

Adapting Granting Systems to Improve Applicants' Consideration of Sex and Gender:

A Toolkit For Research Funders









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Introduction

The UK's first sex and gender policy framework was launched in 2024

From 2023 to 24, MESSAGE convened **over 50 representatives** from across the UK biomedical, health and care research sector to co-design a **sex and gender policy framework for UK research funders**.

The MESSAGE policy framework is designed to be used by funders as a template **to adopt their own sex and gender policy**. The framework wording can be used as written, or adapted as needed.

The framework breaks down consideration of sex and gender into 4 components:

- 1. Which sex and/or gender **characteristic(s)** will be considered and accounted for, and which research participants will be included to reflect these characteristic(s).
- 2. The **target distribution** of participants/subjects by sex and/or gender and why this distribution has been selected to answer the research question.
- 3. Planned **strategies for meeting the target** sex and/or gender distribution.
- 4. Details of any planned **sex- and/or gender-disaggregated analyses**; or, if none are planned, a justification for why.

Access the policy framework <u>here</u>



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

A policy framework for research funders

April 2024

Funders should "adopt MESSAGE" in ways that will have the most impact on their organisational processes

Implementation of sex and gender policies must be accompanied by changes to the granting system to ensure researchers adhere to funder expectations.

Some funders, particularly **smaller medical research charities** with limited capacity, have identified that a policy may not be the most effective way of effecting change in their organisation. In that case, **direct changes to the granting system are still needed** to ensure researchers account for sex and gender at the application stage.

This MESSAGE toolkit sets out 6 steps of action needed to adapt the granting system to ensure sex and gender are accounted for in funding applications.

The content of this toolkit was shaped by discussions with UK research stakeholders during MESSAGE Policy Labs and consultation with sector experts, including those affiliated with organisations that have already implemented sex and gender policies in Canada, the EU and the US.

How are we using the terms sex and gender?

Introducing sex and gender

Sex and gender are **multi-faceted** concepts which are used and understood differently in different contexts, societies, groups and languages. Usage of these terms has changed over time and is likely to continue doing so.

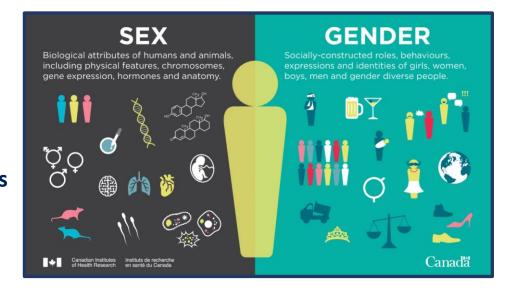
In the context of biomedical, health and care research, **MESSAGE recommends usage of these terms that maximises scientific rigour, precision and knowledge** (see the following pages). We encourage you to bear three things in mind particularly when considering the terms sex and gender:

- 1. Sex and gender do not refer to the same thing.

 These terms are often (incorrectly) conflated in medical research.

 In short, "sex" refers to biological characteristics, whereas

 "gender" refers to an aspect of a person's identity that is shaped
 by social forces.
- 2. Sex and gender are terms which comprise multiple characteristics that have relevance for health and illness.
- 3. Sex and gender may both be relevant for clinical research with human participants, whereas only sex is relevant for preclinical research.



What do we mean by sex?

Sex refers to the **biological attributes** which differentiate females and males, and which can include variations of what are considered female-typical and male-typical characteristics (sometimes known as "variations in sex characteristics" or "intersex").

When considering sex for the purposes of biomedical research, the characteristics of participants/subjects which researchers may need to account for include:

- Sex chromosomes
- Gene expression
- Hormone profile
- Secondary sex characteristics
- Internal reproductive organs
- External reproductive organs
- Other anatomical differences

What do we mean by gender?

Gender refers to an aspect of a person's identity. A person is subjected to a range of social forces (both constraints and privileges) based on their gender, which may influence their behaviours, their perception of themselves and how they are treated by others. All these influences may be relevant for biomedical, health and care research.

When accounting for gender, it is worth keeping in mind that an individual's gender exists on a **spectrum**, **can change over time**, **and intersects with other aspects** of their identity such as their age, ethnicity and sexual orientation.

There is considerable diversity in how people experience and express gender within and across societies.

When considering gender for the purposes of biomedical and health research, the characteristics of participants which researchers may need to account for include:

- Gender identity (the gender with which a person identifies)
- **Gender expression** (how a person outwardly presents themselves in relation to gendered forces)
- **Gender modality** (whether a person's gender identity is the same as their sex assigned at birth or not, i.e. whether they are cisgender or transgender)
- Perceived or presumed gender (how a person's gender is typically understood by those around them, which may differ from their gender identity and/or gender expression)

Timeframe for change in the UK

Whole sector action will enhance policy impact

Through the MESSAGE project, UK research stakeholders defined a **5+ year joint roadmap and milestones for change**. Whole sector action in line with this roadmap will **accelerate policy impact** and is **dependent on roll-out of funding changes** in the next 1-2 years.

Year 1	Year 2	Years 3-4	Years 4-5	Year 6+
Funder milestones				
Implementation of funder	sex and gender policies	Applications which do not account for sex/gender receive lower scores from reviewers	Applications which do not account for sex/gender are not funded Applications which do not account for sex/gender in a high-quality way receive lower scores	Applications which do not account for sex/gender in a high-quality way are not funded
Publisher milestones				
	Introduction of a question for peer reviewers on whether a paper has accounted for sex/gender	Peer reviewer feedback highlights that papers need to account for sex/gender to be accepted		Papers which do not account for sex/gender in a high-quality way are not accepted
Regulator milestones				
Launch of MHRA and HRA diversity guidance	MHRA & HRA: Introduction of a question in approvals process about how sex/gender are accounted for NICE: Introduction of a question in guideline consultations about how sex/gender are accounted for		MHRA & HRA: Applications which do not account for sex/gender are less likely to be accepted NICE: Guidelines which do not account for sex/gender will need to be reviewed and revised	MHRA & HRA: Applications which do not account for sex/gender are not accepted NICE: Guidelines which do not account for sex/gender are not accepted

Step 1: Prepare for policy implementation

Identify who needs to be involved and how to engage them

At the start of the implementation process we recommend that you:

- Identify which team/member(s) of staff will lead this work in your organisation
- Map the teams/individuals who will need to be **involved in approving** any changes, and understand what the **approval process** will look like

It is also beneficial to consider presenting key rationales to those who need to sign-off why these changes are essential.

• You may wish to write a short description of how improved consideration of sex and gender aligns with the organisation's mission, vision, strategic priorities, values and existing policies.

Benefits of improving consideration of sex and gender include:

Enhancing scientific rigour and reproducibility

Ensuring patient safety

Reducing research waste

Establishing the UK as a worldleading site for biomedical, health and care research Maximising research impact

Improving health outcomes

Addressing existing gaps in the evidence base

Getting closer to personalised medicine Minimising adverse drug reactions

Reducing pressures on the NHS and making care more cost-effective

Align sex and gender-related changes with organisation-wide policies and budgets

There may be **other policies held by your organisation** which will be need to be updated to reflect new expectations regarding sex and gender. You may find it useful to undertake a **cross-referencing exercise** to identify these policies and **speak to peer organisations** about changes they have made.

We recommend also accounting for work to update policies and implement changes regarding sex and gender in the organisation's **annual budgets**.

- Relatedly, researchers' adherence to new sex and gender expectations will be accelerated by provision of funding specifically dedicated to the study of sex and gender differences.
- Allocation of seed funding to support researchers to upskill regarding sex and gender intentional research, particularly for engagement with previously underserved populations, would be highly beneficial.

Likewise, you may want to see if any changes are needed to your organisation's data storage and data management processes.

Ensure that sex and gender terminology is used consistently across your organisation and its documentation. You can find recommended usage of the terms 'sex' and 'gender' in the MESSAGE policy framework here.

Prepare for policy rollout to be iterative

It is beneficial to create a **form for researchers to provide feedback on their experience** of responding to new expectations on sex and gender, particularly field-specific challenges, to improve the process in future.

- Consider at what point you will ask researchers to complete this form.
- Plan how frequently and in what way researchers' feedback will be reviewed and used to improve processes.

You may also find it helpful to **run a pilot** in a smaller grant scheme to generate learnings before wider roll-out.

We suggest ensuring **ongoing budget allocation** for work to roll out sex and gender policy expectations for **several years after initial implementation**. This will ensure there is capacity to **adapt processes in response** to applicants' feedback and **progress change over time** in line with the sector's 5-year roadmap for change.

Sharing information with the research community in advance of granting changes will lead to improved uptake from the outset

We encourage you to clearly communicate to researchers and university grant administrators that your organisation will now expect researchers to account for sex and/or gender in their research.

- You can do this in a **public** way (e.g. an announcement on social media) or a more **targeted** way (e.g. an email to researchers on your mailing list).
- You may find it useful to create a page on your website dedicated to your expectations around sex and gender inclusion. This page would link to relevant guidance and policies, including the MESSAGE website.

We recommend that you also raise awareness about these changes among your staff, for example through presentations at all-staff meetings or in newsletters. You may find patient stories an effective way of achieving this, alongside key data about existing sex and gender gaps in your research area.

Sharing information about your plans will also help you to gather **valuable insights about any concerns or questions** the research community may have, which you can then prepare answers for.

Likewise, as you reach key milestones in implementation, we encourage you to keep your research community updated.

Be prepared to answer frequently asked questions

- You may find it useful to **prepare answers to questions** which are commonly asked regarding sex and gender in your field, or which you may find challenging.
- You may also find it valuable to **train staff**, **particularly public-facing staff** including fundraising teams and charity shop staff and volunteers, about **how to respond** to questions about these policy changes.

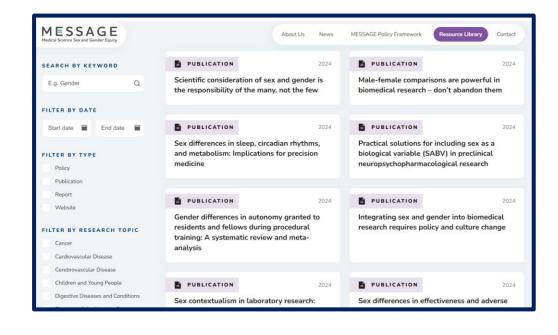
The MESSAGE team has prepared answers to frequently asked questions here

Guidance for researchers

Detailed guidance and examples will be essential to help researchers understand policy expectations and put them into practice in their own work.

The MESSAGE team is producing **educational materials** for researchers, which will be hosted on our **project website**.

On the MESSAGE website, you can find a <u>resource library</u> containing **best practice sex and gender research**. To gain understanding of where to start, researchers can use the library filters to see papers in their field which have accounted for sex and gender in a high-quality way.



We encourage you to <u>submit research</u> to be included in the library (your own or others' research).

Funders may also wish to create **field-specific guidance materials** for the medical condition they particularly fund. This could include case studies of how improved sex and gender consideration can have real-world impact, or guidance on designing the sex/gender distribution of study populations.

Step 2: Update the application form

Application form questions must clearly convey new expectations to researchers

Including a question in funding application forms is essential for prompting researchers to consider how they will account for sex and gender from the outset of study design.

Key considerations for design of an application form question are:

- Including a Yes/No tickbox makes it easier to monitor whether sex and/or gender have been accounted for
- It is critical that researchers provide a justification for their choices, and must therefore have a descriptive
 answer box
- Asking a **specific question on sex and/or gender,** rather than a broader diversity question, is recommended to ensure that researchers dedicate adequate attention to this dimension
- Providing information which breaks down what researchers should do practically to account for sex and gender will lead to greater uptake

We recommend the following application form question wording:

Hav	Have you considered sex and gender dimensions when designing this study?			
	Yes			
	No			

IF YES

How will you account for sex and/or gender dimensions in the proposed study?

We recommend you give details of:

- 1. Which sex and/or gender characteristic(s) will be considered and accounted for, and which research participants will be included to reflect these characteristic(s). Include a description of why the study will account for sex or gender or both to answer the research question.
- 2. The target distribution of participants/subjects by sex and/or gender and why this distribution has been selected to answer the research question.
- 3. Planned strategies for meeting the target sex and/or gender distribution. For research involving primary data collection with human participants, this includes planned strategies for recruiting and retaining the target sex and/or gender distribution of participants. For primary preclinical research, planned actions for procuring, managing and storing/housing the target sex distribution of subjects. For research involving the use of secondary data, a description of the sex and/or gender distribution of participants in the original dataset.
- 4. An analysis plan, including details of any planned sex- and/or gender-disaggregated analyses. If you are not planning to perform a sex- and/or gender-disaggregated analysis, you must explain why.

IF NO

Please provide an evidence-based justification why this study will not consider sex and/or gender.

Guidance on justifications that will or will not be considered can be found here.

Step 3: Guide reviewers

When reviewers provide feedback on sex and gender, applicants pay attention

Researchers are more likely to account for sex and gender in funding applications when they know that reviewers will pay attention to that component, provide feedback on it, and that its score will affect their application's overall score.

Three action areas will increase the likelihood that reviewers consider sex and gender:

- 1. Adopting and disseminating an assessment matrix
- 2. Updating reviewer forms
- 3. Preparing reviewers and embedding nudges during the review process

It is important to consider from the outset how the score given by reviewers to the assessment of the sex and gender component will be factored into the application's overall score.

- Will consideration of sex and gender be considered as part of research excellence, or another existing category for assessment? Should a new assessment criterion be added?
- Will applications that account for sex and gender **poorly** be asked to **share more details, or be rejected**? Will this **shift over time**?

You may also find it useful to arrange for applications to be **initially triaged on the basis of sex and gender considerations** by an in-house member of staff who may be more familiar with sex and gender criteria. Under this process, applications that do not account for sex and gender could be **flagged to reviewers as weaker proposals or not forwarded on** for review (and this action might change over time).

3.1 Adopt and disseminate an assessment matrix

An assessment matrix will standardise reviews of the sex and gender component

Standardising the way in which reviewers assess how an application has accounted for sex and gender, both within and across organisations, is key.

We recommend that assessment covers whether integration has been:

Excellent

Satisfactory

Unsatisfactory

Some applications may have an **acceptable justification** for not accounting for sex and gender (most obviously, the disease or condition only occurring in females or males). Such applications are expected to provide an **evidence-based justification for why they have not accounted for sex and gender**. The above ranking system should be used to assess the quality of the justification.

Acceptable and unacceptable justifications for not accounting for sex and gender can be found in the **MESSAGE policy framework**.

We recommend using this assessment matrix:

	Unsatisfactory	Satisfactory	Excellent
Sex and/or gender characteristic(s) of participants/subjects to be considered	Description given of the sex and/or gender characteristic(s) to be considered, but no justification given for this choice. Sex and gender terms are used incorrectly* and/or interchangeably.	Clear description given of the sex and/or gender characteristic(s) to be considered, alongside a justification for this choice. Sex and gender terms are used correctly.	Clear description given of the sex and/or gender characteristic(s) to be considered, including a detailed justification for this choice which references relevant literature (where possible). Sex and gender terms are used correctly.
Target distribution by sex and/or gender	The study population includes participants/subjects of more than one sex and/or gender. No justification is given for the planned proportion of participants/subjects by sex and/or gender. OR The study population is restricted to one sex and/or gender and no justification is given.	The study population includes participants/subjects of more than one sex and/or gender. A reasonable justification for the planned proportion of participants/subjects by sex and/or gender is given. OR The study population is restricted to one sex and/or gender and a justification is given.	The study population includes participants/subjects of more than one sex and/or gender. A reasonable and detailed justification for the planned proportion of participants/subjects by sex and/or gender is given, which references relevant literature where possible. OR The study population is restricted to one sex and/or gender, and a detailed justification for this choice is given, which references relevant literature where possible.
Planned strategies for achieving the target sex and/or gender distribution of participants/subjects**	No strategies are given, without adequate justification.	Reasonable strategies are proposed, demonstrating consideration of means of engaging historically underserved sex/gender groups. OR No strategies are given and a justification is given (e.g. the study population is justifiably restricted to one sex and/or gender).	Strategies are proposed which demonstrate in-depth consideration of existing literature and propose innovative means of reaching historically underserved sex/gender groups. OR No strategies are given and a detailed justification is given (e.g. the study population is justifiably restricted to one sex and/or gender), which references relevant literature where possible.
Sex- and/or gender- disaggregated analysis	Planned sex- and/or gender-disaggregated analysis is methodologically unsound. For example, analysis will compare the main effects between sex/gender groups, without testing the interaction and quantifying the difference. Or proposed analysis plans adjust/control for sex/gender. OR No sex- and/or gender-disaggregated analyses are planned, without adequate justification.	Sex- and/or gender-disaggregated analyses are planned and are methodologically sound. Interaction terms are added for the determinant of interest and sex and/or gender, without interaction terms for other covariables. Sex and/or gender differences are presented on one risk scale. OR No sex- and/or gender-disaggregated analyses are planned and justification for this choice is given (e.g. the study population is justifiably restricted to one sex and/or gender).	Sex- and/or gender-disaggregated analyses are planned and are methodologically robust. A full interaction model is used and sex and/or gender differences are presented on both the absolute and relative risk scale. OR No sex- and/or gender-disaggregated analyses are planned and a detailed justification for this choice is given (e.g. the study population is justifiably restricted to one sex and/or gender), which references relevant literature where possible.

3.2 Update reviewer forms

Reviewer forms

To ensure reviewers provide relevant feedback to the sex and gender question - and therefore demonstrate to applicants that this part of the application is considered carefully - it is important to add a question box on any forms used by reviewers regarding application content.

The question should be added to all reviewer-related forms, including forms to provide feedback to applicants and those for internal use by review committees only.

We recommend using this wording on any reviewer forms:

На	Has the applicant considered sex and gender dimensions of study design?		
	Yes		
	No		

IF YES

How well did the proposed study account for sex and/or gender dimensions?

Please consider how the study accounted for the following, including the justifications give:

- 1. Which sex and/or gender characteristic(s) will be considered and accounted for, and which research participants will be included to reflect these characteristic(s). Include a description of why the study will account for sex or gender or both to answer the research question.
- 2. The target distribution of participants/subjects by sex and/or gender and why this distribution has been selected to answer the research question.
- 3. Planned strategies for meeting the target sex and/or gender distribution. For research involving primary data collection with human participants, this includes planned strategies for recruiting and retaining the target sex and/or gender distribution of participants. For primary preclinical research, planned actions for procuring, managing and storing/housing the target sex distribution of subjects. For research involving the use of secondary data, a description of the sex and/or gender distribution of participants in the original dataset.
- 4. An analysis plan, including details of any planned sex- and/or gender-disaggregated analyses. If you are not planning to perform a sex- and/or gender-disaggregated analysis, you must explain why.

IF NO

How satisfactory was the justification given for why this study will not consider sex and/or gender?

Please consider if the justification was evidence-based or not. Guidance on justifications are or are not satisfactory can be found <u>here</u>.

3.3 Prepare reviewers and embed nudges during the review process

Reviewers do not need to be sex and gender experts to assess the sex and gender components in applications

The MESSAGE policy framework sets out **four components** which need to be considered for an application to account for sex and gender (see suggested application form wording). **Reviewers do not need to be experts in studying sex and gender differences** to be able to assess if an application has accounted for these dimensions in an excellent, satisfactory, or unsatisfactory way.

Instead, we encourage funders to ensure reviewers are aware of the need to consider and provide feedback on this aspect of an application and are familiar with the assessment matrix. It is beneficial to embed reminders about sex and gender throughout the review process.

Before reviewer panels meet:

- Encourage researchers to access training on how to account for sex and gender. You can direct them to the educational materials on the MESSAGE website.
- Reviewers should have access to and become familiar with the assessment matrix for the sex and gender component.

When reviewer panels meet:

- Nominate a Sex and Gender Champion. This person's responsibility is to raise the question of how well an application has accounted for sex and/or gender to the panel's attention, in case it is missed.
- Show a **slide at the start of the panel meeting** to remind reviewers of the need to pay attention to this dimension.

Step 4: Set expectations with grantees

Once funding is offered, communicate expectations to grantees

Embedding nudges regarding sex and gender at every stage of communication with grantees will emphasise that adherence to what was set out in the application form on this topic is important to the funder and will continue to be scrutinised.

In particular, we encourage you to include text in the **Terms & Conditions of funding**. For example, you could use the following text (selecting the relevant option in the square brackets):

We expect funded research to account for sex and/or gender, as appropriate, at every stage. This means including a representative distribution of [participants/subjects] by sex and/or gender in study samples, as well as conducting sex- and/or gender-disaggregated analysis. We expect any publications from funded research to describe sex and/or gender dimensions of the study, including sample distribution, analyses conducted and any relevant findings (or lack thereof).

Detailed guidance on accounting for sex and/or gender at each stage of the research cycle, including in research outputs, can be found on the Medical Science Sex and Gender Equity (MESSAGE) website.

Step 5: Update reporting forms

Grantee reporting forms are essential for monitoring how well sex and gender are accounted for in practice

It is important to create **accountability** and ensure that applicants follow through on the plans set out in their application form.

Likewise, if researchers are unable to achieve what they set out in their plan regarding sex and gender, it is important to understand why. Better data on these challenges will be key for identifying future solutions.

We suggest including a question on any reporting forms used by grantees to gather information about how plans set out in the application form are reflected in practice. This includes both **interim and final reporting forms**.

We suggest using this question wording:

Has the study met its objectives regarding consideration of sex and/or gender? Please describe strategies you have found effective, challenges you have encountered, and what you would do in future to overcome any challenges encountered.

Step 6: Monitor and evaluate policy impact

Tracking indicators from the outset is key to measuring policy impact

It is important to monitor and evaluate sex and gender policy rollout to understand the positive impact of policies and to identify areas where further work is needed.

We recommend you conduct a **baseline evaluation** of how funding applications account for sex and gender prior to policy rollout. This is essential to demonstrate **progress over time**.

We encourage you to plan moments in your implementation to review collected data and take stock of how policy implementation is progressing. Reflecting on progress and feedback will help you identify ways to improve implementation. This could be done annually.

Indicators can be embedded at 5 stages across the granting process

We recommend collecting data on the following indicators. If organisations collect similar data to each other, it will be possible to monitor and evaluate progress across the UK research sector, for example to demonstrate impact after 5 years.

Stage	Metric	How?
Application stage	How many applications consider sex unsatisfactorily, satisfactorily, and excellently	Application box
Application stage	How many applications consider gender unsatisfactorily, satisfactorily, and excellently	Application box
Review stage	How many reviewers/committees provide feedback on the sex and gender component Feedback form box	
Funding decision	Funding decision What proportion of successful applications consider sex and/or gender	
Progress reporting	rogress reporting Proportion of male to female participants/subjects	
Progress reporting Number/proportion of trans, non-binary and intersex participants		Reporting form box
Progress reporting If sex/gender recruitment targets were met or not, and why		Reporting form box
Research outputs	What proportion of research publications from funded research account for sex and gender	Track using grant numbers

Other indicators that could be used include:

Stage	Metric	How?
Application stage	How many applications integrate sex/gender well	Application box (quant ranking)
Application stage	How many applications integrate sex/gender well	Application box (qual review)
Application stage	How many applicants attend training	Application form tick-box
Review stage	How many reviewers/committees provide quality feedback on the sex and gender component	Feedback form box
Review stage	How many reviewers/committee members attend training	Reviewer onboarding form
Funding decision	What proportion of the funded research portfolio accounts for sex and gender at the application stage	Correlation - application data & grant management data
Progress reporting	If sex- and/or gender-disaggregated analysis has been conducted	Reporting form box

Conclusion

Incremental change is better than no change

The aim of this toolkit is to provide UK medical research funders with the **information**, **content and confidence to update granting systems to ensure researchers account for sex and gender** in study design.

Funders are encouraged to implement all the steps outlined in the toolkit. This may not be feasible, however, and completion of any steps will make a difference and signal that sex- and gender-equitable research is now a priority in the UK research sector. We encourage you to work towards completing all 6 steps over time.

The **MESSAGE team is available** to meet with funders to plan strategies for implementing sex and gender policies for their specific organisation.

Please do get in touch if you would like to discuss this with us!

This toolkit was designed by the MESSAGE project team for UK medical research funders

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