

# MESSAGE

Medical Science Sex and Gender Equity

# Policy Lab Briefing Pack

Co-designing a sex and gender policy framework  
for UK biomedical, health and care research

Wednesday 27th September 2023

M E S S A G E



The George Institute  
for Global Health

UK

**wellcome** trust

Imperial College  
London

# MESSAGE project

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MESSAGE (Medical Science Sex and Gender Equity) is a policy initiative to improve the **integration of sex and gender considerations in data collection, analysis and reporting in UK biomedical, health and care research.**

The aim of the project is:

**To co-design and implement a policy framework for funders which will ensure that biomedical, health and care researchers account for sex and gender in their funding applications and research projects.**

- By “**biomedical, health and care research**” we mean basic (cell & animal), clinical and population research.
- By “**sex and gender policies**” or “**policies that account for sex and gender**”, we mean policies focused on improving integration of sex and gender considerations in data collection, analysis and reporting of biomedical research.

# The Policy Lab series

We are supporting co-design of a policy framework with stakeholders over the course of four Policy Labs:

## Policy Lab 1

May 2023

*Starting the conversation*

## Policy Lab 2

September 2023

*Reviewing and refining a preliminary policy framework*

## Policy Lab 3

January 2024

*Planning for implementation*

## Policy Lab 4

May 2024

*Reflecting on implementation so far*

A policy lab is a collaborative workshop bringing together a range of stakeholders around a particular challenge to:



**Develop new ideas** and practical approaches to address a real-world problem



**Understand barriers and facilitators** for bringing about that change



**Improve outcomes** for users and patients

# What can you do to prepare?

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## Read and reflect on this briefing pack

- What are your immediate responses?
- What is missing? What is striking?
- Did you learn anything new?



## Speak to your colleagues to hear their thoughts

- What do they think about the policy framework? What barriers do they see?
- What ideas do they have about how you can make this a reality in your organisation?



## Think about what you would need for a sex and gender policy to be implemented in your organisation

- What and who would the process involve?
- Which expertise and sign-off would be needed?
- What hurdles do you foresee?



## Be prepared to share your thoughts on the day

# Policy Lab 2: Aims and Scope

# Policy Lab 2 builds on Policy Lab 1 discussions

**Policy Lab 1,** held on 23rd May 2023, asked the question:

**What is needed for UK policies to ensure biomedical researchers account for sex and gender to maximise the value of results and benefits for all patients?**

The session focused on the research sector's vision for sex and gender policies, what policies could achieve, and what would be needed to accompany them to bring about significant change. The group identified two principal priorities:

**Sex and gender policies should be designed and delivered through a whole system approach.**

**Technical capacity-building and culture change across the research sector is needed to support policy implementation.**

**Policy Lab 2** will focus on the **content of a sex and gender policy framework** to be delivered through a whole system approach. We will pay close attention to policy wording to produce a framework that can be adopted by diverse organisations across the sector in a unified approach.

**Policy Lab 3** will focus on policy **implementation**, including capacity building and culture change. This event will take place on **Wednesday 31st January** – save the date!

# The UK lags behind, but can learn from sex and gender (S&G) policy work elsewhere

**Internationally, funders have successfully implemented sex and gender policies** since 1993. Several have conducted evaluations that highlight the effectiveness of policies. **The UK must follow suit.** The first UK policies have been published in the last 10 months by the Medical Research Council ([2022](#) & [2023](#)) and Cancer Research UK ([2023](#)).

**The advantage of designing policies in 2023 is that the UK can use and improve upon what has been done before.**

- Elsewhere, funders have produced policies individually rather than in a **unified way** across the research sector. Co-designing a shared policy framework will **improve cohesion** in UK research and **ease the transition** for researchers, making requirements more likely to be followed.
- MESSAGE research showed that it can be **challenging to locate** international funders' sex and gender policies in one place and **understand the precise expectations** of researchers. A policy that is **simple, clear and accessible** is more likely to be effective.
- Evaluations** of sex and gender policy implementation are not as widespread as they could be ([Hunt et al., 2022](#)). **Consideration of evaluation from the start of the process** in the UK will increase the likelihood of success and iterative improvement.
- It is clear from other countries that a policy framework must be accompanied by **culture change**, including provision of additional funding and **training resources**.
- Among existing policies, there tends to be **more emphasis on the study of sex** than gender differences.
- There are limited well-known and up-to-date sex and gender **policies for regulators** in other countries. This is an opportunity for the UK to be a world leader in adopting new standards.

# Hunt et al. (2022) assess S&G policy designs worldwide

Since Policy Lab 1, the MESSAGE team has produced a **draft sex and gender policy framework**.

The framework is informed by international sex and gender policies' wording and content, as well as discussions from Policy Lab 1 with representatives from across the UK research sector and MESSAGE's consultation with experts in the field.

Hunt, Nielsen & Schiebinger's *A framework for sex, gender, and diversity analysis in research* ([2022](#)) analyses the strengths and weaknesses of existing sex and gender policies worldwide. It presents a **5-step framework** of the components required to **design, implement and evaluate** a sex and gender policy in funding organisations:

1. Definition of terms
2. Proposal guidelines for applicants
3. Instructions for evaluators
4. Training for applicants, evaluators and staff
5. Evaluation of policy implementation



MESSAGE used these 5 steps to **structure our thinking** when developing the MESSAGE policy framework and looking ahead to implementation. Policy Lab 2 will focus mainly on **steps 1 and 2**, relating to policy content and wording.

The 'Evidence and Examples' section of this briefing pack shows the details of other funders' policies in relation to these 5 steps.

# **Policy Lab 2 will focus on the draft policy framework**



The central question of the event will be:

Of the options presented in the draft MESSAGE policy framework, which should be chosen to improve how biomedical, health and care researchers account for sex and gender in the UK?



This question will be answered by representatives from across the research sector, including:

- Funding organisations  
*(Government and charitable)*
- Regulators
- Publishers
- Patient representatives
- Researchers

The MESSAGE team will incorporate your ideas to finalise the **sex and gender policy framework**.

The final framework will be shared with you **before Policy Lab 3**.

# Agenda

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Time	Session
09:30	Breakfast reception
10:00	Welcome and progress since Policy Lab 1
	Choosing the policy requirement
	Choosing definitions
	Choosing guidance for researchers*
13:00	Lunch
13:50	Looking ahead to implementation
15:45	Next steps and thanks
16:00	Close

\*Additional breaks will take place during the morning

# Who is joining us?

Lizzie Streeter – NHS England

Erin Shearman\* & Rachel Conner\* – Department of Health & Social Care

Lilian Hunt\* – Equality, Diversity and Inclusion in Science and Health (EDIS)

Anna Dé – Women's Brain Project

EJ Franks – Gendered Intelligence

Tash Oakes-Monger\* – Trans Learning Partnership

## Funders

Nicola Hopkins & Jo Lawton – NIHR

Cheryl Hewer – UKRI

Ivan Pavlov – MRC

Louise Campbell\* – Chief Scientist Office, Scotland

Janet Difflin\* – Health & Social Care, Northern Ireland

Catriona Manville & Simon Turpin – Association of Medical Research Charities

Suzanne Rix – Blood Cancer UK

Eleanor Garratt-Smith – Breast Cancer Now

Phoebe Kitscha – British Heart Foundation

Karolin Kroese – Cancer Research UK

Tom Shillito – Epilepsy Action

Beth Grimsey – MS Society

Lesley Alborough & Carleigh Krubiner & Teresa Cisneros\* – Wellcome Trust

## Regulators

Kathryn Ord – Medicines & Healthcare products Regulatory Agency (MHRA)

Naho Yamazaki – Health Research Authority (HRA)

Nick O'Callaghan-Staples – National Institute for Health and Care Excellence (NICE)

## Publishers

Agnieszka Freda – Elsevier

Emma Rourke – The BMJ

Heather van Epps – PLOS Medicine

Isabel Goldman\* – Cell Press

Lan-Lan Smith – The Lancet

## Patient representatives

Adeline Berry – PhD student in Human and Health Sciences (Older intersex people)

Kirstie English\* – PhD student in Sociology (Data collection on sex, gender and sexuality)

Rabiah Coon – MS Society

Sophie Strachan – SOPHIA Forum

Wendy Davis – Heart Voices

## Researchers & Clinicians

Alan White\* – Men's Health Forum

Alison Berner – Queen Mary University of London (Oncology and gender medicine)

Anna Louise Pouncey\* – Imperial College London (Vascular surgery)

Charlotte Healey – Imperial College London (PhD student in respiratory pharmacology)

Jessica Gong – University College London (Epidemiology and dementia)

Joanna Martin\* – University of Cardiff (ADHD in young women)

Kathryn Abel\* – University of Manchester (Psychological medicine and reproductive psychiatry)

Laura Castro-Aldrete\* – Women's Brain Project (Neuroscience and Alzheimer's)

Mark Woodward – The George Institute for Global Health (TGI) (Statistics, epidemiology and women's health)

Sean Saifa Wall – University of Huddersfield (PhD student in human and health sciences – intersex people and social policy)

Sally Hines\* – University of Sheffield (Sociology and gender studies)

Zowie Davy – De Montfort University (LGBTQ research)

## Project team

Ross Pow – Policy lab facilitator (The Policy Institute at King's College London)

Robyn Norton\* – Co-PI of MESSAGE (Imperial College London)

Kate Womersley – Co-PI of MESSAGE (Imperial College London)

Alice Witt – Research & Policy Fellow, MESSAGE (TGI)

Louise Cooper – Programme Manager, MESSAGE (TGI)

Marina Politis – Research Assistant, MESSAGE (Glasgow Medical School)

Anastasia Alden – Communications Manager (TGI)

Anna Willis – HR & Communications Coordinator (TGI)

Carinna Hockham – Research Associate (TGI)

Claudia Batz – Policy & Advocacy Advisor (TGI)

Emma Feeny – Global Director of Impact & Engagement (TGI)

Katherine Ripullone\* – Research Associate (TGI)

\* Participants joining online

# House rules

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Policy labs rely on all participants feeling comfortable to engage in open discussion, to share their honest perspectives, and to suggest ideas on issues which can be sensitive and prompt strong opinions.

## We expect all participants to follow our code of conduct:

1. This is an **inclusive space** where people of all sex and gender identities are welcome and valued.  
Please respect people's chosen pronouns and opinions.
2. To ensure we hear a range of opinions and ideas, we ask that after you have spoken you **allow at least three other people to speak before speaking again**, unless you are called on to respond.
3. Academic or practitioner **jargon avoided** where possible.
4. All discussions will follow Chatham House Rules, meaning that **anything said will not be linked back to individuals in any publications or reports** of the event. We ask that you adhere to the spirit of these rules in your actions during and after the day, including not live tweeting (or similar).
5. We will **record plenary sessions** for the purposes of creating an accurate record of the discussion.  
Only the research team will have access to this, and it will be destroyed after use according to data protection regulations.

# Contents

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- 1) MESSAGE draft policy framework**
- 2) Evidence and examples informing the draft policy framework**

**Step 1:** Definition of terms

**Step 2:** Proposal guidelines for applicants

**Step 3:** Instructions for evaluators

**Step 4:** Training for applicants, reviewers and evaluators

**Step 5:** Evaluation of policy implementation

- 3) Next steps**



# MESSAGE Draft Policy Framework

# The policy framework draft

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The full MESSAGE **draft policy framework** is in a Word document **attached to this briefing pack**.

The document presents **options for policy content and wording**. During the policy lab, we will ask you to consider which options will most **improve how researchers account for sex and gender**.

- Where options are marked as **Option 1** or **Option 2** (etc.), choose the one you think is **best**.
- Text marked **(Y/N)** requires you to decide whether a section/line should be **included or not**.
- Sentences **highlighted in yellow** contain wording that needs particular consideration. You will have opportunity to reflect on this during the day.
  - Sections which are not highlighted are still open to your suggestions and edits.

The draft contains **footnotes** to indicate how the wording for each section was developed.

**Read the policy in its entirety then consider the options presented on the following slides.**

# **1. Choosing the policy requirement**

## **– Wording and content**

# A shared policy title would improve cohesion across the sector

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0.1

***Title option 1:*** Inclusive design in UK research: sex and gender dimensions

***Title option 2:*** Accounting for sex and gender in UK research design

***Title option 3: Free text...***

**Option 1** emphasises **inclusion**, with sex and gender as one component of this. This would create scope for adoption of similar policies focused on other areas of inclusion (e.g. race and ethnicity).

**Option 2** is modelled on the title of the **MRC 2023 policy** ‘Embedding diversity in research design’, but with more specific focus on sex and gender.

**Can you think of better wording?** Write your ideas down and prepare to share them during the Lab.

# A policy could “encourage”, “expect”, “require” or “insist” researchers take these actions

CIHR and NIH use “expect”.

The MRC and CRUK use “require”.

Horizon Europe states that the gender dimension should be integrated “by default”, language which is also echoed in the MRC and CRUK policies.

The framework recently co-designed by the Association of Medical Research Institutes in Australia uses the language “insist”.

- 0.2 We encourage/expect/require/insist all research applicants to consider the biological and sociocultural attributes of sex and/or gender in their research. Sex and/or gender should be included in the design, methods and analyses, interpretation, and dissemination of findings of all research, when appropriate.
- 0.3 We encourage/expect/require/insist studies involving cells and tissues (animal or human), and animals to include female and male sexes in the design of experiments and conduct a sex-based analysis. Studies involving humans should include people of diverse sexes and/or genders and carry out a sex- and/or gender-based analysis by default.

This wording could change over time as policies might move from encouraging applicants to account for sex and gender dimensions to making it mandatory. However, wording the policy more strictly from the start may improve uptake.

# Instructions about human studies must make clear to researchers who needs to be studied

**Option 1** reflects the wording of the cells, tissues and animals requirement. It is **not specific** about what is meant by “diverse sexes and/or genders.”

**Option 2** breaks down the different sexes and genders that would need to be included. It **promotes inclusion of sex- and gender-diverse people** but recognises this may not always be possible.

**Option 3** emphasises inclusion of females/males and women/men. It also puts focus on the need to **put effort into recruiting sex- and gender-diverse people**.

- 1.2 From DD MM 2024, [organisation name] requires that researchers study:
- Both sexes in cells, tissues and animals.
  - **Option 1:** Diverse sexes and/or genders in humans.
  - **Option 2:** Female, male and (where possible) **intersex** people and/or women, men and (where possible) gender diverse people.
  - **Option 3:** Women and men and/or females and males in human studies. Efforts should be made to study people with variations in sex characteristics and/or diverse gender identities.
  - **Option 4:** In humans: females, males, people with variations in sex characteristics, women, men, and/or gender diverse people.

**Option 4** lists the groups that should be studied but **does not differentiate between the size** (and therefore availability for research) of the groups.

- Do these options sufficiently encompass inclusion of **trans individuals**?
- Which wording would you choose to describe **intersex people/people with variations of sex characteristics/people with differences of sex development**?

# A policy requirement should be as clear as possible

- 1.3 We expect researchers to include in their applications (**Which of the below should be included? Should anything else be added?**)<sup>2</sup>:
1. The planned distribution of subjects by sex and/or gender.
  2. The rationale for the planned distribution of subjects, drawing on relevant literature.
  3. The proposed outreach activities to recruit the planned distribution of subjects, drawing on relevant literature.
  4. An analysis plan, including details on how sex and/or gender differences will be examined.
- 1.4 In instances where a researcher does not plan to account for sex and/or gender dimensions, a strong justification, drawing on relevant literature, must be given.
- 1.5 We expect researchers' published outputs to include (**Which of the below should be included? Should anything else be added?**)<sup>3</sup>:
1. A description in the Methods section of the sex and/or gender distribution of the sample and the rationale for this selection. Where only one sex or gender is used, the justification for this decision must be explained.
  2. Any study findings which indicate a sex and/or gender difference.
  3. Mention in the Limitations section of any weaknesses in study design related to sex and/or gender considerations, including stating when such considerations are not taken into account.
  4. Data disaggregated by sex and/or gender in supplementary materials.

This section sets out the policy requirement. It covers what researchers should include in their **applications** and in **published outputs**.

It also articulates how researchers must answer the sex and gender question on an application form **if they plan to only study one**.

**Is there anything you would change in this section?** Write it down and prepare to share it during the policy lab.

# Researchers will benefit from guidance on what happens if applications don't account for sex and/or gender (S/G)

1.5 **Option 1:** Integration of sex and/or gender considerations will increase the likelihood of an application being funded.

**Option 2:** Integration of sex and/or gender considerations will increase the likelihood of an application being funded. Applications which do not engage with the sex and/or gender question will not progress further.

**Option 3:** The quality of the integration of sex and/or gender dimensions will affect the likelihood of an application being funded.

**Option 4:** The quality of the integration of sex and/or gender dimensions will affect the likelihood of an application being funded. Applications which do not engage with the sex and/or gender question will not progress further.<sup>4</sup>

**Options 1 & 2** present the integration of sex and gender as a **bonus** that will boost an application's performance.

**Options 3 & 4** focus on the **quality** of plans to integrate S/G in the application.

The final line of **Options 2 & 4** states that an application will be rejected if it does not follow this policy. **Should this sentence be included?**

# An explicit policy scope will help researchers

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1.7 This policy applies to both quantitative and qualitative research.<sup>5</sup> (Y/N)

Other policies focus primarily on quantitative research and are not explicit about the types of research the policy applies to. **Should this policy extend to qualitative studies, and should this be stated here?**

## 2. Choosing definitions – Two options

# S&G definitions can take a 'category' or 'characteristics' approach

Consensus on definitions across the research sector would increase the likelihood of policy impact.

A 'category approach' means defining sex and gender as aggregate categories, rather than as individual characteristics that make up that category. The CIHR, NIH and MRC policies all take a category approach.

A 'characteristics approach' would offer a list of the characteristics that make up wider categories used in typical public understanding and discourse. This approach would ask researchers to consider which characteristic/s is/are most relevant to their research.

A category approach is more in keeping with existing definitions, however there is growing interest in a characteristics approach as it can lead researchers to engage with sex and gender in a more precise, and therefore reproducible, way.

Of the two options presented on the following slides, which will:

- Best help **researchers** to understand what they need to study?
- Be most useful for conducting research that is **rigorous, precise and reproducible**?
- Produce the **clearest findings for disseminating** to your field?
- Be most useful for conducting **meta-analyses**?
- Result in **simplicity and unity** in the research sector?

## Definitions – Option 1

This is a **category** approach.

### If you choose this option:

**Which definition of Gender** do you think works best?

**Option 1 (Gender)** is the MRC definition of Gender.

**Option 2 (Gender)** is a new definition informed by PL1, Horizon Europe and CIHR definitions, and MESSAGE team thinking.

What would you **add or remove** from the wording of the definitions (both sex and gender)?

Is there anything else that should be adjusted in the **framing** of this approach?

#### 2.2.1 In this policy:

2.2.2 '**Sex**' refers to the biological attributes of humans and animals that differentiate female, male and intersex (also referred to as **Differences in Sex Development**), including chromosomes, gene expression, hormone levels and function, reproductive organs and different molecular expressions at cell level.<sup>8</sup> The categories of sex are usually female and male, but there is variation in the presentation of different biological components of sex.<sup>9</sup>

2.2.3 **Option 1 (Gender):** 'Gender' is distinct from sex, and refers to the attribution of behaviours, expectations and roles to different sexes in humans, therefore varies over time and by social and cultural context. Gender is often regarded as binary (for instance, woman or man), however there is diversity in how individuals and groups experience and express gender (such as gender fluid, non-binary).<sup>10</sup>

2.2.4 **Option 2 (Gender):** Gender refers to the socially-constructed roles, behaviours, and identities of girls, women, boys, men, and non-binary and gender diverse people. It influences how people perceive themselves and each other, how they interact, and the distribution of power and resources in society.<sup>11</sup> Gender attitudes and behaviours are complex and change through time and in place. Importantly, gender is diverse, fluid, multidimensional and intersects with other categories, such as sex, age, socioeconomic status, sexual orientation and ethnicity.<sup>12</sup>

2.2.5 It is important that biomedical, health and care researchers have a robust understanding of which sex and/or gender attributes are relevant for their study so they can select appropriate research subjects.

#### 2.2.6 Data collection on sex should include the options:

- Female and Male for cell, tissue and animal studies.
- Female, Male, and Person with variations in sex characteristics/differences of sex development/Intersex as a minimum for human studies.<sup>13</sup>

2.2.7 Data collection on gender (in human studies) should include the options Woman, Man, and Non-binary as a minimum.<sup>14</sup>

2.2.8 Further information about definitions and how to collect sex and gender data can be found [here](#).<sup>15</sup>

## Definitions – Option 2

A **characteristics** approach.

If you choose this option:

Would you keep the same **list of characteristics**? Is there anything you would add or remove?

Should anything else be changed in the **framing** of this approach?

- 2.3.1 In the UK, ‘sex’ is conventionally understood as pertaining to biological characteristics and ‘gender’ as pertaining to sociocultural features. Gendered features are shaped by a society’s norms and a person’s internal connection to a gendered category such as woman, man or non-binary.<sup>16</sup>
- 2.3.2 Biological sex can be classed as female, male or intersex. Intersex individuals have variations or combinations of what are considered XX female-typical and XY male-typical chromosomal, gonadal and genital sex characteristics.<sup>17</sup>
- 2.3.3 A person’s gender exists on a spectrum,<sup>18</sup> can be fluid,<sup>19</sup> and intersects with other characteristics such as age and ethnicity.<sup>20</sup> There is therefore considerable diversity in how individuals and groups experience and express gender.<sup>21</sup>
- 2.3.4 In this policy, we use ‘sex’ and ‘gender’ as single terms which each encapsulate multiple characteristics that have relevance for health and disease. It is important that researchers have a robust understanding of which sex and gender characteristics are relevant for their study so they can select appropriate research subjects. Researchers must be able to justify their selection of research subjects based on the characteristic(s) selected to study.
- 2.3.5 Sex characteristics include:<sup>22</sup>
  - External reproductive organs
  - Hormone profile
  - Internal reproductive organs
  - Secondary sex characteristics
  - Chromosome profile
  - Sex assigned at birth
- 2.3.6 Gender characteristics include:<sup>23</sup>
  - Self-identity
  - Social role (as determined by gender norms)
  - Character traits (as determined by gender norms)
  - Behaviours (as determined by gender norms)
  - Social relationships (as determined by gender norms)
- 2.3.7 Further information on the meaning of these characteristics and their applicability in data collection can be found [here](#).<sup>24</sup> Data collection on sex and gender characteristics should include options which account for variations beyond a female/male or woman/man binary.
- 2.3.8 Further information about definitions and how to collect sex and gender data can be found [here](#).<sup>25</sup>

### 3. Choosing guidance for researchers – Sections and content

## a. Justifying not accounting for S/G

This section would help researchers to understand if their application needs to EITHER **integrate** sex and/or gender dimensions OR provide **adequate justification** for not doing so.

### Should this section be included?

If yes, should any other **appropriate justifications** be included? Should any be removed?

If yes, should any other **unacceptable justifications** be included? Should any be removed?

- 3.1 a. There may be appropriate reasons not to account for sex and gender in study design. (Y/N. If Y, what is missing?)
- 3.1.1 We may still fund single-sex or single-gender studies where there is strong justification in your research proposal for doing so. Cases where the use of a single sex or gender may be appropriate include:
- Diseases or mechanisms relating to a single sex characteristic (for example, ovarian cancer).<sup>27</sup>
  - Diseases or phenomena specific to the experiences of people of a single sex and/or gender.<sup>28</sup>
  - Research into the mechanisms of purely molecular interactions (for example, when investigating protein-protein interactions).<sup>29</sup>
  - Research using immortalised cell lines.<sup>30</sup>
  - Instances where there are acutely scarce resources (for example, human tissue samples of rare diseases).<sup>31</sup>
  - Where costs would be excessive (for example, several times higher than a single-sex or single-gender study).<sup>32</sup>
- 3.1.2 Other reasons for conducting research in a single sex or gender will be considered as part of the peer review process. These may include scientific, logistical, or ethical considerations.<sup>33</sup>
- 3.1.3 In most cases, the following will not be sufficient justification for excluding a sex or gender: (Which of the below should be included, and what else should be added)
- You do not know the sex of the cells, tissues or animals you use.<sup>34</sup>
  - Your existing knowledge of the literature does not include sex and gender considerations in your field.
  - There is a lack of evidence of sex or gender having an effect on the disease, mechanism or phenomenon.<sup>35</sup>
  - Prior work, including pilot studies, has been performed in only one sex or gender.<sup>36</sup>
  - Hormonal variations, including hormonal variability in female subjects across the menstrual cycle or as a result of hormonal replacement therapy.<sup>37</sup>

## b. Statistical guidance

This section informs researchers about the **statistical implications** of this change and the effect on sample sizes. It would be accompanied by more detailed **statistical guidance**, a version of which will be produced by MESSAGE.

### Should this section be included?

If yes, should any other **considerations** be included? Should any be removed?

- 3.2 b. Whether sample sizes need to increase or not depends on the type of research you conduct. (Y/N)
- 3.2.1 b. (i) Cell, tissue or animal studies
- 3.2.2 By using multifactorial statistical analysis, some studies can meet this policy requirement using the same or only modest increases in sample size. However, sample sizes may need to be increased in some instances.<sup>38</sup>
- 3.2.3 You should include details of your expected sample size and planned distribution by sex in your study design and analysis plan.<sup>39</sup> Relevant considerations for this decision-making process include:<sup>40</sup>
- If the study is exploratory or experimental in design.
  - If the study needs to be powered to be statistically significant for both sexes.
- 3.2.4 You can learn more about multifactorial statistical analysis [here](#)<sup>41</sup>.
- 3.2.5 b. (ii) Human studies
- 3.2.6 It may be more difficult to use multifactorial statistical analysis in human studies than animal or cell studies. Where it is not possible, **and in some other circumstances**, sample sizes may need to be increased.
- 3.2.7 You should include details of your expected sample size and planned distribution by sex and/or gender in your study design and analysis plan.<sup>42</sup> Relevant considerations for this decision-making process include:<sup>43</sup>
- If the study is exploratory or experimental in design.
  - If the study needs to be powered to be statistically significant for both sexes.
- 3.2.4 You can learn more about statistical methods for human studies [here](#)<sup>44</sup>. You can find out more about ways to reduce additional costs [here](#).<sup>45</sup>

## c. Additional costs

This section offers guidance to researchers about how **additional expenses** will/will not affect the likelihood of an application being successful.

### Should this section be included?

If **yes**, the wording of this section could be adapted by each funder to reflect their circumstances.

The current wording of this section could be used if funders plan to **cover additional costs**.

If **funders do plan to cover these costs**, should the policy state that costs “**will**” or “**may**” be covered?

If **funders do plan to cover these costs**, should the policy stipulate that additional expenses will **not affect** if an application is funded?

3.3 c. Additional costs when accounting for sex and/or gender dimensions **will be covered**.  
**(Y/N)**

3.3.1 For some studies, increasing sample sizes may lead to extra costs, including but not limited to:

- Additional animal housing.
- Additional compensation for participants.
- Additional recruitment or PPIE activities.
- **Training for researchers**.

3.3.2 **Additional costs to meet the requirements of this policy will not affect the likelihood of an application being funded.**

3.3.3 Many actions to meet the requirements of this policy do not necessitate additional expense. These actions are listed in section (e) as actions and can also be taken by existing grant holders.<sup>46</sup>

If **funders do not plan to cover these costs**, alternative guidance on this point may need to be included. **What should it include?**

## d. Sample distribution

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This section gives researchers guidance on **expected sex and/or gender distributions** of their sample.

### Should this section be included?

If yes, the wording of this section states that there is no one way researchers are expected to plan their sex and/or gender distribution. **Is this the best guidance?**

Should any information be added or removed?

If yes, should this section encourage researchers to **make effort** to include sex and/or gender diverse people where possible? If yes, is there anything you would remove or add to this wording?

- 3.4 d. The planned distribution of research subjects should be tailored to the needs of the study design. (Y/N)
- 3.4.1 This policy does not require one particular distribution of research subjects on the basis of sex and/or gender (e.g. 50% women and 50% men). In some studies, it may be more relevant for the sample to represent the sex and/or gender split in the population as a whole, and in others it may be more relevant for the sample to represent the sex and/or gender split in the disease population.<sup>47</sup> Decisions on sample size split should take into consideration the statistical methods that will be used to analyse the data.
- 3.4.2 You should consider the rationale for your planned distribution and reflect this in your study design and analysis plan. In human studies, **you should take proactive steps to include sex and/or gender diverse research subjects wherever possible.**

You can find more information about planning your sample distribution [here](#).<sup>48</sup>

## e. Existing grants

This section sets out guidance for researchers who already have received funding or submitted an application.

### Should this section be included?

If yes, the wording of this section states that researchers who already hold grants are not required to make changes to existing study design. Is this appropriate guidance?

If yes, the section suggests ways that researchers who have already received funding could nonetheless start to account for sex and gender. Would you add or remove anything here?

3.5 e. This policy will not apply to research that has already been funded or for applications which have already been submitted. (Y/N)

We encourage existing grant holders to explore ways to integrate sex and/or gender considerations throughout the remaining stages of their grant period to make their research more generalisable.<sup>49</sup>

This could include, but is not limited to, the following:

- Familiarising yourself with the literature on sex and/or gender differences in your field.
- Developing methods to disaggregate study data by sex and/or gender.
- Conducting sex- and/or gender-based analysis on study data.
- Describing the sex and/or gender distribution of the sample and the rationale for this selection in paper Methods.
- Acknowledging sex and/or gender differences and not presenting research conducted only on male subjects/men as applicable to all subjects/people.
- Reporting findings that indicate similarities and/or differences between sexes and/or genders.
- Acknowledging when data has not been sex- and/or gender-disaggregated as a limitation of the research.
- Publishing data disaggregated by sex and/or gender in supplementary materials.
- Identifying areas for future research to explore sex and/or gender dimensions further.

# **Evidence and examples which informed the MESSAGE draft policy framework**

# Longstanding S&G policies exist elsewhere

This section shares examples of **how sex and gender initiatives around the world have designed and implemented** policies, analysed by the MESSAGE team and structured in line with Hunt et al. (2022)'s 5-step framework.



The Canadian  
Institutes for  
Health Research



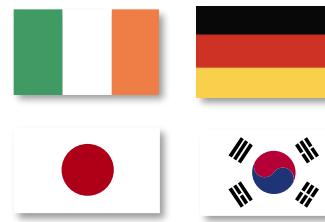
The National  
Institute for Health  
(United States)



Horizon Europe (the  
European  
Commission)



In addition, we include details from the UK's Medical Research Council, which published sex, gender and diversity guidance in November 2022 and June 2023.



Other national funders with policies include Ireland, Germany, Japan and the Republic of Korea.



The George Institute for Global Health is also leading policy development in Australia.

# Policies differ in content and accompanying guidance

This table highlights **what existing funder policies cover**. It should be noted that this is a “**best interpretation**” by the MESSAGE team, as often funders’ information is spread across multiple webpages and information differs between pages.

	CIHR	NIH	Horizon	MRC	CRUK
Single, clear policy for researchers	N	N	N	N (2 policies on S/G)	Y
Required or encouraged	Expect	Require	By default	Require	Require
Description of application success/failure based on S/G question response	Y	N	N	Y	N
Cells, tissues, animals AND humans	Y	N – not cells	Unclear	Y	N
Sex AND gender	Y	Y	Y	Y	N
Quant AND qual	N	N	N	N	N
Must justify when not accounting for S/G?	Y	Y	N	Y	Y
Acceptable exclusion criteria outlined	Y	Y	N	Y	Y
Statistical guidance clarified	Y	Y	Refers to <a href="#">Gendered Innovations</a>	N	Y
Covering additional costs outlined	N	N	N	Y	N
Planned distribution outlined	Y	Y	N	Y	N
Info for existing grants outlined	N	Y	N	Y	Y

# Step 1: Definition of terms

- Clear, quality definitions
- Definitions readily available

“It is important that the same definitions are shared with applicants, evaluators, and staff to support consistency across the agency”

**(Hunt et al., 2022)**

Consider the following definitions of sex and gender used by other funding agencies.

# S&G Definitions – CIHR and NIH



"Sex refers to a set of **biological attributes in humans and animals**. It is primarily associated with physical and physiological features including **chromosomes, gene expression, hormone levels and function, and reproductive/sexual anatomy**. Sex is usually categorized as female or male but there is **variation in the biological attributes** that comprise sex and how those attributes are expressed."



To note:

- No explicit mention of the terms **intersex, variations in sex characteristics or differences in sex development**.
- Sex described as "**primarily**" (not exclusively) associated with physical and physiological features.
- No distinction between **internal and external genitalia** as sex characteristics.

<https://cihr-irsc.gc.ca/e/50836.html> (2021)

"Gender refers to the **socially constructed roles, behaviours, expressions and identities** of girls, women, boys, men, and gender diverse people. It influences how people **perceive themselves and each other**, how they **act and interact**, and the **distribution of power and resources** in society. Gender is usually conceptualized as a **binary** (girl/woman and boy/man) yet there is **considerable diversity** in how individuals and groups understand, experience, and express it."



To note:

- Description of "**gender diverse**" people rather than "**non-binary**".
- Emphasis on convention for gender to be viewed as a **binary**, rather than a spectrum.
- No explicit mention of gender existing on a **spectrum** and being **fluid**.
- No mention that gender differs in **different societies**.

"Sex is a **multidimensional biological construct** based on a cluster of anatomical and physiological traits (sex traits), including **external genitalia, secondary sex characteristics, gonads, chromosomes, and hormones**. Like many in the health research community, NIH usually categorizes sex as **male or female**, although variations do occur, such as **differences in sex development (DSD)**"



To note:

- Mention of **gonads** and **secondary sex characteristics**.
- Sex as a "**multidimensional biological construct**".

<https://nap.nationalacademies.org/catalog/26424/measuring-sex-gender-identity-and-sexual-orientation> (2022)

"**Gender** is multidimensional construct that **links gender identity, gender expression, and social and cultural expectations** around status, characteristics, and behavior **as they are associated with certain sex traits**. A society's gender roles, gender norms, gender relations, and gendered distributions of power are **shaped collectively** by the people within that society."



To note:

- No mention of gender existing on a **spectrum** and being **fluid**.
- Gender described as a construct **built on association with sex traits**.
- Gender as a "**multidimensional construct**".

# S&G Definitions – Horizon Europe

**Sex** “relates to the **biological attributes that distinguish male, female and intersex** according to functions that derive from the **chromosomal complement, reproductive organs, or specific hormones or environmental factors** that affect the expression of phenotypic traits in sexually reproducing organisms. These attributes may or may not be aligned in any individual (Fausto-Sterling, 2012; Ainsworth, 2015).”

**Sex in humans and lab animals may be defined according to:**

1. **Genetic** sex determination
2. **Gametes**
3. **Morphology**
  - Primary sex characteristics
    - Internal reproductive organs and genitalia
    - External genitalia
  - Secondary sex characteristics

“**Intersex conditions** may be defined as variations or combinations of what are considered XY male-typical and XX female-typical chromosomal, gonadal and genital characteristics.”

**To note:**

- Mention of sex deriving from **environmental factors**.
- Reference to **internal and external reproductive organs**.
- Definition encompasses all “**sexually reproducing organisms**”.
- Reference to **secondary sex characteristics**.
- Detailed description of **intersex conditions**.
- Use of **academic citation** within the definition.

**Gender** “refers to **sociocultural norms, identities and relations** that (1) structure societies and organisations and (2) shape behaviours, products, technologies, environments, and knowledges (Schiebinger, 1999; Ridgeway and Correll, 2004). Gender attitudes and behaviours are complex and **change in time and place**. Importantly, **gender is multidimensional** (Hyde et al., 2018) and **intersects** with other social categories, such as sex, age, socioeconomic status, sexual orientation and ethnicity...**Gender is distinct from sex** (Fausto-Sterling, 2012).”

**Gender is an organising structure that is composed of:**

1. **Gender norms**
2. **Gender relations**
3. **Gender identity**

**To note:**

- Distinction between gender as a social structure and as **shaping individual behaviour**.
- Reference to gender being **changeable** with time and place.
- Reference to **intersection** of gender with other characteristics.
- Description of gender as **distinct** from sex.
- Use of **academic citation** within the definition.



# S&G Definitions – Medical Research Council, UK



'Sex' refers to the **biological attributes of humans and animals** that **differentiate male, female and intersex** (also referred to as Differences in Sex Development), including chromosomes, gene expression, hormone levels and function, and reproductive organs. The categories of sex are **usually male and female, but there is variation** in the presentation of different biological components of sex. **Sex is a protected characteristic** under the Equality Act 2010.

## To note:

- Definition in relation to "humans and animals".
- No distinction between **internal and external** reproductive organs.
- No clarification that **sex under the Equality Act 2010 does not refer only to biological sex**.
- Mention of intersex and DSD rather than "variations in sex characteristics".

'Gender' is **distinct from sex**, and refers to the **attribution of behaviours, expectations and roles to different sexes in humans**, therefore varies over time and by social and cultural context. Gender is often regarded as **binary** (for instance, man or woman), however **there is diversity** in how individuals and groups experience and express gender (such as gender fluid, non-binary). **Gender reassignment is a protected characteristic** under the Equality Act 2010.

## To note:

- Describes gender as **distinct** from sex.
- Describes gender as a construct built on association with sex.
- No clarification that **gender is not a protected characteristic under Equality Act 2010**.
- No explanation why it is relevant that gender reassignment is a **protected characteristic**.
- Mentions **gender fluidity** and non-binary gender.

<https://www.ukri.org/publications/mrc-embedding-diversity-in-research-design-policy/embedding-diversity-in-research-design/> (2023)

The MRC's definitions (2023) have been adopted by Cancer Research UK "for consistency across the UK research network".

# Compatibility between definitions and data collection practices is important

- Ideally, a policy framework would adopt sex and gender definitions to align with other definitions and data collection practices in UK research and healthcare systems.
- Access to patient data via the NHS is an asset of UK biomedical, health and care research. However, data collection practices are heterogeneous across NHS services, complex to understand and have been criticised as insufficiently inclusive.
- Most NHS systems collect sex/gender data as 'Person stated gender'. This status is determined through observation of external genitalia at birth. Anyone may ask their GP to change their 'Person stated gender' in the NHS Spine system without a gender recognition certificate.

## Person stated gender options

Code	Description
1	Male
2	Female
9	Indeterminate (unable to be classified as either male or female)

- NHS sexual health, mental health and HIV/AIDS services collect data on 'Gender identity', for which a person's status is determined through their self-identity. A second question gathers data on 'Gender identity same as birth' to determine a person's trans status, also determined via a person's self-identity.

## Gender identity options

Code	Description
1	Male (including trans man)
2	Female (including trans woman)
3	Non-binary
4	Other (not listed)
Z	Not Stated (PERSON[c] asked but declined to provide a response)

## Gender identity same as birth options

Code	Description
Y	Yes - the PERSON[c]'s gender identity is the same as their gender assigned at birth
N	No - the PERSON[c]'s gender identity is not the same as their gender assigned at birth
Z	Not Stated (PERSON[c] asked but declined to provide a response)

# Step 2: Proposal guidelines for applicants

- Instructions to applicants to include [sex- and gender-based analysis]
- Are they encouraged or required?
- Are examples given?
- Specify how is [sex- and gender-based analysis] included at each stage of the research cycle – detail for yes, and justify for no

“Most [agencies] encourage applicants to integrate [sex- and gender-based analysis]; a few require this type of analysis; some only encourage applicants but instruct evaluators to score this element.”

(Hunt et al., 2022)

Consider the wording that the following policies use to articulate a sex and gender requirement.

# Clear policy wording is key

The policy statements below articulate the requirement in one clear, punchy sentence:



**"NIH expects that sex as a biological variable will be factored into research designs, analyses, and reporting in vertebrate animal and human studies.**

Strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for applications proposing to study only one sex". ([here](#))

In 1993, the United States enshrined the “inclusion of women and minorities in clinical research” in law. This is known as the **Revitalization Act 1993**. ([here](#))

**To note:**

- Policy statement only covers sex (**not gender**).
- Policy strengthened through **legal mandate**.



**“Integration of a gender dimension into research and innovation content is a requirement by default”** ([here](#))

Accounting for the gender dimension = “ensuring that the **biological characteristics as well as the social and cultural features**, behaviours and needs of both women and men are taken into consideration”. ([here](#))

In practice, this translates into a requirement that “all Horizon Europe topics, **by default, require sex- and gender-based analysis**, unless topic drafters clearly demonstrate that the gender dimension is not relevant to the proposed topic.” Topics are determined by Horizon Europe, rather than individual researchers. ([here](#))

**To note:**

- Policy statement framed under “gender”, though **expected to cover both sex- and gender-based analysis**.



**“CIHR expects that all research applicants will integrate sex and gender into their research designs, methods and analyses and interpretation and/or dissemination of findings when appropriate”**. ([here](#))

This policy derives from the fact that “CIHR is a signatory on the Government of Canada’s [Health Portfolio Sex-and Gender-Based Analysis Policy](#), as well as the [Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans](#)”. ([here](#))

**To note:**

- Funder policy **strengthened by government policies**.
- Emphasis on sex and gender being integrated in **all stages** of the research process.

# Clear location and format of the policy is also key

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Neither NIH, CIHR nor Horizon Europe **has one single ‘policy document’** on their website. Instead, information about the sex and gender requirements are spread across **multiple different webpages** on each funder’s site.

We found **duplicate or multiple** similar pieces of information and resources had been uploaded. It wasn't clear which was most **up-to-date, useful or relevant**.

It was **difficult to get a clear overview** of the exact requirements from funders, what researchers need to include on their application forms, and how the funder will review this component of a researcher's application.

**The MESSAGE team’s reflections from gathering this information is that funders should:**

- Produce one **single** policy document containing all relevant information.
- Dedicate a **specific area** of the organisation’s website to the sex and gender policy and requirements.
- Appoint a person/team **responsible for oversight and update** of the webpage/site to **minimise duplication** of information and **ensure consistency** in wording across all stipulations.
- Set out further key resources (such as guidance for reviewers) in a **visually clear and accessible** way.
- Ensure **hyperlinks** to other resources are correct, live and relevant.

# MRC policy documents contain guidance for researchers



In November 2022, the MRC published their [Sex in experimental design](#) guidance, which states that “**both sexes of animals, tissues and (non-immortalised) cells should be included** as is appropriate for the particular experiment”.

This policy is for basic researchers only. The policy states that “**Use of both sexes will be the default**”. Further details include:

MRC may still fund single-sex studies where there is strong justification in the research proposal for doing so. Cases where the use of a single sex is likely to be appropriate include:

- where there are acutely scarce resources (for example, human tissue samples of rare diseases)
- research into the mechanisms of purely molecular interactions (for example, when investigating protein-protein interactions)
- single sex mechanisms or diseases (for example, ovarian cancer).

Other reasons for conducting research in a single sex given by applicants will be considered as part of the peer review process. These may include logistical or ethical considerations and should have robust justification.

In most cases, female variability will not be sufficient as a justification for using only one sex. MRC will also not accept as justification that prior work has been performed in only one sex; or that there is a lack of evidence of sex having an effect.

In June 2023, MRC published their [Embedding diversity in research design](#) guidance “**to embed consideration of relevant diversity characteristics into the design and conduct of all MRC-funded research and innovation**”.

This policy highlights sex and gender as two important diversity characteristics. The policy is applicable for all types of research.

## For human research, they require:

- 4.2 As part of their research proposal, applicants for MRC funding who are proposing to conduct research involving animals and their derived tissues and cells, or human tissues and cells, are required to:
- 4.2.1 describe the sex of the animals, tissue and cells to be used
  - 4.2.2 use both sexes of animals, tissues or cells, unless a strong justification not to do so is given
  - 4.2.3 if conducting a single sex experiment, explain the appropriateness of this choice and any limitations of the study as a result

## For cell, animal or tissue research, they require:

- 4.4 As part of their research proposal, applicants for MRC funding are required to describe:
- 4.4.1 the characteristics of the population groups or subpopulations who could benefit from the research being proposed
  - 4.4.2 the approach that they have taken to addressing diversity and promoting inclusion of these groups throughout their research
  - 4.4.3 explain or justify why this approach has been taken

# Cancer Research UK modelled its requirements on MRC policy



Cancer Research UK published [Requirements on integration of sex in experimental design](#) in 2023. They **consulted with MRC** on the policy wording and contents to **maximise uniformity and simplicity** for researchers. However, some policy content differs.

The policy is published on a single webpage.

The requirement is: "**We now require male and female sexes to be used in the design of experiments described in all funding applications to us that involve animals, human and animal tissues, and cells.** However, exceptions, to permit single sex experiments, may be granted, particularly if you have a strong scientifically-based justification."

## Further wording states that:

- "If you don't know the sex of the cells and tissues you use, **you should plan to determine this** as part of your research."
- "We'll roll out these new expectations **gradually** across our funding portfolio and they will continue to evolve"
- "There will be **no retrospective application** of this requirement to existing awards or previously submitted applications, but we encourage all of our researchers to consider how to incorporate these principles where practical and **explore ways to make their discoveries more generalisable.**"

### Use of both male and female sexes will be the default

Both male and female sexes of animals, or tissues or cells should be incorporated into each experiment. There is no requirement to 'balance' or use equal numbers of the sexes, although, where possible, equal numbers will support the best statistical power to examine the sex variable. The new requirement does not apply to the use of immortalised cell lines.

### Exceptions for single-sex studies with justification

We may still fund single-sex studies where there is strong justification in the research proposal for doing so.

Cases where the use of a single sex may be appropriate include:

- single sex biological mechanisms or diseases (for example, ovarian cancer)
- research into the mechanisms of purely molecular interactions (for example, when investigating protein-protein interactions)
- where there are acutely scarce resources (for example, human tissue samples of rare cancers)
- where costs would be excessive (for example, several times higher than a single sex study)

Other reasons for conducting research in a single sex will be considered as part of the peer review process. These may include scientific, logistical or ethical considerations and should have robust justification.

Please note in most cases female variability will not be sufficient as a justification for using only one sex. We will not accept as a justification that prior work has been performed in only one sex or that there is a lack of evidence of sex having an effect.

# The FDA produced a regulatory S&G guideline in 1993

The **US Food & Drug Administration** published a [Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs](#) in 1993. This guideline recognises that “**variations in response to drugs**, including gender-related differences, can arise from pharmacokinetic differences...or pharmacodynamic differences.”

Here, “**gender differences**” confusingly refers to biological differences between males and females.

## The guideline covers:

1. **Inclusion** of patients of both genders in clinical studies.
2. **Analysis** of clinical data, including effectiveness and adverse effects, by gender.
3. Assessment of potential pharmacokinetic **differences between genders**.
  - Including three pharmacokinetics issues specific to women:
    1. Effect of **menstrual status** (both within menstrual cycle and pre/post-menopausal status).
    2. Influence of supplementary **oestrogen treatment** (oral contraceptives, long-acting progesterone).
    3. Influence of the drug on **the pharmacokinetics of oral contraceptives**.
4. Conduct of specific **additional studies in women** when prior analysis indicates gender differences may exist.

A policy for **UK regulators** could draw on this guideline, as could a policy for funders.

## Part VI

### Department of Health and Human Services

Food and Drug Administration

Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs; Notice

# Application form question wording varies

As with policy requirements, funders ask researchers to include sex and gender in their application using **different wording and different formats**. These formats match the funders' existing application forms.



- Gives **detailed information** about the content that researchers should cover in an application form.
- Focuses attention on **additional outreach** needed to recruit diverse groups.

"Address the following points:

- Describe the **planned distribution of subjects** by sex/gender, race, and ethnicity.
- Describe the **rationale for selection** of sex/gender, racial and ethnic group members in terms of the scientific objectives and proposed study design. The description may include but is not limited to information on the population characteristics of the disease or condition under study.
- Describe **proposed outreach programmes** for recruiting sex/gender, racial and ethnic group members.
- Inclusion and Excluded Groups: **Provide a reason for limiting inclusion** of any group by sex/gender and/or ethnicity."

<https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf#page=252>



- Asks applicants to "refer briefly" to the gender dimension, without giving further details of what content/characteristics should be included.

"When relevant for your project, refer briefly to...**How the gender dimension (i.e. sex and/or gender analysis) is taken into account in the project's research and innovation content.**

Note: This section is mandatory except for topics which have been identified in the work programme as not requiring the integration of the gender dimension into R&I content."

[af\\_he-ria-ia-stage-1\\_en.pdf \(europa.eu\)](af_he-ria-ia-stage-1_en.pdf (europa.eu))



- Asks **Yes/No questions initially**, followed by one **descriptive** question.
- Asks applicants to describe "sex and/or gender considerations".

"**Is sex as a biological variable taken into account** in the research design methods, analysis and interpretation, and/or dissemination of findings? Yes/No

**Is gender as a socio-cultural factor taken into account** in the research design, methods, analysis and interpretation, and/or dissemination of findings? Yes/No

If yes, please describe **how you will integrate sex and/or gender considerations** into your research proposal (limit of 2000 characters).

If no, please **explain why sex and/or gender are not applicable** to your research proposal."

[https://cihr-irsc.gc.ca/e/documents/Project\\_Grant\\_Application\\_Instructions\\_EN.pdf](https://cihr-irsc.gc.ca/e/documents/Project_Grant_Application_Instructions_EN.pdf)

# Step 3: Instructions for evaluators

- Instructions for reviewers to include [sex- and gender-based analysis] in their evaluations
- Assessment at each stage of the research process
- Monitoring

“Evaluators are crucial to the success of [sex- and gender-based analysis] policies. CIHR found that ‘targeting applicants alone to adopt new science policies without concomitant pressure by evaluators...may not be effective’”

**(Hunt et al., 2022)**

Consider how the following funders evaluate responses to questions about sex and gender in funding applications.

# Application review criteria

Funders will have to review the sex and gender component of a funding application, which should be **integrated into the funder's existing review system**. Funders must also provide guidance to reviewers.



"Scientific Review Groups will assess each application/proposal as being "**acceptable**" or "**unacceptable**" with regard to the inclusion of racial and ethnic minorities and women in the research project."

[Guidelines for the Review of Inclusion in Clinical Research](#) outline a flowchart for acceptable or unacceptable applications. Within this, reviewers must consider **distribution of subjects, selection criteria and rationale, justification if excluding a group, and outreach plans**.

They must also consider if an application meets requirements for [valid analysis](#) and whether applicants "address whether they plan **to test or not test for differences in effect among sex/gender...groups** and why that is or is not appropriate."



Integration of the gender dimension is one element used to review the "**Excellence**" of an application (other elements are "Impact" and "Quality/Efficiency").

"Details about how the gender dimension will be integrated must be provided in (1) **the concept and (2) the methodology**".



"Reviewers are asked to explicitly assess whether the integration of sex (as a biological variable) **and/or** gender (as a socio-cultural factor) is a **strength, a weakness or not applicable** to the proposal."

"Reviewers are also asked to comment on their assessment and to **provide recommendations to the applicants on how they might improve** the strength of their applications with respect to the integration of sex and/or gender."

# Questions for funders to consider for application evaluation

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- 1** How will inclusion of S/G in an application **be measured**?
  - As its own criteria to be scored ('excellence in consideration of sex and gender') or as one component of a larger criteria ('excellence')?
  - Distinction between pass/fail or a scale of quality (e.g. 1-5 in terms of excellence)?
  
- 2** Who will review inclusion of S/G in applications?
  - What additional expertise is needed? From where will this be sourced?
  
- 3** Where will guidance for reviewers be hosted, and how will you signpost researchers to it?
  
- 4** How will inclusion of S/G in an application **affect the application's overall score and likelihood of being successful**?
  
- 5** What **training** will be needed for reviewers?
  - Where will this training be hosted?

# Step 4: Training for applicants, evaluators and reviewers

- Training, resources, and support available for applicants
- Training, resources, and support available for proposal evaluators

- Training, resources, and support available for relevant agency staff
- Training mandatory through certification
- Development of open access resources: courses and high-quality materials

**Policy implementation will be the focus of Policy Lab 3 (31<sup>st</sup> Jan 2024)**

“[Sex- and gender-based analysis] is not yet consistently part of university curricula in the physical and life sciences, health and biomedicine... Until universities step up to the task, funding agencies need to fill this gap.”

**(Hunt et al., 2022)**

“Use of the same training materials by applicants, evaluators, and agency staff helps to ensure consistency in policies, terminology, and expectations.”

**(Hunt et al., 2022)**

# Step 5: Evaluation of policy implementation

“We strongly recommend that agencies implement evaluation plans as they develop policies to facilitate appropriate quantitative and qualitative evaluation.”

**(Hunt et al., 2022)**

Consider the metrics for evaluation proposed by Hunt et al. and used by the CIHR.

# Aspects of policy implementation to evaluate

Hunt et al. (2022) emphasise the importance of considering evaluation of policy implementation from the start.

They suggest five key areas for evaluation:

**1** Number and proportion of proposals that include [sex- and gender-based analysis].

**2** Number and proportion of proposals that include ***quality*** [sex- and gender-based] analysis.

**3** The quality of evaluators' scoring and comments (qualitative analysis).

**4** Number of applicants, evaluators and staff who engaged in trainings and in what type of training.

**5** The number and proportion of peer-reviewed publication (or other recognised modes of dissemination) that result from funded proposals that incorporated [sex- and gender-based analysis]. To monitor this, funders will need to track papers and research outputs using grant numbers.

What other aspects of policy implementation would you want to see **monitored** and **evaluated** to fit the remit of your organisation?

# Evaluations demonstrate policy success and impact

In 2021, CIHR published an evaluation of its policy implementation showing:

- Applications integrating sex in reporting increased from 22% to 83%.
- Applications integrating gender in reporting increased from 12% to 33%.
- Applications scoring highly for sex and gender more likely to be funded.

RESEARCH

Open Access

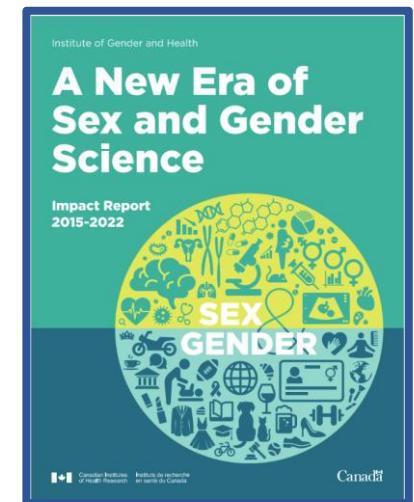


A 10-year longitudinal evaluation of science policy interventions to promote sex and gender in health research

Jenna Haverfield<sup>1</sup> and Cara Tannenbaum<sup>1,2\*</sup>

In 2023, CIHR published its Impact Report for 2015-2022, which measured policy impact in terms of:

- Sex and gender integration in CIHR research proposals increased by **68%** and **28%** respectively from 2011 to 2022.
- Increase in federal health research dollars accounting for sex and gender from **\$58M** to **\$900M**, 2011-2022.
- Proportion of preclinical and human projects integrating sex/gender increased from **10%** to **55%** in preclinical projects and from **42%** to **60%** in human projects.
- Number of PubMed publications with the keywords sex/gender in Canada increased by **64%** in six years.
- Researchers' odds of being funded were **1.8 x** higher if reviewers score sex as a strength and **2.5 x** higher if they score gender as a strength in the proposal.
- Across every CIHR competition from 2011-2019 female investigators were more likely to integrate sex and gender but were shown to receive less funding than male applicants.



[A New Era of Sex and Gender Science Institute of Gender and Health Impact Report 2015-2022 \(cihr-irsc.gc.ca\)](https://www.cihr-irsc.gc.ca/e/50149.html)

# Next steps

# For funders and regulators...

## Statement of intent:

MESSAGE has produced a **template** Statement of Intent for funders and regulators to **sign and publish** to signal upcoming adoption of a sex and gender policy.

We plan for organisations to publish their statement together on **8<sup>th</sup> December 2023**.

### *To meet this deadline:*

- **Review and edit** the statement template to the context of your organisation.
- Identify an appropriate signatory for the statement and **secure a signature** at least **two weeks before 8th December 2023**.
- Attend a group **meeting on 27<sup>th</sup> November 2023** (hosted by MESSAGE) in advance of release of the statement.
- Arrange for your Communications team to **release this statement on 8<sup>th</sup> December 2023**.

## Launch of policy framework in early 2024:

- **Secure buy-in and commitment from relevant decision-makers** in your organisation. **Fix a date in early 2024 for launch** of your organisation's policy.
- Determine who in the organisation will be **responsible for policy implementation** and accountability.
- Arrange for your **application form** to add a question about the integration of sex and gender.
- Decide how your organisation will **free up financial resources** to support researchers' needs during this transition.
- Think about how you will **signpost researchers and reviewers to training resources** (one option will be signposting to resources on the MESSAGE website)
- Consider how your organisation currently reviews applications, and **how review of sex and gender components will be integrated**.
- Discuss how your organisation will **evaluate policy implementation**, including how often evaluations will take place.

# For the MESSAGE team...

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- Finalise policy framework and distribute to funders.
- Coordinate sector-wide publication of our **Statement of Intent** on 8<sup>th</sup> Dec 2023.
- Educational resources on our new website: [www.messageproject.co.uk](http://www.messageproject.co.uk)
- Prepare rollout of **online short course** on 'Navigating Sex and Gender' in spring 2024.
- Arrange and communicate **MESSAGE office hours** for funders to ask questions, brainstorm and receive guidance in the lead up to policy launch in early 2024.

Policy Lab 3 will take place on **31<sup>st</sup> January 2024**. Save the date!

# Additional slides

# Definitions of S&G used in the Equality Act 2010

The UK Equality Act 2010 provides legal protection against discrimination for eight protected characteristics, including **Sex and Gender reassignment**. Sex is, and Gender is not, a **protected characteristic** under UK law. However, the gender a person self-identifies with is covered under the characteristic of “Sex”.

- In February 2023, the UK Minister for Women and Equalities asked the **Equality and Human Rights Commission** to consider if the definition of the protected characteristic of Sex should be **changed to reflect biological sex only**.
- In the UK, **trans people's rights** are tied to their legal sex, which is not currently determined by biological sex (or sex assigned at birth). This move would **threaten these rights** and is therefore highly **controversial**.
- There has **not yet been a resolution** on this decision.

## Sex

In relation to the protected characteristic of sex—

- (a) a reference to a person who has a particular protected characteristic is a reference to a man or to a woman;
- (b) a reference to persons who share a protected characteristic is a reference to persons of the same sex.

## Gender reassignment

- (1) A person has the protected characteristic of gender reassignment if the person is proposing to undergo, is undergoing or has undergone a process (or part of a process) for the purpose of reassigning the person's sex by changing physiological or other attributes of sex.
- (2) A reference to a transsexual person is a reference to a person who has the protected characteristic of gender reassignment.
- (3) In relation to the protected characteristic of gender reassignment—
  - (a) a reference to a person who has a particular protected characteristic is a reference to a transsexual person;
  - (b) a reference to persons who share a protected characteristic is a reference to transsexual persons.

<https://www.legislation.gov.uk/ukpga/2010/15/contents>

# Definitions of S&G used by the Office of National Statistics

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The Office of National Statistics is a **government department** that collects data on the UK population on various topics, including the **national census**.

Their definitions of sex and gender **determine the way government research collects data on sex and gender**.

## 2 . Definitions and differences

The UK government defines sex as:

- referring to the biological aspects of an individual as determined by their anatomy, which is produced by their chromosomes, hormones and their interactions
- generally male or female
- something that is assigned at birth

The UK government defines gender as:

- a social construction relating to behaviours and attributes based on labels of masculinity and femininity; gender identity is a personal, internal perception of oneself and so the gender category someone identifies with may not match the sex they were assigned at birth
- where an individual may see themselves as a man, a woman, as having no gender, or as having a non-binary gender – where people identify as somewhere on a spectrum between man and woman

The [World Health Organisation](#) regional office for Europe describes sex as characteristics that are biologically defined, whereas gender is based on socially constructed features. They recognise that there are variations in how people experience gender based upon self-perception and expression, and how they behave.

# Some examples of funders' more detailed guidance for reviewers

## CIHR checklist for reviewers:

- 2. Quality & appropriateness of research approach with respect to sex/gender considerations**
- Literature Review**
- Clear articulation of any known sex and/or gender differences in the epidemiology, risk factors, conditions, diseases or effects of treatment under study
  - A literature review that describes known sex and/or gender differences, or lack thereof, in the research area under study. Ethnicity, income, occupation and other key social determinants of health, including social roles should be considered as determinants of gender
- Research Question**
- Clear articulation of the type of research question being considered with respect to sex/gender:
    - Identifying sex/gender differences in the intervention/treatment/outcomes under study
    - Explaining these sex/gender differences
    - Establishing that there are no sex/gender differences in the intervention/treatment/outcomes under study
    - Studying sex/gender as a confounder or interaction variable while testing the main study hypothesis
- Study Design & Methods**
- Inclusion and exclusion criteria that consider sex/gender and diverse populations of men and women/boys and girls
  - Description of recruitment strategies to accrue required sample size of men and women/boys and girls
  - Choice of outcome measures that are not gender biased and are sensitive and responsive to sex/gender issues
  - Description of data collection tools/use of administrative datasets with respect to capturing sex-related and gender-related variables of interest (quantitative and qualitative data)
- Analysis & Reporting**
- Description of the data analysis plan (sex-disaggregated or stratified analyses, pathway modeling, use of sex and gender variables as confounders or in interaction terms, if applicable)
  - Sample size calculations to show adequate power for testing hypotheses with respect to sex/gender differences
  - Inclusion of a statement that negative findings with respect to sex/gender will be reported

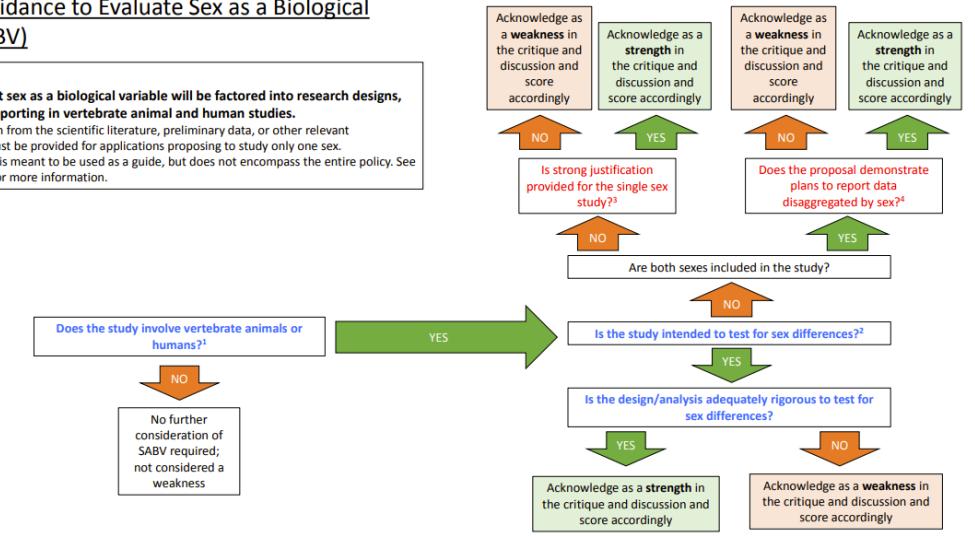
<https://cihr-irsc.gc.ca/e/documents/igh-checklist-SPOR-en.pdf>

## NIH Reviewer Guidance to Evaluate Sex as a Biological Variable:

### Reviewer Guidance to Evaluate Sex as a Biological Variable (SABV)

#### Main points

- NIH expects that sex as a biological variable will be factored into research designs, analyses, and reporting in vertebrate animal and human studies.
- Strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for applications proposing to study only one sex.
- This decision tree is meant to be used as a guide, but does not encompass the entire policy. See [NOT-OD-15-102](#) for more information.



[\(2020\)](https://grants.nih.gov/grants/peer/guidelines_general/sabv_decision_tree_for_reviewers.pdf)

# References

# References

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- Bates et al. (2022) The National Academies Press. Measuring Sex, Gender Identity and Sexual Orientation. [Download: Measuring Sex, Gender Identity, and Sexual Orientation | The National Academies Press](#)
- Canadian Institutes of Health Research. (2019). How to integrate sex and gender into research. [How to integrate sex and gender into research – CIHR \(cihr-irsc.gc.ca\)](#) (September 2023)
- Canadian Institutes of Health Research. (2023) A New Era of Sex and Gender Science, impact report 2015-2022. [Health Portfolio Sex and Gender-Based Analysis Policy - Canada.ca](#) (September 2023)
- Cancer research UK. (2023). Requirements on integration of sex in experimental design. [Requirements on integration of sex in experimental design | Cancer Research UK](#) (September 2023)
- Deutsche Forschungsgemeinschaft. Relevance of Sex, Gender and Diversity in Research. [DFG, German Research Foundation - Relevance of Sex, Gender and Diversity in Research](#) (September 2023)
- European Commission. (2023). Gender equality in research and innovation. [Gender equality in research and innovation \(europa.eu\)](#) (September 2023)
- FDA Center for Drug Evaluation and Research. (1997). [Guidance for industry](#) (September 2023)
- Korean Law Information Center. (2022). Framework Law on Science and Technology. [Framework Law on Science and Technology | National Statute Information Center | Text > statutes](#) (September 2023)
- Schiebinger et al. (2011-2020). [Gendered Innovations in Science, Health & Medicine, Engineering, and Environment](#) (September 2023)
- Government of Canada. (2023) Health Portfolio Sex and Gender Based Analysis Plus Policy: advancing equity, diversity and inclusion. [Health Portfolio Sex and Gender-Based Analysis Policy - Canada.ca](#) (September 2023)
- Government of Japan. (2021) Science Technology and Innovation Basic Plan. [Science, Technology, and Innovation Basic Plan \(cao.go.jp\)](#)
- Haverfield, J and Tannenbaum, C. (2021). A 10-year longitudinal evaluation of science policy interventions to promote sex and gender in health research. [Health Research Policy and Systems, 19:94. A 10-year longitudinal evaluation of science policy interventions to promote sex and gender in health research | Health Research Policy and Systems | Full Text \(biomedcentral.com\)](#)
- Horizon Europe Programme. (2023). Standard application form (HE RIA, IA stage 1 version 8.0). [af\\_he-ria-ia-stage-1\\_en.pdf \(europa.eu\)](#)
- Hunt, L; Wullum Nielsen, M and Schiebinger, L. (2022). [A framework for sex, gender and diversity analysis in research](#), Science, 377, 6614, pp1492-1495
- Irish Research Council. (2016). Policies and Practice to promote gender equality and the integration of gender analysis in research. [Policies and Practice to promote gender equality and the integration of gender analysis in research](#) (September 2023)

# References cont.

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- London Assembly Health Committee. (2022). Trans health matters: improving access to healthcare for trans and gender-diverse Londoners. [Trans health matters: improving access to healthcare for trans and gender-diverse Londoners](#). (September 2023)
- NHS. (2023). NHS Data Model and Dictionary Person Stated Gender Code. [PERSON STATED GENDER CODE \(datadictionary.nhs.uk\)](#) (September 2023)
- NHS. (2023). NHS Data Model and Dictionary. Gender identity code. [GENDER IDENTITY CODE \(datadictionary.nhs.uk\)](#) (September 2023)
- NHS. (2023). NHS Data Model and Dictionary. Gender identity same at birth indicator. [GENDER IDENTITY SAME AT BIRTH INDICATOR \(datadictionary.nhs.uk\)](#)
- NIH. (2021). Policy on Sex as a Biological Variable. [NIH Policy on Sex as a Biological Variable | Office of Research on Women's Health](#) (September 2023)
- NIH. (2017). Grants and Funding. <https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm> (September 2023)
- NIH. (2019). Guidelines for the Review of Inclusion on the basis of sex/gender, race, ethnicity and age in clinical research. [A 10-year longitudinal evaluation of science policy interventions to promote sex and gender in health research | Health Research Policy and Systems | Full Text \(biomedcentral.com\)](#) (September 2023)
- NIH. (2018). General instructions for NIH and other PHS agencies. [General Instructions for NIH and Other PHS Agencies](#) (September 2023)
- Publications Office of the European Union. (2023). [Home - Publications Office of the EU \(europa.eu\)](#) (September 2023)
- Sex and Gender Health Policy. (2021). Understanding, promoting and developing policies for sex and gender sensitive research across health and medical research. [Sex and Gender Health Policy](#) (September 2023)
- UK Research and Innovation. (2023). MRC embedding diversity in research design. [MRC embedding diversity in research design – UKRI](#) (September 2023)
- UK Research and Innovation. (2023). MRC embedding diversity in research design. [Sex in experimental design – MRC – UKRI](#) (September 2023)

# MESSAGE Policy Lab 2

Wednesday 27th September 2023

 **Scale Space, 58 Wood Lane, White City, London, W12 7RZ**

Link to [Google Maps](#)

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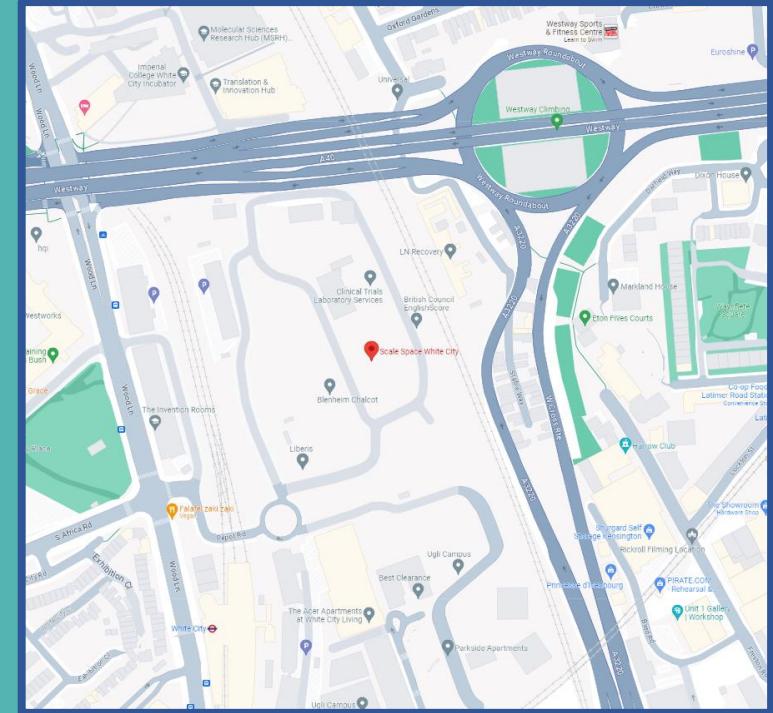
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