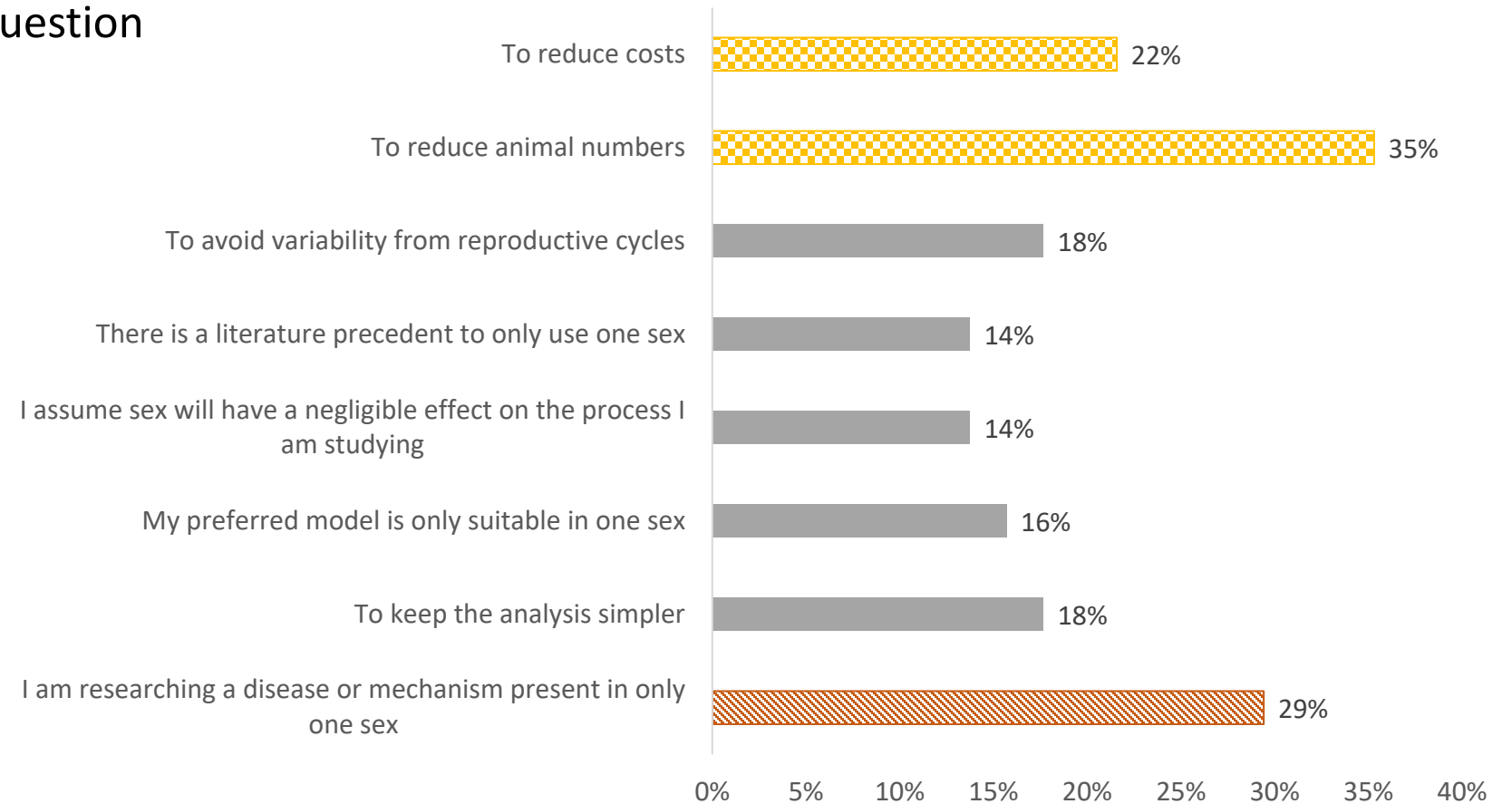
Cells

1. Complexity of study design (58%)
2. Sourcing appropriate materials (53%)
3. Cost (40%)

Consideration of sex in animal studies

- 33% reported only using one sex of animal. Asked a follow up question about why.

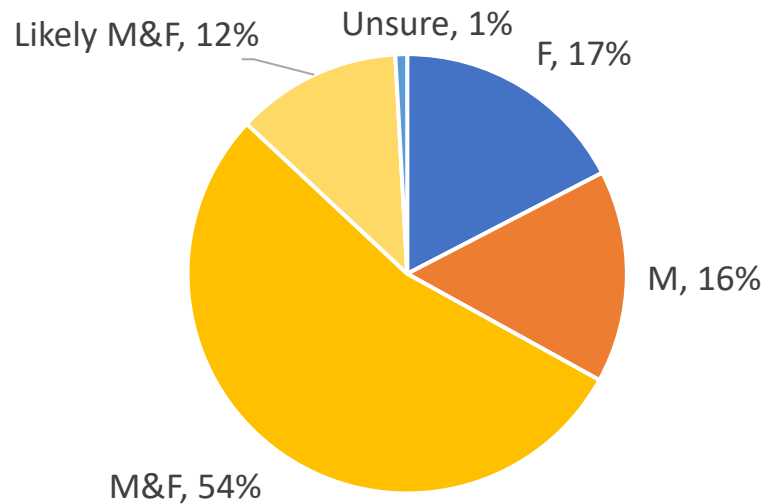
Justifications for only using one sex of animal



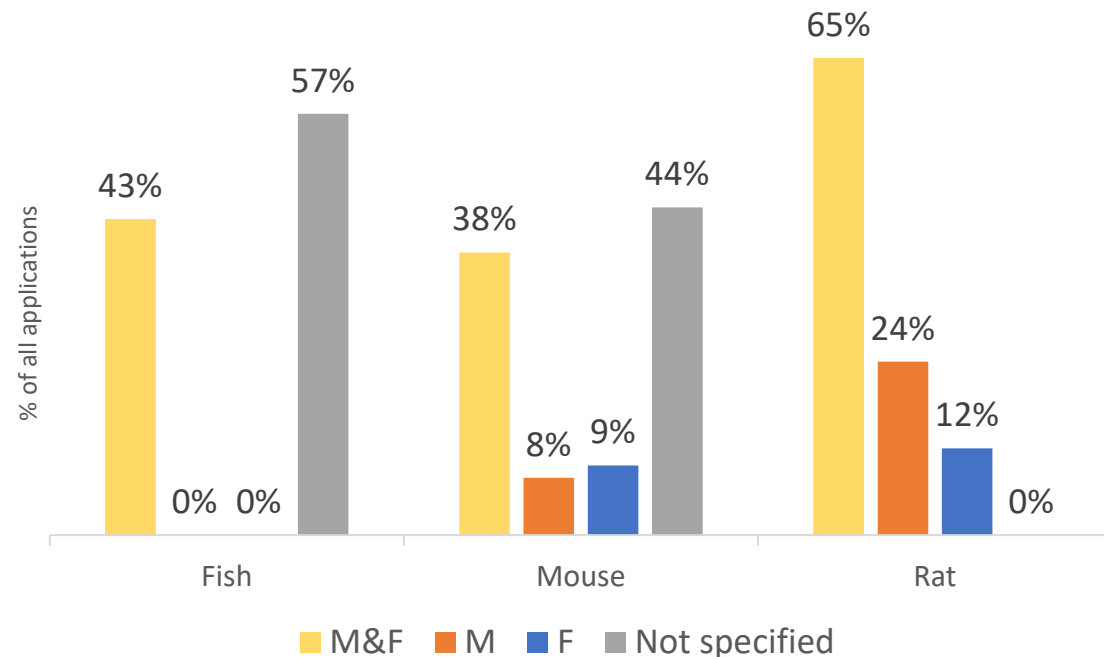
Analysis of grants involving animals

- Only 44% of applications include any information about sex (May 2020)
- 54% planned to use both male and female animals.
- Single sex users are roughly equal in use of male or female

Where sex is specified, what sex is used?



Sex of animal used by species of animal



Inclusion of sex in experimental design

1. Information on the sex of animals, tissues and cells (except immortalised cells) to be used is necessary as part of robust experimental design plans.
2. If sex is unknown, applicants should plan to determine it as part of their plans
3. MRC will expect applicants to use both sexes of animals, tissues, and cells by default
4. Applicants should clearly explain the justification for single sex studies, noting the results may be less applicable to the other sex
5. There are many valid justifications for not using both sexes

Justifications for single sex studies

Where applicants use only one sex:

- The applicant must demonstrate it falls into one of the predefined categories
 - Rare/exceptionally limited resources (e.g. tissue samples of rare diseases)
 - Single sex disease or mechanism (e.g. ovarian cancer)
 - Purely molecular interaction under study (e.g. protein-protein interactions)
- Or it must be otherwise justified as necessary
 - This might include logistical issues, welfare, model suitability
- Female variability and prior work performed in one sex are unlikely to be accepted as justification

Practical details

- Assessed at peer review and by funding boards and panels, as part of the assessment of the experimental design
- In the first year, applications will not be rejected before the applicant is given an opportunity to respond
- MRC will fund well designed applications, where the costs are appropriately justified
- Researchers should submit grant costings based on the cost of performing their experiments in both sexes, as appropriate.

[Home](#) > [Medical Research Council \(MRC\)](#) > [Guidance for applicants](#) > [Additional guidance for researchers](#) > **Sex in experimental design**

Sex in experimental design

The Medical Research Council (MRC) is committed to funding the best quality medical research, which is relevant to and benefits the whole of society.

Guidance on new requirements

From September 2022, MRC will require both sexes to be used in the experimental design of grant applications involving animals, and human and animal tissues and cells, unless there is a strong justification for not doing so.

We also expect applications to include information about the sex of the animals used in experiments, as well as the sex of studied tissues and cells. If you don't know the sex of the cells and tissues you use, you should plan to determine it as part of your research.



Related content

⇒ [Sex in experimental design: summary report](#)

Working Group on Sex in Experimental Design of Animal Research

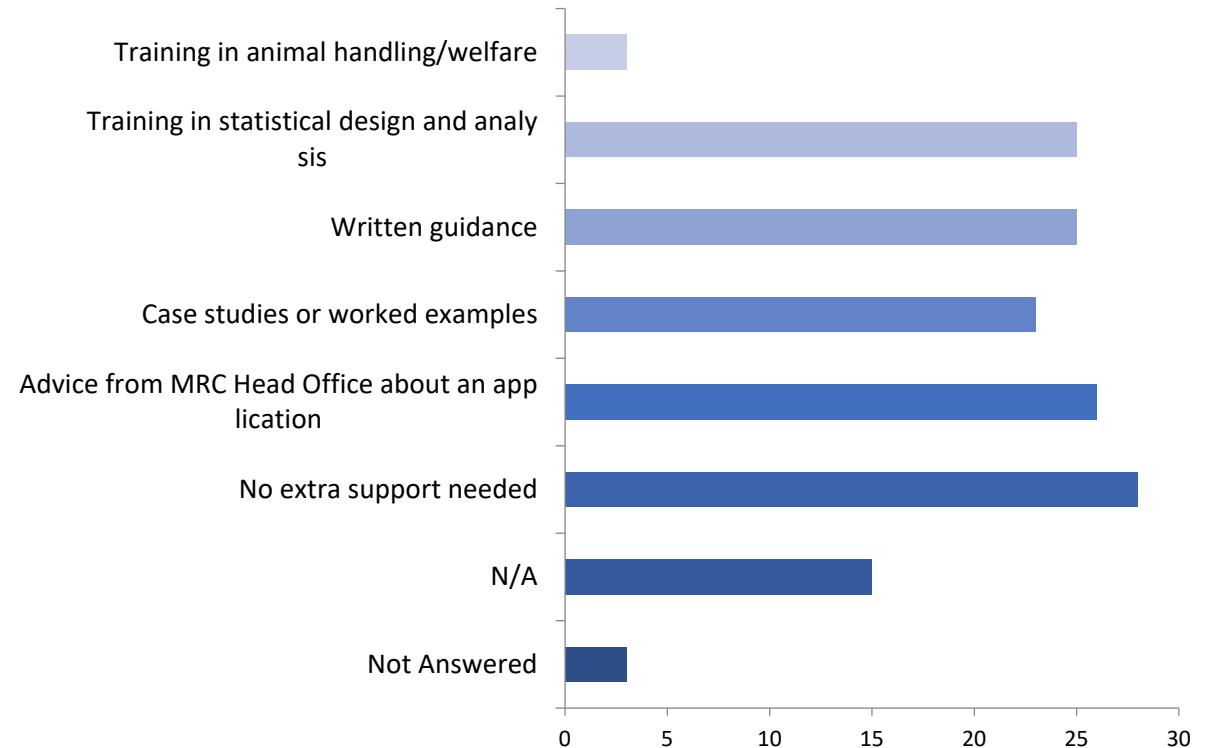
Meeting Report
6 September 2021



MRC's ongoing engagement

- Jan 2022 Engagement Hub survey after launch
- Around half of respondents (53%) said there were barriers to implementing this in their work
- A third (33%) say they already do this or are ready to begin

4: In order to start using both sexes in your research or research that you manage/support, what additional support from MRC would you need or find helpful, if any?



Further information

- Guidance on how to apply this to your research here:
www.ukri.org/councils/mrc/guidance-for-applicants/policies-and-guidance-for-researchers/sex-in-experimental-design/
- NC3Rs Experimental Design Assistant -
<https://eda.nc3rs.org.uk/experimental-design-animal-characteristics#sex>



MRC guidance on sex
in experimental design

For further info, contact:

Relevant MRC Programme Manager for the funding opportunity

Stella Child – stella.child@mrc.ukri.org or DiversityinResearch@mrc.ukri.org