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Accounting for Sex and Gender in Research

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Session aims

To understand:

- the background of NIHR's inclusive research design requirements
- the rationale for accounting for sex and gender as a condition of funding
- what the requirements are for accounting for sex and gender in research
- what we mean by sex and gender
- how to account for sex and/or gender across the research lifecycle
- where to seek further information and guidance



Background



NIHR: funding inclusive research



Stage 1: inclusive design - domestic programmes

For domestic funding opportunities that opened on or after 27th November 2024, inclusive research design is now a condition of funding.

This means that NIHR requires applicants to formally:

1. Describe their approach to inclusive design across the research lifecycle
2. Cost for these inclusive design components



Stage 2: sex and gender - domestic programmes



Stage 2 - launch 10th November 2025

Why sex and gender?





Why sex and gender?

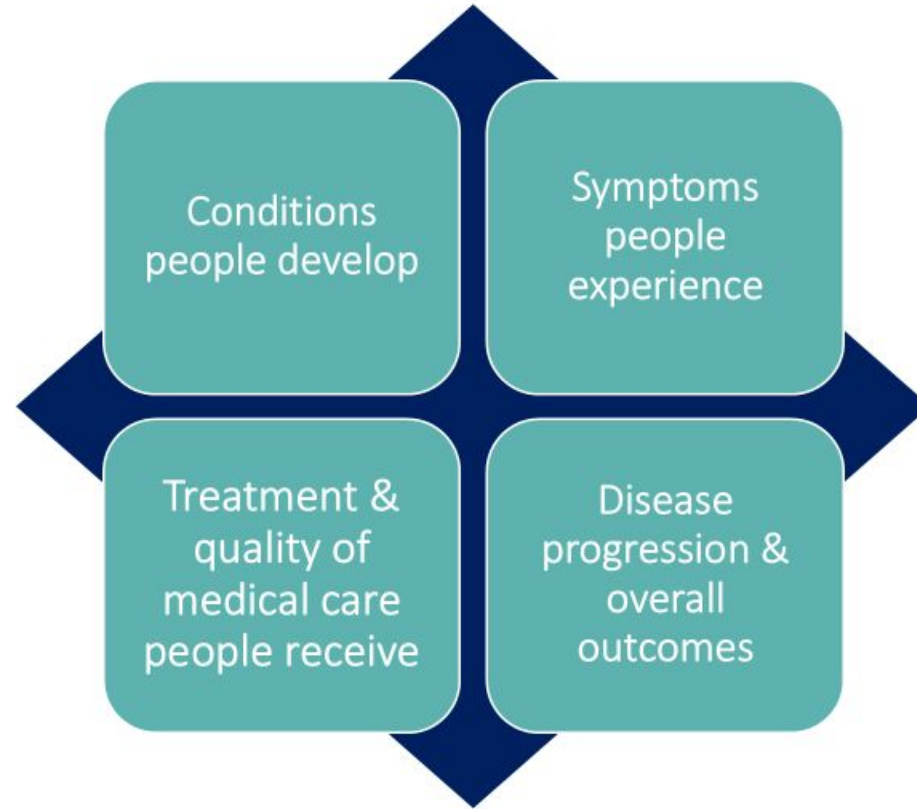
- NIHR's Research Inclusion Strategy 2022 - 2027 committed to developing an approach for sex and gender in research
- Reinforced our commitment through a Statement of Intent
- Supports the long term aims of the Women's Health Strategy for England
- Cross-sector initiative as part of the MESSAGE project

Why do researchers need to account for sex and gender?

Dr Kate Womersley - Co-Principal Investigator, Imperial College London

Alice Witt - Research & Policy Fellow, The George Institute for Global Health

Sex and gender influence health and disease



Preclinical Research



5.5 x
more males
than females

- **Convention**
- **Underappreciation** of how sex may affect outcomes
- Assumption that females are more **variable** than males e.g. oestrous cycle

Clinical Research



In Phase I trials, only
20% of participants
are women

- Men over-represented in trials
- Assumptions about **women's appetite for risk**
- **Pregnancy** and **breastfeeding** excluded by default

Sex and gender data gaps translate into worse health outcomes



When sex and gender-specific diagnostic criteria were used, the ratio of **men and boys : women and girls diagnosed with autism changed from 10:1 to 3:1** (Looms et al. 2017).

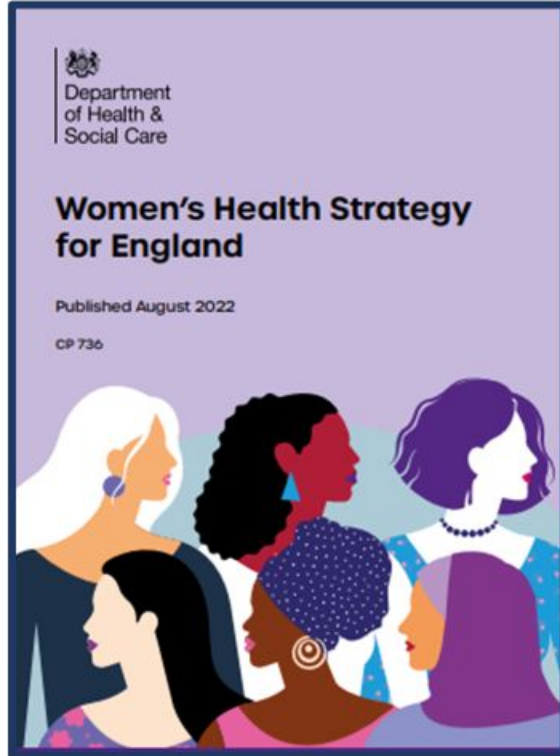


Data on effectiveness of beta blocker – heart attacks medication – were only recently sex-disaggregated. The study found that **women treated with beta blockers were nearly 3 times more likely to die** compared with women not given the drug (Butler et al., 2025).



Antipsychotics are dosed in a sex-neutral way. Female patients often receive **a higher dose than they need**, which is effective for the indication (e.g. psychosis) but exposes them to a **greater burden of side effects** than male patients. (Hoekstra et al., 2021).

UK policies and reports highlight gaps in the medical evidence base regarding sex and gender



Funder policies improve integration of sex and gender in research



Canadian Institutes for Health Research: [Sex and Gender in Health Research](#) (2010)



National Institutes of Health (United States): [Sex as a Biological Variable](#) (2016)



European Commission - Horizon Europe: [Integration of the gender dimension](#) (2016)

RESEARCH

Open Access

A 10-year longitudinal evaluation of science policy interventions to promote sex and gender in health research

Jenna Haverfield¹ and Cara Tannenbaum^{1,2*}



In 2021, no UK funder or regulator had a sex and gender policy in place

MESSAGE

Medical Science Sex and Gender Equity

Co-designing and implementing a policy framework for funders to ensure that biomedical, health and care researchers account for sex and gender at every stage of research design

MESSAGE has benefited from the input of experts across many sectors and disciplines



Professor Robyn Norton
Founding Director, The George Institute for Global Health



Dr Esther Mukuka
Head of Research Inclusion, NIHR



Dr Lilian Hunt
EDIS Lead, Wellcome Trust



Dr Catriona Manville
Head of Policy, AMRC



Dr Michael Brady
National Advisor for LGBT Health, NHS England



Professor Chloe Orkin
Professor of Infection and Inequities, QMUL



Professor Cara Tannenbaum
Former Scientific Director of the Institute of Gender and Health, CIHR



Professor Londa Schiebinger
Professor of History of Science, Stanford University



Dr Katharine Jenkins
Reader in Philosophy, University of Glasgow



Dr Natasha Karp
Director of Biostatistics, Astra Zeneca



Agnieszka Freda
Gender and diversity working group lead, Elsevier

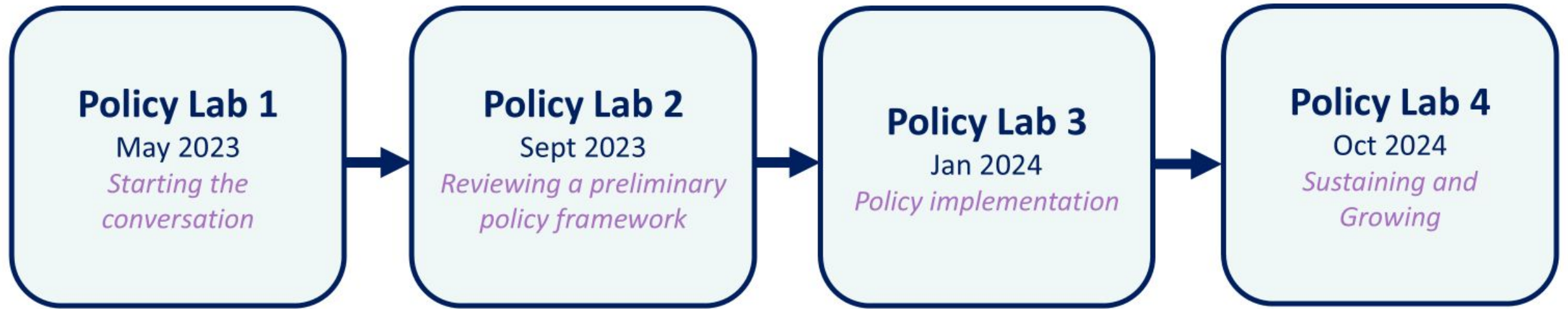


Professor Mark Woodward
Chair of Statistics, Epidemiology and Women's Health, Imperial College London

MESSAGE has taken a unique whole-sector approach



MESSAGE ran four Policy Labs over two years



You can find the policy framework and training resources on our website

<https://e-learning.messageproject.co.uk/>

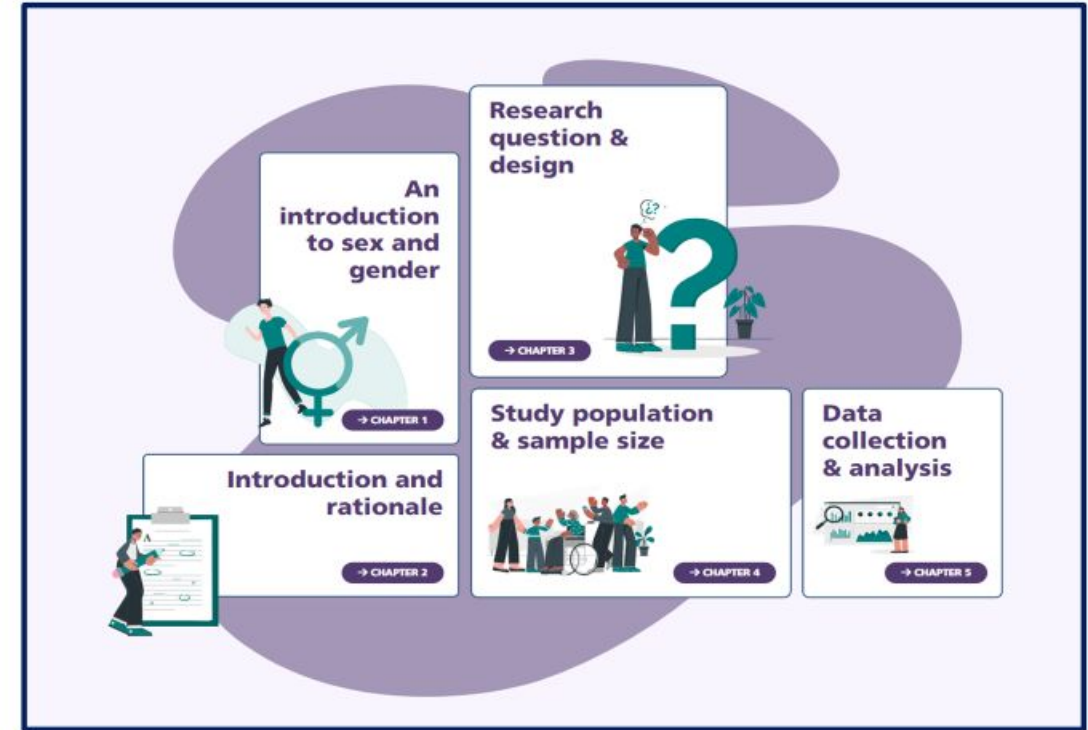
MESSAGE

Medical Science Sex and Gender Equity

**Accounting for sex and gender in
biomedical, health and care research**

A policy framework for research funders

April 2024



MESSAGE: MESSAGE@georgeinstitute.org.uk

Website: www.messageproject.co.uk

THANK YOU

Prof Robyn Norton

Prof Helena Legido-Quigley

Dr Marina Politis

Rachel Fowden-Hulme

Celestine Donovan-Bradley

Dr Carinna Hockham

Emma Feeny

Prof Mark Woodward

Dr Sanne Peters

Prof Jane Hirst

...and more (always)

What are NIHR's requirements?



Accounting for sex and gender as a condition of funding



NIHR's Sex and Gender in Research Policy sets out:

- our requirements for sex and gender in research
- how we use the terms 'sex' and 'gender'



Applies to **Domestic awards**, all programmes (from 10th Nov 2025): *rolled out with One NIHR system*

The following processes will be impacted and have been amended accordingly:



What does the policy include?

Policy contents:

- Purpose and scope
- Principles
- How to use the terms and concepts of sex and gender
- NIHR requirements for sex and gender in funding applications
- NIHR requirements for award monitoring
- Terminology

The policy recognises that ‘sex’ and ‘gender’:

- are separate and multi-faceted concepts
- used and understood differently in different contexts, societies, groups and languages

Policy available on NIHR’s website

www.nihr.ac.uk/about-us/who-we-are/policies-and-guidelines/sex-and-gender-research

What does the policy include?

The policy provides full details of:

- how researchers must use the terms 'sex' and 'gender'
- different sex and/or gender characteristics researchers need to consider
- requirements for disaggregating data

The application guidance provides more detailed information about how researchers should meet the policy requirements

The assessment criteria provides the core areas committees will assess applications on

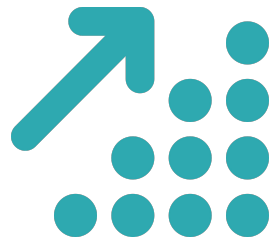
Policy available on NIHR's website

www.nihr.ac.uk/about-us/who-we-are/policies-and-guidelines/sex-and-gender-research

What does the policy apply to?

Within scope

- Applications for domestic research programmes
- Applications for personal career development awards with a research plan
- Publications reporting NIHR awards



Out of scope

- NIHR Research Infrastructure and/or Consortium funding calls
- Global Health Research programme
- Applications for personal career development awards without a research plan
- NIHR research that is funded prior to the policy launch date

Application guidance

- Sex and gender built into the current inclusive research funding application guidance
- Specific section on expectations which covers justifications for single-sex and/or single-gender research
- Specific requirements for collecting demographic data for sex, gender or both
- Specific requirements for including data for sex and gender characteristics

Brief guidance included
in the application at
outline and full
application stages



Full details of how to
meet the requirements
available via a
dedicated web page



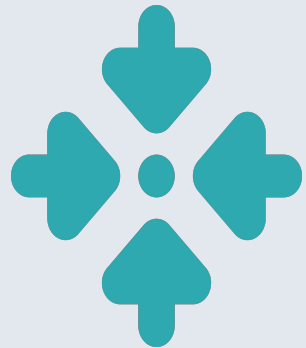
Further support
available via the NIHR
Research Support
Service (RSS)



Sex and gender assessment criteria

To meet the requirements for considering sex and gender in research, your application must present a clear, evidence-based rationale explaining how sex, gender or both have been accounted for across the research lifecycle.

This must include:



- appropriate evidence-based rationale for the sampling approach for sex, gender or both
- clear justification for any inclusion and exclusion criteria, including for single-sex studies
- appropriate plans to conduct disaggregated analysis by sex, gender or both as appropriate to the sampling strategy

Monitoring

To ensure compliance, researchers will report on both inclusive design and sex and gender elements during the progress reporting mechanism

The NIHR will:

- review the progress of research projects against their plan
- review any issues and their impact
- identify whether they need extra support
- take a continuous learning approach and respond accordingly



Sex and gender terminology



Sex



- Refers to biological attributes differentiating **females** and **males**. Sex can also include variations of what are considered female-typical and male-typical characteristics, sometimes known as ‘variations in sex characteristics’ (VSC) or ‘intersex’ (I)
- Such sex characteristics include: sex chromosomes, hormone profile, gene expression, secondary sex characteristics, internal and external reproductive organs
- Researchers funded by NIHR must always report on how studies have accounted for sex characteristic(s).
 - They must clearly state if sex was only determined using the ‘sex assigned at birth’ classification

Gender



- Gender refers to an aspect of a person's identity, including being a **man**, **woman** or **non-binary**; or being **cisgender** or **transgender**. A person experiences a range of social and cultural forces, which may influence their behaviours, their self-perception and how they are treated by others
- Gender is not binary, exists on a spectrum, can change over time, and intersects with other aspects of identity (e.g. age, ethnicity, disability, sexual orientation)
- If your research is particularly impacted by societal factors rather than purely biological ones, gender will be relevant to your research and should be considered

Accounting for sex and/or gender across the research lifecycle





1. Developing Question and Rationale

- When describing your research problem, identify any sex or gender inequalities, e.g., prevalence, outcomes or experiences.
- Consider the intersectionality of sex and/or gender with other demographic characteristics.
- If you propose to focus on just one sex or gender group, justify why this is appropriate.



2. Building a Research Team

- Consider whether your team would be strengthened by being more diverse.
- If planning to engage with under-served sex and/or gender groups, demonstrate your team's relevant skills and experience to achieve this.
- Team members may need training around cultural competence and unconscious bias.



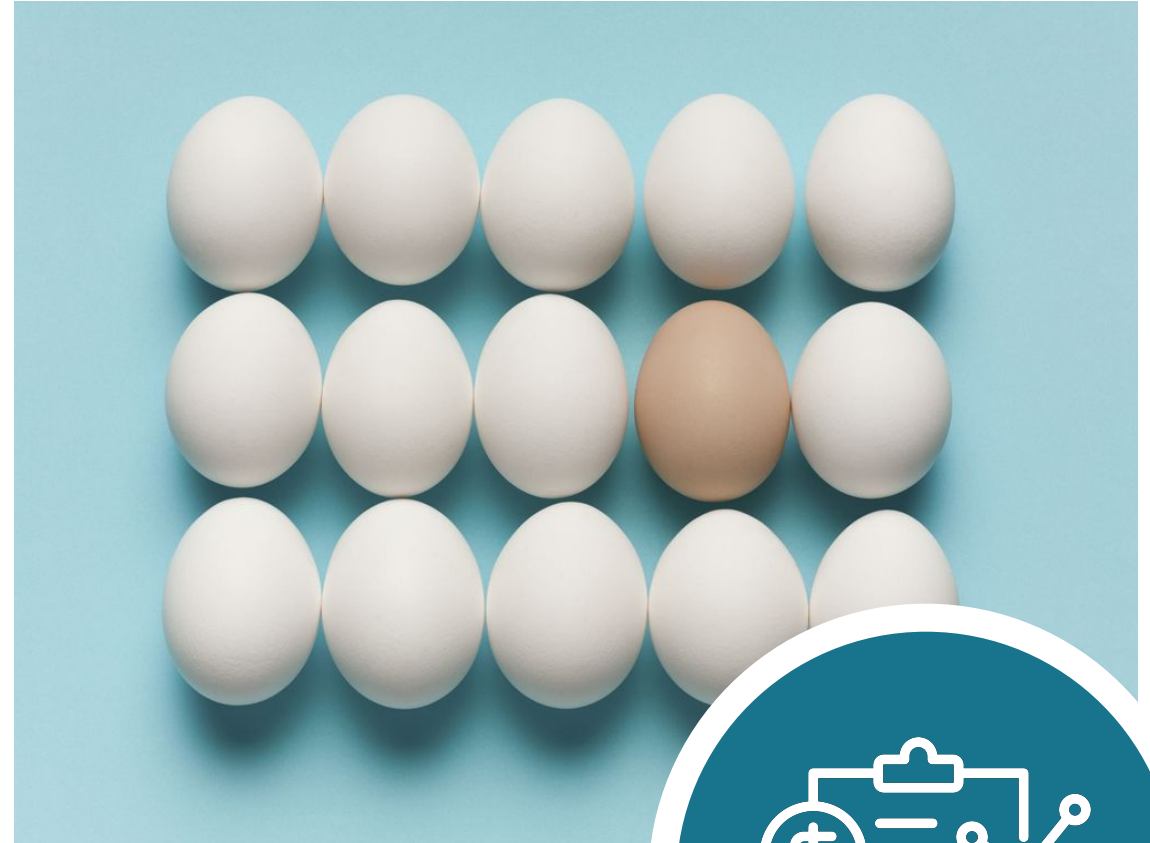
3. Involving People and Communities

- Adopt a multi-pronged recruitment approach for recruiting diverse public and community partners.
- Identify and address any barriers to involvement and engagement for under-served sex and gender groups.
- Be aware of any cultural or political sensitivities.
- Public contributors may need training on sex and gender terminology and inclusive research practices.



4. Sampling

- Provide an evidence-based justification for any sex- or gender-specific exclusion criteria.
- Decide whether your sample needs to be representative of sex and/or gender in the population of interest, or whether any over-sampling is needed.
- Explain whether you will collect demographic data about sex, gender or both, and how.



5. Data Collection

- Think clearly about how you will apply the terms 'sex' and 'gender' in your data collection
- Approach data demographic collection sensitively and pragmatically
- Consider the inclusivity of any interventions as well as research design
- Existing resources:
 - on characteristics and appropriate terminology (e.g. [MESSAGE e-learning](#))
 - inclusive and ethical research with trans people ([Adams et al., 2017](#); [Alpert et al., 2022](#))



6. Data Analysis and Presentation

- Avoid using 'sex' and 'gender' interchangeably
- Conduct pre-specified subgroup analyses where possible - NIHR does not require these to be statistically powered
- Disaggregate sex and gender data (Peters and Woodward, 2023); trial results across populations (De Paoli, et al., 2022); EDI reporting requirements (Treweek, et al., 2025)



7. Knowledge Mobilisation

- Include people from relevant and diverse sex and/or gender groups from the outset.
- Plan to take your research findings back to the communities who have been involved, and outline the next steps to them.
- Working with all stakeholders to disseminate findings and achieve planned impact (e.g. [Sands et al., 2023](#); see also [NIHR KM guidance](#)).



8. Budgeting for Inclusion

- Specify and justify costs for inclusive research, including to account for sex and/or gender
 - These costs should be included in the required budget line for research inclusion
- Ideas:
 - Training for understanding mistrust
 - Childcare or respite care costs
 - Time and expertise for analysis
 - Stakeholder costs for inputting into dissemination



Final points



How much detail do I put in my application?

- The policy is new so there will be a learning curve for all
- The policy provides clear detail on how to use the terms 'sex' and 'gender' along with the different sex and/or gender characteristics to consider
- We will fund research that accounts for characteristics specific to one sex or one gender, if strong, acceptable justification is provided. See application guidance for examples of acceptable justifications
- There will always be compromises e.g., costs, time, feasibility, etc., justification is key



We want to hear about your experience applying the requirements
please complete our [feedback form](https://forms.gle/PAELjgM713qDfwNp8)

Political, legal and media climates



Divisions in society / media narratives

- Policy focus is on underrepresentation in research
- Policy takes an inclusive approach and focuses on all sexes and gender, therefore not excluding any groups
- Understanding sex and gender differences increases accuracy, translatability and reproducibility of research
- Not accounting for sex and gender in research leads to untested assumptions
- Accounting for both sex and gender ultimately results in better science

UK Supreme Court *For Women Scotland* Judgement

- We have sought and will continue to seek legal advice as appropriate
- The policy does not directly engage with the court ruling

Where to access further resources and support



NIHR Research Inclusion application guidance for researchers:

<https://www.nihr.ac.uk/about-us/who-we-are/research-inclusion/funding-application-guidance>

NIHR Sex and Gender in Research policy:

<https://www.nihr.ac.uk/about-us/who-we-are/policies-and-guidelines/sex-and-gender-research>

NIHR Research Support Service (RSS): www.nihr.ac.uk/support-and-services/research-support-service
and NIHR RSS EDI Toolkit: www.rssleicesterresources.org.uk/edi-toolkit

NIHR Research Inclusion: www.nihr.ac.uk/about-us/who-we-are/research-inclusion

NIHR Learn: Research Inclusion space: <https://learn.nihr.ac.uk/>

MESSAGE website www.messageproject.co.uk and MESSAGE Sex and Gender E-Learning:
<https://e-learning.messageproject.co.uk>

References



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Thank you for watching

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